EUROPEAN COMMISSION

Foodstuffs

Coordinated instruments

Position on 30.4.1994

EN

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NOTICE

It is to be noted that this document is a compilation without official status and is intended solely as a guide to Community legislation on the subject concerned.

Neither the Commission of the European Communities nor any person acting on its behalf can be held liable for the use made of the information contained in it.

EXPLANATORY NOTE

This publication contains all the Community legislation relating to the sector in question. Texts which have been amended are set out in coordinated form incorporating all the changes made to the original instruments.Texts which have not been amended are reproduced from the Official Journal.

Instruments which could not be included for technical reasons will be available in a later version.

Cover page (the boxes preceding the coordinated text)

The coordinated text is preceded by the following information (see examples):

1) A Notice

This points out that the text is intended for information only and cannot therefore be regarded as legally binding.

2) The basic instrument

Information relating to the basic instrument is set out as follows:

-- the identification number in the CELEX database:

378L0664;

-- the full title of the instrument

78/664/EEC: COUNCIL DIRECTIVE OF 25 JULY 1978 LAYING DOWN SPECIFIC CRITERIA OF PURITY FOR ANTIOXIDANTS WHICH MAY BE USED IN FOODSTUFFS INTENDED FOR HUMAN CONSUMPTION

-- the reference to the Official Journal in which the instrument was published:

Official Journal No L 223, 14/08/1978, p. 30;

-- the date on which the Member States were notified of the instrument

Date of notification: 31/07/1978;

-- in the case of Directives, the date of transposition (the date by which Member States must have amended their own legislation to bring it into line with Community rules):

Date of transposition: 01/02/1980; see Art. 3.

3) Amending instruments

These are set out in chronological order, as follows:

-- the identification number in the CELEX database;

-- the abridged title of the instrument, followed by a number in square brackets indicating the source of the amendment incorporated in the text: **[no]**;

-- the reference to the Official Journal in which the instrument was published;

-- the date on which the Member States were notified of the instrument;

-- in the case of Directives, the date of transposition.

AMENDED BY

382L0712
82/712/EEC: COUNCIL DIRECTIVE OF 18 OCTOBER 1982 [1]
OFFICIAL JOURNAL NO L 297, 23/10/1982, P. 31
DATE OF NOTIFICATION: 29/10/1982
DATE OF TRANSPOSITION: 30/06/1984; SEE ART. 2

The coordinated text

The coordinated text includes only the articles and annexes of the instrument and not the citations or recitals.

Amendments are incorporated in the instrument as follows (see examples):

1) Incorporation of amendment

-- An amendment replacing or supplementing the original text is shown as follows:

" amending text " **[no]**;

Article 5

" 1. Notwithstanding Article 2 (1), Member States may authorize the use of hexamethylenetetramine:

a) in semi-preserved fish and fishery products whose pH is more than 4.5, provided that, when the product is marketed, the level of this substance does not exceed 500 mg/kg;
b) in caviar (sturgeon eggs) and other fish eggs, not smoked, provided that, when the product is marketed, the level of this substance does not exceed 1g/kg " **[10]**

N.B. To show that an amendment has been made the new text is put in inverted commas followed by a number in square brackets. Where the inverted commas denote an amendment, a space is inserted between them and the text.

-- An amendment made for the sole purpose of deleting part of the original text is indicated as follows:

"..." [no]:

3. "..." [17];

-- On the cover page of some coordinated instruments reference is made to amending instruments that have no effect on the basic text. These usually involve amendments which have been subsequently repealed, and accordingly no longer figure in the coordinated text.

2) Source of amendment

-- The source of an amendment can be found by means of the number in square brackets immediately following the new text; this number refers back to the details of the amending instrument on the cover page:

" b) in caviar (sturgeon eggs) and other fish eggs, not smoked, provided that, when the product is marketed, the level of this substance does not exceed 1g/kg " **[10]**

3) Comments in square brackets [ ]

-- These are used to provide information which may be helpful in understanding the amendments; they do not form part of the text:

" 2. " **[17]** " by way of derogation from article 1, member States may maintain the provisions of their national laws relating to the use of formaldehyde in grano padano cheese provided that when the final product is marketed, the level of formaldehyde, free and/or combined, shall not exceed 0.5 milligram per kilogram. " **[14]** [the paragraph was inserted by **[14]**; **[17]** deletes 5(2) and 5(3)(b), 5(3)(a) becomes 5(2)]

4) Annexes

The annexes are coordinated in the same way as the substantive provisions.
It should be noted that:

-- the presentation of tables differs from that in the Official Journal;

-- drawings and symbols cannot be reproduced and the Official Journal should therefore be consulted.

Abbreviations

For instruments

R : Regulation

L : Directive

D : Decision

AA : Act of Accession

X : Other Acts

For the institutions

CS : Council

COM : Commission

A reference is to be read as follows:

L	CS	69/414	OJ
Type of instrument: Directive	Author: Council	Year/number of the Directive or Decision	*Official Journal of the European Communities*
OJ L	OJ C	291/69	SE
Official Journal L series	Official Journal C series	Number of the Official Journal/year	Special Edition
JO			
Journal officiel des Communautés européennes			

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GENERAL TEXTS

19.11.69 Official Journal of the European Communities No L 291/9

COUNCIL DECISION

of 13 November 1969

setting up a Standing Committee for Foodstuffs

(69/414/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community;

Having regard to the draft decision submitted by the Commission;

Whereas it is desirable that, for cases where the Council delegates powers to the Commission in respect of foodstuffs, a Committee should be set up, consisting of representatives of the Member States, for the purpose of ensuring close co-operation between the Member States and the Commission and of enabling the latter to consult experts;

Whereas it is furthermore desirable that such co-operation extend to all fields covered by Community rules on these matters; whereas that Committee should accordingly be empowered to consider any question relating to such fields;

HAS DECIDED AS FOLLOWS:

Article 1

A Standing Committee for Foodstuffs (hereinafter called the 'Committee') is hereby set up and shall consist of representatives of the Member States with a representative of the Commission as Chairman.

Article 2

The Committee shall, in the cases and under the conditions provided for therein, carry out the duties devolving upon it under the instruments relating to foodstuffs adopted by the Council.

It may, moreover, consider any other question arising under such instruments and referred to it by its Chairman either on his own initiative or at the request of a Member State.

Article 3

The Committee shall adopt its own rules of procedure.

Done at Brussels, 13 November 1969.

For the Council

The President

L. DE BLOCK

COMMISSION OF THE EUROPEAN COMMUNITIES
Directorate-General
INDUSTRY
III.E.1

III/3939/93
SJ/260/90-EN
Brussels, 11.05.1993
/50/01/00/GG/cvi

RULES OF PROCEDURE OF THE STANDING COMMITTEE FOR FOODSTUFFS

THE STANDING COMMITTEE FOR FOODSTUFFS,

Having regard to the Council Decision 69/414/EEC [1] setting up a Standing Committee for Foodstuffs, and in particular Article 3 thereof,

HAS ADOPTED THESE RULES OF PROCEDURE:

Article 1

The Committee shall be convened by the Chairman either on his own initiative or at the request of a representative of a Member State.

Joint meetings of the Committee and other Committees may be convened on matters in which they both have competence. (a)

Article 2

The Chairman shall draw up the agenda.

The agenda shall distinguish between

(a) draft measures on which an opinion is requested of the Committee in accordance with the procedure laid down in Article 2.III.a of Council Decision 87/373/EEC [2];

(b) draft measures on which an opinion is requested of the Committee in accordance with the procedure laid down in Article 2.III.b of Council Decision 87/373/EEC [2];

(c) matters on which the Committee is consulted;

(d) other matters referred to the Committee, in particular under Article 2 of the Council Decision 69/414/EEC [1] either on the initiative of the Chairman or at the written request of a member of the Committee.

Article 3

The notice convening the meeting, the agenda, the draft measures on which the Committee's opinion is requested and any other working paper shall be transmitted by the Chairman to the members of the Committee in the manner set out in the second paragraph of Article 11. These documents must reach the Offices of the Permanent Representatives of the Member States not later than 21 days before the date of the meeting.

At the request of a member of the Committee or on his own initiative, the Chairman may, in urgent cases and where the measures to be adopted must be applied immediately, shorten the time allowed for transmittal specified in the first paragraph to 10 clear working days before the date of the meeting.

In cases of extreme urgency, the Chairman may, at the request of a member of the Committee or on his own initiative, include an item on the agenda for a meeting in the course of that meeting. (b)

Article 4

Where an opinion is requested, if a substantive amendment is made to the draft or if a draft, the subject of which is on the agenda, is submitted in the

(1) OJ No L 291, 19.11.1969, p. 9.
(2) OJ No L 197, 18.07.1987, p. 33.

course of the meeting, or if a new item is included on the agenda, the Chairman, at the request of a member, shall defer the vote to the end of the meeting; if there are particular difficulties, the Chairman shall extend the meeting until the following day . (c)

Article 5

If the Committee has not delivered an opinion within the period of time set by the Chairman, the Chairman may extend that period, except in cases of urgency, until the end of the following meeting.

Article 6

Each Member State shall be represented by not more than five officials. The delegation of each Member State shall be considered to be a single member of the Committee.

The representative of a Member State may, if need be, represent one other Member State. The Chairman shall be informed of this in writing or by written telecommunication by the Office of the Permanent Representative of any Member State which arranges to be represented in this way.

The number of members of the Committee required to be present for an opinion to be delivered shall constitute the quorum required for the Committee to decide on draft measures as referred to in Article 2 (a) (b).

Article 7

The Committee may set up working parties to consider specific matters. The working parties shall report to the Committee.

The Committee may decide to hear experts on specific points at the request of a member or on the initiative of the Chairman. The experts shall not take part in the decisions of the Committee.

Article 8

If necessary, the opinion of the Committee may be obtained by written procedure.

To this end, the Chairman shall send the draft measures on which the opinion of the Committee is requested to the members of the Committee in the manner set out in the second paragraph of Article 11.

Any Member State which has not made known its opposition to or intention to abstain from taking a position on the draft measures within the time specified by the Chairman shall be deemed to have agreed to them; the time allowed shall be not less than 30 days.

However, if a Member State requests that the draft measures be considered in the course of a meeting of the Committee, the written procedure shall thereby terminate; the Chairman shall convene the Committee as soon as possible.

Article 9

Secretarial services for the Committee shall be provided by the Commission.

Article 10

A summary record of each meeting shall be drawn up on the responsibility of the Chairman; the record shall include any opinions delivered on draft measures as referred to in Article 2, points (a) (b) and any opinions expressed on matters as referred to in Article 2, points (c) (d). The record shall be sent to the members of the Committee in the manner set out in the second paragraph of Article 11.

The members of the Committee shall inform the Chairman in writing of any comments that they may have. The Committee shall be informed of these comments by the Chairman. In the event of disagreement, the amendment proposed shall be discussed at the next meeting. If the disagreement persists, the amendment shall be attached to the record of that meeting.

Article 11

Correspondence concerning the Committee shall be addressed to the Commission at the offices of the Directorate-General Industry, for the attention of the Chairman of the Committee.

Correspondence for members of the Committee shall be addressed to the Offices of the Permanent Representatives; at the request of a Member State, a copy shall be addressed direct to an official designated by that Member State.

Article 12

The proceedings of the Committee shall be confidential.

Statements to be entered in the minutes :

(a) "The Commission undertakes, in case of difficulty in the application of the dispositions of this article, to make a report with a view to its re-examination."

(b) "It is understood that this disposition must permit neither the Commission nor Member States to introduce matters for which the absolute necessity is not evident."

(c) "It is agreed that the purpose of postponing voting to the end of the meeting and of extending the meeting to the folowing day is to enable the delegations to ask for instruction."

374D0234

74/234/EEC: COMMISSION DECISION OF 16 APRIL 1974 RELATING TO THE INSTITUTION OF A SCIENTIFIC COMMITTEE FOR FOOD

OFFICIAL JOURNAL NO L 136, 20/05/1974, P. 1

AMENDED BY

386D0241
86/241/EEC: COMMISSION DECISION OF 25 APRIL 1986 [1]
OFFICIAL JOURNAL NO L 163, 19/06/1986, P. 40

ARTICLE 1

A SCIENTIFIC COMMITTEE FOR FOOD HEREINAFTER CALLED THE "COMMITTEE" IS HEREBY ESTABLISHED BY THE COMMISSION.

ARTICLE 2

1. THE COMMITTEE MAY BE CONSULTED BY THE COMMISSION ON ANY PROBLEM RELATING TO THE PROTECTION OF THE HEALTH AND SAFETY OF PERSONS ARISING FROM THE CONSUMPTION OF FOOD, AND IN PARTICULAR ON THE COMPOSITION OF FOOD, PROCESSES WHICH ARE LIABLE TO MODIFY FOOD, THE USE OF FOOD ADDITIVES AND OTHER PROCESSING AIDS AS WELL AS THE PRESENCE OF CONTAMINANTS.

2. THE COMMITTEE MAY DRAW THE ATTENTION OF THE COMMISSION TO ANY SUCH PROBLEM.

ARTICLE 3

THE COMMITTEE SHALL BE COMPOSED OF NOT MORE THAN " 18 MEMBERS " **[1]**.

ARTICLE 4

THE MEMBERS OF THE COMMITTEE SHALL BE NOMINATED BY THE COMMISSION FROM HIGHLY QUALIFIED SCIENTIFIC PERSONS HAVING COMPETENCE IN THE FIELDS REFERRED TO IN ARTICLE 2.

ARTICLE 5

THE COMMITTEE SHALL ELECT A CHAIRMAN AND TWO VICE-CHAIRMEN FROM ITS MEMBERS. THE ELECTION SHALL TAKE PLACE BY SIMPLE MAJORITY OF THE MEMBERS.

ARTICLE 6

1. THE MANDATE OF A MEMBER, CHAIRMAN OR VICE-CHAIRMAN OF THE COMMITTEE SHALL HAVE A TERM OF THREE YEARS. IT SHALL BE RENEWABLE. HOWEVER, THE CHAIRMAN AND VICE-CHAIRMEN OF THE COMMITTEE MAY NOT BE IMMEDIATELY RE-ELECTED AFTER BEING IN OFFICE FOR TWO CONSECUTIVE PERIODS OF THREE YEARS. THE DUTIES SHALL NOT BE SUBJECT TO REMUNERATION.
AFTER THE EXPIRY OF THE PERIOD OF THREE YEARS, THE MEMBERS, CHAIRMEN, OR VICE-CHAIRMEN OF THE COMMITTEE, REMAIN IN OFFICE UNTIL THEIR REPLACEMENT OR THE RENEWAL OF THEIR MANDATE.

2. WHERE A MEMBER, CHAIRMAN OR VICE-CHAIRMAN OF THE COMMITTEE FINDS IT IMPOSSIBLE TO FULFIL HIS MANDATE OR IN THE CASE OF HIS VOLUNTARY RESIGNATION HE SHALL BE REPLACED FOR THE REMAINING TERM OF THE MANDATE IN ACCORDANCE WITH THE PROCEDURE PROVIDED, AS THE CASE MAY BE, IN ARTICLE 4 OR ARTICLE 5.

ARTICLE 7

1. THE COMMITTEE MAY FORM WORKING GROUPS FROM AMONG ITS MEMBERS.

2. THE MANDATE OF THE WORKING GROUPS SHALL BE TO REPORT TO THE COMMITTEE ON THE SUBJECTS REFERRED TO THEM BY THE LATTER.

ARTICLE 8

1. THE COMMITTEE AND THE WORKING GROUPS SHALL MEET AT THE INVITATION OF A REPRESENTATIVE OF THE COMMISSION.

2. THE REPRESENTATIVE OF THE COMMISSION AS WELL AS OTHER OFFICIALS AND INTERESTED AGENTS OF THE COMMISSION ASSIST AT THE MEETINGS OF THE COMMITTEE AND THE WORKING GROUPS.

3. THE REPRESENTATIVE OF THE COMMISSION MAY INVITE INDIVIDUALS HAVING PARTICULAR EXPERTISE IN THE SUBJECT BEING STUDIED TO PARTICIPATE AT THE MEETINGS.

4. THE SERVICES OF THE COMMISSION SHALL FORM THE SECRETARIAT OF THE COMMITTEE, AND THE WORKING GROUPS.

ARTICLE 9

1. THE DELIBERATIONS OF THE COMMITTEE SHALL RELATE TO THE REQUESTS FOR OPINION PUT BY THE REPRESENTATIVE OF THE COMMISSION.
THE REPRESENTATIVE OF THE COMMISSION, IN REQUESTING THE OPINION OF THE COMMITTEE MAY FIX THE LENGTH OF TIME WITHIN WHICH THE OPINION IS TO BE GIVEN.

2. WHERE THE OPINION REQUESTED IS THE SUBJECT OF THE UNANIMOUS AGREEMENT OF THE MEMBERS OF COMMITTEE, THESE LATTER ESTABLISH THE COMMON CONCLUSIONS. IN THE ABSENCE OF UNANIMOUS AGREEMENT, THE VARIOUS POSITIONS TAKEN IN THE COURSE OF THE DELIBERATIONS SHALL BE ENTERED IN A REPORT DRAWN UP UNDER THE RESPONSIBILITY OF THE REPRESENTATIVE OF THE COMMISSION.

ARTICLE 10

WITHOUT PREJUDICE TO THE PROVISIONS OF ARTICLE 214 OF THE TREATY THE MEMBERS OF THE COMMITTEE SHALL BE OBLIGED NOT TO DIVULGE INFORMATION COMING TO THEIR KNOWLEDGE AS A RESULT OF THE WORK OF THE COMMITTEE WHEN THE REPRESENTATIVE OF THE COMMISSION INFORMS THEM THAT THE OPINION REQUESTED RELATES TO MATERIAL OF A CONFIDENTIAL NATURE.
IN THIS CASE ONLY THE MEMBERS OF THE COMMITTEE AND THE REPRESENTATIVES OF THE COMMISSION SHALL BE PRESENT AT THE MEETINGS.

ARTICLE 11

THE PRESENT DECISION MAY BE AMENDED BY THE COMMISSION IN THE LIGHT OF EXPERIENCE ACQUIRED.

380D1073

80/1073/EEC: COMMISSION DECISION OF 24 OCTOBER 1980 ESTABLISHING A NEW STATUTE OF THE ADVISORY COMMITTEE ON FOODSTUFFS

OFFICIAL JOURNAL NO L 318, 26/11/1980, P. 28

[This decision replaces Commission Decision 75/420/EEC]

ARTICLE 1

1. THERE IS HEREBY ATTACHED TO THE COMMISSION AN ADVISORY COMMITTEE ON FOODSTUFFS. IT MAY BE CONSULTED BY THE COMMISSION ON ALL PROBLEMS CONCERNING THE HARMONIZATION OF LEGISLATION RELATING TO FOODSTUFFS.

2. THE PERMANENT MEMBERS OF THE COMMITTEE MAY INDICATE TO THE COMMISSION THE DESIRABILITY OF CONSULTING OR INFORMING THE COMMITTEE ON ANY MATTER WITHIN THE LATTER'S COMPETENCE ON WHICH ITS OPINION HAS NOT BEEN SOUGHT.

ARTICLE 2

1. THE COMMITTEE SHALL CONSIST OF 10 PERMANENT MEMBERS AND 20 EXPERTS DIVIDED INTO FIVE ECONOMIC GROUPS REPRESENTING AGRICULTURE, COMMERCE, CONSUMERS, INDUSTRY AND EMPLOYEES.

2. EACH OF THE GROUPS LISTED IN PARAGRAPH 1 SHALL HAVE TWO PERMANENT MEMBERS ASSISTED BY FOUR EXPERTS.

3. THE PERMANENT MEMBERS SHALL HAVE THE TASK OF ENSURING THE COORDINATION OF THE WORK IN THEIR GROUP.
THEIR TERM OF OFFICE SHALL BE THREE YEARS AND SHALL BE RENEWABLE. THEY SHALL REMAIN IN OFFICE UNTIL THEY ARE REPLACED OR UNTIL THEIR APPOINTMENTS ARE RENEWED.
THE TERM OF OFFICE OF A PERMANENT MEMBER SHALL TERMINATE BEFORE EXPIRY OF THREE YEARS OR THE RESIGNATION OR DECEASE OF SUCH MEMBER.
THE TERM OF OFFICE OF A REPLACEMENT PERMANENT MEMBER SHALL EXPIRE AT THE SAME TIME AS THE TERMS OF OFFICE OF THE OTHER PERMANENT MEMBERS.

4. THE BODIES AND ORGANIZATIONS LISTED IN THE ANNEX SHALL PROPOSE TO THE COMMISSION FOR THEIR RESPECTIVE ECONOMIC GROUPS CANDIDATES FOR APPOINTMENT AS PERMANENT MEMBERS, AND SHALL APPOINT THE EXPERTS WHO WILL ASSIST THEM.
THEY SHALL PROPOSE TO THE COMMISSION, EACH IN RESPECT OF ITS OWN INTERESTS, FOUR CANDIDATES OF DIFFERENT NATIONALITY FROM WHOSE NUMBER THE COMMISSION SHALL APPOINT THE PERMANENT MEMBERS.
THEY SHALL INFORM THE SECRETARIAT OF THE COMMITTEE, BY LETTER ADDRESSED AT LEAST EIGHT DAYS BEFORE EACH MEETING, OF THE NAME(S) AND ADDRESS(ES) OF THE EXPERTS THEY PROPOSE TO ASSIGN TO EACH SUBJECT APPEARING ON THE AGENDA.

5. IN THE ABSENCE OF A SINGLE COMMUNITY BODY OR ORGANIZATION REPRESENTING A GROUP COVERED BY THE COMMITTEE, THE COMMISSION SHALL APPOINT THE PERMANENT MEMBERS FOR THAT GROUP ON THE BASIS OF THE PROPOSALS FROM THE MOST REPRESENTATIVE AMONG THE EXISTING ORGANIZATIONS SET UP AT COMMUNITY LEVEL, IN ACCORDANCE WITH THE PROCEDURE SET OUT IN PARAGRAPH 4.

IN THIS CASE THE PERMANENT MEMBERS APPOINTED BY THE COMMISSION SHALL, WITH THE ASSISTANCE OF THOSE ORGANIZATIONS, JOINTLY APPOINT THE EXPERTS BROUGHT IN TO ASSIST THEM.

6. ORGANIZATIONS AND BODIES PRESENTING A CANDIDATE FOR APPOINTMENT AS A PERMANENT MEMBER MAY ASK THE COMMISSION TO REPLACE HIM DURING THE MEMBER'S TERM OF OFFICE.

ARTICLE 3

1. THE CHAIRMANSHIP OF THE COMMITTEE SHALL BE HELD FOR A PERIOD OF THREE YEARS BY A PERMANENT MEMBER OF ONE OF THE ECONOMIC GROUPS REPRESENTED ON IT.

2. THE CHAIRMAN SHALL BE ELECTED AT THE FIRST BALLOT BY A MAJORITY VOTE OF TWO-THIRDS OF THE PERMANENT MEMBERS PRESENT AND AT SUBSEQUENT BALLOTS BY A MAJORITY VOTE OF THE PERMANENT MEMBERS PRESENT.

3. THE PERMANENT MEMBERS SHALL ELECT TWO VICE-CHAIRMEN FROM THE PERMANENT MEMBERS OF THE ECONOMIC GROUPS TO WHICH THE CHAIRMAN DOES NOT BELONG, IN ACCORDANCE WITH THE PROCEDURE SET OUT IN PARAGRAPH 2.

ARTICLE 4

THE COMMISSION SHALL PROVIDE THE SECRETARIAT FOR THE WORK OF THE COMMITTEE.
IT SHALL DRAW UP THE AGENDAS FOR MEETINGS, INVITE MEMBERS WHOSE ATTENDANCE IS REQUIRED AND SUPPLY THEM WITH DOCUMENTATION.

ARTICLE 5

THE COMMITTEE MAY SET UP WORKING PARTIES TO EXAMINE TECHNICAL SUBJECTS IN CONNECTION WITH THE DRAFTING OF REGULATORY MEASURES CONCERNING FOODSTUFFS.
THE COMMISSION SHALL PROVIDE THE CHAIRMAN AND THE SECRETARIAT FOR THESE WORKING PARTIES.

ARTICLE 6

THE COMMISSION MAY INVITE EXPERTS WHO HAVE SPECIAL COMPETENCE IN A SUBJECT INCLUDED ON THE AGENDA AND WHO DO NOT BELONG TO ONE OF THE COMMITTEE'S WORKING PARTIES, TO PARTICIPATE IN THE WORK OF THE COMMITTEE OR ITS WORKING PARTIES.
ANY PERSON THUS INVITED SHALL PARTICIPATE ONLY IN DISCUSSIONS IN RESPECT OF THE SUBJECT WHICH IS THE REASON FOR HIS ATTENDANCE.

ARTICLE 7

REPRESENTATIVES OF THE COMMISSION DEPARTMENTS CONCERNED SHALL TAKE PART IN MEETINGS OF THE COMMITTEE AND OF ITS WORKING PARTIES.

ARTICLE 8

1. THE COMMISSION MAY, ON A PROPOSAL FROM THE BODIES AND ORGANIZATIONS LISTED IN THE ANNEX, APPOINT OBSERVERS TO PROVIDE ADMINISTRATIVE LIAISON WITH THE SECRETARIAT OF THE COMMITTEE FOR THE TERM OF OFFICE OF THE PERMANENT MEMBERS.

2. THE OBSERVERS MAY ATTEND MEETINGS OF THE COMMITTEE AND WORKING PARTIES. THEY MAY NOT TAKE PART IN THE DISCUSSIONS.

ARTICLE 9

1. NO VOTE SHALL BE TAKEN AFTER THE DISCUSSIONS OF THE COMMITTEE AND ITS WORKING PARTIES.

2. WHERE THE COMMITTEE IS CONSULTED ON A DRAFT REGULATORY MEASURE OR WHERE THE COMMISSION REQUESTS AN OPINION FROM THE WORKING PARTIES REFERRED TO IN ARTICLE 2 (1) ON A SUBJECT FALLING WITHIN THE COMMITTEE'S COMPETENCE, THE SECRETARIAT SHALL DRAW UP A DRAFT OPINION WHICH SHALL BE SUBMITTED TO THE PERMANENT MEMBERS OF THE COMMITTEE.
WITHIN A TIME LIMIT TO BE DETERMINED BY THE COMMISSION AFTER CONSULTATION OF PERMANENT MEMBERS, THE SECRETARIAT SHALL COLLECT ANY REQUESTS FOR CORRECTIONS FROM THE PARTICIPANTS IN THE COMMITTEE MEETING. IN THE ABSENCE OF SUCH REQUESTS WITHIN THE TIME LIMIT LAID DOWN, THE OPINION SHALL BE CONSIDERED ADOPTED.

3. THE DISCUSSIONS OF THE WORKING PARTIES REFERRED TO IN ARTICLE 5 SHALL BE THE SUBJECT OF A RECORD WHICH SHALL BE SUBMITTED TO THE MEMBERS OF THE WORKING PARTIES, TO THE PERMANENT MEMBERS OF THE COMMITTEE AND TO THE OBSERVERS UNDER THE CONDITIONS LAID DOWN IN PARAGRAPH 2.

ARTICLE 10

PARTICIPATION IN THE WORK OF THE COMMITTEE AND ITS WORKING PARTIES SHALL NOT BE SUBJECT TO ANY REMUNERATION.

ARTICLE 11

THE OPINIONS AND/OR RECORDS OF THE DISCUSSIONS SHALL BE COMMUNICATED AT THEIR REQUEST TO THE COUNCIL AND TO THE STANDING COMMITTEE ON FOODSTUFFS.

ARTICLE 12

WITHOUT PREJUDICE TO THE PROVISIONS OF ARTICLE 214 OF THE TREATY, THOSE TAKING PART IN MEETINGS OF THE COMMITTEE SHALL BE UNDER AN OBLIGATION NOT TO DISCLOSE INFORMATION WHICH HAS COME TO THEIR KNOWLEDGE THROUGH THE WORK OF THE COMMITTEE OR ITS WORKING PARTIES, WHERE THE COMMISSION INFORMS THEM THAT THE OPINION REQUESTED OR THE QUESTION RAISED IS ON A MATTER OF A CONFIDENTIAL NATURE.

ARTICLE 13

DECISION 75/420/EEC IS HEREBY REPEALED (1).

ARTICLE 14

THIS DECISION SHALL ENTER INTO FORCE ON 26 NOVEMBER 1980.

ANNEX

LIST OF BODIES AND ORGANIZATIONS REFERRED TO IN ARTICLE 2 (4)

ECONOMIC GROUP / BODIES AND ORGANIZATIONS

AGRICULTURE: THE COMMITTEE OF AGRICULTURAL ORGANIZATIONS OF THE EUROPEAN ECONOMIC COMMUNITY (COPA), JOINTLY WITH THE GENERAL COMMITTEE FOR AGRICULTURAL COOPERATION IN THE EEC COUNTRIES (COGECA)

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(1) OJ No L 182, 12/07/1975, p. 35.

Communication on the free movement of foodstuffs within the Community

(89/C 271/03)

SUMMARY

Introduction

The foodstuffs sector is without doubt one of the few which have a direct bearing on every individual in the Community. Given that trade is intensifying and that consumers are confronted with an ever greater diversity of foodstuffs on the market, the Commission has felt it necessary to indicate how and to what extent the provisions of the Treaty aimed at eliminating obstacles to trade between Member States have to be applied to the movement of foodstuffs.

The Commission's strategy essentially consists in combining the adoption of harmonized rules at Community level, which are applicable to all foodstuffs marketed in the Community, with the principle of mutual recognition of national regulations and standards for matters which do not require the adoption of Community legislative measures.

Community legislation

In the foodstuffs sector the Commission is proposing the adoption of harmonized rules at Community level only for matters relating to public health, the protection of consumers, fairness of commercial transactions and environmental protection. Generally speaking these will be horizontal measures (i.e. applicable to foodstuffs in general) covering such aspects as food additives, pesticide residues, materials and articles in contact with foodstuffs, certain manufacturing and treatment processes and the labelling, presentation and advertising of products. The Commission will make sure that these provisions are kept up to date and supplemented, in particular with regard to the official inspection of foodstuffs.

However, in certain cases, the Community will be able to adopt sectoral provisions considered necessary for the implementation of other Community policies (for example, standards governing composition, definition of 'organic' production). Moreover, as has already been indicated, the Commission intends to promote a policy of product quality at the Community level. In this context it is necessary to provide for a Community framework for prescribing approval procedures and mutual recognition of quality labels and of claims permitting the recognition of quality products and products of characteristic or traditional origin or manufacture. The Commission will also examine how to improve the accuracy of the designation of foodstuffs, particularly in the standard of claims made in their labelling.

Rules applicable in the absence of Community legislation

General

In the absence of harmonized Community rules the Member States have the power to lay down, in respect of their own production, rules governing the manufacture, composition, packaging and presentation of foodstuffs. On the other hand, they are required to admit to their territory foodstuffs lawfully produced and marketed in the other Member States. The importation and marketing of foodstuffs lawfully produced and marketed in another Member State may be restricted, in the absence of harmonized rules at Community level, only where such a measure:

— can be demonstrated to be necessary in order to satisfy mandatory requirements (public health, protection of consumers, fairness of commercial transactions, environmental protection),

— is proportionate to the desired objective, and

— is the means of achieving that objective which least hinders trade.

These principles, which the Commission set out in its communication concerning the consequences of the judgment in the Cassis de Dijon case, have been confirmed in a large number of subsequent decisions by the Court of Justice, in particular in its judgment in the Beer case.

This dispute concerned certain provisions of German law restricting the use of the designation 'beer' to fermented beverages manufactured solely from malted barley, hops, yeast and water and imposing an absolute ban on the marketing of beers containing additives. The Court ruled that these provisions were incompatible with the principle of the free movement of goods within the Community enshrined in Article 30 of the EEC Treaty inasmuch as they constituted a barrier to the importation and marketing of beers lawfully produced and marketed in other Member States.

On the question of the use of the designation 'beer', the Court held that while it is legitimate to seek to enable consumers who attribute specific qualities to beers manufactured from particular raw materials to make their choice in the light of that consideration, that possibility may be ensured by means which do not prevent the importation of products which have been lawfully manufactured and marketed in other Member States and, in particular, by the affixing of suitable labels giving the nature of the product sold.

The Court also ruled that the German rules on additives applicable to beer were contrary to the principle of proportionality, since they result in the exclusion of all the additives authorized in the other Member States and not the exclusion of just some of them for which there is concrete justification by reason of the risks which they involve in view of the eating habits of the German population. It also observed that these rules did not lay down any procedure whereby traders can obtain authorization for the use of a specific additive in the manufacture of beer by means of a measure of general application where such additive does not present a risk to public health and meets a real need, especially a technological one.

Specific problems

The principles laid down by the Court in this judgment provide the basis for resolving most of the problems arising in connection with the free movement of foodstuffs, especially those relating to:

— the name under which imported foodstuffs are sold (trade description),

— the presence of additives in imported foodstuffs.

Trade description

As far as the trade description of an imported foodstuff is concerned the importer can in fact choose:

— either to keep the name under which the product is lawfully marketed in the Member State of manufacture,

— or to adopt the trade description under which similar products are marketed in the importing Member State.

Indeed, there is no reason why the product should not bear both trade descriptions at the same time, provided that this does not create confusion for the purchaser.

The only instance in which this choice can be restricted is where the product presented under one or other, or both, of the trade descriptions differs in terms of its composition or manufacture from the goods generally known under the same descriptions in the Community to such an extent that it cannot be regarded as belonging to either category.

Where the imported product does not have certain characteristics that are considered essential, in the importing Member State, for the use of a particular trade description, it is the responsibility of the importer to ensure that the labelling of the imported product gives the consumer the proper information about the nature and characteristics of the product, to enable it to be distinguished from products with which it might be confused.

Generally speaking, the only instance in which the marketing of an imported foodstuff can be restricted by the application of national measures designed to avoid confusion in the mind of the consumer between two different products is when the labelling, packaging or presentation of the product are actually liable to create confusion as to the nature, characteristics or origin of the product and where this confusion cannot be prevented by measures that hinder free trade less.

Additives

The importation of a foodstuff containing an additive that is authorized in the Member State of manufacture, but prohibited in the importing Member State, must be authorized if:

— the additive does not represent a danger to public health, taking into account the findings of international scientific research and the eating habits in the importing Member State, and

— the use of this additive meets a genuine need, in particular of a technological or economic nature.

To this end, the Member States must institute an authorization procedure that is easily accessible to traders and can be concluded within a reasonable time (not more than 90 days). Under such a procedure it will be for the responsible national authorities in the Member States to demonstrate that the refusal to grant authorization is justified on grounds relating to the protection of public health. Furthermore, it must be open to traders to challenge before the courts an unjustified failure to grant authorization.

These principles also apply in cases where the importation of a foodstuff lawfully produced and marketed in another Member State is restricted on grounds other than the protection of health.

Conclusion

Community foodstuffs legislation must ensure that there is a high level of public health protection and that the consumer is accurately and adequately informed as to the nature, characteristics and, where appropriate, the origin of the foodstuffs placed on the market. These provisions will be supplemented so as to guarantee that all foodstuffs produced and marketed in the Community satisfy the requirements of public health protection, consumer and environmental protection and fair trading.

For aspects not covered by Community legislation, the case-law of the Court of Justice provides a basis for ensuring the free movement of foodstuffs.

The completion of an internal market in this sector, accompanied by an active promotion of product quality, should also ensure consumer access to the great variety of the Community's agri-food production by offering producers the advantages and outlets of a large market.

COMMUNICATION

A. INTRODUCTION

1. In its White Paper on completing the internal market, the Commission described the measures it intends to take in order to establish and ensure the smooth running of the internal market by the 1992 deadline. The Commission's strategy essentially consists in combining the principles of the mutual recognition of national rules and standards, based on Articles 30 to 36 of the EEC Treaty, with a new approach to the harmonization of laws based mainly on Article 100a, which was inserted into the Treaty by the Single Act.

2. As far as foodstuffs are concerned, the Commission set out the main lines of the new approach to harmonization in its communication of 8 November 1985 entitled 'Completion of the internal market: Community legislation on foodstuffs'. That communication specifies those matters which have to be settled by legislative action and those which do not call for the adoption of a binding legal instrument, and is aimed at striking a new balance between the legislative powers retained by the Council and the implementing powers conferred on the Commission.

The measures which must continue to be the subject of Community legislation are:

— first, those which are designed to protect the health and life of humans, as referred to in Article 36 (food additives, materials and articles in contact with

foodstuffs, contaminants, manufacturing or treatment processes and dietary foodstuffs), and

— secondly, those which are necessary to satisfy certain mandatory requirements, such as the need to ensure fair trading and the protection of consumers (labelling, presentation and advertising of products) and to provide for official checks.

3. In order to protect the consumer against misleading practices and to ensure the fairness of commercial transactions, the Commission's efforts in those areas are directed mainly towards providing the Community with horizontal rules applicable to all foodstuffs, ensuring that the consumer is correctly and precisely informed of the nature and characteristics of the product, the amount supplied, the date by which it should be consumed, the price, etc. However, in certain cases, the Community will be able to adopt sectoral provisions considered necessary for implementing other Community policies (for example, composition standards, definition of 'organic' production methods).

4. (a) Furthermore, in its communication 'The future of rural society' the Commission indicated its intention to promote a policy of product quality at Community level. The concern to protect agricultural and food products that are identifiable in terms of their geographical origin, their method of production and their special qualities has led to the appearance of controlled origin designations or 'labels' in the Member States. Consequently, the Commission feels that a Community approach needs to be considered. In this connection the Commission will shortly be suggesting a general framework for the use of quality marks or labels to identify products which:

— are subject to a special production quality requirement (cheese, butter, prepared cut meats, durum wheat pasta),

— originate in areas known for their traditional production (poultry, drinks, meat of particular breeds),

— can be shown to have been produced using special methods ('free range', 'organic').

The Commission also intends to define certain claims describing modes of production or manufacture, origin or source (e.g. 'free range', 'non-industrial' or 'traditional' produce, 'from animals fed in the traditional way', 'upland product', etc.). The same approach ought to be followed for the granting of controlled origin designations. The approval procedures for recognition at Community level ought to enable a clear link to be established between product quality and geographical origin (soil, herbage cover, vine variety, know-how, etc.). So far, wine and, only recently, spirituous beverages, are the only areas which have been covered by specific rules protecting geographical indications. The Commission also believes that there is a need for quality-linked, across-the-board protection of geographical indications, also covering origin designations, for other food products. Such a comprehensive approach not confined to products originating in the countryside would also have the advantage of facilitating the introduction of a Community policy to replace the bilateral agreements used so far between Member States and the defence of a uniform policy at an international level.

(b) On the other hand, the Commission does not in principle intend to propose that the Council adopt harmonized rules relating to product quality (compositional rules or recipes), i.e. requirements relating to composition and manufacture, other than those concerning the protection of public health, with which foodstuffs must comply.

It should be pointed out, however, that the composition standards adopted or to be adopted under the common agricultural policy as part of the efforts to attain the objectives set out in Article 39 of the Treaty, and which are not part of food legislation in the strict sense, will continue to apply.

B. RULES APPLICABLE IN THE ABSENCE OF COMMUNITY PROVISIONS

I. GENERAL

5. This communication therefore defines the scope of Articles 30 to 36 of the Treaty in the foodstuffs sector, in all areas which have not yet been regulated completely and definitively by Community action. In that respect, it follows on from the Commission's communication on the consequences of the Cassis de Dijon case, in which it set out certain principles for interpreting the judgment delivered by the Court of Justice on 20 February 1979.

6. Those principles have been confirmed and developed in greater detail on many occasions in subsequent Court decisions and in particular, as far as foodstuffs are concerned, in the judgment in the Beer case. The Commission is consequently in a position to specify in this communication:

— Member States' obligations with regard to the free movement of foodstuffs, under Articles 30 to 36 of the Treaty, as interpreted by the Court,

— the rights conferred on traders and individuals by the direct applicability of Articles 30 to 36 of the Treaty and the legal remedies available to them should those rights not be respected.

7. As of 1 January 1989 Member States are required to communicate to the Commission, under the procedure for the provision of information introduced by Directive 83/189/EEC, draft technical regulations relating to foodstuffs. The principles developed in this communication will therefore also be applied by the Commission in assessing whether drafts thus notified are compatible with Community law.

8. Harmonized provisions (Directives or Regulations) have been adopted at Community level to regulate certain aspects of the production and marketing of specific foodstuffs. In the case of other products and matters concerning the marketing of the above-mentioned products that are not covered by Community legislation, Member States have the power in principle, in the absence of harmonized rules, to lay down rules relating to the manufacture, composition, packaging and presentation of foodstuffs. The Court of Justice has ruled, however, that barriers to the free movement of goods resulting from differences between national provisions applied without distinction to national and imported products should be accepted only where such provisions:

— can be demonstrated to be necessary in order to satisfy mandatory requirements such as the protection of consumers, the fairness of commercial transactions and the protection of the environment,

— are proportionate to the desired objective, and

— are the means for achieving that objective which least hinders trade.

The Commission has already explained how it interprets these principles (see its communication on Cassis de Dijon). The aim of the following considerations is to determine, in the light of a very large number of Court decisions, how the principles are applied in various specific cases in the foodstuffs sector. Reference will be made only to measures that apply without distinction to national and imported products. It should be pointed out that many other measures are incompatible *per se* with Article 30 of the Treaty, in particular where they apply specifically to imported products (import formalities and checks, the requirement that a representative be established on the national territory, etc.).

9. The Court has consistently held that only the need to protect the health and life of humans, animals or plants can justify a complete ban on the marketing of a foodstuff. Consequently the Commission is endeavouring, as a matter of priority, to regulate matters relating to health protection at Community level. Whilst, in the absence of common or harmonized rules, it is in principle for the Member States to regulate, each on its own territory, matters concerning the production, marketing, consumption, labelling and designation of products, this is subject to the condition that the measures adopted do not form an obstacle to Intra-Community trade. Member States are required to fulfil certain obligations concerning the free movement of goods and deriving from the EEC Treaty itself and they are set out below (point III). The protection of consumers and the fairness of commercial transactions, which are mandatory requirements according to decisions of the Court, can, for their part, be ensured by measures that have a less restrictive effect on trade than a marketing ban, in particular by labelling the foodstuff in a way that correctly informs the consumer and avoids any risk of confusion: in this area, therefore, the main aim is to ensure that foodstuffs are adequately labelled and their free movement is not unduly restricted (point II).

II. BARRIERS TO THE FREE MOVEMENT OF FOODSTUFFS OTHER THAN THOSE INTENDED TO PROTECT PUBLIC HEALTH

General

10. The main conclusions to be drawn from decisions of the Court concerning barriers to the free movement of foodstuffs that are not intended to protect public health can be summarized as follows. The marketing of a foodstuff imported from another Member State where it is lawfully produced and marketed cannot, in principle, be prohibited, for reasons associated with the protection of consumers or the fairness of commecial transactions, if the foodstuff is adequately labelled in terms of its nature and characteristics, including compliance with the relevant Community legislation. As the Court has pointed out in many individual cases, an obligation to affix an adequate label concerning the nature and characteristics of a product put on the market is always a measure that hinders trade less than a marketing ban and nearly always suffices to ensure consumer protection and fair trading. As the Court has explicitly stated, this principle is not defeated by the fact that many foodstuffs are consumed on licensed premises and in restaurants and the like, since the consumer can be informed of the nature and characteristics of the products even in such cases (for example, by means of information displayed on the casks or taps, in the case of beers served on draught).

11. Generally speaking, the only case where the marketing of an imported foodstuff can be restricted by national measures seeking to avoid confusion in the

consumer's mind between two different products is when the labelling, packaging or presentation of the product is actually liable to create confusion as to the nature, characteristics or origin of the product, and where this confusion cannot be prevented by measures that hinder free trade less.

Importance of labelling

12. The aforementioned principle attaches considerable importance to the labelling of foodstuffs. The Community has, however, adopted particularly detailed common rules on the topic, at the forefront of which is Council Directive 79/112/EEC. These rules are supplemented and amended when the need arises. The Commission is aware that these rules are not as clear and effective as one would wish and has thus sent the Council a proposal for a Directive amending Directive 79/112/EEC that seeks to eliminate the possibilities for derogations left to the discretion of Member States and to complete the information given to consumers in specific cases. The Commission is shortly to make another proposal concerning the indication of ingredients. It must also be pointed out that the Commission sent the Council, in October 1988, two proposals for Directives concerning the nutrititonal labelling of foodstuffs. The Commission will also be taking various measures relating to labels and designations of origin as part of its policy on the quality of products from the countryside (see above).

13. The main difficulty left pending by Directive 79/112/EEC, in the context of the free movement of goods, concerns the name under which foodstuffs are sold. The Directive provides that the name under which a foodstuff is sold shall be the name laid down by whatever laws, regulations or administrative provisions apply to the foodstuff in question or, in the absence of any such name, the name customary in the Member State where the product is sold to the ultimate consumer, or a description of the foodstuff and, if necessary, of its use, that is sufficiently precise to inform the purchaser of its true nature and to enable it to be distinguished from products with which it could be confused.

Another difficulty concerns the claims applicable to foodstuffs and additional descriptions. In this connection Directive 79/112/EEC states that the Council is to draw up a non-exhaustive list of the claims whose use must be banned or restricted. The Commission also intends to define the conditions in which certain foodstuffs, particularly those of agricultural origin, could be marketed bearing a statement that they have been produced 'organically'.

Trade description

14. National regulations relating to the names under which foodstuffs are sold can pose, from the standpoint of the free movement of goods, two types of problem:

— either the imported product is disqualified from bearing the name under which it is marketed in the Member State of manufacture, that name being reserved, in the importing Member State, for products displaying certain characteristics,

— or the imported product has to be sold under a generic name that is mandatory, in the importing Member State, for the products concerned.

15. In the first case, the laws of the importing Member State deprive the imported product of a trade description to which it is entitled in the Member State of manufacture and impose on it a trade description that is less well known or less appreciated by the consumer than the one of which it is deprived, the latter being reserved for products conforming to a national recipe. The Court of Justice has ruled that a Member State may not reserve a generic trade description for:

— products manufactured on its territory (judgment in the Sekt case),

— products manufactured from specific raw materials (judgments in the Vinegar, Beer, Pasta and Meat products cases),

— products containing a given concentration of one of their characteristic ingredients (judgments in the Miro and Deserbais cases),

— fresh produce, to the exclusion of products that have undergone a specific treatment, where the characteristics of the latter do not differ substantially from those of the fresh produce (judgment in the Smanor case),

in order to deprive products imported from another Member State where they are lawfully marketed under the disputed description of that description.

16. As the Court has stressed, while it is legitimate to seek to enable consumers who attribute specific qualities to products manufactured from particular raw materials or containing a particular concentration of a characteristic ingredient to make their choice on the basis of that factor, that possibility may nevertheless be ensured by means that do not prevent the importation of products which have been lawfully produced and marketed in other Member States, in particular by the affixing of suitable labels giving the nature of the product on sale, which allows the consumer to make his choice with full knowledge of the facts and ensures the transparency of commercial transactions and offers for sale. An imported foodstuff should therefore be deprived of the name under which it is sold in the Member State

of origin only where it differs, in terms of its composition or manufacture, from goods generally known under the same name in the Community to such an extent that it cannot be regarded as belonging to the same category (judgments in the Smanor and Deserbais cases).

17. In the second aforementioned case, a trade description is imposed on the imported product in the importing Member State that differs from the one it lawfully bears in the Member State of manufacture. In this connection, the Court of Justice has stated that while it may be necessary to extend to imported products the obligation, laid down by national rules relating to a given product, to use a description that is sufficiently precise to inform the purchaser of the nature, characteristics and, where appropriate, the origin of the product and to enable it to be distinguished from products with which it might be confused, there is no longer any need for such protection if the details given on the original label of the imported product convey at least the same information on the nature, characteristics and, where appropriate, the origin of the product, and are just as capable of being understood by consumers in the importing Member State, as the description prescribed by the rules to that State (judgment in the Fietje case).

18. The Commission has deduced from the foregoing considerations that the importer of a foodstuff has the choice between either:

— maintaining the name under which the product is lawfully marketed in the Member State of manufacture, or

— adopting the trade description under which similar products are marketed in the importing Member State.

That choice may be restricted only where the product presented under a given description differs, in terms of its composition or manufacture, from goods generally known under that description in the Community to such an extent that it cannot be regarded as belonging to the same category.

Furthermore, where the imported product does not display certain characteristics that are regarded in the importing Member State as essential in order for a given trade description to be used, it is for the importer to ensure that the labelling of the imported product informs the consumer adequately of its nature and characteristics, so that it can be distinguished from products with which it might be confused. This may mean that the labelling of the imported product has to comprise certain details that are not mandatory under Directive 79/112/EEC in its present form, such as the indication of a raw material in the trade description or the indication of the content of a characteristic ingredient. The Commission is therefore shortly to put forward a proposal aimed at making it mandatory to indicate the quantity of ingredients that are essential to the characteristics of a foodstuff, specifying the cases in which foodstuffs composed of a single ingredient do not need to bear a list of ingredients and making it mandatory to indicate the ingredients in beverages with an alcoholic strength of more than 1,2 % by volume (see also the measures announced in the communication 'The future of rural society').

Under no circumstances, however, may the indications that can be imposed with a view to informing the consumer of the characteristics of products comprise statements that are unfavourable to products which do not conform to a traditional recipe in the importing Member State.

In the Commission's view there is no reason, provided that it does not result in any risk of confusion for the purchaser, why the imported product should not bear two trade descriptions:

— the one under which it is known and lawfully marketed in the Member State of manufacture,

— the one under which similar products are known and marketed in the importing Member State or which is mandatory under the rules of that State.

Lastly, these matters should not be confused with the question of the language in which the trade description is to be drawn up: that issue is settled by Article 14 of Directive 79/112/EEC, which provides that the mandatory labelling particulars must appear in a language easily understood by purchasers, unless other measures have been taken to ensure that the purchaser is informed; such particulars may be indicated in more than one language.

Packaging

19. As in the case of trade descriptions, two types of situation can arise where the imported product cannot be marketed in the importing Member State in the packaging in which it is sold in the Member State of manufacture:

— either that packaging is reserved in the importing Member State for products displaying certain characteristics,

— or a different packaging is mandatory, in the importing Member State, for the product in question.

20. In the first case, the laws of the importing Member State reserve a given packaging for products displaying certain characteristics or originating from a given area. The Court of Justice has ruled that a Member State may not reserve a given packaging for:

— products displaying certain characteristics (judgment in the Pétillant de raisins case), or

— products originating from a given area (judgment in the Prantl case),

so as to prohibit the marketing of a product imported from another Member State, where it is fairly and traditionally marketed in the disputed packaging. As the Court has stated, the concern to prevent consumers from confusing products of different quality and origin is worthy in itself. Nevertheless, in a common market system, the protection of the consumer against misleading practices, the fairness of commercial transactions and the protection of the environment must be guaranteed with regard on all sides for the fair and traditional practices observed in the various Member States.

21. In the second case, a packaging different from the one in which it is marketed in the Member State of manufacture is imposed on the imported product in the importing Member State.

In this connection, the Court has stated that, although it may be necessary to take measures in order to prevent two different products from being confused in the mind of the consumer, the application by one Member State to foodstuffs lawfully produced and marketed in another Member State of legislation which prescribes for those products a specific kind of packaging, to the exclusion of any other form, considerably exceeds the requirements of the object in view (judgment in the Rau case).

Clearly, consumers may be protected just as effectively by other measures, for example by rules on labelling, which hinder the free movement of goods less.

22. The Commission has deduced from the foregoing considerations that a Member State may prohibit, on grounds of packaging, imports of a foodstuff from another Member State, in which it is lawfully and fairly produced and marketed in the packaging in question, only where:

— that packaging is actually liable to create confusion in the mind of the consumer as to the nature or origin of the foodstuff, and

— such confusion cannot be prevented by measures that restrict the free movement of goods less, such as labelling requirements.

The measures taken by the Member States to lessen the environmental impact of waste arising from the packaging of foodstuffs are also liable to present an obstacle to the free movement of foodstuffs.

Such measures may admittedly be justified on grounds relating to the need to protect the environment, which is an imperative requirement within the meaning of the decisions of the Court; indeed, Council Directive 85/339/EEC requires the Member States to draw up programmes for reducing the quantity of containers for liquid foodstuffs in household waste which to be finally disposed of. Nevertheless, the measures taken to that end must be proportionate to the objective in view; if a Member State has a choice of various methods for meeting that objective it must choose the means that least restricts free trade, as stated by the Court of Justice in its judgment of 20 September 1988. In that judgment the Court ruled that, in the absence of Community provisions, the restrictions on free trade in the form of a requirement to introduce a refundable deposit system for containers were not disproportionate to the objective in view.

The Commission is currently examining with the Member States the exact conditions under which the various deposit systems are compatible with Community law, and will shortly be proposing an amendment to Directive 85/339/EEC.

Ranges of prepackages

23. Application in the Member States of quantity or capacity ranges for marketing prepackaged foodstuffs clearly creates problems for the free movement of the products concerned where the national ranges do not coincide. The Community has consequently undertaken to harmonize them. Nevertheless, the ranges adopted so far at Community level (Directives 75/106/EEC and 80/232/EEC) do not cover all foodstuffs and are for the most part optional in that Member States, although required to accept prepackages for the quantities laid down in the Directives, are free also to accept any other quantities where they deem it necessary. The problem is therefore whether Member States can prohibit the marketing on their territory of a prepackaged foodstuff, on the grounds that the quantity prepackaged is not allowed in their range, where the foodstuff is imported from another Member State in which it is lawfully marketed in the prepackage concerned. The Court has not so far had to pronounce on this question.

24. The Commission takes the view that the general principles developed by the Court in Cassis de Dijon and subsequent judgments command the following solution. While legislative measures intended to ensure fair trading and prevent confusion in the mind of the consumer

between similar but different quantities or between quantities that make price comparisons extremely difficult are indisputably justified, as recognized by the Community legislator, such measures can, however, be applied to foodstuffs imported from another Member State, in which they are lawfully marketed in the disputed packaging, only where that packaging is actually of such a kind as to give rise to the confusion which the legislative measures in question seek to avoid (judgment in the De Kikvorsch case).

25. The Commission will, however, endeavour to alleviate the abovementioned difficulties by presenting to the Council suitable proposals aimed at abolishing the optional nature of the existing ranges and extending the quantity ranges to further categories of products, as expressly requested by the Council in its resolution of 7 June 1988 on consumer protection in the indication of the prices of foodstuffs and non-food products.

Substitute products

26. Certain national provisions prohibit the marketing and importation of products that are substitutes for certain basic foodstuffs to which special importance is attached. These are complete marketing bans, since the sale of the substitute products in question is prohibited under any trade description whatsoever.

27. The Court has ruled that, provided the substitute product presents no hazard to health and is provided with a sufficiently clear label indicating its nature and characteristics and avoiding any possibility of its being confused with the product it can replace, prohibition of the substitute product does not serve a purpose which is in the general interest and such as to take precedence over the requirements of the free movement of goods (judgment in the Gilli case). As regards the risk of the original products being forced off the market by their substitutes, because the cost of producing the latter is lower, the Court has ruled that a Member State may not use a mandatory requirement such as consumer protection in order to shield a product from the effects of price competition on the grounds of the economic difficulties caused by the removal of barriers to intra-Community trade (judgment in the Milk substitutes case).

The principles set out above do not, however, preclude other measures adopted by the Community under the common agricultural policy and which would ban the use of certain substitute products (such as synthetic alcohol).

III. BARRIERS TO THE FREE MOVEMENT OF FOODSTUFFS INTENDED TO PROTECT PUBLIC HEALTH

General

28. As has already been stated, only the protection of public health can justify a complete ban on importing and marketing foodstuffs imported from another Member State where they are lawfully produced and marketed. In a consistent line of decisions, the Court has stated that, in so far as uncertainties persist in the present state of scientific research, it is for the Member States, in the absence of harmonization, to decide what degree of protection of health and life of humans they intend to ensure, having regard, however, to the requirements of the free movement of goods with the Community. It is those requirements that the Commission intends to highlight and define in greater detail below.

29. In general terms, the application to products imported from other Member States of a prohibition on marketing foodstuffs laid down by a national provision is compatible with Community law only if that provision is compatible with relevant secondary Community law or, in the total or partial absence of hormonized provisions, if

— the provision in question pursues a legitimate health policy objective,

— the other conditions necessary for Article 36 of the Treaty to apply, as interpreted by the Court, are satisfied.

30. In the Commission's view, laws that pursue a legitimate health policy objective (protection of the population in general or of certain particularly sensitive groups) are essentially those which:

— prohibit, restrict or limit the use of food additives,

— ensure that materials and articles coming into contact with foodstuffs are inert with regard to the latter,

— prohibit or limit the presence, on or in foodstuffs, of residues of pesticides or other contaminants,

— lay down the microbiological criteria that must be met by certain foodstuffs,

— regulate the use of certain food production or treatment processes,

— require that the labelling include information necessary to ensure the protection of human health.

31. Insofar as the application of such legislative measures is liable to restrict the free movement of foodstuffs, the Commission has undertaken, with a view to completing the internal market in this sector, to harmonize the provisions regulating such matters.

The principles set out below should therefore be regarded as forming a system applicable until the entry into force of the harmonized provisions, which will be adopted gradually. Thus as far as additives are concerned, it is planned that directives will lay down, for each category of additives, not only a list of additives whose use is authorized, to the exclusion of all others, but also a list of the foodstuffs in which those additives may be used, the conditions of such use and, where appropriate, a restriction on the technological purpose it serves (see Council Directive 89/107/EEC).

32. Pending such harmonized provisions, Member States are required, under Articles 30 to 36 of the Treaty, to limit prohibitions on marketing foodstuffs imported from other Member States to cases where such measures are actually necessary in order to safeguard public health.

The Court has thus stated that, in the case of a foodstuff containing an additive which is authorized in the Member State of manufacture but prohibited in the importing Member State, the latter must allow the foodstuff in question to be imported where, taking into account the findings of international scientific research and eating habits in the importing Member State, the additive does not present a risk to public health and meets a genuine need, particularly of a technological nature (judgments in the Sandoz, Motte, Muller and Beer cases). The Court has also laid down certain requirements for the form to be taken by the authorization procedure that the Member States have to apply for the purpose (judgments in the Müller and Beer cases).

33. The Commission takes the view that the principles developed by the Court concerning additives should be extended and applied to other cases where, in the absence of Community legislation, the marketing of foodstuffs is prohibited as a result of the application of a legislative measure that pursues a legitimate health policy objective (in this connection see the judgment in the Mirepoix case).

It follows that in all cases where such legislative measures extend a prohibition of that type to the marketing of a foodstuff imported from another Member State where it is lawfully marketed, the importing Member State must allow the traders concerned to request, under a procedure complying with the minimum requirements set out below, that the marketing of the foodstuff in question be authorized. The requirements set out below relate to the substance (points 33, 34 and 35) and the form (points 36 to 40) of the procedure.

Such authorization should, however, be required only in the case of a new product on being put on the market for the first time. It is, moreover, self-evident that a Member State may always exempt foodstuffs or certain categories of foodstuffs which are lawfully produced and marketed in another Member State from such an authorization procedure.

Examination of requests for authorization

34. In assessing the risks a foodstuff presents to public health, the authorities of the importing Member State must:

— take account to the findings of international scientific research, and in particular the results of the work of the Community's Scientific Committee for Food, the FAO's Codex Alimentarius Commission and the World Health Organization (judgment in the Beer case),

— review the maximum permitted concentrations if it appears to them that the grounds on which they were laid down have changed, for example following the discovery of a new use for a given substance (judgment in the Heijn case),

— recognize the results of analyses, tests and checks carried out in the Member State of manufacture and placed at their disposal or available to them on request (judgment in the Biologische Produkten case).

They may take account of:

— the usual diet and state of health of their population (judgment in the Heijn case),

— eating habits on their territory (judgments in the Melkunie and Beer cases).

When assessing the need for the use of certain substances or certain manufacturing processes and treatment methods, the authorities of the importing Member State must take into consideration:

— the assessment of that need made by the authorities of the Member State where the product has been lawfully produced and marketed (judgment in the Beer case),

— the raw materials used and manufacturing methods customarily applied in the Member State of manufacture (judgment in the Beer case) and the differences in climatic conditions from one Member State to another (judgment in the Heijn case).

The Commission also takes the view that the authorities of the importing Member State cannot dispute the need to use a specific substance in a given foodstuff where they have themselves authorized the use in the same foodstuff of a different substance that meets the same need.

35. According to the Commission, in the specific case of a foodstuff containing an additive which is not authorized in that foodstuff, but appears on a Community approved list and meets an established technological need, prohibition of that foodstuff can be justified only on the grounds of the risk of the acceptable daily intake (ADI) being exceeded, since the general harmlessness of the additive has already been assessed.

Implementation of the authorization procedure

36. As regards the implementation of the authorization procedure, the Court has stated that:

— the procedure must be easily accessible to traders (judgment in the Muller case),

— it must be capable of being completed within a reasonable period of time (judgment in the Beer case),

— any unjustified failure to grant authorization must be open to judicial review (judgment in the Beer case),

— any authorization must be the subject of a measure with general application (judgment in the Beer case).

The Commission interprets those principles in the following manner.

37. If the authorization procedure is to be easily accessible to traders, adequate information must be provided on both the possibility of introducing a request for authorization and the items to be submitted in support of that request. The latter must not include documents or information that traders cannot reasonably be expected to possess. It is for the competent authorities of the Member States to cooperate with a view to exchanging the documents and information necessary for carrying out their tasks.

38. The time it takes for the competent authorities of the importing Member State to decide on a request for authorization should not exceed 90 days. Under such a procedure, the authorities in question do not have to give a ruling on a new question (such as the authorization of a new additive), but essentially carry out a fresh evaluation, in the light of differing assessments made in another Member State, of the data on which their initial decision not to permit a particular use of an additive was based.

39. Should authorization be refused, the applicant must be informed in writing of the decision and grounds for refusal.

Where a decision has not been taken within the abovementioned period, the applicant must be informed in writing of the reasons for the delay and the new period within which a decision is expected to be taken.

In both cases, such information must mention the court before which any action challenging the refusal or failure to grant authorization is to be brought and the time allowed for bringing such actions.

40. Where authorization is granted, it must take the form of a measure having general application. This means that all imported foodstuffs that fulfil the conditions for the authorization must be covered by it.

C. FINAL REMARKS

41. The Commission invites the Member States to examine their legislation and administrative practices in the light of the principles set out in this communication and, where necessary, bring them into line with those principles.

42. The Commission would stress that Articles 30 to 36 of the Treaty, whose scope is defined in this communication, have direct effect and are directly applicable in the Member States' domestic legal systems. This means, in particular, that any court hearing a case within its jurisdiction is under the obligation to apply those provisions in full, as interpreted by the Court of Justice, and to protect the rights they confer on individuals by refusing to apply any contrary national provision, whether adopted before or after the Treaty.

D. REFERENCES

Commission communications

— Cassis de Dijon (OJ No C 256, 30. 10. 1980, p. 2)

— White Paper on completing the internal market (COM(85) 310 final)

— Completion of the internal market: Community legislation on foodstuffs (COM(85) 603 final)

— Perspectives for the common agricultural policy (COM(85) 333 final)

The future of rural society (COM(88) 501 final)

Council Directives

— Council Directive 75/106/EEC of 19 December 1974 on the approximation of the laws of the Member States relating to the making-up by volume of certain prepackaged liquids (OJ No L 42, 15. 2. 1975, p. 1).

— Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain prepackaged products (OJ No L 46, 21. 2. 1976, p. 1).

— Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (OJ No L 33, 8. 2. 1979, p. 1).

— Council Directive 80/232/EEC of 15 January 1980 on the approximation of the laws of the Member States relating to the ranges of nominal quantities and nominal capacities permitted for certain prepackaged products (OJ No L 51, 25. 2. 1980, p. 1).

— Council Directive 83/189/ECC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ No L 109, 26. 4. 1983, p. 8).

— Council Directive 85/239/EEC of 27 June 1985 on containers of liquids for human consumption (OJ No L 176, 6. 7. 1985, p. 18).

— Council Directive 88/182/EEC of 22 March 1988 amending Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ No L 81, 26. 3. 1988, p. 75).

— Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (OJ No L 40, 11. 2. 1989, p. 27).

Judgments of the Court of Justice

— Judgment of 20 February 1975 in Case 12/74 *(Sekt)* [1975] ECR 181

— Judgment of 20 February 1979 in Case 120/79 *(Cassis de Dijon)* [1979] ECR 649

— Judgment of 26 June 1980 in Case 788/79 *(Gilli)* [1980] ECR 2071

— Judgment of 16 December 1980 in Case 27/80 *(Fletje)* [1980] ECR 3839

— Judgment of 9 December 1981 in Case 193/80 *(Vinegar)* [1981] ECR 3019

— Judgment of 17 December 1981 in Case 272/80 *(Biologische produkten)* [1981] ECR 3227

— Judgment of 10 November 1982 in Case 261/81 *(Rau)* [1982] ECR 3961

— Judgment of 17 March in Case 94/82 *(De Kikvorsch)* [1983] ECR 947

— Judgment of 14 July 1983 in Case 174/82 *(Sandoz)* [1983] ECR 2445

— Judgment of 13 March 1984 in Case 16/83 *(Prantl)* [1984] ECR 1229

— Judgment of 6 June 1984 in case 97/83 *(Melkunie)* [1984] ECR 2367

— Judgment of 19 September 1984 in Case 94/83 *(Heijn)* [1984] ECR 3263

— Judgment of 26 November 1985 in Case 182/84 *(Miro)* [1985] ECR 3731

— Judgment of 10 December 1985 in Case 247/84 *(Motte)* [1985] ECR 3887

— Judgment of 13 March 1986 in Case 54/85 *(Mirepoix)* [1986] ECR 1074

— Judgment of 6 May 1986 in Case 304/84 *(Muller)* [1986] ECR 1521

— Judgment of 4 December 1986 in Case 178/85 *(Pétillant de raisin)* [1986] ECR 3894

— Judgment of 12 March 1987 in Cases 176/84 and 178/84 *(Beer)* [1987] ECR 1213 and 1262

— Judgment of 23 February 1988 in Case 216/84 *(Milk substitutes)* Not yet reported

— Judgment of 14 July 1988 in Cases 407/85 and 90/86 *(Pasta)* Not yet reported

— Judgment of 14 July 1988 in Case 298/87 *(Smanor)* Not yet reported

— Judgment of 20 September 1988 in Case 302/86 *(Packaging of beverages)* Not yet reported

— Judgment of 22 September 1988 in Case 286/86 *(Deserbais)* Not yet reported

— Judgment of 2 February 1989 in Case 247/87 *(Meat products)* Not yet reported

— Judgment of 11 May 1989 in Case 78/86 *(Milk substitutes)* Not yet reported

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE 93/5/EEC

of 25 February 1993

on assistance to the Commission and cooperation by the Member States in the scientific examination of questions relating to food

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas the completion and smooth operation of the internal market for foodstuffs make it necessary to examine and evaluate scientific questions relating to food, particularly when these questions concern human health ;

Whereas consumers are entitled to a Community food policy which promotes safe food particularly regarding nutritional, microbiological and toxicological issues ;

Whereas in order to assist with this task the Commission set up a Scientific Committee for Food by Decision 74/234/EEC (4) ;

Whereas consultation of this Committee is currently required, in relation to questions of public health, by a number of Directives such as those on dietetic foodstuffs, materials and articles intended to come into contact with foodstuffs, additives, flavourings and extraction solvents ;

Whereas the Scientific Committee for Food should be involved much more widely in Community policies that affect food, diet and public health ;

Whereas the process of achieving a satisfactory scientific base for matters relating to food safety must, in the interests of consumers and industry be independent, transparent and effective and must reflect the situation existing in all Member States ;

Whereas in order to ensure the smooth running of this Committee the Community needs scientific support from the Member States ;

Whereas the Community also needs scientific support for other questions of public interest essential to the operation of the internal market, such as the handling of incidents involving food contamination and in general where it is necessary to lay down new rules concerning foodstuffs which may affect human health ;

Whereas, in order to ensure that these tasks are carried out, the Commission must have access to the information and assistance available in the Member States, which must facilitate the accomplishment of its tasks ;

Whereas in the Member States there are various bodies whose task is to provide their governments with scientific back-up on questions concerning foodstuffs ; whereas it is necessary to use these resources effectively to support Community activities through cooperation ;

(1) OJ No C 108, 23. 4. 1991, p. 7 and OJ No C 107, 28. 4. 1992, p. 13.
(2) OJ No C 94, 13. 2. 1992, p. 286 and Decision of 20 January 1993 (not yet published in the Official Journal).
(3) OJ No C 14, 20. 1. 1992, p. 6.
(4) OJ No L 136, 20. 5. 1974, p. 1.

Whereas Member States shall take all the necessary measures including financial measures, within the limits of their resources, to enable their competent authorities and bodies to cooperate with the Commission and lend it the assistance it needs in the scientific examination of questions of public interest relating to food;

Whereas there must therefore be an approximation of the provisions governing these bodies in order that they may cooperate with the Commission with the aim especially of drawing up future rules to ensure the free movement of foodstuffs, on the basis of all the scientific data available;

Whereas it is necessary to enhance and strengthen the powers and expertise of the Scientific Committee for Food, particularly with the aim of increasing the effectiveness of the Community in food issues;

Whereas it is necessary to make provision for third countries to participate in this cooperation;

Whereas the Commission must be responsible for the management of this cooperation and the Member States for their part must assist in this task, in the context of the Standing Committee for Food;

Whereas the completion of the internal market should give rise to increased participation of the Community in meetings and work on foodstuffs of international organizations and also in bilateral relations,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. Member States shall take the necessary measures to enable their competent authorities and bodies to cooperate with the Commission and lend it the assistance it needs in the scientific examination of questions of public interest relating to food, particularly in the field of public health, through disciplines such as those associated with medicine, nutrition, toxicology, biology, hygiene, food technology, biotechnology, novel foods and processes, risk assessment techniques, physics and chemistry.

2. (a) The cooperation procedure of this Directive shall apply when a Council act requires the opinion of the Scientific Committee for Food.

(b) Where appropriate, the application of the cooperation procedure of ths Directive to other questions relating to the protection of the health and safety of persons arising from the consumption of food shall be decided in accordance with the procedure laid down in Article 5.

Article 2

Each Member State shall designate the authority or body which will be responsible for the cooperation with the Commission and for distribution of work to appropriate institutes within Member States as regards the tasks laid down in Article 3 and shall notify the Commission accordingly.

The Commission shall publish in the *Official Journal of the European Communities* and update the list of designated authorities referred to in the preceding paragraph.

Each designated authority shall send to the Commission a list of the institutes participating in the cooperation procedure in its jurisdiction, and any modifications to that list. The Commission shall circulate this information to the above authorities and other interested parties.

Article 3

1. The principal tasks to be carried out by the institutes participating in the cooperation shall include those listed in the Annex.

2. The following measures shall be adopted in accordance with the procedure laid down in Article 5:

— establishment of rules for the administrative management of the cooperation, including:

  — measures to ensure the transparency of recommendations made by the Scientific Committee for Food,

  — procedures for the presentation and appraisal of dossiers;

— establishment, and updating at least every six months, of the inventory of tasks and their associated priorities.

3. The tasks to be carried out in accordance with the inventory adopted in accordance with paragraph 2, second indent, shall be distributed in accordance wit the procedure laid down in Article 5 on the basis of scientific expertise and within the limits set by the resources available in the Member States.

Article 4

The Commission may, after consultation with the authorities or bodies mentioned in Article 2, invite institutes in third countries to participate, on a voluntary basis, in carrying out the tasks necessary for the achievement of the objectives of this Directive and, in particular, the tasks listed in the inventory mentioned in Article 3 (2) second indent. Where an institute in a third country has agreed to participate in the carrying out of tasks, the Commission shall take that participation into account when allocating tasks under Article 3 (3).

In no event may the participation referred to in the first paragraph involve charges for the Community budget.

Article 5

The Commission shall be assisted by the Standing Committee on Food set up by Decision 69/414/EEC (1), hereafter referred to as the 'Committee'.

The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council had decided against the said measures by a simple majority.

Article 6

The Commission shall report to the European Parliament and to the Council on the structures, works and efficiency of the Scientific Committee for Food within three years of the implementation of this Directive and every three years thereafter.

Article 7

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 June 1993. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The methods of making such reference shall be laid down by the Member States.

2. Member States shall communicate to the Commission the main provisions of domestic law which they adopt in the field governed by this Directive.

Article 8

This Directive is addressed to the Member States.

Done at Brussels, 25 February 1993.

For the Council

The President

J. TRØJBORG

(1) OJ No L 291, 19. 11. 1969, p. 9.

ANNEX

The principal tasks to be carried out by the institutes participating in the cooperation shall include :

— drawing up protocols for the assessment of risks relating to food components and elaborating methods of nutritional evaluation ;

— assessing the nutritional adequacy of the diet ;

— examining test data submitted to the Community rule and the production of a monograph for assessment by the Scientific Committee for Food ;

— carrying out food intake surveys, particularly those necessary for the determination or evaluation of the conditions of use of food additives or the laying down of limit values for other substances in food ;

— conducting investigations relating to components of diets of the various Member States or of biological or chemical food contaminants ;

— helping the Commission honour the Community's international commitments by providing expertise on food safety questions.

HORIZONTAL LEGISLATION

LABELLING

379L0112

79/112/EEC: " COUNCIL DIRECTIVE OF 18 DECEMBER 1978 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO THE LABELLING, PRESENTATION AND ADVERTISING OF FOODSTUFFS " [3]

OFFICIAL JOURNAL NO L 33, 08/02/1979, P. 1
DATE OF NOTIFICATION: 22/12/1978
DATE OF TRANSPOSITION: 22/12/1980; SEE ART. 22
DATE OF TRANSPOSITION: 22/12/1982; SEE ART. 22

AMENDED BY

385L0007
85/7/EEC: COUNCIL DIRECTIVE OF 19 DECEMBER 1984 **[1]**
OFFICIAL JOURNAL NO L 2, 03/01/1985, P. 22
DATE OF NOTIFICATION: 27/12/1984

386L0197
86/197/EEC: COUNCIL DIRECTIVE OF 26 MAY 1986 **[2]**
OFFICIAL JOURNAL NO L 144, 29/05/1986, P. 38
DATE OF TRANSPOSITION: 01/05/1988; SEE ART. 2
DATE OF TRANSPOSITION: 01/05/1989; SEE ART. 2

389L0395
89/395/EEC: COUNCIL DIRECTIVE OF 14 JUNE 1989 **[3]**
OFFICIAL JOURNAL NO L 186, 30/06/1989, P. 17
DATE OF TRANSPOSITION: 20/12/1990; SEE ART. 2
DATE OF TRANSPOSITION: 20/06/1992; SEE ART. 2

391L0072
91/72/EEC: COMMISSION DIRECTIVE OF 16 JANUARY 1991 **[4]**
OFFICIAL JOURNAL NO L 42, 15/02/1991, P. 27
DATE OF NOTIFICATION: 07/02/1991
DATE OF TRANSPOSITION: 30/06/1992; SEE ART. 2
DATE OF TRANSPOSITION: 01/01/1994; SEE ART. 2

393L0102
93/102/EC: COMMISSION DIRECTIVE OF 16 NOVEMBER 1993 **[5]**
OFFICIAL JOURNAL NO L 291, 25/11/1993, P. 14
DATE OF TRANSPOSITION: 31/12/1994; SEE ART. 3

ARTICLE 1

1. THIS DIRECTIVE CONCERNS THE LABELLING OF FOODSTUFFS TO BE DELIVERED AS SUCH TO THE ULTIMATE CONSUMER AND CERTAIN ASPECTS RELATING TO THE PRESENTATION AND ADVERTISING THEREOF.

" 2. This Directive shall apply also to foodstuffs intended for supply to restaurants, hospitals, canteens and other similar mass caterers (hereinafter referred to as "mass caterers"). " **[3]**

3. FOR THE PURPOSE OF THIS DIRECTIVE,

(a) "LABELLING" SHALL MEAN ANY WORDS, PARTICULARS, TRADE MARKS, BRAND NAME, PICTORIAL MATTER OR SYMBOL RELATING TO A FOODSTUFF AND PLACED ON ANY PACKAGING, DOCUMENT, NOTICE, LABEL, RING OR COLLAR ACCOMPANYING OR REFERRING TO SUCH FOODSTUFF;

(b) "PRE-PACKAGED FOODSTUFF" SHALL MEAN ANY SINGLE ITEM FOR PRESENTATION AS SUCH " to the ultimate consumer and to mass caterers " **[3]**, CONSISTING OF A FOODSTUFF AND THE PACKAGING INTO WHICH IT WAS PUT BEFORE BEING OFFERED FOR SALE, WHETHER SUCH PACKAGING ENCLOSES THE FOODSTUFF COMPLETELY OR ONLY PARTIALLY, BUT IN ANY CASE IN SUCH A WAY THAT THE CONTENTS CANNOT BE ALTERED WITHOUT OPENING OR CHANGING THE PACKAGING.

ARTICLE 2

1. THE LABELLING AND METHODS USED MUST NOT:

(a) BE SUCH AS COULD MISLEAD THE PURCHASER TO A MATERIAL DEGREE, PARTICULARLY:

(i) AS TO THE CHARACTERISTICS OF THE FOODSTUFF AND, IN PARTICULAR, AS TO ITS NATURE, IDENTITY, PROPERTIES, COMPOSITION, QUANTITY, DURABILITY, ORIGIN OR PROVENANCE, METHOD OF MANUFACTURE OR PRODUCTION,

(ii) BY ATTRIBUTING TO THE FOODSTUFF EFFECTS OR PROPERTIES WHICH IT DOES NOT POSSESS,

(iii) BY SUGGESTING THAT THE FOODSTUFF POSSESSES SPECIAL CHARACTERISTICS WHEN IN FACT ALL SIMILAR FOODSTUFFS POSSESS SUCH CHARACTERISTICS;

" (b) subject to Community provisions applicable to natural mineral waters and foodstuffs for particular nutritional uses, attribute to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties. " **[3]**

2. THE COUNCIL, IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 100 OF THE TREATY, SHALL DRAW UP A NON-EXHAUSTIVE LIST OF THE CLAIMS WITHIN THE MEANING OF PARAGRAPH 1, THE USE OF WHICH MUST AT ALL EVENTS BE PROHIBITED OR RESTRICTED.

3. THE PROHIBITIONS OR RESTRICTIONS REFERRED TO IN PARAGRAPHS 1 AND 2 SHALL ALSO APPLY TO:

(a) THE PRESENTATION OF FOODSTUFFS, IN PARTICULAR THEIR SHAPE, APPEARANCE OR PACKAGING, THE PACKAGING MATERIALS USED, THE WAY IN WHICH THEY ARE ARRANGED AND THE SETTING IN WHICH THEY ARE DISPLAYED;

(b) ADVERTISING.

ARTICLE 3

1. IN ACCORDANCE WITH ARTICLES 4 TO 14 AND SUBJECT TO THE EXCEPTIONS CONTAINED THEREIN, INDICATION OF THE FOLLOWING PARTICULARS ALONE SHALL BE COMPULSORY ON THE LABELLING OF FOODSTUFFS:

(1) THE NAME UNDER WHICH THE PRODUCT IS SOLD,

(2) THE LIST OF INGREDIENTS,

(3) IN THE CASE OF PREPACKAGED FOODSTUFFS, THE NET QUANTITY,

(4) " The date of minimum durability or, in the case of foodstuffs which, from the microbiological point of view, are highly perishable, the "use by" date. " **[3]**

(5) ANY SPECIAL STORAGE CONDITIONS OR CONDITIONS OF USE,

(6) THE NAME OR BUSINESS NAME AND ADDRESS OF THE MANUFACTURER OR PACKAGER, OR OF A SELLER ESTABLISHED WITHIN THE COMMUNITY.
HOWEVER, THE MEMBER STATES SHALL BE AUTHORIZED, IN RESPECT OF BUTTER PRODUCED IN THEIR TERRITORY, TO REQUIRE ONLY AN INDICATION OF THE MANUFACTURER, PACKAGER OR SELLER.
WITHOUT PREJUDICE TO THE NOTIFICATION PROVIDED FOR IN ARTICLE 22, MEMBER STATES SHALL INFORM THE COMMISSION AND THE OTHER MEMBER STATES OF ANY MEASURE TAKEN PURSUANT TO THIS PARAGRAPH,

(7) PARTICULARS OF THE PLACE OF ORIGIN OR PROVENANCE IN THE CASES WHERE FAILURE TO GIVE SUCH PARTICULARS MIGHT MISLEAD THE CONSUMER TO A MATERIAL DEGREE AS TO THE TRUE ORIGIN OR PROVENANCE OF THE FOODSTUFF,

(8) INSTRUCTIONS FOR USE WHEN IT WOULD BE IMPOSSIBLE TO MAKE APPROPRIATE USE OF THE FOODSTUFF IN THE ABSENCE OF SUCH INSTRUCTIONS.

" (9) WITH RESPECT TO BEVERAGES CONTAINING MORE THAN 1,2 % BY VOLUME OF ALCOHOL, THE ACTUAL ALCOHOLIC STRENGTH BY VOLUME. " **[2]**

2. NOTWITHSTANDING THE PREVIOUS PARAGRAPH, MEMBER STATES MAY RETAIN NATIONAL PROVISIONS WHICH REQUIRE INDICATION OF THE FACTORY OR PACKAGING CENTRE, IN RESPECT OF HOME PRODUCTION.

3. THE PROVISIONS OF THIS ARTICLE SHALL BE WITHOUT PREJUDICE TO MORE PRECISE OR MORE EXTENSIVE PROVISIONS REGARDING WEIGHTS AND MEASURES.

ARTICLE 4

1. COMMUNITY PROVISIONS APPLICABLE TO SPECIFIED FOODSTUFFS AND NOT TO FOODSTUFFS IN GENERAL MAY PROVIDE FOR DEROGATIONS, IN EXCEPTIONAL CASES, FROM THE REQUIREMENTS LAID DOWN IN ARTICLE 3 (1), POINTS 2 AND 4, PROVIDED THAT THIS DOES NOT RESULT IN THE PURCHASER BEING INADEQUATELY INFORMED.

2. COMMUNITY PROVISIONS APPLICABLE TO SPECIFIED FOODSTUFFS AND NOT TO FOODSTUFFS IN GENERAL MAY PROVIDE THAT OTHER PARTICULARS IN ADDITION TO THOSE LISTED IN ARTICLE 3 MUST APPEAR ON THE LABELLING.
WHERE THERE ARE NO COMMUNITY PROVISIONS, MEMBER STATES MAY MAKE PROVISION FOR SUCH PARTICULARS IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 16.

" 3. The Community provisions referred to in paragraphs 1 and 2 shall be adopted in accordance with the procedure laid down in Article 17. " **[3]**

ARTICLE 5

1. THE NAME UNDER WHICH A FOODSTUFF IS SOLD SHALL BE THE NAME LAID DOWN BY WHATEVER LAWS , REGULATIONS OR ADMINISTRATIVE PROVISIONS APPLY TO THE FOODSTUFF IN QUESTION OR, IN THE ABSENCE OF ANY SUCH NAME, THE NAME CUSTOMARY IN THE MEMBER STATE WHERE THE PRODUCT IS SOLD " to the ultimate consumer and to mass caterers " **[3]**, OR A DESCRIPTION OF THE FOODSTUFF AND, IF NECESSARY, OF ITS USE, THAT IS SUFFICIENTLY PRECISE TO INFORM THE PURCHASER OF ITS TRUE NATURE AND TO ENABLE IT TO BE DISTINGUISHED FROM PRODUCTS WITH WHICH IT COULD BE CONFUSED.

2. NO TRADE MARK, BRAND NAME OR FANCY NAME MAY BE SUBSTITUTED FOR THE NAME UNDER WHICH THE PRODUCT IS SOLD.

3. THE NAME UNDER WHICH THE PRODUCT IS SOLD SHALL INCLUDE OR BE ACCOMPANIED BY PARTICULARS AS TO THE PHYSICAL CONDITION OF THE FOODSTUFF OR THE SPECIFIC TREATMENT WHICH IT HAS UNDERGONE (E.G. POWDERED, FREEZE-DRIED, DEEP-FROZEN, CONCENTRATED, SMOKED) IN ALL CASES WHERE OMISSION OF SUCH INFORMATION COULD CREATE CONFUSION IN THE MIND OF THE PURCHASER.

" Any foodstuff which has been treated with ionizing radiation must bear one of the following indications:

- in Spanish "irradiado" or "tratado con radiacíon ionizante",
- in Danish: "bestrålet/ ..." or "strålekonserveret" or "behandlet med ioniserende stråling" or "konserveret med ioniserende stråling",
- in German: "bestrahlt" or "mit ionisierenden Strahlen behandelt",
- in Greek: [see OJ for the Greek characters] or [see OJ for the Greek characters],
- in English: "irradiated" or "treated with ionizing radiation",
- in French: "traité par rayonnements ionisants" or "traité par ionisation",
- in Italian: "irradiato" or "trattato con radiazioni ionizzanti",
- in Dutch: "doorstraald" or "door bestraling behandeld" or "met ioniserende stralen behandeld",
- in Portuguese: "irradiado" or "tratado por irradiações" or "tratado por radiação ionizante". " **[3]**

ARTICLE 6

1. INGREDIENTS SHALL BE LISTED IN ACCORDANCE WITH THIS ARTICLE AND THE ANNEXES.

2. INGREDIENTS NEED NOT BE LISTED IN THE CASE OF:

(a) - FRESH FRUIT AND VEGETABLES, INCLUDING POTATOES, WHICH HAVE NOT BEEN PEELED, CUT OR SIMILARLY TREATED,
- CARBONATED WATER, THE DESCRIPTION OF WHICH INDICATES THAT IT HAS BEEN CARBONATED,
- FERMENTATION VINEGARS DERIVED EXCLUSIVELY FROM A SINGLE BASIC PRODUCT, PROVIDED THAT NO OTHER INGREDIENT HAS BEEN ADDED;

(b) - CHEESE,
- BUTTER,
- FERMENTED MILK AND CREAM,

PROVIDED THAT NO INGREDIENT HAS BEEN ADDED OTHER THAN LACTIC PRODUCTS, ENZYMES AND MICRO-ORGANISM CULTURES ESSENTIAL TO MANUFACTURE, OR THE SALT NEEDED FOR THE MANUFACTURE OF CHEESE OTHER THAN FRESH CHEESE AND PROCESSED CHEESE;

(c) PRODUCTS CONSISTING OF A SINGLE INGREDIENT.

3. IN THE CASE OF BEVERAGES CONTAINING MORE THAN 1,2 % BY VOLUME OF ALCOHOL, THE COUNCIL, ACTING ON A PROPOSAL FROM THE COMMISSION, SHALL, BEFORE THE EXPIRY OF A PERIOD OF FOUR YEARS FOLLOWING NOTIFICATION OF THIS DIRECTIVE, DETERMINE THE RULES FOR LABELLING INGREDIENTS. "..." **[2]**

4. (a) "INGREDIENT" SHALL MEAN ANY SUBSTANCE, INCLUDING ADDITIVES, USED IN THE MANUFACTURE OR PREPARATION OF A FOODSTUFF AND STILL PRESENT IN THE FINISHED PRODUCT, EVEN IF IN ALTERED FORM.

(b) WHERE AN INGREDIENT OF THE FOODSTUFF IS ITSELF THE PRODUCT OF SEVERAL INGREDIENTS, THE LATTER SHALL BE REGARDED AS INGREDIENTS OF THE FOODSTUFF IN QUESTION.

(c) THE FOLLOWING SHALL NOT BE REGARDED AS INGREDIENTS:

(i) THE CONSTITUENTS OF AN INGREDIENT WHICH HAVE BEEN TEMPORARILY SEPARATED DURING THE MANUFACTURING PROCESS AND LATER REINTRODUCED BUT NOT IN EXCESS OF THEIR ORIGINAL PROPORTIONS;

(ii) - ADDITIVES:

-- WHOSE PRESENCE IN A GIVEN FOODSTUFF IS SOLELY DUE TO THE FACT THAT THEY WERE CONTAINED IN ONE OR MORE INGREDIENTS OF THAT FOODSTUFF, PROVIDED THAT THEY SERVE NO TECHNOLOGICAL FUNCTION IN THE FINISHED PRODUCT,
-- WHICH ARE USED AS PROCESSING AIDS;

- SUBSTANCES USED IN THE QUANTITIES STRICTLY NECESSARY AS SOLVENTS OR MEDIA FOR ADDITIVES OR FLAVOURING.

(d) IN CERTAIN CASES DECISIONS MAY BE TAKEN IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 17 AS TO WHETHER THE CONDITIONS DESCRIBED IN (c) (ii) ARE SATISFIED.

5. (a) THE LIST OF INGREDIENTS SHALL INCLUDE ALL THE INGREDIENTS OF THE FOODSTUFF, IN DESCENDING ORDER OF WEIGHT, AS RECORDED AT THE TIME OF THEIR USE IN THE MANUFACTURE OF THE FOODSTUFF. IT SHALL APPEAR PRECEDED BY A SUITABLE HEADING WHICH INCLUDES THE WORD "INGREDIENTS".
HOWEVER:

- ADDED WATER AND VOLATILE PRODUCTS SHALL BE LISTED IN ORDER OF THEIR WEIGHT IN THE FINISHED PRODUCT; THE AMOUNT OF WATER ADDED AS AN INGREDIENT IN A FOODSTUFF SHALL BE CALCULATED BY DEDUCTING FROM THE TOTAL AMOUNT OF THE FINISHED PRODUCT THE TOTAL AMOUNT OF THE OTHER INGREDIENTS USED. THIS AMOUNT NEED NOT BE TAKEN INTO CONSIDERATION IF IT DOES NOT EXCEED 5 % BY WEIGHT OF THE FINISHED PRODUCT;
- INGREDIENTS USED IN CONCENTRATED OR DEHYDRATED FORM AND RECONSTITUTED AT THE TIME OF MANUFACTURE MAY BE LISTED IN ORDER OF WEIGHT AS RECORDED BEFORE THEIR CONCENTRATION OR DEHYDRATION;
- IN THE CASE OF CONCENTRATED OR DEHYDRATED FOODS WHICH ARE INTENDED TO BE RECONSITUTED BY THE ADDITION OF WATER, THE INGREDIENTS MAY BE LISTED IN ORDER OF PROPORTION IN THE RECONSTITUTED PRODUCT PROVIDED THAT THE LIST OF INGREDIENTS IS ACCOMPANIED BY AN EXPRESSION SUCH AS "INGREDIENTS OF THE RECONSTITUTED PRODUCT", OR "INGREDIENTS OF THE READY-TO-USE PRODUCT";
- IN THE CASE OF MIXTURES OF FRUIT OR VEGETABLES WHERE NO PARTICULAR FRUIT OR VEGETABLE SIGNIFICANTLY PREDOMINATES IN PROPORTION BY WEIGHT, THOSE INGREDIENTS MAY BE LISTED IN ANOTHER ORDER PROVIDED THAT THAT LIST OF INGREDIENTS IS ACCOMPANIED BY AN EXPRESSION SUCH AS "IN VARIABLE PROPORTION";
- IN THE CASE OF MIXTURES OF SPICES OR HERBS, WHERE NONE SIGNIFICANTLY PREDOMINATES IN PROPORTION BY WEIGHT, THOSE INGREDIENTS MAY BE LISTED IN ANOTHER ORDER PROVIDED THAT THAT LIST OF INGREDIENTS IS ACCOMPANIED BY AN EXPRESSION SUCH AS "IN VARIABLE PROPORTION";

(b) INGREDIENTS SHALL BE DESIGNATED BY THEIR SPECIFIC NAME, WHERE APPLICABLE, IN ACCORDANCE WITH THE RULES LAID DOWN IN ARTICLE 5.
HOWEVER:

- " ingredients which belong to one of the categories listed in Annex I and are constituents of another foodstuff may be designated by the name of that category only. Alterations to the list of categories in Annex I may be effected in accordance with the procedure laid down in Article 17; " **[3]**

- INGREDIENTS BELONGING TO ONE OF THE CATEGORIES LISTED IN ANNEX II MUST BE DESIGNATED BY THE NAME OF THAT CATEGORY, FOLLOWED BY THEIR SPECIFIC NAME OR EEC NUMBER; IF AN INGREDIENT BELONGS TO MORE THAN ONE OF THE CATEGORIES, THE CATEGORY APPROPRIATE TO THE PRINCIPAL FUNCTION IN THE CASE OF THE FOODSTUFF IN QUESTION SHALL BE INDICATED; AMENDMENTS TO THIS ANNEX BASED ON ADVANCES IN SCIENTIFIC AND TECHNICAL KNOWLEDGE SHALL BE ADOPTED IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 17;
- " flavourings shall be designated in accordance with Annex III to this Directive. " **[4]**
" These provisions shall be adopted in accordance with the procedure laid down in Article 17; " **[3]**
- " the specific Community provisions governing the indication of treatment of an ingredient with ionizing radiation shall be adopted subsequently in accordance with Article 100a of the Treaty. " **[3]**

6. COMMUNITY PROVISIONS OR, WHERE THERE ARE NONE, NATIONAL PROVISIONS MAY LAY DOWN THAT THE NAME UNDER WHICH A SPECIFIC FOODSTUFF IS SOLD IS TO BE ACCOMPANIED BY MENTION OF A PARTICULAR INGREDIENT OR INGREDIENTS. THE PROCEDURE LAID DOWN IN ARTICLE 16 SHALL APPLY TO ANY SUCH NATIONAL PROVISIONS.
" The Community provisions referred to in this paragraph shall be adopted in accordance with the procedure laid down in Article 17. " **[3]**

7. IN THE CASE REFERRED TO IN PARAGRAPH 4 (b), A COMPOUND INGREDIENT MAY BE INCLUDED IN THE LIST OF INGREDIENTS, UNDER ITS OWN DESIGNATION IN SO FAR AS THIS IS LAID DOWN BY LAW OR ESTABLISHED BY CUSTOM, IN TERMS OF ITS OVERALL WEIGHT, PROVIDED THAT IT IS IMMEDIATELY FOLLOWED BY A LIST OF ITS INGREDIENTS.
SUCH A LIST, HOWEVER, SHALL NOT BE COMPULSORY:

- WHERE THE COMPOUND INGREDIENT CONSTITUTES LESS THAN 25 % OF THE FINISHED PRODUCT; HOWEVER, THIS EXEMPTION SHALL NOT APPLY IN THE CASE OF ADDITIVES, SUBJECT TO THE PROVISIONS OF PARAGRAPH 4 (c),
- WHERE THE COMPOUND INGREDIENT IS A FOODSTUFF FOR WHICH A LIST OF INGREDIENTS IS NOT REQUIRED UNDER COMMUNITY RULES.

8. NOTWITHSTANDING PARAGRAPH 5 (a), THE WATER CONTENT NEED NOT BE SPECIFIED:

(a) WHERE THE WATER IS USED DURING THE MANUFACTURING PROCESS SOLELY FOR THE RECONSTITUTION OF AN INGREDIENT USED IN CONCENTRATED OR DEHYDRATED FORM;

(b) IN THE CASE OF A LIQUID MEDIUM WHICH IS NOT NORMALLY CONSUMED.

ARTICLE 7

1. WHERE THE LABELLING OF A FOODSTUFF PLACES EMPHASIS ON THE PRESENCE OR LOW CONTENT OF ONE OR MORE INGREDIENTS WHICH ARE ESSENTIAL TO THE SPECIFIC PROPERTIES OF THE FOODSTUFF, OR WHERE THE DESCRIPTION OF THE FOODSTUFF HAS THE SAME EFFECT, THE MINIMUM OR MAXIMUM PERCENTAGE, AS THE CASE MAY BE, USED IN THE MANUFACTURE THEREOF SHALL BE STATED.
THIS INFORMATION SHALL APPEAR EITHER IMMEDIATELY NEXT TO THE NAME UNDER WHICH THE FOODSTUFF IS SOLD OR IN THE LIST OF INGREDIENTS IN CONNECTION WITH THE INGREDIENT IN QUESTION.
IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 17, IT MAY BE DECIDED THAT, IN THE CASE OF CERTAIN INGREDIENTS, THE PERCENTAGE REFERRED TO IN THIS PARAGRAPH SHALL BE EXPRESSED IN ABSOLUTE TERMS.

2. PARAGRAPH 1 SHALL NOT APPLY:

(a) IN THE CASE OF LABELLING WHICH IS INTENDED TO CHARACTERIZE A FOODSTUFF IN ACCORDANCE WITH ARTICLE 5 (1) OR WHICH IS REQUIRED UNDER COMMUNITY PROVISIONS OR, WHERE THERE ARE NONE, UNDER NATIONAL PROVISIONS APPLICABLE TO CERTAIN FOODSTUFFS;

(b) IN THE CASE OF INGREDIENTS USED IN SMALL QUANTITIES ONLY AS FLAVOURINGS.

3. COMMUNITY PROVISIONS OR, WHERE THERE ARE NONE, NATIONAL PROVISIONS MAY STIPULATE FOR CERTAIN FOODSTUFFS, AS WELL AS IN THE CASE REFERRED TO IN PARAGRAPH 2 (a), THAT QUANTITIES OF CERTAIN INGREDIENTS MUST BE INDICATED EITHER IN ABSOLUTE TERMS OR AS PERCENTAGES AND THAT, WHERE APPROPRIATE, MENTION SHOULD BE MADE OF ANY ALTERATION IN THE QUANTITIES OF THESE INGREDIENTS.
THE PROCEDURE LAID DOWN IN ARTICLE 16 SHALL APPLY TO ANY SUCH NATIONAL PROVISIONS.
" The Community provisions referred to in this paragraph shall be adopted in accordance with the procedure laid down in Article 17. " **[3]**

ARTICLE 8

1. THE NET QUANTITY OF PREPACKAGED FOODSTUFFS SHALL BE EXPRESSED:

- IN UNITS OF VOLUME IN THE CASE OF LIQUIDS,
- IN UNITS OF MASS IN THE CASE OF OTHER PRODUCTS,

USING THE LITRE, CENTILITRE, MILLILITRE, KILOGRAM OR GRAM, AS APPROPRIATE.
COMMUNITY PROVISIONS OR, WHERE THERE ARE NONE, NATIONAL PROVISIONS APPLICABLE TO CERTAIN SPECIFIED FOODSTUFFS MAY DEROGATE FROM THIS RULE.
THE PROCEDURE LAID DOWN IN ARTICLE 16 SHALL APPLY TO ANY SUCH NATIONAL PROVISIONS.

2. (a) WHERE THE INDICATION OF A CERTAIN TYPE OF QUANTITY (E.G. NOMINAL QUANTITY, MINIMUM QUANTITY, AVERAGE QUANTITY) IS REQUIRED BY COMMUNITY PROVISIONS OR, WHERE THERE ARE NONE, BY NATIONAL PROVISIONS, THIS QUANTITY SHALL BE REGARDED AS THE NET QUANTITY FOR THE PURPOSES OF THIS DIRECTIVE.
WITHOUT PREJUDICE TO THE NOTIFICATION PROVIDED FOR IN ARTICLE 22, MEMBER STATES SHALL INFORM THE COMMISSION AND THE OTHER MEMBER STATES OF ANY MEASURE TAKEN PURSUANT TO THIS POINT.

(b) COMMUNITY PROVISIONS OR, WHERE THERE ARE NONE, NATIONAL PROVISIONS MAY, FOR CERTAIN SPECIFIED FOODSTUFFS CLASSIFIED BY QUANTITY IN CATEGORIES, REQUIRE OTHER INDICATIONS OF QUANTITY.
THE PROCEDURE LAID DOWN IN ARTICLE 16 SHALL APPLY TO ANY SUCH NATIONAL PROVISIONS.

(c) WHERE A PREPACKAGED ITEM CONSISTS OF TWO OR MORE INDIVIDUAL PREPACKAGED ITEMS CONTAINING THE SAME QUANTITY OF THE SAME PRODUCT, THE NET QUANTITY SHALL BE INDICATED BY MENTIONING THE NET QUANTITY CONTAINED IN EACH INDIVIDUAL PACKAGE AND THE TOTAL NUMBER OF SUCH PACKAGES. INDICATION OF THESE PARTICULARS SHALL NOT, HOWEVER, BE COMPULSORY WHERE THE TOTAL NUMBER OF INDIVIDUAL PACKAGES CAN BE CLEARLY SEEN AND EASILY COUNTED FROM THE OUTSIDE AND WHERE AT LEAST ONE INDICATION OF THE NET QUANTITY CONTAINED IN EACH INDIVIDUAL PACKAGE CAN BE CLEARLY SEEN FROM THE OUTSIDE.

(d) WHERE A PREPACKAGED ITEM CONSISTS OF TWO OR MORE INDIVIDUAL PACKAGES WHICH ARE NOT REGARDED AS UNITS OF SALE, THE NET QUANTITY SHALL BE GIVEN BY INDICATING THE TOTAL NET QUANTITY AND THE TOTAL NUMBER OF INDIVIDUAL PACKAGES. COMMUNITY PROVISIONS OR, WHERE THERE ARE NONE, NATIONAL PROVISIONS NEED NOT, IN THE CASE OF CERTAIN FOODSTUFFS, REQUIRE INDICATION OF THE TOTAL NUMBER OF INDIVIDUAL PACKAGES.
WITHOUT PREJUDICE TO THE NOTIFICATION PROVIDED FOR IN ARTICLE 22, MEMBER STATES SHALL INFORM THE COMMISSION AND THE OTHER MEMBER STATES OF ANY MEASURE TAKEN PURSUANT TO THIS POINT.

3. IN THE CASE OF FOODSTUFFS NORMALLY SOLD BY NUMBER, MEMBER STATES NEED NOT REQUIRE INDICATION OF THE NET QUANTITY PROVIDED THAT THE NUMBER OF ITEMS CAN CLEARLY BE SEEN AND EASILY COUNTED FROM THE OUTSIDE OR, IF NOT, IS INDICATED ON THE LABELLING.
WITHOUT PREJUDICE TO THE NOTIFICATION PROVIDED FOR IN ARTICLE 22, MEMBER STATES SHALL INFORM THE COMMISSION AND THE OTHER MEMBER STATES OF ANY MEASURE TAKEN PURSUANT TO THIS PARAGRAPH.

4. " Where a solid foodstuff is presented in a liquid medium, the drained net weight of the foodstuff shall also be indicated on the labelling.
For the purposes of this paragraph, "liquid medium" shall mean the following products, possibly in mixtures and also where frozen or quick-frozen, provided that the liquid is merely an adjunct to the essential elements of that preparation and is thus not a decisive factor for the purchase: water, aqueous solutions of salts, brine; aqueous solutions of food acids, vinegar; aqueous solutions of sugars, aqueous solutions of other sweetening substances; fruit or vegetable juices in the case of fruit or vegetables.
This list may be supplemented in accordance with the procedure laid down in Article 17.
Methods of checking the drained net weight shall be determined in accordance with the procedure laid down in Article 17. " **[3]**

5. IT SHALL NOT BE COMPULSORY TO INDICATE THE NET QUANTITY IN THE CASE OF FOODSTUFFS:

(a) WHICH ARE SUBJECT TO CONSIDERABLE LOSSES IN THEIR VOLUME OR MASS AND WHICH ARE SOLD BY NUMBER OR WEIGHED IN THE PRESENCE OF THE PURCHASER;

(b) THE NET QUANTITY OF WHICH IS LESS THAN 5 g OR 5 ml; HOWEVER, THIS PROVISION SHALL NOT APPLY TO SPICES AND HERBS.

COMMUNITY PROVISIONS OR, WHERE THERE ARE NONE, NATIONAL PROVISIONS APPLICABLE TO SPECIFIED FOODSTUFFS MAY IN EXCEPTIONAL CASES LAY DOWN THRESHOLDS WHICH ARE HIGHER THAN 5 g OR 5 ml PROVIDED THAT THIS DOES NOT RESULT IN THE PURCHASER BEING INADEQUATELY INFORMED.
WITHOUT PREJUDICE TO THE NOTIFICATION PROVIDED FOR IN ARTICLE 22, MEMBER STATES SHALL INFORM THE COMMISSION AND THE OTHER MEMBER STATES OF ANY MEASURE TAKEN PURSUANT TO THIS PARAGRAPH.

6. UNTIL THE END OF THE TRANSITIONAL PERIOD DURING WHICH THE USE OF THE IMPERIAL UNITS OF MEASUREMENT CONTAINED IN CHAPTER D OF THE ANNEX TO DIRECTIVE 71/354/EEC OF 18 OCTOBER 1971 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO UNITS OF MEASUREMENT (1), AS LAST AMENDED BY DIRECTIVE 76/770/EEC (2), IS AUTHORIZED IN THE COMMUNITY, IRELAND AND THE UNITED KINGDOM MAY PERMIT THE QUANTITY TO BE EXPRESSED ONLY IN IMPERIAL UNITS OF MEASUREMENT CALCULATED ON THE BASIS OF THE FOLLOWING CONVERSION RATES:

- 1 ml = 0,0352 FLUID OUNCES,
- 1 l = 1,760 PINTS OR 0,220 GALLONS,
- 1 g = 0,0353 OUNCES (AVOIRDUPOIS),
- 1 kg = 2,205 POUNDS.

" 7. The Community provisions referred to in paragraphs 1, 2 (b) and (d) and 5 shall be adopted in accordance with the procedure laid down in Article 17. " **[3]**

ARTICLE 9

1. THE DATE OF MINIMUM DURABILITY OF A FOODSTUFF SHALL BE THE DATE UNTIL WHICH THE FOODSTUFF RETAINS ITS SPECIFIC PROPERTIES WHEN PROPERLY STORED. IT SHALL BE INDICATED IN ACCORDANCE WITH THE PROVISIONS OF THIS ARTICLE.

2. THE DATE SHALL BE PRECEDED BY THE WORDS:

- "BEST BEFORE ..." WHEN THE DATE INCLUDES AN INDICATION OF THE DAY,
- "BEST BEFORE END ..." IN OTHER CASES.

"..." **[3]**

3. THE WORDS REFERRED TO IN PARAGRAPH 2 SHALL BE ACCOMPANIED BY:

- EITHER THE DATE ITSELF, OR
- A REFERENCE TO WHERE THE DATE IS GIVEN ON THE LABELLING.

IF NEED BE, THESE PARTICULARS SHALL BE FOLLOWED BY A DESCRIPTION OF THE STORAGE CONDITIONS WHICH MUST BE OBSERVED IF THE PRODUCT IS TO KEEP FOR THE SPECIFIED PERIOD.

4. THE DATE SHALL CONSIST OF THE DAY, MONTH AND YEAR IN UNCODED CHRONOLOGICAL FORM.
HOWEVER, IN THE CASE OF FOODSTUFFS:

- WHICH WILL NOT KEEP FOR MORE THAN THREE MONTHS, AN INDICATION OF THE DAY AND THE MONTH WILL SUFFICE,
- WHICH WILL KEEP FOR MORE THAN THREE MONTHS BUT NOT MORE THAN 18 MONTHS, AN INDICATION OF THE MONTH AND YEAR WILL SUFFICE,
- WHICH WILL KEEP FOR MORE THAN 18 MONTHS, AN INDICATION OF THE YEAR WILL SUFFICE.

THE MANNER OF INDICATING THE DATE MAY BE SPECIFIED ACCORDING TO THE PROCEDURE LAID DOWN IN ARTICLE 17.

5. " In their own territories the Member States may, until 31 December 1992, permit the minimum durability period to be expressed otherwise than in terms of the date of minimum durability. Without prejudice to the notification provided for in Article 22, Member States shall notify the Commission and the other Member States of any measure taken under this paragraph. " **[3]**

6. " Subject to Community provisions imposing other types of date indication, an indication of the durability date shall not be required for:

- fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated. This derogation shall not apply to sprouting seeds and similar products such as legume sprouts,
- wines, liqueur wines, sparkling wines, aromatized wines and similar products obtained from fruits other than grapes, and beverages falling within CN codes 2206 00 91, 2206 00 93 and 2206 00 99 and manufactured from grapes or grape musts,
- beverages containing 10 % or more by volume of alcohol,
- soft drinks, fruit juices, fruit nectars and alcoholic beverages in individual containers of more than five litres, intended for supply to mass caterers,
- bakers' or pastry cooks' wares which, given the nature of their content, are normally consumed within 24 hours of their manufacture,
- vinegar,
- cooking salt,
- solid sugar,
- confectionery products consisting almost solely of flavoured and/or coloured sugars,
- chewing gums and similar chewing products,
- individual portions of ice-cream. " **[3]**

" ARTICLE 9a

1. In the case of foodstuffs which, from the microbiological point of view, are highly perishable and are therefore likely after a short period to constitute an immediate danger to human health, the date of minimum durability shall be replaced by the "use by" date.

2. The date shall be preceded by the words:

- in Spanish: "fecha de caducidad",
- in Danish: "sidste anvendelsesdato",
- in German: "verbrauchen bis",
- in Greek: [see OJ for the Greek characters],
- in English: "use by",
- in French: "à consommer jusqu'au",
- in Italian: "da consumare entro",
- in Dutch: "te gebruiken tot",
- in Portuguese: "a consumir até".

These words shall be accompanied by:

- either the date itself, or
- a reference to where the date is given on the labelling.

These particulars shall be followed by a description of the storage conditions which must be observed.

3. The date shall consist of the day, the month and, possibly, the year, in that order and in uncoded form.

4. In some cases it may be decided by the procedure laid down in Article 17 whether the conditions laid down in paragraph 1 are fulfilled. " **[3]**

ARTICLE 10

1. THE INSTRUCTIONS FOR USE OF A FOODSTUFF SHALL BE INDICATED IN SUCH A WAY AS TO ENABLE APPROPRIATE USE TO BE MADE THEREOF.

2. COMMUNITY PROVISIONS OR, WHERE THERE ARE NONE, NATIONAL PROVISIONS MAY, IN THE CASE OF CERTAIN FOODSTUFFS, SPECIFY THE WAY IN WHICH THE INSTRUCTIONS FOR USE SHOULD BE INDICATED.
THE PROCEDURE LAID DOWN IN ARTICLE 16 SHALL APPLY TO SUCH NATIONAL PROVISIONS.

" The Community provisions referred to in this paragraph shall be adopted in accordance with the procedure laid down in Article 17. " **[3]**

" ARTICLE 10a

THE RULES CONCERNING INDICATION OF THE ALCOHOLIC STRENGTH BY VOLUME SHALL, IN THE CASE OF PRODUCTS COVERED BY TARIFF HEADING NOS 22.04 AND 22.05, BE THOSE LAID DOWN IN THE SPECIFIC COMMUNITY PROVISIONS APPLICABLE TO SUCH PRODUCTS.
IN THE CASE OF OTHER BEVERAGES CONTAINING MORE THAN 1,2 % BY VOLUME OF ALCOHOL, THESE RULES SHALL BE LAID DOWN IN ACCORDANCE WITH THE PROCEDURE PROVIDED FOR IN ARTICLE 17. " **[2]**

ARTICLE 11

" 1. (a) When the foodstuffs are prepackaged, the particulars provided for in Articles 3 and 4 (2) shall appear on the prepackaging or on a label attached thereto.

(b) Notwithstanding point (a) and without prejudice to Community provisions on nominal quantities, where prepackaged foodstuffs are:

- intended for the ultimate consumer but marketed at a stage prior to sale to the ultimate consumer and where sale to a mass caterer is not involved at that stage,
- intended for supply to mass caterers for preparation, processing, splitting or retail sale,

the particulars required under Articles 3 and 4 (2) need appear only on the commercial documents referring to the foodstuffs where it can be guaranteed that such documents, containing all the labelling information, either accompany the foodstuffs to which they refer or were sent before or at the same time as delivery.

(c) In the cases referred to in (b), the particulars referred to in Article 3 (1) (1), (4) and (6) and, where appropriate, that referred to in Article 9a, shall also appear on the external packaging in which the foodstuffs are presented for marketing.

2. These particulars shall be easy to understand and marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible.
They shall not in any way be hidden, obscured or interrupted by other written or pictorial matter.

3. (a) The particulars listed in Article 3 (1), points 1, 3, 4 and 9 shall appear in the same field of vision. This requirement may be extended to the particulars provided for in Article 4 (2).

(b) However, for glass bottles intended for re-use, upon which one of the particulars listed in point (a) is indelibly marked, this requirement shall not apply for a period of 10 years following notification of this Directive.

4. In the case of the glass bottles intended for re-use which are indelibly marked and which therefore bear no label, ring or collar and packaging or containers the largest surface of which has an area of less than 10 cm^2 only the particulars listed in Article 3 (1) (1), (3) and (4) need be given. In this case, paragraph 3 (a) shall not apply.

5. Member States may, until 31 December 1996, refrain from requiring the minimum durability date or the "use by" date to be mentioned in respect of bottles referred to in paragraph 4.

6. Ireland, the Netherlands and the United Kingdom may derogate from Article 3 (1) and paragraph 3 (a) of this Article in the case of milk and milk products put up in glass bottles intended for re-use.

7. The Member States shall inform the Commission of any measure taken pursuant to paragraphs 5 or 6. " **[3]**

ARTICLE 12

WHERE FOODSTUFFS ARE OFFERED FOR SALE TO THE " to the ultimate consumer or to mass caterers " **[3]** WITHOUT PREPACKAGING, OR WHERE FOODSTUFFS ARE PACKAGED ON THE SALES PREMISES AT THE CONSUMER'S REQUEST OR PREPACKAGED FOR DIRECT SALE, THE MEMBER STATES SHALL ADOPT DETAILED RULES CONCERNING THE MANNER IN WHICH THE PARTICULARS SPECIFIED IN ARTICLE 3 AND ARTICLE 4 (2) ARE TO BE SHOWN.
THEY MAY DECIDE NOT TO REQUIRE THE PROVISION OF ALL OR SOME OF THESE PARTICULARS, PROVIDED THAT THE " purchaser " **[3]** STILL RECEIVES SUFFICIENT INFORMATION.

ARTICLE 13

THIS DIRECTIVE SHALL NOT AFFECT THE PROVISIONS OF NATIONAL LAWS WHICH, IN THE ABSENCE OF COMMUNITY PROVISIONS, IMPOSE LESS STRINGENT REQUIREMENTS FOR THE LABELLING OF FOODSTUFFS PRESENTED IN FANCY PACKAGING SUCH AS FIGURINES OR SOUVENIRS.

ARTICLE 14

MEMBER STATES SHALL REFRAIN FROM LAYING DOWN REQUIREMENTS MORE DETAILED THAN THOSE ALREADY CONTAINED IN ARTICLES 3 TO 11 CONCERNING THE MANNER IN WHICH THE PARTICULARS PROVIDED FOR IN ARTICLE 3 AND ARTICLE 4 (2) ARE TO BE SHOWN.
THE MEMBER STATES SHALL, HOWEVER, ENSURE THAT THE SALE OF FOODSTUFFS WITHIN THEIR OWN TERRITORIES IS PROHIBITED IF THE PARTICULARS PROVIDED IN ARTICLE 3 AND ARTICLE 4 (2) DO NOT APPEAR IN A LANGUAGE EASILY UNDERSTOOD BY PURCHASERS, UNLESS OTHER MEASURES HAVE BEEN TAKEN TO ENSURE THAT THE PURCHASER IS INFORMED. THIS PROVISION SHALL NOT PREVENT SUCH PARTICULARS FROM BEING INDICATED IN VARIOUS LANGUAGES.

ARTICLE 15

1. MEMBER STATES MAY NOT FORBID TRADE IN FOODSTUFFS WHICH COMPLY WITH THE RULES LAID DOWN IN THIS DIRECTIVE BY THE APPLICATION OF NON-HARMONIZED NATIONAL PROVISIONS GOVERNING THE LABELLING AND PRESENTATION OF CERTAIN FOODSTUFFS OR OF FOODSTUFFS IN GENERAL.

2. PARAGRAPH 1 SHALL NOT APPLY TO NON-HARMONIZED NATIONAL PROVISIONS JUSTIFIED ON GROUNDS OF:

- PROTECTION OF PUBLIC HEALTH,
- PREVENTION OF FRAUD, UNLESS SUCH PROVISIONS ARE LIABLE TO IMPEDE THE APPLICATION OF THE DEFINITIONS AND RULES LAID DOWN BY THIS DIRECTIVE,
- PROTECTION OF INDUSTRIAL AND COMMERCIAL PROPERTY RIGHTS, INDICATIONS OF PROVENANCE, REGISTERED DESIGNATIONS OF ORIGIN AND PREVENTION OF UNFAIR COMPETITION.

ARTICLE 16

WHERE REFERENCE IS MADE TO THIS ARTICLE, THE FOLLOWING PROCEDURE SHALL APPLY:

1. WHEN A MEMBER STATE MAINTAINS THE PROVISIONS OF ITS NATIONAL LAWS, IT SHALL INFORM THE COMMISSION AND THE OTHER MEMBER STATES THEREOF WITHIN A PERIOD OF TWO YEARS AFTER NOTIFICATION OF THIS DIRECTIVE;

2. SHOULD A MEMBER STATE DEEM IT NECESSARY TO ADOPT NEW LEGISLATION, IT SHALL NOTIFY THE COMMISSION AND THE OTHER MEMBER STATES OF THE MEASURES ENVISAGED AND GIVE THE REASONS JUSTIFYING THEM. THE COMMISSION SHALL CONSULT THE MEMBER STATES WITHIN THE STANDING COMMITTEE ON FOODSTUFFS IF IT CONSIDERS SUCH CONSULTATION TO BE USEFUL OR IF A MEMBER STATE SO REQUESTS.
MEMBER STATES MAY TAKE SUCH ENVISAGED MEASURES ONLY THREE MONTHS AFTER SUCH NOTIFICATION AND PROVIDED THAT THE COMMISSION'S OPINION IS NOT NEGATIVE.
IN THE LATTER EVENT, AND BEFORE THE EXPIRY OF THE ABOVEMENTIONED PERIOD, THE COMMISSION SHALL INITIATE THE PROCEDURE PROVIDED FOR IN ARTICLE 17 IN ORDER TO DETERMINE WHETHER THE ENVISAGED MEASURES MAY BE IMPLEMENTED SUBJECT, IF NECESSARY, TO THE APPROPRIATE MODIFICATIONS.

ARTICLE 17

" Where the procedure laid down in this Article is to be followed, the matter shall be referred to the Standing Committee on Foodstuffs (hereinafter called "the Committee") by its chairman, either on his own initiative or at the request of a representative of a Member State.
The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of Decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.
The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.
If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.
If, on the expiry of a period three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission. " **[3]**

ARTICLE 18

"..." **[3]**

ARTICLE 19

IF TEMPORARY MEASURES PROVE NECESSARY TO FACILITATE THE APPLICATION OF THIS DIRECTIVE, THEY SHALL BE ADOPTED IN ACCORDANCE WITH THE PROCEDURE PROVIDED FOR IN ARTICLE 17.

ARTICLE 20

THIS DIRECTIVE SHALL NOT AFFECT COMMUNITY PROVISIONS RELATING TO THE LABELLING AND PRESENTATION OF CERTAIN FOODSTUFFS ALREADY ADOPTED AT THE TIME OF ITS NOTIFICATION. ANY AMENDMENTS NECESSARY TO HARMONIZE SUCH PROVISIONS WITH THE RULES LAID DOWN IN THIS DIRECTIVE SHALL BE DECIDED IN ACCORDANCE WITH THE PROCEDURE APPLICABLE TO EACH OF THE PROVISIONS IN QUESTION.

ARTICLE 21

THIS DIRECTIVE SHALL NOT APPLY TO PRODUCTS FOR EXPORT OUTSIDE THE COMMUNITY.

ARTICLE 22

1. MEMBER STATES SHALL MAKE SUCH AMENDMENTS TO THEIR LAWS AS MAY BE NECESSARY TO COMPLY WITH THE PROVISIONS OF THIS DIRECTIVE AND SHALL FORTHWITH INFORM THE COMMISSION THEREOF; THE LAWS THUS AMENDED SHALL BE APPLIED IN SUCH A WAY AS TO:

- PERMIT TRADE IN THOSE PRODUCTS WHICH COMPLY WITH THE PROVISIONS OF THIS DIRECTIVE NO LATER THAN TWO YEARS AFTER ITS NOTIFICATION,
- PROHIBIT TRADE IN THOSE PRODUCTS WHICH DO NOT COMPLY WITH THE PROVISIONS OF THIS DIRECTIVE FOUR YEARS AFTER ITS NOTIFICATION.

2. HOWEVER, MEMBER STATES MAY:

(a) IN THE CASE OF CERTAIN FOODSTUFFS, REDUCE THE PERIOD SPECIFIED IN THE SECOND INDENT OF PARAGRAPH 1;

(b) IN THE CASE OF CERTAIN FOODSTUFFS WHICH KEEP FOR A LONG TIME, EXTEND THE PERIOD SPECIFIED IN THE SECOND INDENT OF PARAGRAPH 1;

(c) WITHOUT PREJUDICE TO THE FIRST INDENT OF ARTICLE 23 (1) (b), IN THE CASE OF FOODSTUFFS WHICH WILL KEEP FOR MORE THAN 12 MONTHS, EXTEND TO SIX YEARS THE PERIOD LAID DOWN IN THE SECOND INDENT OF PARAGRAPH 1 ABOVE AS REGARDS THE OBLIGATION TO INDICATE THE DATE OF MINIMUM DURABILITY.

3. IN THE CASE REFERRED TO:

(a) IN PARAGRAPH 2 (a), THE PROCEDURE LAID DOWN IN ARTICLE 16 (2) SHALL APPLY TO ANY NATIONAL PROVISION;

(b) IN PARAGRAPH 2 (b) AND (c), MEMBER STATES SHALL INFORM THE COMMISSION AND THE OTHER MEMBER STATES OF ANY MEASURE TAKEN PURSUANT TO THE SAID POINTS.

4. MEMBER STATES SHALL ALSO ENSURE THAT THE COMMISSION RECEIVES THE TEXT OF ANY ESSENTIAL PROVISION OF NATIONAL LAW WHICH THEY ADOPT IN THE FIELD GOVERNED BY THIS DIRECTIVE.

ARTICLE 23

"..." **[3]**

ARTICLE 24

THIS DIRECTIVE SHALL ALSO APPLY TO THE FRENCH OVERSEAS DEPARTMENTS.

ARTICLE 25

THIS DIRECTIVE SHALL NOT APPLY TO FOODSTUFFS MARKETED IN GREENLAND, INTENDED FOR LOCAL CONSUMPTION.

ARTICLE 26

THIS DIRECTIVE IS ADDRESSED TO THE MEMBER STATES.

ANNEX I

" Categories of ingredients which may be designated by the name of the category rather than the specific name

Definition

Refined oils other than olive oil

Designation

"Oil", together with
- either the adjective "vegetable" or "animal", as appropriate, or
- an indication of their specific vegetable or animal origin

The adjective "hydrogenated" must accompany the indication of a hydrogenated oil

Definition

Refined fats

Designation

"Fat", together with
- either the adjective "vegetable" or "animal", as appropriate, or
- an indication of their specific vegetable or animal origin

The adjective "hydrogenated" must accompany the indication of a hydrogenated fat

Definition

Mixtures of flour obtained from two or more cereal species

Designation

"Flour", followed by a list of the cereals from which it has been obtained, in descending order by weight

Definition

Starches, and starches modified by physical means or by enzymes

Designation

Starch

Definition

All species of fish where the fish constitutes an ingredient of another foodstuff and provided that the name and presentation of such foodstuff does not refer to a specific species of fish

Designation

Fish

Definition

All types of cheese where the cheese or mixture of cheeses constitutes an ingredient of another foodstuff and provided that the name of presentation of such foodstuff does not refer to a specific type of cheese

Designation

Cheese

Definition

All spices not exceeding 2% by weight of the foodstuff

Designation

Spice(s) or mixed spices

Definition

All herbs or parts of herbs not exceeding 2% by weight of the foodstuff

Designation

Herb(s) or mixed herbs

Definition

All types of gum preparations used in the manufacture of gum base for chewing gum

Designation

Gum base

Definition

All types of crumbed baked cereal products

Designation

Crumbs or rusks as appropriate

Definition

All types of sucrose

Designation

Sugar

Definition

Anhydrous dextrose or dextrose monohydrate

Designation

Dextrose

Definition

Glucose syrup and anhydrous glucose syrup

Designation

Glucose syrup

Definition

All types of milk protein (caseins, caseinates and whey proteins) and mixtures thereof

Designation

Milk proteins

Definition

Press, expeller or refined cocoa butter

Designation

Cocoa butter

Definition

All crystallized fruit not exceeding 10% of the weight of the foodstuff

Designation

Crystallized fruit

Definition

Mixtures of vegetables not exceeding 10% of the weight of the foodstuff

Designation

Vegetables

Definition

All types of wine as defined in Council Regulation (EEC) No 822/87 (3)

Designation

Wine " **[5]**

ANNEX II

" Categories of ingredients which must be designated by the name of their category followed by their specific name or EC number

Colour
Preservative
Anti-oxidant
Emulsifier
Thickener
Gelling agent
Stabilizer
Flavour enhancer
Acid
Acidity regulator
Anti-caking agent
Modified starch (4)
Sweetener
Raising agent
Anti-foaming agent
Glazing agent
Emulsifying salts (5)
Flour treatment agent
Firming agent
Humectant
Bulking agent
Propellent gas " **[5]**

" ANNEX III

Designation of flavourings in the list of ingredients

1. Flavourings shall be designated either by the word "flavouring(s)" or by a more specific name or description of the flavouring.

2. The word "natural" or any other word having substantially the same meaning may be used only for flavourings in which the flavouring component contains exclusively flavouring substances as defined in Article 1 (2) (b) (i) and/or flavouring preparations as defined in Article 1 (2) (c) of Directive 88/388/EEC (6) on flavourings.

3. If the name of the flavouring contains a reference to the vegetable or animal nature or origin of the incorporated substances, the word "natural" or any other word having substantially the same meaning may not be used unless the flavouring component has been isolated by appropriate physical processes, enzymatic or microbiological processes or traditional food-preparation processes solely or almost solely from the foodstuff or the flavouring source concerned. " **[4]**

(1) OJ No L 243, 29/10/1971, p. 29.
(2) OJ No L 262, 27/09/1976, p. 204.
(3) OJ No L 84, 27/03/1987, p. 1.
(4) The specific name or EC number need not be indicated.
(5) Only for processed cheeses and products based on processed cheeses.
(6) OJ No L 184, 15/07/1988, p. 61.

Commission communication concerning the use of languages in the marketing of foodstuffs in the light of the judgment in the Peeters case

(93/C 345/03)

A. INTRODUCTION

1. This communication follows on from the communication on the free movement of foodstuffs within the Community (1).

2. Given the extent of the problem of language in the marketing of foodstuffs, the Commission feels it is worth recalling the relevant principles deriving from Articles 30 *et seq.* of the EC Treaty enshrining the principle of the free movement of goods, as interpreted by the Court of Justice of the European Communities, and from Article 14 of Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (2) (3).

3. For the purposes of this communication the Commission takes labelling to mean 'any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a foodstuff and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such foodstuff' (Article 1 (3) (a) of Directive 79/112/EEC).

4. In the wine sector, Article 3 (5) of Regulation (EEC) No 2392/89 of 24 July 1989 laying down general rules for the description and presentation of wines and grape musts (4), lays down specific conditions for the use of languages in the labelling of those products.

B. GENERAL PROBLEMS AND PRINCIPLES: ASSESSMENT WITH REGARD TO COMMUNITY LAW

5. A great many national regulations require that certain particulars appearing on a foodstuff be drafted in, or at least translated into, the official language(s) of the country of marketing.

6. Requirements of this nature, even when applied indiscriminately to domestic and imported products alike, are liable to create barriers to intra-Community trade since producers established in other Member States will be forced to affix *ad hoc* labelling for the country of marketing or to have the documents accompanying the product translated.

7. This obligation, which is liable to generate additional costs for operators, is nonetheless justified where intended to protect the ultimate consumer by informing him of the nature, composition, conditions of use and guarantees of the product.

8. A distinction should be drawn here between products which are intended for sale to the consumer unaltered and those which are not. For the first category, national rules must be looked at in the light of Article 14 of Directive 79/112/EEC and Article 30 of the EC Treaty. For the second category, only Article 30 is applicable.

9. Food products are not intended to be delivered in the unaltered state, (a) if they still have to be processed, e.g. intermediate products to be used by the food industry, and (b) if they still need or are due to be adapted by the economic operator who receives them and will sell them. This is the case, for instance, when a product's packaging will be altered or is inappropriate for sale to the ultimate consumer (e.g. products delivered loose prior to sale to the ultimate consumer). The same applies where an economic operator wishes or is legally or contractually bound to alter, supplement or correct a product's labelling. These situations can arise when an economic operator markets food products from another Member State which are largely or completely unknown to consumers in the country of importation and wishes to promote them through specific labelling better suited to the social and cultural peculiarities of the market concerned.

10. These two scenarios are examined individually: foodstuffs which may not be sold unaltered to the ultimate consumer and to which Article 30 of the EC Treaty applies are dealt with under section C;

(1) OJ No C 271, 24. 10. 1989, p. 3.
(2) This communication does not deal with information for workers to ensure satisfactory conditions of hygiene and safety at work, since this is covered in a specific Community act.
(3) OJ No L 33, 8. 2. 1979, p. 1.
(4) OJ No L 232, 9. 8. 1989, p. 13.

products intended for sale unaltered to the ultimate consumer and which are covered by Article 14 of Directive 79/112/EEC, as interpreted in the light of Article 30 of the EC Treaty, are looked at in section D.

C. ARTICLE 30 OF THE EC TREATY

11. Concerning the first scenario, that is to say transactions between producers, importers, wholesalers and retailers who carry out a final adaptation of the product or its packaging, including labelling, the following considerations must be taken into account.

12. In the normal course of trade the abovementioned operators have few problems with language: either they speak the language of their economic partners or they can ask their suppliers, within the framework of their contractual relations, to supply all the information they need to carry out their business properly and to use and process the product correctly. In this case it would be excessive, and hence run counter to Article 30 of the EC Treaty, to impose the use of a particular language.

13. The situation changes at the stage of sale to the ultimate consumer since foodstuffs are then marketed in their final state and Article 14 of Directive 79/112/EEC, as interpreted in the light of Article 30 of the EC Treaty, is applicable. This difference in approach is understandable, given that consumers cannot be assumed to know the languages of the other Member States, unlike operators for whom such knowledge goes with their business or who are in a position to obtain the information they need. Consumers' health must therefore be protected and consumers must be given information enabling them to make informed choices.

14. Articles 30 to 36 must also be applied in accordance with the principle of proportionality. With regard to this, the Court indicated in its judgment of 16 December 1992 (Case C-169/91 'Stoke and Norwich') that 'appraising the proportionality of national rules which pursue a legitimate aim under Community law involves weighing the national interest in attaining that aim against the Community interest in ensuring the free movement of goods' (point 15 of the legal grounds of the judgment).

15. It follows, as the Court found in its judgment of 18 June 1991 (Case C-369/89 'Peeters'), that 'the obligation exclusively to use the language of the linguistic region (of marketing) constitutes a measure having equivalent effect to a quantitative restriction on imports, prohibited by Article 30 of the EC Treaty'.

16. However, the principle of proportionality is applied without prejudice to the right of administrations to request, at a stage prior to the retail stage, a translation of the labelling where this is necessary for the proper accomplishment of their official tasks (e.g. inspection at the wholesale stage).

17. Nonetheless, a Member State would be overstepping the mark if it requested an authenticated translation or one legalized by a consular or administrative authority (see the Court's judgment of 17 June 1987 in Case 154/87, Commissison v. Italy). Similarly, it would be disproportionate to impose an excessively short deadline for such a translation except in special circumstances (e.g. rapidly perishable products).

18. It is clear that, with regard to particulars which are not compulsory under the rules in force and in respect of which a Member State imposes the use of a specific language, the principle of proportionality deriving from Article 30 likewise applies.

D. ARTICLE 14 OF DIRECTIVE 79/112/EEC

19. In adopting Article 14 of Directive 79/112/EEC, the Community legislature has not departed from the principles deriving from Article 30 of the Treaty on the free movement of goods: the second paragraph of that Article lays down that the particulars which must appear on the label must be given in a language easily understood by purchasers, unless other measures have been taken to ensure that the purchaser is informed. The Article also stipulates that such particulars may be indicated in various languages.

20. This provision is addressed to the Member States and allows them considerable scope for interpreting the concept of language easily understood by the consumer with regard to the abovementioned compulsory information. This scope is nonetheless bound by the limits set by the Court of Justice in its interpretation of Articles 30 *et seq.* of the EC Treaty (see section C above). Even if Directive 79/112/EEC was adopted with a view to eliminating barriers to the free movement of foodstuffs resulting from divergence between national laws on the labelling of such products (see the first recital of the Directive), it can only contribute towards the implementation of Article 30 of the EC Treaty.

21. We therefore need to specify the conditions in which, by virtue of Community law, a Member State is entitled to impose the use of its official national language(s) and is bound to accept the use of other

languages as substitutes, in the light, *inter alia*, of the problems highlighted by the transposition of Article 14 of Directive 79/112/EEC.

22. Article 1 (1) of the Directive indicates the scope of Article 14: the labelling in question applies to all stages of marketing provided that the foodstuff is to be delivered unaltered to the ultimate consumer, including mass caterers, i.e. it is not to undergo any further processing or preparation. The scope of this rule has been discussed in section B above.

The language(s) which may be used in the labelling of foodstuffs

23. Pursuant to Article 14 of Directive 79/112/EEC and in order to inform and protect the consumer, labelling information must be given in an easily understood language, which generally means the official language(s) of the country of marketing.

24. The principle of proportionality, which underlies Article 14 of the Directive, involves weighing the benefits of achieving the goal of national regulations, in this instance consumer information, against the benefits of the free movement of goods.

25. The purpose of the second paragraph of Article 14 is therefore to ban products whose labelling cannot be understood by the purchaser rather than to impose the use of a particular language.

26. This means that a Member State which imposed the exclusive use of its official language(s) would be infringing both Article 14 of Directive 79/112/EEC, which expressly prohibits such restrictions, and Article 30 of the EC Treaty, for the reasons given in section C.

27. As indicated above, the Court of Justice confirmed this interpretation in its judgment in the Peeters case when it said that a national rule imposing the exclusive use of a specific language would constitute a measure of equivalent effect and would therefore infringe Article 30 of the EC Treaty.

28. In the operative part of the same judgment the Court ruled that Article 30 of the EC Treaty and Article 14 of Directive 79/112/EEC preclude a national law from requiring the exclusive use of a specific language for the labelling of foodstuffs without allowing for the the possibility of using another language easily understood by purchasers or of ensuring that the purchaser is informed by other measures.

29. It should be pointed out with regard to the purpose of Article 14 that what matters is not so much the language itself as the content of the particulars given on the label. The fact that a language is used for a particular does not mean that the use of that language is justified for all the other particulars.

1. **The concept of the easily understood language**

30. The concept of 'a language easily understood by purchasers' must obviously be left to the discretion of Member States. Similarly, an official language of the Member State of marketing will in principle be a language allowing consumers a good understanding of the labelling.

31. Moreover, a distinction can be drawn between a language which is easily understood and terms and expressions which are easily understood. Article 11 (2) of Directive 79/112/EEC requires that labelling particulars be easy to understand. It cannot be ruled out that such terms and expressions, although expressed in a foreign language, might be easily understood.

2. **Obligatory use of the official language: conditions and limitations**

32. The purpose of Article 14 of Directive 79/112/EEC is to ensure that the particulars which have to appear on the labelling pursuant to Articles 3, 4 and 16 of the Directive are comprehensible. The provision places no obligation on the person responsible for labelling to translate foreign terms and expressions which are easily understood. Such terms and expressions must be understandable, however, there can be no question of operators shirking their responsibilities in respect of consumer information.

33. On the other hand, it may be unnecessary to require importers automatically to translate every particular labelling in order to ensure comprehensibility, in which case such a requirement would run counter to Article 30 of the EC Treaty and Article 14 of Directive 79/112/EEC. Thus Member States can, in application of Article 14 of Directive 79/112/EEC, require that their official language(s) be used for the particulars which must appear on the labelling of foodstuffs intended for sale to the ultimate consumer in the unaltered state on condition that this requirement does not exclude the use of other languages or recourse to other measures to inform the purchaser.

3. **Criteria for the use of easily understood terms and expressions not belonging to the official language(s) of the Member State of sale to the ultimate consumer**

34. Member States are responsible for ensuring compliance with the principles set out in Article 30

of the EEC Treaty and Article 14 of Directive 79/112/EEC and must accordingly permit the use in labelling of foreign terms and expressions, on condition that this does not impair the consumer's understanding.

35. The grounds of consumer protection which may justify the imposition of the official language(s) of a Member State no longer apply when foreign terms and expressions appearing on product labelling are easily understood and therefore fulfil their informative function.

36. The various exceptions to the use of the official language(s) of the Member State of marketing are as follows:

(a) *use of terms and expressions generally known to the consumer*

37. A number of terms and expressions expressed in a language foreign to the ultimate consumer will be familiar in the Member States (e.g. 'made in . . .');

(b) *use of terms which are untranslatable or have no equivalent in the official language(s) of the Member State of sale*

38. Where a foreign term has no equivalent in the official language(s) of the Member State of sale the importer has no choice but to use that term. A necessarily approximative translation of the term would be liable to mislead the consumer. There could be no question of opposing the importation of the product concerned solely because a term did no exist in the official language(s) concerned.

39. Moreover, a Member State's laws must not 'crystallize given consumer habits' by preventing the marketing of a new product in its territory (judgments of 27 February 1980, Case 170/78 'tax arrangements applying to wine', and 12 March 1987, Case 178/84 'beer purity law' paragraph 32 of the legal grounds of the judgment);

(c) *use of terms and expressions easily understood thanks to similarity of spelling*

40. These are terms and expressions which differ from the same words in the official language(s) of the Member State of marketing only in their spelling.

41. In these cases the original label of the imported product can provide information on the nature of the product and may be as comprehensible to consumers in the importing Member State as the term in the official language.

42. Original particulars concerning a characteristic of the product and which are close to the terms in the official language must be precise enough to indicate the true nature of the product to the purchaser and enable him to distinguish it from products with which it might be confused. Examples include coffee, lychees, mangos, puree and soya.

43. With regard to the particular problem of sales names and the indication they give of the composition of a product the Commission would point out that the relevant principles were set out in points 14 *et seq.* of its communication of 24 October 1989 on the free movement of foodstuffs within the Community (OJ No C 271, 24 October 1989).

E. FINAL REMARKS

44. The Commission believes that in the labelling of foodstuffs sold to the ultimate consumer in the unaltered state the use of terms belonging to a language other than the official language(s) should, in practice, remain the exception.

45. In any event, the Commission will continue to check and monitor the application of Article 30 of the EC Treaty and Article 14 of Directive 79/112/EEC, ensuring that the consumer is properly informed and that terms belonging to non-official languages may be used in the cases referred to in this communication.

Commission interpretative communication on the names under which foodstuffs are sold

(91/C 270/02)

Introduction

This interpretative communication is further to the Commission's communication on the free movement of foodstuffs within the Community (1), the purpose of which was to clarify the scope of Articles 30 and 36 of the EEC Treaty as regards foodstuffs, an area where there is no exhaustive body of applicable Community legislation. It thus dealt with all matters concerning free movement of foodstuffs and specified the obligations of Member States and the rights of economic operators.

It has become clear, however, that there are certain matters which need to be further clarified, in the light of specific cases which the Commission has had to deal with and resolve.

The Commission therefore proposes to issue specific interpretative communications when necessary to go more thoroughly into particular questions broached in the general communication.

The name under which a product is sold is one matter covered in some detail by the general communication (2), and which deserves further clarification as regards the conditions under which the Member States of destination may impose on a product a name which is different from that under which it is marketed in the producing Member State.

This constitutes an exception to the principle of free movement as set out in the general communication, whereby the importer of a foodstuff should have the choice between the name in the importing country or the exporting country, or both (3).

It is therefore necessary for the conditions and cases of application to be strictly delimited.

Conditions under which a name different from that used in the producing country may be required in the importing country

A name different from that used in the producing country may be required of an importer, for access to the market in another Member State, only if the imported product differs from goods generally known under the same name in the Community to such an extent that it cannot be regarded as belonging to the same category (4).

The Court of Justice, in the 'Smanor' (5) and 'Deserbais' (6) cases, has identified the situations in which a different name is necessary to ensure that consumers are protected against the danger of confusion between different products.

According to this case law, if the product does not possess the characteristics for which it is known in the Community, labelling is not sufficient to ensure that the consumer is correctly informed and a different name may therefore be required.

This general principle requires there to be a precise definition of what constitutes a 'characteristic' of a product, which can only be determined on the basis of the essential features of legally produced products generally known under the same name in the Community. This means that it cannot be based on characteristics known to the consumer in the importing country alone, for that would be tantamount to freezing consumer habits in the different Member States, ignoring the changes bound to be brought about by the single market, as was stated by the Court in its judgment in Case 178/84 relating to the German law on purity of beer (7).

What constitutes a characteristic of a product should be determined by a case-by-case examination. This must be based on objective considerations and not merely on what the consumer expects. The factors cited by the Court include:

— definitions in the FAO/WHO Codex alimentarius,

(1) OJ No C 271, 24. 10. 1989, p. 3.
(2) Op. cit., paragraphs 14 to 18.
(3) Op. cit., paragraph 18.
(4) Op. cit., paragraph 18. See also paragraph 13 of the Deserbals judgment (footnote 6 below).
(5) Judgment of 14 July 1988 in Case 298/87 [1988] ECR 4489.
(6) Judgment of 22 September 1988 in Case 286/86 [1988] ECR 4907.
(7) Judgment of 12 March 1987 [1987] ECR 1227.

— the rules and regulations of Member States,

— the composition or method of manufacture of products,

— references in any Community acts, including the tariff nomenclature used in implementing the Common Customs Tariff.

Only a substantial difference in one of the characteristics referred to above is enough to justify a different description. Thus, in the Deserbais case, which involved the name 'Edam', the Court ruled that the fact of a cheese not being in precise conformity with a standard of the FAO Codex alimentarius (minimum fat content) was not enough for it to be denied the right to bear the name in question.

The cases mentioned in the present communication have been resolved in the context of the Commission's procedures preparatory to an action under Article 169 and in infringement procedures. None the less, the Commission considers it useful to draw the attention of all Member States and economic operators to the principles enunciated by the Court as well as to the solutions which have been found in this area and which would be applied in future to similar cases.

It follows that the principles laid down in the present communication and the individual solutions which have been found do not affect the possibility for Member States to permit the sale on their territories of foodstuffs bearing their original names; however, the conditions under which a Member State may legitimately refuse the use of an original name liable to mislead the consumer are set out explicitly. In such a case, Member States are entitled to require a different name so as to alert the consumer to the real nature of the product. This is limited, however, by the fact that such name must not be such as to denigrate the imported product.

Vinegar

The products obtained from the fermentation of agricultural products (such as wine, alcohol, cider, perry, beer, malt and fermented fruit musts) are legally produced and marketed in the Community as vinegar.

In four Member States, the products resulting from double fermentation (alcohol and acetic acid) are found on the market alongside products obtained from the dilution with water of synthetic acetic acid produced by a chemical process.

Of these four Member States, two make no distinction as to the name of these products, and allow both to be called 'vinegar'. The other two do make such a distinction.

The problem is what name to adopt for vinegar obtained by dilution when it is imported into Member States where that method of production is not used.

Applying the criteria referred to above, and specifically that concerning the process of manufacture, it is possible to determine the essential characteristics of the product known in the Community as 'vinegar'.

The Commission has established that in 10 Member States the name 'vinegar' is confined to the product obtained by the same process of double fermentation, that is, using alcohol and acetic acid, whatever the raw material used.

In addition the customs tariff nomenclature distinguishes between products derived from the double alcoholic and acetic fermentation of products of agricultural origin and 'substitutes for vinegar obtained from acetic acid' (1).

The Commission has concluded that a product obtained, not by double fermentation but by dilution, does not possess the characteristic considered in the Community to be essential for it to be described as vinegar, i. e. the manufacturing process used to obtain the product, and must therefore be considered as falling within another category.

The Commission therefore considers that a Member State may legitimately prohibit the marketing on its territory, under the description 'vinegar', of products obtained by dilution with water of acetic acid, even if the products have been legally manufactured and marketed under that name in another Member State.

Yoghurt

In the 'Smanor' judgment referred to above, the Court defined the basic characteristic of yoghurt. The Court noted that both the FAO/WHO Codex alimentarius and

(1) Commission Regulation (EEC) No 2472/90 of 31 July 1990, amending Annex I to Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff, OJ No L 247, 10. 9. 1990, p. 1. The combined nomenclature code for vinegar is 2209 00.

the regulations of several Member States indicated that it was a characteristic of yoghurt to contain live lactic bacteria (1), in large quantities (paragraph 22 of the judgment), but not in any fixed proportion or number.

The Commission has consequently concluded that a Member State is legitimately entitled to refuse to allow a product, which has undergone treatment and no longer contains live bacteria, to be described as 'yoghurt' or by any other name containing a reference to yoghurt. Such a reference could mislead the consumer as to the real nature of the product which could not be overcome by additional corrective labelling.

Caviar

The problem arose of whether lumpfish eggs sold in one Member State as 'caviar' could be marketed under the same name in other Member States which limited the use of the term 'caviar' exclusively to sturgeon eggs. The point at issue was thus whether the name 'caviar' was a generic term denoting fish eggs or should be restricted to the product made from sturgeon eggs only. On the basis of the criteria laid down by the Court, the Commission has come to the conclusion set out below.

In the absence of any definition in the FAO/WHO Codex alimentarius, a number of Community acts, whose aim was not to achieve harmonization in this matter, none the less contain indications that caviar means the eggs of sturgeon only, other products being described as 'caviar substitutes' (2).

Moreover, only two Member States allow the name 'caviar' to be used for fish eggs generically. The Commission has thus concluded that the name 'caviar' should be considered as being generally recognized in the Community to mean sturgeon eggs.

Consequently importing Member States may legitimately refuse the use of this name on their territory for products not possessing this essential characteristic.

Final note

The Commission would point out that the cases referred to above must continue to constitute exceptions to the principle that the importer of a foodstuff is allowed to choose between the name in the importing country or that in the exporting country, or both.

The Commission will thus continue to monitor the application of Community law, so as to restrict the cases where a change of name may be justified to those for which a set of similar arguments lead to the conclusion that the products are different in their essential characteristics.

(1) Namely: *Streptococcus salivarius* subsp. *thermophilus* and *Lactobacillus delbrueckii* subsp. *bulgaricus*.

(2) Council Regulation (EEC) No 3529/87 of 23 November 1987 amending Annex VI to Regulation (EEC) No 3796/81 on the common organization of the market in fishery products and the Annex to Regulation (EEC) No 950/68 on the Common Customs Tariff, OJ No L 336, 26. 11. 1987, p. 3, and Regulation (EEC) No 2472/90 (see footnote 1, page 3); CN code 1604 30.

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DIRECTIVE

of 22 July 1983

introducing temporary measures for the designation of certain ingredients in the labelling of foodstuffs for sale to the ultimate consumer

(83/463/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (1), and in particular Article 19 thereof,

Whereas, pursuant to the second indent of Article 6 (5) (b) of Directive 79/112/EEC, ingredients belonging to one of the categories listed in Annex II thereof must be designated in the list of ingredients by the name of that category, followed by their specific name or EEC number;

Whereas, as Community legislation currently stands, not all of the ingredients in question have been assigned an EEC number; whereas full advantage cannot therefore be taken of the choice offered by the abovementioned labelling rule;

Whereas the Community is required to complete its rules relating to the categories of ingredients listed in Annex II to Directive 79/112/EEC; whereas, as new Community provisions are adopted in these areas, EEC numbers that can be used in the labelling of foodstuffs will become available;

Whereas, as an interim measure aimed at facilitating the application of Directive 79/112/EEC, a temporary numbering system for those ingredients that have not yet received an EEC number should be made available to those responsible for labelling foodstuffs, pending the adoption of these new provisions;

Whereas a system of this kind is not intended to affect the provisions under which the use of the ingredients in question is authorized, prohibited or limited;

Whereas this Directive can relate only to ingredients belonging to the categories of use listed in Annex II to Directive 79/112/EEC; whereas if, however, other categories were added to that Annex, it could also prove necessary to assign numbers to ingredients belonging to such categories;

Whereas, due to the scientific and technical developments in progress on artificial sweeteners, the ingredients in that category cannot yet all be enumerated and in view of this difficulty it is not yet appropriate to include these ingredients in the temporary arrangements introduced by this Directive;

Whereas, pursuant to Article 23 (1) (a) of Directive 79/112/EEC, Member States may make it optional to designate the specific name or EEC number of

(1) OJ No L 33, 8. 2. 1979, p. 1.

ingredients belonging to one of the categories listed in Annex II thereof; whereas this provision is not affected by this Directive;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Pending the implementation of Community provisions introducing new EEC numbers, the numbers listed in the Annex may, in accordance with the second indent of Article 6 (5) (b) of Directive 79/112/EEC, be used in place of the specific name to designate the corresponding ingredients where the latter's technological function classifies them in one or more of the categories listed in Annex II to Directive 79/112/EEC.

Article 2

Member States shall make such amendments to their laws as may be necessary to comply with this Directive and shall forthwith inform the Commission thereof.

Without prejudice to the provisions under which the use of the corresponding ingredients is authorized, prohibited or limited, Member States shall, not later than 1 July 1984, allow the numbers listed in the Annex to be used.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 22 July 1983.

For the Commission
Karl-Heinz NARJES
Member of the Commission

ANNEX

Temporary No	Specific name of the ingredient
101a	Riboflavin-5-phosphate
107	Yellow 2G
128	Red 2G
133	Brilliant Blue FCF
154	Brown FK
155	Brown HT
234	Nisin
240	Formaldehyde
262	Sodium acetate
296	Malic acid (DL + L)
297	Fumaric acid
343	Magnesium orthophosphate
350	Sodium malates (i) Sodium malate (ii) Sodium hydrogen malate
351	Potassium malates (i) Potassium malate (ii) Potassium hydrogen malate
352	Calcium malates (i) Calcium malate (ii) Calcium hydrogen malate
353	Metatartaric acid
354	Calcium tartrate
355	Adipic acid
363	Succinic acid
370	1,4-heptono-lactone
375	Nicotinic acid
380	Tri-Ammonium citrate
381	(i) Ammonium ferric citrate (ii) Ammonium ferric citrate, green
385	Calcium disodium EDTA
416	Karaya gum
430	Polyoxyethylene (8) stearate
431	Polyoxyethylene (40) stearate
432	Polyoxyethylene (20) sorbitan monolaurate
433	Polyoxyethylene (20) sorbitan mono-oleate
434	Polyoxyethylene (20) sorbitan mono-palmitate
435	Polyoxyethylene (20) sorbitan mono-stearate
436	Polyoxyethylene (20) sorbitan tristearate
442	Ammonium phosphatides
476	Polyglycerol polyricinoleate

Temporary No	Specific name of the ingredient
478	Lactylated fatty acid esters of glycerol and propylene glycol
479	Thermally oxidized soya bean oil interacted with mono- and di-glycerides of fatty acids
491	Sorbitan monostearate
492	Sorbitan tristearate
493	Sorbitan monolaurate
494	Sorbitan mono-oleate
495	Sorbitan monopalmitate
500	Sodium carbonates (i) Sodium carbonate (ii) Sodium hydrogen carbonate (iii) Sodium sesquicarbonate
501	Potassium carbonates (i) Potassium carbonate (ii) Potassium hydrogen carbonate
503	Ammonium carbonates (i) Ammonium carbonate (ii) Ammonium hydrogen carbonate
504	Magnesium carbonate
505	Ferrous carbonate
507	Hydrochloric acid
508	Potassium chloride
509	Calcium chloride
510	Ammonium chloride
511	Magnesium chloride
513	Sulphuric acid
514	Sodium sulphate
515	Potassium sulphate
516	Calcium sulphate
518	Magnesium sulphate
520	Aluminium sulphate
521	Aluminium sodium sulphate
523	Aluminium ammonium sulphate
524	Sodium hydroxide
525	Potassium hydroxide
526	Calcium hydroxide
527	Ammonium hydroxide
528	Magnesium hydroxide
529	Calcium oxide
530	Magnesium oxide
535	Sodium ferrocyanide
536	Potassium ferrocyanide
537	Ferrous hexacyano-manganate

Temporary No	Specific name of the ingredient
540	*Di* Calcium diphosphate
541	(i) Sodium aluminium phosphate, acid (ii) Sodium aluminium phosphate, basic
542	Edible bone phosphate
543	Sodium calcium polyphosphate
544	Calcium polyphosphate
545	Ammonium polyphosphate
546	Magnesium pyrophosphate
550	Sodium silicates (i) Sodium silicate (ii) Sodium metasilicate
551	Silicon dioxide
552	Calcium silicate
553a	(i) Magnesium silicate, synthetic (ii) Magnesium *tri*silicate
553b	Talc
554	Sodium aluminium silicate
555	Potassium aluminium silicate
556	Calcium aluminium silicate
557	Zinc silicate
558	Bentonite
559	(i) Kaolin, light (ii) Kaolin, heavy
570	Stearic acid
571	Ammonium stearate
572	Magnesium stearate
573	Aluminium stearate
574	Gluconic acid
575	Glucono-delta-lactone
576	Sodium gluconate
577	Potassium gluconate
578	Calcium gluconate
579	Ferrous gluconate
620	L-glutamic acid
621	Monosodium glutamate
622	Monopotassium glutamate
623	Calcium glutamate
624	Ammonium glutamate
625	Magnesium glutamate
626	Guanylic acid
627	Sodium guanylate
628	Potassium guanylate

Temporary No	Specific name of the ingredient
629	Calcium guanylate
630	Inosinic acid
631	Sodium inosinate
632	Potassium inosinate
633	Calcium inosinate
635	Sodium-5'-ribonucleotide
636	Maltol
637	Ethyl Maltol
900	Dimethylpolysiloxane
901	(i) Beeswax, white (ii) Beeswax, yellow
902	Candellila wax
903	Carnauba wax
904	Shellac
905	Mineral hydrocarbons, Paraffins
906	Benzoin gum
907	Refined microcrystalline wax
908	Rice bran wax
913	Lanolin
915	Glycerol-, methyl- or penta-erithrytol esters of (partially) (hydrogenated or polymerized) colophane
920	L-Cysteine and its hydrochlorides, sodium and potassium salts
921	L-Cystine and its hydrochlorides, sodium and potassium salts
922	Potassium persulphate
923	Ammonium persulphate
924	Potassium bromate
925	Chlorine
926	Chlorine dioxide
927	Azoformamide

COMMISSION DIRECTIVE

of 15 April 1987

on the indication of alcoholic strength by volume in the labelling of alcoholic beverages for sale to the ultimate consumer

(87/250/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (1), as last amended by Directive 86/197/EEC (2), and in particular the second paragraph of Article 10a thereof,

Whereas Article 3 of Directive 79/112/EEC made it mandatory, in the labelling of beverages containing more than 1,2 % by volume of alcohol, to indicate the actual alcoholic strength by volume;

Whereas rules concerning the manner of such indication must be laid down;

Whereas, in the case of products classified under headings No 22.04 and 22.05 of the Common Customs Tariffs, such rules are laid down in the specific Community provisions applicable to them;

Whereas this Directive applies to all other beverages containing more than 1,2 % by volume of alcohol;

Whereas the Annex to Council Directive 76/766/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to alcohol tables (3) lays down Community rules on the definition and on the method of determining and expressing alcoholic strength by volume;

Whereas this Directive may therefore be confined to introducing the provisions that must supplement such rules;

Whereas for the purpose of establishing tolerances, due regard should be given to the nature of the different beverages concerned, the degree of variability observed and the technical difficulties involved in ensuring that the declared value is consistent with the actual value;

Whereas one or more Community methods of analysis for determining alcoholic strength by volume will have to be adopted in good time in order to allow Directive 79/112/EEC and this Directive to be applied correctly;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive concerns the indication of the actual alcoholic strength by volume in the labelling of beverages containing more than 1,2 % by volume of alcohol other than those classified under headings No 22.04 and 22.05 of the Common Customs Tariff.

Article 2

1. Alcoholic strength shall be determined at 20 °C.

2. The figure for alcoholic strength shall be given to not more than one decimal place. It shall be followed by the symbol '% vol.' and may be preceded by the word 'alcohol' or the abbreviation 'alc.'.

Article 3

1. The positive and negative tolerances allowed in respect of the indication of the alcoholic strength by volume shall be as follows, expressed in absolute values:

(a) Beverages not specified below:

0,3 % vol.;

(b) Beers having an alcoholic strength not exceeding 5,5 % vol.; beverages classified under subheading 22.07 B II of the Common Customs Tariff and made from grapes:

0,5 % vol.;

(c) Beers having an alcoholic strength exceeding 5,5 % vol.; beverages classified under subheading 22.07 B I of the Common Customs Tariff and made from grapes; ciders, perries, fruit wines and the like, obtained from fruits other than grapes, whether or not semi-sparkling or sparkling; beverages based on fermented honey:

1 % vol.;

(d) Beverages containing macerated fruit or parts of plants:

1,5 % vol.

2. The tolerances set out in paragraph 1 shall apply without prejudice to the tolerances deriving from the method of analysis used for determining the alcoholic strength.

(1) OJ No L 33, 8. 2. 1979, p. 1.
(2) OJ No L 144, 29. 5. 1986, p. 38.
(3) OJ No L 262, 27. 9. 1976, p. 149.

Article 4

1. Member States shall, where necessary, amend their legislation to comply with this Directive and shall forthwith inform the Commission thereof; legislation thus amended shall be applied in such a manner as to:

— permit trade in products which comply with this Directive by 1 May 1988 at the latest,

— prohibit trade in products which do not comply with this Directive as from 1 May 1989.

2. However, trade in beverages which do not comply with this Directive, labelled before the date in the second indent of paragraph 1, shall be permitted until stocks are exhausted.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 15 April 1987.

For the Commission

COCKFIELD

Vice-President

389L0396

89/396/EEC: COUNCIL DIRECTIVE OF 14 JUNE 1989 ON INDICATIONS OR MARKS IDENTIFYING THE LOT TO WHICH A FOODSTUFF BELONGS

OFFICIAL JOURNAL NO L 186, 30/06/1989, P. 21
DATE OF TRANSPOSITION: 20/06/1990; APPLICATION SEE ART. 7
DATE OF TRANSPOSITION: 01/07/1992; APPLICATION SEE ART. 7

AMENDED BY

391L0238
91/238/EEC: COUNCIL DIRECTIVE OF 22 APRIL 1991 **[1]**
OFFICIAL JOURNAL NO L 107, 27/04/1991, P. 50

392L0011
92/11/EEC: COUNCIL DIRECTIVE OF 3 MARCH 1992 **[2]**
OFFICIAL JOURNAL NO L 65, 11/03/1992, P. 32

ARTICLE 1

1. This Directive concerns the indication which allows identification of the lot to which a foodstuff belongs.

2. For the purposes of this Directive, "lot" means a batch of sales units of a foodstuff produced, manufactured or packaged under practically the same conditions.

ARTICLE 2

1. A foodstuff may not be marketed unless it is accompanied by an indication as referred to in Article 1 (1).

2. However, paragraph 1 shall not apply:

(a) to agricultural products which, on leaving the holding are:

- sold or delivered to temporary storage, preparation or packaging stations,
- transported to producers' organizations, or
- collected for immediate integration into an operational preparation or processing system;

(b) when, at the point of sale to the ultimate consumer, the foodstuffs are not prepackaged, are packaged at the request of the purchaser or are prepackaged for immediate sale;

(c) to packagings or containers, the largest side of which has an area of less than 10 cm;

" (d) to individual portions of ice cream. The indication enabling the lot to be identified must appear on the combined package. " **[1]**

3. Member States may, until 31 December 1996, refrain from requiring the indication referred to in Article 1 (1) to be mentioned in the case of the glass bottles intended for re-use which are indelibly marked and which therefore bear no label, ring or collar.

ARTICLE 3

The lot shall be determined in each case by the producer, manufacturer or packager of the foodstuff in question, or the first seller established within the Community.
The indication referred to in Article 1 (1) shall be determined and affixed under the responsibility of one or other of those operators. It shall be preceded by the letter "L" except in cases where it is clearly distinguishable from the other indications on the label.

ARTICLE 4

When the foodstuffs are prepackaged, the indication referred to in Article 1 (1) and, where appropriate, the letter "L" shall appear on the prepackaging or on a label attached thereto.
When the foodstuffs are not prepackaged, the indication referred to in Article 1 (1) and, where appropriate, the letter "L" shall appear on the packaging or on the container or, failing that, on the relevant commercial documents.
It shall in all cases appear in such a way as to be easily visible, clearly legible and indelible.

ARTICLE 5

When the date of minimum durability or "use by" date appears on the label, the indication referred to in Article 1 (1) need not appear on the foodstuff, provided that the date consists at least of the uncoded indication of the day and the month in that order.

ARTICLE 6

This Directive shall apply without prejudice to the indications laid down by specific Community provisions.
The Commission shall publish and keep up to date a list of the provisions in question.

ARTICLE 7

Member States shall, where necessary, amend their laws, regulations or administrative provisions so as to:

- authorize trade in products complying with this Directive by not later than 20 June 1990,
- " prohibit trade in products not complying with this Directive with effect from 1 July 1992. However, trade in products placed on the market or labelled before that date and not conforming with this Directive may continue until stocks run out. " **[2]**

They shall forthwith inform the Commission thereof.

ARTICLE 8

This Directive is addressed to the Member States.

COUNCIL DIRECTIVE
of 24 September 1990
on nutrition labelling for foodstuffs

(90/496/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas it is important that measures should be adopted with a view to the progressive establishment of the internal market by 31 December 1992; whereas the internal market is an area without internal frontiers in which freedom of movement is ensured for goods, persons, services and capital;

Whereas there is growing public interest in the relationship between diet and health and in the choice of an appropriate diet to suit individual needs;

Whereas the Council and the Representatives of the Governments of the Member States meeting within the Council, in their resolution of 7 July 1986 on the European programme against cancer, considered the improvement of nutrition to be a priority;

Whereas knowledge of the basic principles of nutrition and appropriate nutrition labelling of foodstuffs would contribute significantly towards enabling the consumer to make this choice;

Whereas the provision of nutrition labelling should assist action in the area of nutrition education for the public;

Whereas, for the benefit of the consumer on the one hand, and to avoid any possible technical barriers to trade on the other, nutrition labelling should be presented in a standardized form applying throughout the Community;

Whereas foodstuffs bearing nutrition labelling should conform to the rules laid down in this Directive;

Whereas all other forms of nutrition labelling should be prohibited but foodstuffs bearing no nutrition labelling should be able to circulate freely;

Whereas, to appeal to the average consumer and to serve the purpose for which it is introduced, and given the current low level of knowledge on the subject of nutrition, the information provided should be simple and easily understood;

Whereas application of this Directive for a certain length of time will enable valuable experience on the subject to be gained and consumer reaction to the way in which nutrition information is presented to be evaluated thus enabling the Commission to review the rules and propose any appropriate amendments;

Whereas in order to encourage interested parties, especially small and medium-sized undertakings, to provide nutrition labelling for as many products as possible, measures to make information more complete and more balanced should be introduced gradually;

Whereas the rules laid down in this Directive should also take into account the *Codex Alimentarius* guidelines on nutrition labelling;

Whereas general labelling provisions and definitions are contained in Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (4), as last amended by Directive 89/395/EEC (5); whereas this Directive can therefore be confined to those provisions pertaining to nutrition labelling,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive concerns nutrition labelling of foodstuffs to be delivered as such to the ultimate consumer. It shall also apply to foodstuffs intended for supply to restaurants, hospitals, canteens and other similar mass caterers (hereinafter referred to as 'mass caterers').

(1) OJ No C 282, 5. 11. 1988, p. 8 and OJ No C 296, 24. 11. 1989, p. 3.
(2) OJ No C 158, 26. 6. 1989, p. 250 and OJ No C 175, 16. 7. 1990, p. 76.
(3) OJ No C 159, 26. 6. 1989, p. 41.
(4) OJ No L 33, 8. 2. 1979, p. 1.
(5) OJ No L 186, 30. 6. 1989, p. 17.

2. This Directive shall not apply to:

— natural mineral waters or other waters intended for human consumption,

— diet integrators/food supplements.

3. This Directive shall apply without prejudice to the labelling provisions of Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (1) and specific Directives as referred to in Article 4 of that Directive.

4. For the purposes of this Directive:

(a) 'nutrition labelling' means any information appearing on labelling and relating to:

(i) energy value;

(ii) the following nutrients:

— protein,
— carbohydrate,
— fat,
— fibre,
— sodium,
— vitamins and minerals listed in the Annex and present in significant amounts as defined in that Annex.

Changes to the list of vitamins, minerals and their recommended daily allowances shall be adopted in accordance with the procedure laid down in Article 10;

(b) 'nutrition claim' means any representation and any advertising message which states, suggests or implies that a foodstuff has particular nutrition properties due to the energy (calorific value) it

— provides,
— provides at a reduced or increased rate or
— does not provide,

and/or due to the nutrients it

— contains,
— contains in reduced or increased proportions or
— does not contain.

A reference to qualities or quantities of a nutrient does not constitute a nutrition claim in so far as it is required by legislation.

In accordance with the procedure laid down in Article 10, it may be decided in certain cases whether the conditions described in this point are satisfied;

(c) 'protein' means the protein content calculated using the formula: protein = total Kjeldahl nitrogen × 6,25;

(d) 'carbohydrate' means any carbohydrate which is metabolized in man, and includes polyols;

(e) 'sugars' means all monosaccharides and disaccharides present in food, but excludes polyols;

(f) 'fat' means total lipids, and includes phospholipids;

(g) 'saturates' means fatty acids without double bond;

(h) 'mono-unsaturates' means fatty acids with one *cis* double bond;

(i) 'polyunsaturates' means fatty acids with *cis, cis*-methylene interrupted double bonds;

(j) 'fibre' means the material to be defined in accordance with the procedure laid down in Article 10 and measured by the method of analysis to be determined in accordance with that procedure;

(k) 'average value' means the value which best represents the amount of the nutrient which a given food contains, and reflects allowances for seasonal variability, patterns of consumption and other factors which may cause the actual value to vary.

Article 2

1. Subject to paragraph 2, nutrition labelling shall be optional.

2. Where a nutrition claim appears on labelling, in presentation or in advertising, with the exclusion of generic advertising, nutrition labelling shall be compulsory.

Article 3

The only nutrition claims permitted shall be those relating to energy, to the nutrients listed in Article 1 (4) (a) (ii) and to substances which belong to or which are components of a category of those nutrients. Provisions restricting or prohibiting nutrition claims within the meaning of this Article may be adopted by the procedure laid down in Article 10.

Article 4

1. Where nutrition labelling is provided, the information to be given shall consist of either group 1 or group 2 in the following order:

Group 1

(a) energy value;

(b) the amounts of protein, carbohydrate and fat.

Group 2

(a) energy value;

(b) the amounts of protein, carbohydrate, sugars, fat, saturates, fibre and sodium.

2. Where a nutrition claim is made for sugars, saturates, fibre or sodium, the information to be given shall consist of group 2.

(1) OJ No L 186, 30. 6. 1989, p. 27.

3. Nutrition labelling may also include the amounts of one or more of the following:

— starch,
— polyols,
— mono-unsaturates,
— polyunsaturates,
— cholesterol,
— any of the minerals or vitamins listed in the Annex and present in significant amounts as defined in that Annex.

4. The declaration of substances which belong to or are components of one of the categories of nutrients referred to in paragraphs 1 and 3 shall be compulsory where a nutrition claim is made.

In addition, where the amount of polyunsaturates and/or mono-unsaturates and/or the cholesterol rate is given, the amount of saturates shall also be given, the declaration of the latter not constituting — in this case — a nutrition claim within the meaning of paragraph 2.

Article 5

1. The energy value to be declared shall be calculated using the following conversion factors:

— carbohydrate (except polyols)	4 kcal/g	— 17 kJ/g
— polyols	2,4 kcal/g	— 10 kJ/g
— protein	4 kcal/g	— 17 kJ/g
— fat	9 kcal/g	— 37 kJ/g
— alcohol (ethanol)	7 kcal/g	— 29 kJ/g
— organic acid	3 kcal/g	— 13 kJ/g

2. Provisions concerning the following points shall be adopted in accordance with the procedure laid down in Article 10:

— amendments to the conversion factors mentioned in paragraph 1,
— the addition to the list in paragraph 1 of substances which belong to or are components of one of the categories of nutrients referred to in that paragraph and their conversion factors in order to calculate more precisely the energy value of foodstuffs.

Article 6

1. The declaration of the energy value and of the proportion of nutrients or their components shall be numerical. The units to be used are the following:

— energy — kJ and kcal — protein — carbohydrate — fat — fibre — sodium	grams (g)
— cholesterol — vitamins and minerals	milligrams (mg) the units specified in the Annex

2. Information shall be expressed per 100 g or per 100 ml. In addition, this information may be given per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated.

3. In accordance with the procedure laid down in Article 10 it may be decided that the information in paragraphs 1 and 2 may also be given in graphical form according to formats to be determined.

4. The amounts mentioned shall be those of the food as sold. Where appropriate, this information may relate to the foodstuff after preparation, provided that sufficiently detailed preparation instructions are given and the information relates to the food as prepared for consumption.

5. (a) Information on vitamins and minerals must also be expressed as a percentage of the recommended daily allowance (RDA) given in the Annex for the amounts as specified in paragraph 2.

(b) The percentage of the recommended daily allowance (RDA) for vitamins and minerals may also be given in graphical form. Rules for implementing this subparagraph may be adopted in accordance with the procedure laid down in Article 10.

6. Where sugars and/or polyols and/or starch are declared, this declaration shall immediately follow the declaration of the carbohydrate content in the following manner:

— carbohydrate	g
of which:	
— sugars	g
— polyols	g
— starch	g

7. Where the amount and/or type of fatty acid and/or the cholesterol rate is declared, this declaration shall immediately follow the declaration of total fats in the following manner:

— fat	g
of which:	
— saturates	g
— mono-unsaturates	g
— polyunsaturates	g
— cholesterol	mg

8. The declared values shall, according to the individual case, be average values based on:

(a) the manufacturer's analysis of the food;

(b) a calculation from the known or actual average values of the ingredients used;

(c) a calculation from generally established and accepted data.

The rules for implementing the first paragraph with regard in particular to the differences between the declared values and those established in the course of official checks shall be decided upon in accordance with the procedure laid down in Article 10.

Article 7

1. The information covered by this Directive must be presented together in one place in tabular form, with the numbers aligned if space permits. Where space does not permit, the information shall be presented in linear form.

It shall be printed in legible and indelible characters in a conspicuous place.

2. Member States shall ensure that the information covered by this Directive appears in a language easily understood by purchasers, unless other measures have been taken to ensure that the purchaser is informed. This provision shall not prevent such information from being indicated in more than one language.

3. Member States shall refrain from laying down requirements more detailed than those already contained in this Directive concerning nutrition labelling.

Article 8

In the case of non-prepackaged foodstuffs put up for sale to the ultimate consumer or to mass caterers and foodstuffs packed at the point of sale at the request of the purchaser or prepackaged with a view to immediate sale, the extent of the information referred to in Article 4 and the manner of its communication may be determined by national provisions until the eventual adoption of Community measures in accordance with the procedure laid down in Article 10.

Article 9

Any measures likely to have an effect on public health shall be adopted after consultation of the Scientific Committee for Food set up by Decision 74/234/EEC (1).

Article 10

1. Where the procedure laid down in this Article is to be followed, the matter shall be referred to the Standing Committee for Foodstuffs set up by Decision 69/414/EEC (2) (hereinafter referred to as 'the Committee') by its chairman, either on his own initiative or at the request of the representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

(b) Where the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

(c) If, on expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 11

1. Member States shall take the measures necessary to comply with this Directive and shall forthwith inform the Commission thereof. Those measures shall be applied in such a way as to:

— permit trade in products complying with this Directive by 1 April 1992,

— prohibit trade in products which do not comply with this Directive with effect from 1 October 1993.

2. Until .... (five years following notification of this Directive), the declaration in nutrition labelling, either on a voluntary basis or following a nutrition claim, of one or more of the following nutrients; sugars, saturates, fibre, sodium, shall not trigger the obligation set out in Article 4 (1) and (2) to declare all these nutrients.

3. The Commission shall, by .... (eight years after notification of this Directive), submit to the European Parliament and the Council a report on the application of

(1) OJ No L 136, 20. 5. 1974, p. 1.

(2) OJ No L 291, 19. 11. 1969, p. 9.

this Directive. At the same time, it shall submit to the Council any appropriate proposals for amendment.

Article 12

This Directive is addressed to the Member States.

Done at Brussels, 24 September 1990.

For the Council

The President

V. SACCOMANDI

ANNEX

Vitamins and minerals which may be declared and their recommended daily allowances (RDAs)

Vitamin A µg	800	Vitamin B12 µg	1
Vitamin D µg	5	Biotin mg	0,15
Vitamin E mg	10	Pantothenic acid mg	6
Vitamin C mg	60	Calcium mg	800
Thiamin mg	1,4	Phosphorus mg	800
Riboflavin mg	1,6	Iron mg	14
Niacin mg	18	Magnesium mg	300
Vitamin B6 mg	2	Zinc mg	15
Folacin µg	200	Iodine µg	150

As a rule, 15 % of the recommended allowance specified in ths Annex supplied by 100 g or 100 ml or per package if the package contains only a single portion should be taken into consideration in deciding what constitutes a significant amount.

FOOD ADDITIVES

COUNCIL DIRECTIVE

of 21 December 1988

on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption

(89/107/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission,

In cooperation with the European Parliament (1),

Having regard to the opinion of the Economic and Social Committee (2),

Whereas differences between national laws relating to food additives and the conditions for their use hinder the free movement of foodstuffs; whereas they may create conditions of unfair competition, thereby directly affecting the establishment or functioning of the common market;

Whereas the approximation of these laws is therefore necessary;

Whereas these requirements should be included in a comprehensive directive, where neccessary drawn up in stages;

Whereas the drawing-up of lists of categories of food additives to be covered by a directive is a matter to be decided by the Council acting under the procedure laid down in Article 100a of the Treaty;

Whereas the use of food additives belonging to such categories should be authorized only on the basis of agreed scientific and technological criteria laid down by the Council;

Whereas in drawing up lists of additives and the conditions for their use the Scientific Committee for Food, set up by Commission Decision 74/234/EEC (3), should be consulted before the adoption of provisions likely to affect public health;

Whereas it must be possible to adopt the list of authorized additives to scientific and technical developments; whereas in that case, it may be appropriate also to have, in addition to the rules of procedure laid down by the Treaty, a system permitting the Member States to contribute, by the adoption of temporary national measures, to the search for a Community solution;

Whereas the determination of the criteria of purity for such food additives and the drawing-up of methods of analysis and sampling are technical matters to be entrusted to the Commission;

Whereas existing Community provisions on colouring matters, preservatives, anti-oxidants and emulsifiers, stabilizers, thickeners and gelling agents will require amendment on the basis of this Directive;

Whereas, in all cases where the Council empowers the Commission to implement rules relating to foodstuffs, provision should be made for a procedure instituting close cooperation between Member States and the Commission within the Standing Committee on Foodstuffs set up by Commission Decision 69/414/EEC (4),

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to food additives the various categories of which are given in Annex I and which are used or intended to be used as ingredients during the manufacture or preparation of a foodstuff and are still present in the final product, even if in altered form, hereinafter called 'food additives'.

2. For the purposes of this Directive 'food additive' means any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods.

(1) OJ No C 99, 13. 4. 1987, p. 65 and OJ No C 12, 16. 1. 1989.
(2) OJ No C 328, 22. 12. 1986, p. 5.
(3) OJ No L 136, 20. 5. 1974, p. 1.
(4) OJ No L 291, 19. 11. 1969, p. 9.

3. This Directive shall not apply to:

(a) processing aids (1);

(b) substances used in the protection of plants and plant products in conformity with Community rules relating to plant health;

(c) flavourings for use in foodstuffs, falling within the scope of Council Directive 88/388/EEC (2);

(d) substances added to foodstuffs as nutrients (for example minerals, trace elements or vitamins).

Article 2

1. In respect of any category of food additive listed in Annex I for which lists have been drawn up pursuant to Article 3 (3), only those food additives included in such lists may be used in the manufacture or preparation of foodstuffs and only under the conditions of use specified therein.

2. The inclusion of food additives in one of the categories in Annex I shall be on the basis of the principal function normally associated with the food additive in question. However, the allocation of the additive to a particular category does not exclude the possibility of the additive being authorized for several functions.

3. Food additives shall be included in a list on the basis of the general criteria described in Annex II.

Article 3

1. Particular provisions in respect of the additives in the categories given in Annex I shall be laid down in a comprehensive directive, including existing specific directives on particular categories of additives. That directive may, however, be drawn up in stages.

2. The Council shall, acting on a proposal from the Commission under the procedure laid down in Article 100a of the Treaty, adopt:

(a) a list of additives the use of which is authorized to the exclusion of all others;

(b) the list of foodstuffs to which these additives may be added, the conditions under which they may be added and, where appropriate, a limit on the technological purpose of their use;

(c) the rules on additives used as carrier substances and solvents, including where necessary their purity criteria.

3. The following shall be adopted under the procedure laid down in Article 11:

(a) the criteria of purity for the additives in question;

(b) where necessary, the methods of analysis needed to verify that the criteria of purity referred to in (a) are satisfied;

(c) where necessary, the procedure for taking samples and the methods for the qualitative and quantitative analysis of food additives in and on foodstuffs;

(d) other rules necessary to ensure compliance with the provisions of Article 2.

Article 4

1. Where a Member State, as a result of new information or of a re-assessment of existing information made since this Directive, or the comprehensive directive referred to in Article 3, was adopted, has detailed grounds for considering that the use of additives in food, although it complies with this Directive or any list drawn up under Article 3, endangers human health, that Member State may temporarily suspend or restrict application of the provisions in question in its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

2. The Commission shall examine the grounds given by the Member State referred to in paragraph 1 as soon as possible within the Standing Committee on Foodstuffs, and shall then deliver its opinion forthwith and take the appropriate measures.

3. If the Commission considers that amendments to this Directive or to the comprehensive directive referred to in Article 3 are necessary in order to resolve the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure laid down in Article 11, with a view to adopting those amendments; the Member State which has adopted safeguard measures may in that event retain them until the amendments have been adopted.

Article 5

1. In order to take account of scientific or technical developments which have occurred since the adoption of a list in accordance with Article 3, a Member State may

(1) For the purpose of this Directive, 'processing aid' means any substance not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product.

(2) OJ No L 184, 15. 7. 1988, p. 61.

provisionally authorize the marketing and use within its territory of an additive from one of the categories listed in Annex I and not included in the relevant list provided that the following conditions are satisfied:

(a) the authorization shall be limited to a maximum period of two years;

(b) the Member State shall ensure that foodstuffs containing an additive which it has authorized are officially monitored;

(c) in the authorization the Member State may require that foodstuffs manufacted with the additive in question shall bear a special indication.

2. The Member State shall communicate to the other Member States and to the Commission the text of any authorization decision adopted pursuant to paragraph 1, within two months of the date on which the decision takes effect.

3. Before the two-year period stipulated in paragraph 1 (a) has expired the Member State may request the Commission to include in the list adopted in accordance with Article 3 the additive which had been the subject of national authorization pursuant to paragraph 1 of this Article. At the same time, the Member State shall provide the evidence which, in its view, supports such inclusion and shall indicate how the additive is to be used. If the Commission considers this request to be justified, it shall operate the procedure laid down in Article 100a of the Treaty in order to amend the list adopted in accordance with Article 3. The Council shall act on a proposal from the Commission, within 18 months from the date on which the matter was referred to it.

4. If, within the two-year period stipulated in paragraph 1, the Commission does not submit a proposal in accordance with paragraph 3, or if the Council does not act within the 18-month period stipulated in paragraph 3, the national authorization must be cancelled. At the same time, any authorization granted by another Member State for the same additive must be cancelled.

5. No new authorization for the same additive may be granted unless the scientific or technical development made since the cancellation provided for in paragraph 4 so justifies.

Article 6

Provisions that may have effect upon public health shall be adopted after consultation with the Scientific Committee for Food.

Article 7

1. Food additives not intended for sale to the ultimate consumer may be marketed only if their packaging or containers bear the following information, which must be conspicuous, clearly legible and indelible:

(a) — for food additives sold singly or mixed with each other, for each additive, the name laid down by any Community provisions applying and its EEC number or, in the absence of such provisions, a description of the additive that is sufficiently precise to enable it to be distinguished from additives with which it could be confused, in descending order of the proportion by weight in the total,

— when other substances or materials or food ingredients to facilitate storage, sale, standardization, dilution or dissolution of a food additive or food additives are incorporated in the additives, the name of the additive in accordance with the first indent and an indication of each component in descending order of the proportion by weight in the total;

(b) — either the statement 'for use in food',

— or the statement 'restricted use in food',

— or a more specific reference to its intended food use;

(c) if necessary, the special conditions of storage and use;

(d) directions for use, if the omission thereof would preclude appropriate use of the additive;

(e) a mark identifying the batch or lot;

(f) the name or business name and address of the manufacturer or packager, or of a seller established within the Community;

(g) an indication of the percentage of any component which is subject to a quantitative limitation in a food or adequate compositional information to enable the purchaser to comply with any Community provisions, or in their absence national provisions, applying to the food. Where the same quantitative limitation applies to a group of components used singly or in combination, the combined percentage may be given as a single figure;

(h) the net quantity;

(i) any other information provided for in the comprehensive Directive referred to in Article 3.

2. By way of derogation from paragraph 1, the information required in point (a), second indent, and points (d) to (g), may appear merely on the documents relating to the consignment which are to be supplied with or prior to the delivery, provided that the indication 'intended for the manufacture of foodstuffs and not for retail sale' appears on a conspicuous part of the packaging or container of the product in question.

Article 8

Food additives intended for sale to the ultimate consumer may be marketed only if their packagings or containers bear the following information, which must be conspicuous, clearly legible and indelible:

(a) the name under which the product is sold. This name shall be constituted by the name laid down by any Community provisions applying to the product in question plus its EEC number or, in the absence of such provisions, by a description of the product that is sufficiently precise to enable it to be distinguished from products with which it could be confused;

(b) the information required by Article 7 (1) (a) to (f), and (h);

(c) the date of minimum durability within the meaning of Article 9 of Council Directive 79/112/EEC (1);

(d) any other information provided for in the comprehensive directive referred to in Article 3.

Article 9

Articles 7 and 8 shall not affect more detailed or more extensive laws, regulations or administrative provisions regarding weights and measures, or applying to the presentation, classification, packaging and labelling of dangerous substances and preparations or the transport of such substances.

Article 10

Member States shall refrain from laying down requirements more detailed than those contained in Articles 7 and 8 concerning the manner in which the particulars provided for therein are to be shown.

The particulars provided for in Articles 7 and 8 shall appear in a language easily understandable to purchasers unless other measures have been taken to ensure that the purchaser is informed. This provision shall not prevent such particulars from being indicated in various languages.

Article 11

1. Where the procedure laid down in this Article is to be followed, the chairman shall refer the matter to the Standing Committee on Foodstuffs either on his own initiative or at the request of the representative of a Member State.

2. The Commission representative shall submit to the committee a draft of measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the qualified majority laid down in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the intended measures when they are in accordance with the Committee's opinion;

(b) where the intended measures are not in accordance with the opinion of the committee, or in the absence of any opinion, the Commission shall forthwith submit to the Council a proposal relating to the measures to be taken. The Council shall act on a qualified majority.

If, on the expiry of three months from the date on which the matter was referred to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures.

Article 12

1. Member States shall take all measures necessary to ensure that food additives belonging to the categories defined in Annex I may be marketed only if they conform to the definitions and rules laid down in this Directive and the Annexes thereto.

2. Member States may not prohibit, restrict or obstruct the marketing of food additives, food or food ingredients on grounds relating to food additives, if these comply with the provisions of this Directive, the existing specific directives and the comprehensive directive referred to in Article 3.

3. Paragraph 2 shall not affect national provisions applicable in the absence of corresponding provisions in the comprehensive directive referred to in Article 3.

Article 13

Measures to bring existing Community directives into line with this Directive shall be adopted according to the procedure laid down in Article 11.

Article 14

1. Member States shall take all measures necessary to comply with this Directive within 18 months of its notification. They shall forthwith inform the Commission thereof. The measures taken shall:

— authorize, two years after notification of this Directive, the marketing and use of food additives complying with this Directive;

(1) OJ No L 33, 8. 2. 1979, p. 1.

— prohibit, not later than three years after notification (1) of this Directive, the marketing and use of food additives which do not comply with this Directive.

2. Paragraph 1 shall not affect existing Community provisions or those national provisions which, in the absence of the comprehensive directives referred to in Article 3, apply to certain groups of food additives or specify the foodstuffs in or on which food additives complying with this Directive may be used.

Article 15

This Directive is addressed to the Member States.

Done at Brussels, 21 December 1988.

For the Council
The President
V. PAPANDREOU

(1) This Directive was notified to the Member States on 28 December 1988.

ANNEX I

Categories of food additives

Colour
Preservative
Anti-oxidant
Emulsifier
Emulsifying salt
Thickener
Gelling agent
Stabilizer (1)
Flavour enhancer
Acid
Acidity regulator (2)
Anti-caking agent
Modified starch
Sweetener
Raising agent
Anti-foaming agent
Glazing agent (3)
Flour treatment agent
Firming agent
Humectant
Sequestrant (4)
Enzyme (4) (5)
Bulking agent
Propellent gas and packaging gas

(1) This category also comprises foam stabilizers.
(2) These can act as two-way acidity regulators.
(3) These substances include lubricants.
(4) Inclusion of these terms in this list is without prejudice to any future decision or mention thereof in the labelling of foodstuffs intended for the final consumer.
(5) Only those used as additives.

ANNEX II

General criteria for the use of food additives

1. Food additives can be approved only provided that:

— there can be demonstrated a reasonable technological need and the purpose cannot be achieved by other means which are economically and technologically practicable,

— they present no hazard to the health of the consumer at the level of use proposed, so far as can be judged on the scientific evidence available,

— they do not mislead the consumer.

2. The use of food additives may be considered only where there is evidence that the proposed use of the additive would have demonstrable advantages of benefit to the consumer, in other words it is necessary to establish the case for what is commonly referred to as 'need'. The use of food additives should serve one or more of the purposes set out from points (a) to (d) and only where these purposes cannot be achieved by other means which are economically and technologically practicable and do not present a hazard to the health of the consumer:

(a) to preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified only where the food does not constitute a significant item in a normal diet or where the additive is necessary for the production of foods for groups of consumers having special dietary needs;

(b) to provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;

(c) to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not so change the nature, substance or quality of the food as to deceive the consumer;

(d) to provide aids in manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities.

3. To assess the possible harmful effects of a food additive or derivatives thereof, it must be subjected to appropriate toxicological testing and evaluation. The evaluation should also take into account, for example, any cumulative, synergistic or potentiating effect of its use and the phenomenon of human intolerance to substances foreign to the body.

4. All food additives must be kept under continuous observation and must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information.

5. Food additives must at all times comply with the approved criteria of purity.

6. Approval for food additives must:

(a) specify the foodstuffs to which these additives may be added and the conditions under which they may be added;

(b) be limited to the lowest level of use necessary to achieve the desired effect;

(c) take into account any acceptable daily intake, or equivalent assessment, established for the food additive and the probable daily intake of it from all sources. Where the food additive is to be used in foods eaten by special groups of consumers, account should be taken of the possible daily intake of the food additive by consumers in those groups.

II

(Acts whose publication is not obligatory)

COMMISSION

FIRST COMMISSION DIRECTIVE

of 28 July 1981

laying down Community methods of analysis for verifying that certain additives used in foodstuffs satisfy criteria of purity

(81/712/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to the Council Directive of 23 October 1962 on the approximation of the laws of the Member States concerning the colouring matters authorized for use in foodstuffs intended for human consumption (1), as last amended by Directive 78/144/EEC (2), and in particular Article 11 (2) thereof,

Having regard to Council Directive 64/54/EEC of 5 November 1963 on the approximation of the laws of the Member States concerning the preservatives authorized for use in foodstuffs intended for human consumption (3), as last amended by Directive 79/40/EEC (4), and in particular Article 8 (2) thereof.

Having regard to Council Directive 70/357/EEC of 13 July 1970 on the approximation of the laws of the Member States concerning the antioxidants authorized for use in foodstuffs intended for human consumption (5), as last amended by Directive 78/143/EEC (6), and in particular Article 5 (2) thereof.

Whereas these provisions lay down that Community methods of analysis shall be established for verifying that these additives satisfy general and specific criteria of purity;

Whereas a first series of methods for which the studies have been completed should now be adopted;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Member States shall prescribe that the analyses necessary for verifying that certain additives used in foodstuffs satisfy the general and specific criteria of

(1) OJ No 115, 11. 11. 1962, p. 2645/62.
(2) OJ No L 44, 15. 2. 1978, p. 20.
(3) OJ No 12, 27. 1. 1964, p. 161/64.
(4) OJ No L 13, 19. 1. 1979, p. 50.
(5) OJ No L 157, 18. 7. 1970, p. 31.
(6) OJ No L 44, 15. 2. 1978, p. 18.

purity shall be carried out according to the methods described in Annex II, the scope of which is laid down in Annex I.

Article 2

The Member States shall bring into force the laws, regulations or administrative provisions necessary to comply with this Directive not later than 20 February 1983. They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 28 July 1981.

For the Commission
Karl-Heinz NARJES
Member of the Commission

ANNEX I

SCOPE OF THE COMMUNITY METHODS OF ANALYSIS FOR VERIFYING THAT CERTAIN ADDITIVES USED IN FOODSTUFFS MEET PURITY CRITERIA

I. INTRODUCTION

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II. COLOURING MATTERS

II.1. Determination of substances extractable with diethyl ether from water-soluble sulphonated organic colouring matters used in foodstuffs using Annex II, method 1.

III. PRESERVATIVES

III.1. Determination of formic acid, formates and of other oxidizable impurities in acetic acid (E 260), potassium acetate (E 261), sodium diacetate (E 262) and calcium acetate (E 263) using Annex II, method 2.

III.2. Determination of non-volatile substances in propionic acid (E 280) using Annex II, method 3.

III.3. Determination of the loss of mass on drying of sodium nitrite (E 250) using Annex II, method 4.

III.4. Limit test for salicylic acid in ethyl *p*-hydroxybenzoate (E 214), ethyl *p*-hydroxybenzoate, sodium salt (E 215), *n*-propyl *p*-hydroxybenzoate (E 216), *n*-propyl *p*-hydroxybenzoate, sodium salt (E 217), methyl *p*-hydroxybenzoate (E 218) and methyl *p*-hydroxybenzoate, sodium salt (E 219) using Annex II, method 5.

III.5. Determination of free acetic acid in sodium diacetate (E 262) using Annex II, method 6.

III.6. Determination of sodium acetate in sodium diacetate (E 262) using Annex II, method 7.

III.7. Limit test for determination of aldehydes in sorbic acid (E 200) in sodium, potassium and calcium sorbates (E 201, E 202, E 203) and in propionic acid (E 280) using Annex II, method 8.

IV. ANTIOXIDANTS

IV.1. Determination of the number of peroxide groups of lecithins (E 322) using Annex II, method 9.

IV.2. Determination of toluene-insoluble substances in lecithins (E 322) using Annex II, method 10.

IV.3. Limit test for reducing substances in sodium, potassium and calcium lactates (E 325, E 326 and E 327) using Annex II, method 11.

IV.4. Determination of volatile acids in orthophosphoric acid (E 338) using Annex II, method 12.

IV.5. Limit test for nitrates in orthophosphoric acid (E 338) using Annex II, method 13.

IV.6. Determination of water-insoluble substances in mono-, di- and tri-sodium orthophosphate and mono-, di- and tri-potassium orthophosphates (E 339(i), E 339(ii), E 339(iii), E 340(i), E 340(ii), E 340(iii)) using Annex II, method 14.

V. GENERAL

V.1. Determination of pH in food additives using Annex II, method 15.

ANNEX II

METHODS OF ANALYSIS RELATING TO THE CRITERIA OF PURITY OF FOOD ADDITIVES

INTRODUCTION

1. Preparation of the analysis sample

1.1. *General*

The mass of the laboratory sample intended for analysis must normally be 50 g unless a larger quantity is required for a specific determination.

1.2. *Sample preparation*

The sample shall be made homogeneous prior to analysis.

1.3. *Preservation*

The prepared sample shall always be kept in an air-tight and moisture-tight container and stored so that deterioration is prevented.

2. Reagents

2.1. *Water*

2.1.1. Wherever mention is made of water for solution, dilution or washing purposes, distilled water, or demineralized water of at least equivalent purity, is intended.

2.1.2. Wherever reference is made to 'solution' or 'dilution' without further indication of a reagent, an aqueous solution is intended.

2.2. *Chemicals*

All chemicals shall be of analytical reagent quality except where otherwise specified.

3. Equipment

3.1. *List of equipment*

The list of equipment contains only those items with a specialized use and items with a particular specification.

3.2. *Analytical balance*

Analytical balance means a balance with a sensitivity of 0·1 mg or greater.

4. Expression of results

4.1. *Results*

The result stated in the official analysis report shall be the mean value of at least two determinations the repeatability of which is satisfactory.

4.2. *Calculation of percentage*

Unless otherwise stated the results shall be expressed as a percentage by mass of the original sample as received at the laboratory.

4.3. *Number of significant figures*

The number of significant figures in the result so expressed shall be governed by the precision of the method.

METHOD 1

DETERMINATION OF SUBSTANCES EXTRACTABLE WITH DIETHYL ETHER FROM WATER-SOLUBLE SULPHONATED ORGANIC COLOURING MATTERS INTENDED FOR FOODSTUFFS

1. **Scope and field of application**

The method determines substances extractable with diethyl ether in water soluble sulphonated organic colouring matters which have not been mixed with any support.

2. **Definition**

Substances extractable with diethyl ether: the content of material as determined by the method specified.

3. **Principle**

Extract the colouring matter with diethyl ether and weigh the extracted residue after evaporation of the ether.

4. **Reagents**

4.1. Diethyl ether, dry, peroxide-free (dried with the aid of freshly calcined calcium chloride).

5. **Apparatus**

5.1. Soxhlet apparatus with flask.

5.2. Desiccator, containing freshly activated silica gel or equivalent desiccant with a water content indicator.

5.3. Analytical balance.

5.4. Oven, thermostatically controlled at 85 ± 2 °C.

6. **Procedure**

Accurately weigh, to the nearest 10 mg, about 10 g of the sample of the colouring matter on a piece of filter paper. Fold the paper, put it into a paper thimble and close the latter with some fat-free cotton wool. Extract for six hours with diethyl ether (4.1) in a Soxhlet extraction apparatus (5.1). Evaporate the ether at as low a temperature as possible. Place

the Soxhlet flask, which has been previously weighed, with the residue in the oven (5.4) at 85 ± 2 °C for 20 minutes to dry. Transfer the flask to a desiccator (5.2), cover with a loose-fitting lid and allow to cool. Weigh the flask and residue.

Repeat the drying and weighing until two successive weighings differ by less than 0·5 mg. Should an increase in mass occur, the lowest recorded reading will be used in the calculation.

7. **Expression of results**

7.1. *Formula and method of calculation*

The content of substances extractable with ether, as a percentage of the sample, is given by:

$$\frac{m_1 \times 100}{m_0}$$

where:

m_1 = mass in grams of the residue after evaporation,

m_0 = initial mass in grams of the sample taken.

7.2. *Repeatability*

The difference between the results of two determinations when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 20 mg per 100 g of sample.

METHOD 2

DETERMINATION OF FORMIC ACID, FORMATES AND OTHER OXIDIZABLE IMPURITIES IN ACETIC ACID (E 260), POTASSIUM ACETATE (E 261), SODIUM DIACETATE (E 262) AND CALCIUM ACETATE (E 263)

1. **Scope and field of application**

The method determines formic acid, formates and other oxidizable impurities, expressed as formic acid in:

— acetic acid (E 260),

— potassium acetate (E 261),

— sodium diacetate (E 262),

— calcium acetate (E 263).

2. **Definition**

Formic acid, formates and other oxidizable impurities content: the content of formic acid, formates and other oxidizable impurities as determined by the method specified.

3. **Principle**

The solution of the sample is treated with excess of standard potassium permanganate in alkaline conditions to form manganese dioxide. The manganese dioxide and excess potassium permanganate are determined iodometrically in acid conditions and the concentration of oxidizable impurities calculated and expressed as formic acid.

4. **Reagents**

4.1. Potassium iodide.

4.2. Potassium permanganate, 0·02 mol/l.

4.3. Sodium carbonate (anhydrous).

4.4. Sodium thiosulphate, 0·1 mol/l.

4.5. Starch solution (approximately 1 % m/v).

4.6. Dilute sulphuric acid: add 90 ml of sulphuric acid (ρ_{20} = 1·84 g/ml) to water and dilute to 1 l.

5. **Apparatus**

5.1. Water bath, boiling.

5.2. Analytical balance.

6. **Procedure**

If the test sample is the free acid, accurately weigh, to the nearest 10 mg, about 10 g of the sample and dilute with 70 ml of water and add a solution containing 10 g of anhydrous sodium carbonate (4.3) in 30 ml of water. If the sample is a salt, accurately weigh, to the nearest 10 mg, about 10 g of the sample and dissolve in 100 ml of water. Add 1 g anhydrous sodium carbonate (4.3) and shake to dissolve. Add 20 ml of 0·02 mol/l potassium permanganate (4.2) and heat on a boiling water bath for 15 minutes. Cool the mixture. Add 50 ml of dilute sulphuric acid (4.6) and 0·5 g of potassium iodide (4.1). Swirl the mixture until all precipitated manganese dioxide has redissolved. Titrate with 0·1 mol/l sodium thiosulphate (4.4) until the solution becomes pale yellow in colour. Add a few drops of starch solution (4.5) and continue the titration until the solution becomes colourless.

7. **Expression of results**

7.1. *Formula and method of calculation*

The percentage of formic acid, formates and of other oxidizable impurities, expressed as formic acid, is given by:

$$\frac{2{\cdot}3b}{m_0} \times \left(\frac{100a}{b} - V\right)$$

where:

a = molarity of potassium permanganate,

b = molarity of sodium thiosulphate,

m_0 = initial mass in grams of the sample taken,

V = volume in millilitres of 0·1 mol/l sodium thiosulphate used in the titration.

7.2. *Repeatability*

The difference between the results of two determinations when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 5 mg per 100 g of sample.

8. **Notes**

8.1. A volume of 11·3 ml of 0·1 mol/l sodium thiosulphate is equivalent to 0·2 % formic acid in a 10 g sample.

8.2. If there is no formate present, the volume required will be 20 ml, but if there is more than 0·27 % (m/m) of formic acid present, there will be insufficient excess of potassium permanganate and a fixed minimum volume of 8 ml will be obtained. In this case repeat the determination using a smaller sample weight.

METHOD 3

DETERMINATION OF NON-VOLATILE SUBSTANCES IN PROPIONIC ACID (E 280)

1. **Scope and field of application**

The method determines non-volatile substances in propionic acid (E 280).

2. **Definition**

The content of non-volatile material in propionic acid: the content of non-volatile material as determined by the method specified.

3. **Principle**

The sample is evaporated and then dried at 103 ± 2 °C and the residue determined gravimetrically.

4. **Apparatus**

4.1. Evaporation vessel, silica or platinum and of sufficient size to contain 100 g of sample.

4.2. Oven, electrically heated, thermostatically controlled at 103 ± 2 °C.

4.3. Analytical balance.

4.4. Water bath, boiling.

4.5. Desiccator, containing freshly activated silica gel or equivalent desiccant with water content indicator.

5. **Procedure**

Weigh, to the nearest 0·1 g, 100 g of the sample of propionic acid into a previously dried and weighed vessel (4.1). Evaporate over a boiling water bath in a fume cupboard (4.4). When all the propionic acid has evaporated, place in an oven (4.2) at 103 ± 2 °C for one hour. Place in a desiccator and allow to cool and then weigh. Repeat the heating, cooling and weighing operations until the difference between two successive weighings is less than 0·5 mg. Should an increase in mass occur the lowest recorded reading will be used in the calculation.

6. **Expression of results**

6.1. *Formula and method of calculation*

The non-volatile matter content, calculated as a percentage of the sample, is given by:

$$\frac{100 \times m_1}{m_0}$$

where:

m_1 = mass in grams of the residue after evaporation,

m_0 = mass in grams of the sample taken.

6.2. *Repeatability*

The difference between the results of two determinations, carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 5 mg per 100 g of sample.

METHOD 4

DETERMINATION OF THE LOSS OF MASS ON DRYING OF SODIUM NITRITE (E 250)

1. **Scope and field of application**

The method determines the loss of mass on drying of sodium nitrite (E 250).

2. **Definition**

The moisture content of sodium nitrite; the loss of mass on drying as determined by the method specified.

3. **Principle**

The loss of mass on drying is obtained by heating in an oven at 103 ± 2 °C, weighing and calculation of the loss in mass.

4. **Apparatus**

4.1. Oven, electrically heated, thermostatically controlled at 103 ± 2 °C.

4.2. Weighing dish, flat-bottomed, glass, of diameter 60 to 80 mm and depth at least 25 mm, with loose-fitting lid.

4.3. Desiccator, containing freshly activated silica gel or equivalent desiccant with water content indicator.

4.4. Analytical balance.

5. **Procedure**

Remove the lid from the weighing dish (4.2) and heat dish and lid in the oven (4.1) at 103 ± 2 °C for one hour. Replace the lid and place the dish (4.2) with its lid in the desiccator (4.3) and allow to cool to room temperature. Weigh the covered dish (4.2) to the nearest

10 mg. Accurately weigh, to the nearest 10 mg, approximately 10 g of sample into the covered dish. Remove the lid and place both dish and lid in the oven (4.1) for one hour at 103 ± 2 °C. Replace the lid and allow the covered dish to cool to room temperature in the desiccator (4.3). Weigh it to the nearest 10 mg. Repeat the heating, cooling and weighing until the difference between two successive weights is less than 10 mg. Should an increase in mass occur, the lowest recorded reading will be used in the calculation.

6. **Expression of results**

6.1. *Formula and method of calculation*

The loss of mass on drying, calculated as a percentage by mass of the sample, is given by:

$$\frac{100 \times (m_2 - m_3)}{(m_2 - m_1)}$$

where:

m_1 = mass in grams of the dish,

m_2 = mass in grams of the dish and sample before drying,

m_3 = mass in grams of the dish and sample after drying.

6.2. *Repeatability*

The difference between the results of two determinations, carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 100 mg per 100 g of sample.

METHOD 5

LIMIT TEST FOR SALICYLIC ACID IN ETHYL *p*-HYDROXYBENZOATE (E 214), ETHYL-*p*-HYDROXYBENZOATE, SODIUM SALT (E 215), *n*-PROPYL *p*-HYDROXYBENZOATE (E 216), *n*-PROPYL *p*-HYDROXYBENZOATE, SODIUM SALT (E 217), METHYL *p*-HYDROXYBENZOATE (E 218), METHYL *p*-HYDROXYBENZOATE, SODIUM SALT (E 219)

1. **Scope and field of application**

The method detects salicylic acid in ethyl *p*-hydroxybenzoate (E 214), *n*-propyl *p*-hydroxybenzoate (E 216), and methyl *p*-hydroxybenzoate (E 218) and in their sodium salts (E 215, E 217 and E 219).

2. **Definition**

The detection of the limit test concentration of salicylic acid: the limit test result as determined by the method specified.

3. **Principle**

A violet colouration is produced from the reaction of ammonium iron (III) sulphate with a solution of the sample. Its intensity is compared with that produced by a reference solution.

4. **Reagents**

4.1. Ammonium iron (III) sulphate solution, 0·2 % m/v. Prepare by dissolving 0·2 g of ammonium iron (III) sulphate dodecahydrate in 50 ml of water, add 10 ml of nitric acid, 10 % v/v, and dilute to 100 ml with water.

4.2. Ethanol, 95 % v/v.

4.3. Salicylic acid solution, 0·1 g/l.

4.4. Sulphuric acid, 1 mol/l.

5. **Apparatus**

5.1. Nessler cylinders, graduated at 50 ml. Total volume approximately 60 ml.

6. **Procedure**

6.1. *Ethyl, n-propyl and methyl p-hydroxybenzoate samples*

6.1.1. Weigh, to the nearest 1 mg, 0·1 g of the sample and dissolve in 10 ml of 95 % v/v ethanol (4.2). Transfer the solution to a graduated Nessler cylinder (5.1) and dilute to 50 ml with water. Stir and add 1 ml of ammonium iron (III) sulphate solution (4.1) while stirring. Allow to stand for one minute.

6.1.2. Prepare a comparison solution at the same time by repeating 6.1.1, but replacing the 0·1 g of sample by 1 ml of salicylic acid solution (4.3).

6.1.3. Compare the colouring in the sample solution with that appearing in the comparison solution.

6.2. *Sodium salts of ethyl, n-propyl and methyl p-hydroxybenzoate samples*

6.2.1. Repeat 6.1.1 acidifying to pH 5 using 1 mol/l sulphuric acid (4.4) before dilution to 50 ml.

6.2.2. Repeat 6.1.2.

6.2.3. Repeat 6.1.3.

7. **Expression of results**

7.1. *Limit test interpretation*

If the reddish-violet colour appearing in the sample solution tube is more intense than that appearing in the comparison solution tube, the test is positive and the sample contains more than 0·1 % salicylic acid.

7.2. *Sensitivity*

The limit of detection of the test is 30 mg of salicylic acid per 100 g of sample.

7.3. *Observations*

The results of two limit tests carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall be identical.

METHOD 6

DETERMINATION OF FREE ACETIC ACID IN SODIUM DIACETATE (E 262)

1. **Scope and field of application**

The method determines acetic acid in sodium diacetate (E 262).

2. **Definition**

The acetic acid content: the content of acetic acid as determined by the method specified.

3. **Principle**

Direct titration of the acetic acid in the sample using standard sodium hydroxide solution and phenolphthalein indicator.

4. **Reagents**

4.1. Phenolphthalein solution 1% (m/v) in ethanol.

4.2. Sodium hydroxide, 1 mol/l.

5. **Apparatus**

5.1. Analytical balance.

6. **Procedure**

Weigh, to the nearest 1 mg, about 3 g of the test sample and dissolve in about 50 ml of water. Add two or three drops of phenolphthalein indicator solution (4.1) and titrate with 1 mol/l sodium hydroxide (4.2) until a red tint persists for five seconds.

7. **Expression of results**

7.1. *Formula and method of calculation*

The acetic acid content, as a percentage of the sample mass, is given by:

$$\frac{6{\cdot}005 \times V \times c}{m_0}$$

where:

V = volume in millilitres of sodium hydroxide (4.2) required,

c = concentration of the sodium hydroxide solution in mol/l,

m_0 = initial mass in grams of the sample taken.

7.2. *Repeatability*

The difference between the results of two determinations when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 500 mg per 100 g of sample.

8. **Comment**

A volume of 20 ml is obtained when 3 g of a sample containing 40 % acetic acid is titrated with 1 mol/l sodium hydroxide.

METHOD 7

DETERMINATION OF SODIUM ACETATE IN SODIUM DIACETATE (E 262)

1. **Scope and field of application**

The method determines sodium acetate and water, expressed as sodium acetate, in sodium diacetate (E 262).

2. **Definition**

Sodium acetate content: the content of sodium acetate and water expressed as sodium acetate as determined by the method specified.

3. **Principle**

The sample is dissolved in glacial acetate acid, before titration, with standard perchloric acid, using crystal violet as indicator.

4. **Reagents**

4.1. Glacial acetic acid $\rho_{20 \cdot C}$ = 1·049 g/ml) (for non-aqueous titrations).

4.2. Crystal violet, CI No 42555 indicator solution, 0·2 % (m/v) in glacial acetic acid.

4.3. Potassium hydrogen phtalate, $C_8H_5KO_4$.

4.4. Acetic anhydride $(CH_3CO)_2O$.

4.5. Perchloric acid, 0·1 mol/l in glacial acetic acid. This must be prepared and standardized as follows:

Weigh P g of perchloric acid solution into a 1 000 ml volumetric flask fitted with a ground-glass stopper. The quantity P is calculated from the formula:

$$P = \frac{1\,004.6}{m}$$

where m is the concentration (per cent m/m) of perchloric acid determined by alkalimetric titration (70 to 72 % m/m acid is the most suitable). Add about 100 ml of glacial acetic acid and then a quantity, Q g, of acetic anhydride in successive small portion, stirring and cooling the mixture continuously during the additions. The quantity Q may be calculated from the formula:

$$Q = \frac{(567 \times P) - 5\,695}{a}$$

where P is the weighed amount of perchloric acid and a is the concentration (per cent m/m) of the acetic anhydride. Stopper the flask and allow to stand for 24 hours in a dark place, then add sufficient glacial acetic acid to produce 1 000 ml of solution. The solution prepared in this way is practically anhydrous. Standardize the solution against potassium hydrogen phthalate as follows:

Weigh accurately, to the nearest 0·1 mg, about 0·2 g of potassium hydrogen phthalate, previously dried at 110 °C for two hours, and dissolve in 25 ml of glacial acetic acid in a titration flask, warming gently. Cool, add two drops of a 0·2 % (m/m) crystal violet solution (4.2) in glacial acetic acid and titrate with the perchloric acid solution until the colour of the indicator changes to pale green. Carry out a blank titration using the same volume of solvent and deduct the value of the blank from the value found in the actual determination. Each 20·42 mg of potassium hydrogen phthalate is equivalent to 1 ml of 0·1 mol/l perchloric acid.

5. **Apparatus**

5.1. Analytical balance.

6. **Procedure**

Weigh, to the nearest 0·5 mg, about 0·2 g of the sample and dissolve in 50 ml of glacial acetic acid (4.1). Add a few drops of crystal violet indicator solution (4.2) and titrate to a pale green end-point, using standard 0·1 mol/l perchloric acid (4.5).

7. **Expression of results**

7.1. *Formula and method of calculation*

The sodium acetate content, as defined in section 2 (definition), expressed as a percentage by weight of the sample, is given by the following formula:

$$\frac{8{\cdot}023 \times V \times c}{m_0}$$

where:

V = volume in millilitres of the standard perchloric acid (4.5) used,

c = molarity of the perchloric acid solution (4.5),

m_0 = initial mass in grams of the sample taken.

7.2. *Repeatability*

The difference between the results of two determinations when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 1·5 g per 100 g of sample.

8. **Observations**

The reagents used in this method are toxic and explosive and need careful handling.

METHOD 8

LIMIT TEST FOR ALDEHYDES IN SORBIC ACID (E 200), SODIUM, POTASSIUM AND CALCIUM SORBATES (E 201, E 202, E 203) AND PROPIONIC ACID (E 280)

1. **Scope and field of application**

The method detects aldehydes, expressed as formaldehyde, in:

— sorbic aid (E 200),

— sodium, potassium and calcium sorbates (E 201, E 202, E 203),

— propionic acid (E 280).

2. **Definition**

The detection of the limit test concentration of aldehydes: the limit test result as determined by the method specified.

3. **Principle**

The aldehydes in the test solution, and the formaldehyde in a comparison solution, react with Schiff's reagent to produce red coloured complexes, the intensities of which are compared.

4. **Reagents**

4.1. Formaldehyde standard solution (0·01 mg/ml): prepared by dilution of concentrated formaldehyde solution (400 mg/ml).

4.2. Schiff's reagent.

5. **Procedure**

5.1. Weigh, to the nearest 1 mg, about 1 g of the sample, add to 100 ml of water and shake. Filter the solution if necessary and treat 1 ml of filtrate or sample solution with 1 ml of Schiff's reagent (4.2). At the same time, treat 1 ml of formaldehyde comparison solution (4.1) with 1 ml of Schiff's reagent (4.2).

5.2. Compare the colour in the sample solution with that appearing in the comparison solution.

6. **Expression of results**

6.1. *Limit test interpretation*

If the red colour appearing in the sample solution tube is more intense than that appearing in the comparison solution tube, the test is positive and the sample contains more than 0·1 % aldehydes, expressed as formaldehyde.

6.2. *Sensitivity*

The limit of detection of this test is 30 mg of formaldehyde per 100 g of sample.

6.3. *Observations*

The result of two limit tests when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall be identical.

METHOD 9

DETERMINATION OF THE PEROXIDE NUMBER IN LECITHINS (E 322)

1. **Scope and field of application**

The method determines the peroxide number in lecithins (E 322).

2. **Definition**

Peroxide number of lecithins: the result obtained as determined by the method specified.

3. **Principle**

Oxidation of potassium iodide by the peroxides of lecithin and titration of the iodine liberated using standard sodium thiosulphate solution.

4. **Reagents**

4.1. Acetic acid glacial.

4.2. Chloroform.

4.3. Potassium iodide.

4.4. Sodium thiosulphate, 0·1 mol/l or 0·01 mol/l.

4.5. Starch solution (approximately 1 % m/v).

5. **Apparatus**

5.1. Analytical balance.

5.2. Apparatus, as shown in the figure, consisting of:

5.2.1. round-bottomed flask, 100 ml;

5.2.2. reflux condenser;

5.2.3. glass tube, 250 mm long and 22 mm internal diameter, fitted with ground glass joints;

5.2.4. micro beaker (external dimension of 20 mm diameter and 35 to 50 mm height).

6. **Procedures**

6.1. Place 10 ml of glacial acetic acid (4.1) and 10 ml of chloroform (4.2) in the 100 ml flask (5.2.1). Fit the glass tube (5.2.3) and reflux condenser (5.2.2) and gently boil the mixture for two minutes to expel all dissolved air. Dissolve 1 g of potassium iodide (4.3) in 1·3 ml of water and add this solution to the mixture in the flask (5.2.1) taking care that the boiling is not interrupted.

If a yellow colour appears at this stage the determination must be rejected and repeated using fresh reagents.

6.2. Accurately weigh, to the nearest 1 mg, about 1 g of the sample and, after a further two minutes of boiling, add the weighed sample to the contents of the flask (5.2.1) again taking care that the boiling remains continuous. For this purpose the sample should be contained in a micro-beaker (5.2.4) which may be lowered through the glass tube (5.2.3) with a glass rod, the bottom of which has been suitably shaped as shown in the diagram. The condenser (5.2.2) may be removed for a short time. Continue boiling for three to four minutes. Stop heating and immediately disconnect the condenser (5.2.2). Quickly add 50 ml of water through the glass tube (5.2.3). Remove the glass tube (5.2.3) and cool the flask (5.2.1) to room temperature under the water tap. Titrate with sodium thiosulphate (0·1 mol/l or 0·01 mol/l) (4.4) until the aqueous layer becomes pale yellow. Add 1 ml of starch solution (4.5) and continue the titration until the blue colour is discharged. Shake the flask (5.2.1) well during the titration to ensure the complete extraction of iodine from the non-aqueous layer.

6.3. Obtain a blank titration value by repeating the complete procedure 6.1 and 6.2, but without adding the sample.

7. **Expression of results**

7.1. *Formula and method of calculation*

The peroxide number in the sample, in milliequivalents per kilogram, is given by:

$$\frac{1\,000 \times a \times (V_1 - V_2)}{m_0}$$

where:

V_1 = volume in millilitres of thiosulphate solution required for the titration of the sample (6.2),

V_2 = volume in millilitres of thiosulphate solution required for the titration of the blank (6.3),

a = concentration of sodium thiosulphate solution in mol/l,

m_0 = initial mass in grams of the sample taken.

7.2. *Repeatability*

The difference between the results of two determinations carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 0·5 (expressed as a peroxide number in milliequivalents per kilogram of sample).

8. **Notes**

8.1. The choice of the concentration of the sodium thiosulphate used depends on the anticipated titration value. If less than 0·5 ml of 0·1 mol/l sodium thiosulphate is required, repeat the determination using 0·01 mol/l sodium thiosulphate.

8.2. The determination should not be carried out in strong light.

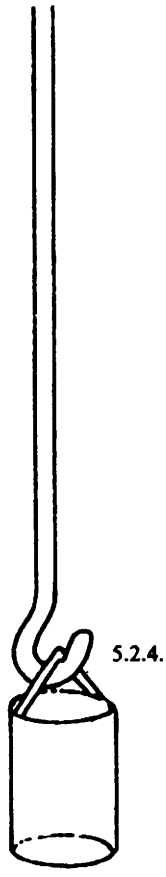
5.2.2. Reflux condenser

5.2.3. Glass tube:

— length: 250 mm

— internal diameter: 22 mm

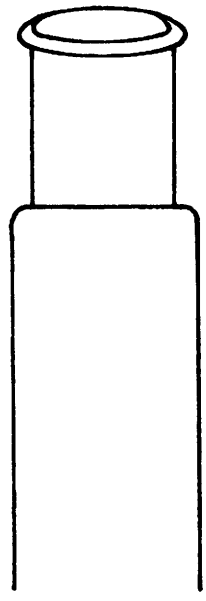
5.2.1. Round-bottom flask (100 ml)



5.2.4. Micro beaker:

— external diameter: 20 mm

— height: 35 to 50 mm



Apparatus for the determination of peroxide number in lecithins

METHOD 10

DETERMINATION OF TOLUENE-INSOLUBLE MATTER IN LECITHINS (E 322)

1. **Scope and field of application**

The method determines the toluene-insoluble matter in lecithins (E 322).

2. **Definition**

The toluene-insoluble matter content: the content of toluene-insoluble matter as determined by the method specified.

3. **Principle**

The sample is dissolved in toluene, filtered, and the residue dried and weighed.

4. **Reagents**

4.1. Toluene.

5. **Apparatus**

5.1. Sintered glass crucible, 30 ml capacity, G 3 or equivalent porosity.

5.2. Drying oven, electrically heated and thermostatically controlled at 103 ± 2 °C.

5.3. Water bath, operating at a temperature not exceeding 60 °C.

5.4. Desiccator, containing freshly activated silica gel or equivalent desiccant with a water content indicator.

5.5. Conical flask of 500 ml.

5.6. Vacuum pump.

5.7. Analytical balance.

6. **Procedure**

6.1. Dry a 30 ml sintered glass crucible (5.1) in an oven at 103 ± 2 °C (5.2). Transfer the crucible to desiccator (5.4), allow to cool and then weigh.

6.2. Thoroughly mix the sample of lecithins, if necessary after warming in a water bath (5.3). Weigh, to the nearest 1 mg, about 10 g of the sample into a conical flask (5.5). Add 100 ml of toluene (4.1) and swirl the mixture until all the lecithin has apparently dissolved. Filter the solution through the sintered glass crucible (5.1). Wash the conical flask (5.5) with 25 ml of toluene (4.1) and pass the washings through the crucible (5.1). Repeat this process with another 25 ml of toluene (4.1). Remove excess toluene from the crucible (5.1) by suction.

6.3. Dry the crucible (5.1) in the drying oven (5.2) at 103 ± 2°C for two hours. Place in desiccator (5.4) and allow to cool. Weigh the crucible and residue when cool.

6.4. Repeat 6.3 until the difference in weight between two successive weighings is less than 0·5 mg.

Should an increase in mass occur, the lowest recorded reading will be used in the calculation.

7. **Expression of results**

7.1. *Formula and method of calculation*

The content of toluene insoluble substances is given by:

$$\frac{100\,(m_2 - m_1)}{m_0}$$

where:

m_1 = mass in grams of the empty crucible (6.1),

m_2 = mass in grams of the crucible and residues (6.4),

m_0 = initial mass in grams of the sample taken.

7.2. *Repeatability*

The difference between the results of two determinations carried out in simultaneous or rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 30 mg per 100 g of sample.

METHOD 11

LIMIT TEST FOR REDUCING SUBSTANCES IN SODIUM, POTASSIUM AND CALCIUM LACTATES (E 325, E 326, E 327)

1. **Scope and field of application**

The test detects qualitatively reducing substances in:

— sodium lactate (E 325),

— potassium lactate (E 326),

— calcium lactate (E 327).

2. **Definition**

The detection of the limit test concentration of reducing substances: the limit test result as determined by the method specified.

3. **Principle**

Fehling's solution is reduced by substances capable of exhibiting reducing action. Such substances will normally be reducing sugars.

4. **Reagents**

4.1. Fehling's solution A: 6·93 g of copper sulphate pentahydrate is dissolved in water and made up 100 ml with water.

4.2. Fehling's solution B: 34·6 g of potassium sodium tartrate and 10 g of sodium hydroxide are dissolved in water and made up to 100 ml with water.

5. **Procedures**

Weigh, to the nearest 1 mg, about 1 g of the sample and dissolve in 10 ml of warm water. Add 2 ml of Fehling's solution A (4.1) and 2 ml of Fehling's solution B (4.2) and then boil the mixture for one minute and observe whether a colour change occurs. The precipitation of calcium sulphate, which sometimes occurs, does not interfere.

6. **Expression of results**

6.1. *Limit test interpretation*

If there is a colour change after boiling (5), the test is positive and the presence of reducing substances is indicated.

6.2. *Sensitivity*

The limit of detection for reducing substances reacting is 100 mg glucose per 100 g of sample.

6.3. *Observations*

6.3.1. The results of two limit tests carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall be identical.

6.3.2. All of the Fehling solutions react if 2 % glucose is present in the sample.

METHOD 12

DETERMINATION OF VOLATILE ACIDS IN ORTHOPHOSPHORIC ACIDS (E 338)

1. **Scope and field of application**

The method determines volatile acids, expressed as acetic acid, in orthophosphoric acid (E 338).

2. **Definition**

Volatile acid content: the content of volatile acids, expressed as acetic acid, as determined by the method specified.

3. **Principle**

Water is added to the sample and the solution is distilled. The distillate is titrated against standard sodium hydroxide solution and the acidity calculated and expressed as acetic acid.

4. **Reagents**

4.1. Pheolphthalein solution, 1 % (m/v) in ethanol.

4.2. Sodium hydroxide, 0·01 mol/l.

5. **Apparatus**

5.1. Distillation apparatus including a spray trap.

6. **Procedure**

Weigh, to the nearest 50 mg, about 60 g of the sample and place the weighed sample and 75 ml of freshly boiled cooled water in the distillation flask fitted with the spray trap (5.1). Mix and then distil about 50 ml.

Titrate the distillate with standard 0·01 mol/l sodium hydroxide (4.2) using phenolphthalein (4.1) as indicator. Continue the titration until the first red tint in the solution persists for 10 seconds.

7. **Expression of results**

7.1. *Formula and method of calculation*

The content of volatile acids, expressed as milligrams per kilogram of acetic acid, is given by:

$$\frac{600 \times V}{m_0}$$

where:

V = volume in millilitres of 0·01 mol/l sodium hydroxide solution used for neutralization,

m_0 = mass in grams of the orthophosphoric acid sample.

7.2. *Repeatability*

The difference between the results of two determinations carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 1 mg per 100 g of sample.

METHOD 13

LIMIT TEST FOR NITRATE IN ORTHOPHOSPHORIC ACID (E 338)

1. **Scope and field of application**

This method detects nitrates in orthophosphoric acid (E 338).

2. **Definition**

The detection of the limit test concentration of nitrate, expressed as sodium nitrate; the limit test result as determined by the method specified.

3. **Principle**

The sample is added to indigo carmine solution in a concentrated sulphuric acid medium. The blue colouration present is discharged by oxidizing agents including nitrates.

4. **Reagents**

4.1. Indigo carmine solution, 0·18 % (m/v): dissolve 0·18 g of sodium indigotin disulphonate in water and make up to 100 ml with water.

4.2. Sodium chloride solution, 0·05 % (m/v).

4.3. Sulphuric acid concentrated (ρ_{20} = 1·84 g/ml).

5. **Procedure**

Measure 2 ml of the sample and dilute to 10 ml with the sodium chloride solution (4.2). Add 0·1 ml of carmine indigo solution (4.1) and then slowly add 10 ml of concentrated sulphuric acid (4.3), cooling during the addition. Note whether the blue colouration of the solution persists for five minutes.

6. **Expression of results**

6.1. *Limit test interpretation*

If the blue colouration is discharged within five minutes the test is positive and the content of oxidizing agents, expressed as sodium nitrate, is greater than 5 mg/kg.

6.2. *Observations*

6.2.1. Carry out a blank test.

6.2.2. The results of two limit tests when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall be identical.

6.2.3. Indigo carmine solution should not be used if it has been prepared for more than 60 days.

6.2.4. If a positive result is obtained the sample may contain nitrates and other oxidizing agents and the test must be repeated using ISO Method 3709 (1976) 'Phosphoric acid for industrial use (including foodstuffs) — determination of oxides of nitrogen content — 3,4-xylenol spectrophometric method'.

METHOD 14

DETERMINATION OF WATER-INSOLUBLE SUBSTANCES PRESENT IN MONO-, DI- AND TRI-SODIUM ORTHOPHOSPHATES AND MONO-, DI- AND TRI-POTASSIUM ORTHOPHOSPHATES (E 339(i), E 339(ii), E 339(iii), E 340(i), E 340(ii) AND E 340(iii))

1. **Scope and field of application**

The method determines water-insoluble matter in:

— mono-sodium orthophosphate (E 339(i)),

— di-sodium orthophosphate (E 339(ii)),

— tri-sodium orthophosphate (E 339(iii)),

— mono-potassium orthophosphate (E 340(i)),

— di-potassium orthophosphate (E 340(ii)),

— tri-potassium orthophosphate (E 340(iii)).

2. **Definition**

Water insoluble matter: the content of water-insoluble matter as determined by the method specified.

3. **Principle**

The sample is dissolved in water and filtered through a suitable porcelain crucible. After washing and drying the residue is weighed and calculated as water-insoluble matter.

4. **Apparatus**

4.1. Sintered porcelain crucible, porosity G 3 or equivalent.

4.2. Desiccator, containing freshly activated silica gel with a water content indicator, or equivalent desiccant.

4.3. Oven, thermostatically controlled at 103 ± 2 °C.

4.4. Polypropylene beaker, 400 ml.

4.5. Water bath, boiling.

5. **Procedure**

Weigh, to the nearest 10 mg, about 10 g of the sample of phosphate and dissolve in 100 ml of hot water by bringing to the boil in a polypropylene beaker (4.4) and maintaining on a hot water bath (4.5) for 15 minutes. Filter the solution through a previously cleaned, dried and weighed crucible (4.1). Wash the insoluble residue with hot water. Place the crucible with residue in the oven (4.3) and dry at 103 ± 2 °C for two hours.

Place the crucible in the desiccator and allow to cool and weigh the crucible.

Repeat the drying, cooling and weighing until the difference in weight of two successive weighings is less than 0·5 mg. Should an increase in mass occur the lowest recorded reading will be used in the calculation.

6. **Expression of results**

6.1. *Formula and method of calculation*

The content of water-insoluble matter in the sample is given by:

$$\frac{m_1}{m_0} \times 100$$

where:

m_1 = mass in grams of the residue after drying,

m_0 = mass in grams of the sample taken.

6.2. *Repeatability*

The difference between the results of two determinations carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 10 mg per 100 g of sample.

METHOD 15

DETERMINATION OF THE pH OF FOOD ADDITIVES

1. **Scope and field of application**

The method outlines general instructions on how to determine the pH of food additives.

2. **Definition**

The pH of a food additive: the pH value as determined by the method specified.

3. **Principle**

The pH value of an aqueous solution of the dissolved or slurried sample is conventionally determined using a glass electrode, reference electrode and pH meter.

4. **Reagents**

4.1. Calibrate the instrument using the following buffer solutions:

4.1.1. Buffer solution pH 6·88 at 20 °C, consisting of equal volume 0·05 mol/l potassium dihydrogen phosphate (KH_2PO_4) and 0·05 mol/l disodium hydrogen ortho phosphate dyhidrate ($Na_2HPO_4 \cdot 2H_2O$).

4.1.2. Buffer solution pH 4 at 20 °C, consisting of 0·05 mol/l potassium hydrogen phthalate ($C_8H_5KO_4$).

4.1.3. Buffer solution pH 9·22 at 20 °C, consisting of 0·05 mol/l sodium borate ($Na_2B_4O_7 \cdot 10H_2O$).

4.2. Saturated or 3 mol/l potassium chloride solution, or other suitable solution prescribed by the electrode manufacturer, to fill the reference electrode.

4.3. Distilled water, carbon dioxide-free, having a pH between 5 and 6.

5. **Apparatus**

5.1. pH meter, with an accuracy within 0·01 pH units.

5.2. Electrodes, either a combined glass electrode or single glass and reference electrodes together with suitable clamps to hold the electrodes.

5.3. Magnetic stirrer, with heater element.

5.4. Thermometer, calibrated over the range 0 to 100 °C.

6. **Procedure**

6.1. *Standardization of the pH meter*

The glass electrodes must be set using the instructions given by the manufacturer. The pH reading from the electrodes must be regularly checked by comparison with buffer solutions of known pH.

Electrodes should be washed with water and then gently wiped with a soft tissue or should be rinsed with water and then twice with the next sample/standard solution before being placed in the next sample/standard solution to be used.

If the sample to be considered has an acid pH, the buffer solutions used to check the pH reading should be those of pH 4 (4.1.2) and pH 6·88 (4.1.1). If the sample to be analyzed has an alkaline pH, the buffer solutions to be used to check the pH reading should be those of pH 9·22 (4.1.3) and pH 6·88 (4.1.1).

6.2. *Measurement of the sample solution*

The concentration of sample to be used or the sample preparation procedure to be adopted is as prescribed in the appropriate Community food additive Directive.

Prepare the sample solution as directed using distilled water (4.3) and then adjust to 20 °C while stirring. Stop the stirring, place the glass electrodes in the solution and after two minutes note the pH on the pH meter (5.1).

7. Expression of results

7.1. *Repeatability*

The difference between the results of two determinations when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 0·05 pH unit.

8. Note

This method is only applicable to those pH requirements in Community food additives Directives where the food additive is dissolved or slurried in water.

362L2645

62/2645/EEC: COUNCIL DIRECTIVE ON THE APPROXIMATION OF THE RULES OF THE MEMBER STATES CONCERNING THE COLOURING MATTERS AUTHORIZED FOR USE IN FOODSTUFFS INTENDED FOR HUMAN CONSUMPTION

OFFICIAL JOURNAL NO 115, 11/11/1962, P. 2645; ENGLISH SPECIAL EDITION, 1959-1962, p. 279
DATE OF NOTIFICATION: 26/10/1962
DATE OF TRANSPOSITION: 26/10/1963; SEE ART. 12

AMENDED BY

365L0469
65/469/EEC: COUNCIL DIRECTIVE OF 25 OCTOBER 1965 **[1]**
OFFICIAL JOURNAL NO 178, 26/10/1965, P. 2793; ENGLISH SPECIAL EDITION, 1965-1966, P. 82
DATE OF NOTIFICATION: 26/10/1965
DATE OF TRANSPOSITION: 31/12/1966; SEE ART. 5

367L0653
67/653/EEC: COUNCIL DIRECTIVE OF 24 OCTOBER 1967 **[2]**
OFFICIAL JOURNAL NO 263, 30/10/1967, P. 4; ENGLISH SPECIAL EDITION,1967, P. 285
DATE OF NOTIFICATION: 25/10/1967
DATE OF TRANSPOSITION: 01/01/1968; SEE ART. 2

368L0419
68/419/EEC: COUNCIL DIRECTIVE OF 20 DECEMBER 1968 **[3]**
OFFICIAL JOURNAL NO L 309, 24/12/1968, P. 24; ENGLISH SPECIAL EDITION,1968 II, P. 597
DATE OF NOTIFICATION: 21/12/1968

370L0358
70/358/EEC: COUNCIL DIRECTIVE OF 13 JULY 1970 **[4]**
OFFICIAL JOURNAL NO L 157, 18/07/1970, P. 36; ENGLISH SPECIAL EDITION,1970 II, P. 434
DATE OF NOTIFICATION: 16/07/1970

172B
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE KINGDOM OF DENMARK, IRELAND AND THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND AND THE ADJUSTMENTS TO THE TREATIES **[5]**
OFFICIAL JOURNAL NO L 73, 27/03/1972, P. 120; ENGLISH SPECIAL EDITION, 27/03/1972, P. 120

376L0399
76/399/EEC: COUNCIL DIRECTIVE OF 6 APRIL 1976 **[6]**
OFFICIAL JOURNAL NO L 108, 26/04/1976, P. 19
DATE OF NOTIFICATION: 09/04/1976
DATE OF TRANSPOSITION: 31/12/1976
DATE OF TRANSPOSITION: 31/12/1977

378L0144
78/144/EEC: COUNCIL DIRECTIVE OF 30 JANUARY 1978 **[7]**
OFFICIAL JOURNAL NO L 44, 15/02/1978, P. 20
DATE OF NOTIFICATION: 01/02/1978
DATE OF TRANSPOSITION: 02/02/1979; SEE ART. 5

179H
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE HELLENIC REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES **[8]**
OFFICIAL JOURNAL NO L 291, 19/11/1979, P. 110

381L0020
81/20/EEC: COUNCIL DIRECTIVE OF 20 JANUARY 1981 **[9]**
OFFICIAL JOURNAL NO L 43, 14/02/1981, P. 11
DATE OF NOTIFICATION: 23/02/1981
DATE OF TRANSPOSITION: 01/07/1981; SEE ART. 2

385L0007
85/7/EEC: COUNCIL DIRECTIVE OF 19 DECEMBER 1984 **[10]**
OFFICIAL JOURNAL NO L 2, 03/01/1985, P. 22
DATE OF NOTIFICATION: 27/12/1984

185I
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE KINGDOM OF SPAIN AND THE PORTUGUESE REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES **[11]**
OFFICIAL JOURNAL NO L 302, 15/11/1985, P. 214

ARTICLE 1

1. SAVE AS OTHERWISE PROVIDED IN ARTICLE 2, 3, 4 OR 13, MEMBER STATES SHALL NOT AUTHORIZE THE USE FOR COLOURING FOODSTUFFS INTENDED FOR HUMAN CONSUMPTION (HEREINAFTER CALLED "FOODSTUFFS") OF ANY COLOURING MATTERS OTHER THAN THOSE LISTED IN ANNEX I.

2. THE USE OF SUCH COLOURING MATTERS FOR COLOURING FOODSTUFFS SHALL NOT BE SUBJECT TO ANY GENERAL PROHIBITION.

3. WHERE THE USE IN FOODSTUFFS OF ONE OF THE COLOURING MATTERS LISTED IN ANNEX I MIGHT ENDANGER HUMAN HEALTH, A MEMBER STATE MAY, FOR A MAXIMUM PERIOD OF ONE YEAR, SUSPEND THE AUTHORIZATION TO USE THAT COLOURING MATTER IN FOODSTUFFS. IT SHALL INFORM THE OTHER MEMBER STATES AND THE COMMISSION OF ANY SUCH SUSPENSION WITHIN ONE MONTH. THE COUNCIL SHALL, ACTING UNANIMOUSLY ON A PROPOSAL FROM THE COMMISSION AND BY DIRECTIVE, FORTHWITH DECIDE WHETHER THE LIST IN ANNEX I SHOULD BE AMENDED AND, IF SO, TO WHAT EXTENT. THE COUNCIL MAY, IF NECESSARY, EXTEND THE PERIOD SET IN THE FIRST SENTENCE OF THIS PARAGRAPH.

4. THE PROVISIONS OF THIS DIRECTIVE SHALL ALSO APPLY TO IMPORTED PRODUCTS, WHETHER OR NOT PROCESSED, INTENDED FOR CONSUMPTION WITHIN THE COMMUNITY.

" ARTICLE 2

1. BY WAY OF DEROGATION FROM ARTICLE 1, MEMBER STATES MAY AUTHORIZE THE USE IN FOODSTUFFS OF THE SUBSTANCES LISTED IN ANNEX II.

2. WITHIN THREE YEARS FOLLOWING NOTIFICATION OF THIS DIRECTIVE, THE COMMISSION SHALL RE-EXAMINE THE DEROGATIONS IN PARAGRAPH 1 AND SHALL PROPOSE ANY NECESSARY AMENDMENTS TO THE COUNCIL. " **[7]**

ARTICLE 3

THIS DIRECTIVE SHALL NOT AFFECT NATIONAL RULES CONCERNING NATURAL SUBSTANCES WHICH ARE USED IN THE MANUFACTURE OF CERTAIN FOODSTUFFS BECAUSE OF THEIR AROMATIC, SAPID OR NUTRITIVE PROPERTIES BUT WHICH ALSO HAVE A SUBSIDIARY COLOURING PROPERTY, FOR EXAMPLE PAPRIKA, TURMERIC, SAFFRON AND SANDAL-WOOD IN PARTICULAR.

ARTICLE 4

THIS DIRECTIVE SHALL NOT AFFECT NATIONAL RULES CONCERNING COLOURING MATTERS AUTHORIZED:

(a) FOR COLOURING THE SHELLS OF HARD BOILED EGGS, TOBACCO AND MANUFACTURED TOBACCO;

(b) FOR STAMPING MEAT, CITRUS FRUIT, CHEESE-RINDS, THE SHELLS OF EGGS AND OTHER EXTERNAL " parts of foodstuffs not usually consumed " (R1).

ARTICLE 5

THIS DIRECTIVE SHALL NOT AFFECT NATIONAL RULES SPECIFYING WHICH FOODSTUFFS MAY BE COLOURED BY MEANS OF THE COLOURING MATTERS LISTED IN ANNEXES I AND II OR ON WHAT CONDITIONS THEY MAY BE SO TREATED.

ARTICLE 6

THE MEMBER STATES SHALL, FOR DILUTING OR DISSOLVING THE COLOURING MATTERS LISTED IN ANNEX I, AUTHORIZE THE USE OF THE FOLLOWING PRODUCTS ONLY:

SODIUM CARBONATE AND SODIUM HYDROGEN CARBONATE
SODIUM CHLORIDE
SODIUM SULPHATE
GLUCOSE
LACTOSE
SUCROSE
DEXTRINS
STARCHES
ETHANOL
GLYCEROL
SORBITOL
EDIBLE OILS AND FATS
BEESWAX
WATER
" CITRIC ACID
TARTARIC ACID
LACTIC ACID
" GELATIN " (R2)
PECTINS
AMMONIUM, SODIUM AND POTASSIUM ALGINATES

" ESTERS OF L-ASCORBIC ACID WITH STRAIGHT-CHAIN C14, C16 AND C18 FATTY ACIDS " (R2) (AUTHORIZED EXCLUSIVELY FOR THE COLOURING MATTERS LISTED UNDER NOS E 160 AND E 161 IN ANNEX I) " **[1]**

ARTICLE 7

BY WAY OF DEROGATION FROM ARTICLES 5 AND 6, MEMBER STATES MAY AUTHORIZE THE USE OF PIGMENT RUBINE AND OF BURNT UMBER, WHETHER OR NOT MIXED WITH PARAFFIN WAX OR WITH OTHER HARMLESS SUBSTANCES, ONLY FOR COLOURING CHEESE-RINDS.

ARTICLE 8

1. THE MEMBER STATES SHALL TAKE ALL MEASURES NECESSARY:

- TO ENSURE THAT THE COLOURING MATTERS LISTED IN ANNEX I, WHERE THESE ARE USED TO COLOUR FOODSTUFFS, SATISFY THE CRITERIA, BOTH GENERAL AND SPECIFIC, LAID DOWN IN ANNEX III;
- TO ENSURE THAT THE PRODUCTS LISTED IN ARTICLE 6, WHERE THESE ARE USED TO DILUTE OR DISSOLVE THE COLOURING MATTERS LISTED IN ANNEX I, SATISFY THE GENERAL CRITERIA OF PURITY LAID DOWN IN ANNEX III, SECTION A (1) AND (2) (b).

" 2. BY WAY OF DEROGATION FROM THE PROVISIONS OF PARAGRAPH 1, MEMBER STATES MAY UNTIL 31 DECEMBER 1966 AT THE LATEST AUTHORIZE THE USE IN FOODSTUFFS OF COLOURING MATTERS LISTED IN ANNEX I WHICH DO NOT SATISFY THE GENERAL CRITERIA OF PURITY LAID DOWN IN ANNEX III, SECTION A (1) (a), WITH REGARD TO LEAD CONTENT. " **[1]**

ARTICLE 9

1. THE MEMBER STATES SHALL TAKE ALL MEASURES NECESSARY TO ENSURE THAT THE COLOURING MATTERS LISTED IN ANNEX I ARE PLACED ON THE MARKET ONLY IF THEIR PACKAGINGS OR CONTAINERS BEAR:

(a) THE NAME AND ADDRESS OF THE MANUFACTURER OR OF THE SELLER ESTABLISHED WITHIN THE EUROPEAN ECONOMIC COMMUNITY;

(b) THE NUMBER OF COLOURING MATTER OR MATTERS ACCORDING TO THE EUROPEAN ECONOMIC COMMUNITY NUMBERING SYSTEM GIVEN IN ANNEX I;

(c) THE WORDS "COLOURING MATTER FOR FOODSTUFFS".

2. " When the particulars required under paragraph 1 appear on the packages or containers and if the words required under paragraph 1 (c) are expressed in at least one official language of the Community, Member States shall not prohibit imports of the colours listed in Annex I on the ground that they consider the labelling inadequate.
However, any importing Member State may require the latter words to be expressed in its official language or languages. " **[5]**

ARTICLE 10

THIS DIRECTIVE SHALL APPLY TO CHEWING GUM IN SO FAR AS THE LATTER CONTAINS ANY COLOURING MATTER.

ARTICLE 11

1. THE COUNCIL, ACTING UNANIMOUSLY ON A PROPOSAL FROM THE COMMISSION, MAY AMEND BY DIRECTIVE THE CRITERIA OF PURITY LAID DOWN IN ANNEX III IF IT BECOMES EVIDENT, IN PARTICULAR IN THE LIGHT OF SCIENTIFIC RESEARCH, THAT THIS IS NECESSARY FOR THE PROTECTION OF PUBLIC HEALTH.

" 2. THE PROCEDURE LAID DOWN IN ARTICLE 11a SHALL BE USED TO ESTABLISH:

- THE METHODS OF ANALYSIS NEEDED TO VERIFY THAT THE GENERAL AND SPECIFIC CRITERIA OF PURITY LAID DOWN IN ANNEX III TO THIS DIRECTIVE ARE SATISFIED;
- THE PROCEDURE FOR TAKING SAMPLES AND THE METHODS FOR THE QUALITATIVE AND QUANTITATIVE ANALYSIS OF COLOURING MATTERS IN AND ON FOODSTUFFS. " **[4]**

" ARTICLE 11a

1. WHERE THE PROCEDURE LAID DOWN IN THIS ARTICLE IS TO BE FOLLOWED, MATTERS SHALL BE REFERRED BY THE CHAIRMAN, EITHER ON HIS OWN INITIATIVE OR AT THE REQUEST OF THE REPRESENTATIVE OF A MEMBER STATE TO THE STANDING COMMITTEE FOR FOODSTUFFS (HEREINAFTER CALLED THE "COMMITTEE") SET UP BY THE COUNCIL DECISION OF 13 NOVEMBER 1969 (1).

2. THE REPRESENTATIVE OF THE COMMISSION SHALL SUBMIT TO THE COMMITTEE A DRAFT OF THE MEASURES TO BE ADOPTED. THE COMMITTEE SHALL DELIVER ITS OPINION ON THE DRAFT WITHIN A TIME LIMIT SET BY THE CHAIRMAN ACCORDING TO THE URGENCY OF THE MATTER. OPINIONS SHALL BE DELIVERED BY A MAJORITY OF " fifty-four " **[11]** VOTES, THE VOTES OF THE MEMBER STATES BEING WEIGHTED AS PROVIDED IN ARTICLE 148 (2) OF THE TREATY. THE CHAIRMAN SHALL NOT VOTE.

3. (a) THE COMMISSION SHALL ADOPT THE MEASURES ENVISAGED WHERE THEY ARE IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE.

(b) WHERE THE MEASURES ENVISAGED ARE NOT IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE, OR IF NO OPINION IS DELIVERED, THE COMMISSION SHALL WITHOUT DELAY PROPOSE TO THE COUNCIL THE MEASURES TO BE ADOPTED. THE COUNCIL SHALL ACT BY A QUALIFIED MAJORITY.

(c) IF, WITHIN THREE MONTHS OF THE PROPOSAL BEING SUBMITTED TO IT, THE COUNCIL HAS NOT ACTED, THE PROPOSED MEASURES SHALL BE ADOPTED BY THE COMMISSION. " **[4]**

" ARTICLE 11b

THE PROVISIONS OF ARTICLE 11a SHALL APPLY " FOR A PERIOD OF TWO YEARS FROM THE DATE ON WHICH THE MATTER WAS FIRST REFERRED TO THE COMMITTEE AFTER 1 JANUARY 1985 " **[10]** EITHER UNDER ARTICLE 11a (1) OR UNDER ANY OTHER CORRESPONDING PROVISION. " **[4]**

ARTICLE 12

1. MEMBER STATES SHALL, WITHIN A PERIOD OF ONE " year following " (R1) NOTIFICATION OF THIS DIRECTIVE, AMEND THEIR RULES IN ACCORDANCE WITH THE ABOVE PROVISIONS. THE RULES THUS AMENDED SHALL APPLY TO PRODUCTS PLACED ON THE MARKET IN MEMBER STATES NOT LATER THAN TWO YEARS AFTER THAT NOTIFICATION.

" 2. WHERE THE LAST SENTENCE OF ARTICLE 2 (2) IS APPLICABLE, THE DATE SET IN ARTICLE 2 (1) SHALL BE SUBSTITUTED FOR THE DATE OF NOTIFICATION REFERRED TO IN THE PRECEDING PARAGRAPH. " **[1]**

" HOWEVER, IN THE CASE OF SULPHONATED ORCEIN, APPLICATION OF THE AMENDED RULES MAY BE DEFERRED UNTIL 1 JANUARY 1972. " **[3]**

ARTICLE 13

THIS DIRECTIVE SHALL NOT AFFECT THE PROVISIONS OF NATIONAL RULES CONCERNING PRODUCTS INTENDED FOR EXPORTATION FROM THE COMMUNITY.

ARTICLE 14

THIS DIRECTIVE SHALL ALSO APPLY IN THE FRENCH OVERSEAS DEPARTMENTS.

ARTICLE 15

THIS DIRECTIVE IS ADDRESSED TO THE MEMBER STATES.

[The tables set out in Annex I and Annex II are not displayed here: see OJ No 115 of 11/11/1962, p. 2645 and further amended by Directives **[1] [2] [6] [7] [9]** and see (R1), (R2) and (R3)]

ANNEX III

CRITERIA OF PURITY

A. GENERAL CRITERIA OF PURITY

" Unless otherwise provided in the specific criteria in Section B the colouring matters referred to in Annex I are required to satisfy the following criteria of purity: " **[1]**

1. Inorganic impurities

(a) They " shall not contain more " (R1) than 5 mg/kg of arsenic and not more than 20 mg/kg of lead;

(b) They " shall not contain more " (R1) than 100 mg/kg of the following substances, taken separately: antimony, copper, chromium, zinc, barium sulphate; " or more than 200 mg/kg " (R1) of these products taken together;

(c) " They shall not contain " (R1) cadmium, mercury, selenium, tellurium, thallium, uranium or chromates, or soluble " barium compounds " (R1) in detectable quantities.

2. Organic impurities

(a) They should not contain 2-naphthylamine, benzidine, amino-4-diphenyl (or xenylamine) or their derivatives;

(b) They should not contain polycyclic aromatic hydrocarbons;

(c) Synthetic organic colouring matters " shall not contain more " (R1) than 0.01% of free aromatic amines;

(d) Synthetic organic colouring matters " shall not contain more " (R1) than 0.5% of intermediate synthetic products other than free aromatic amines;

(e) Synthetic organic colouring matters " shall not contain more than 4% of subsidiary colouring " (R1) matters (isomers, homologues, etc.);

(f) Sulphonated organic colouring matters should contain not more than 0.2% of substances extractable by diethyl ether.

B. SPECIFIC CRITERIA OF PURITY

E101 - Lactoflavin (Riboflavin)

Lumiflavin: Prepare ethanol-free chloroform as follows: shake 20 ml of chloroform with 20 ml of water gently but carefully for three minutes and allow time to separate. Draw off the chloroform layer and repeat the operation twice using 20 ml each time. Finally, filter the chloroform through dry filter paper, shake the filtrate well for five minutes with 5 g of powdered anhydrous sodium sulphate, leave the mixture to settle for two hours, then decant or filter the clear chloroform. Shake 25 mg of riboflavin with 10 ml of ethanol-free chloroform for five minutes, then filter: the colour of the filtrate should not be more intense than that of an aqueous solution obtained by diluting 3 ml of 0.1 N potassium dichromate to 1000 ml.

E102 - Tartazine

Products insoluble in water: not more than 0.2%
" Subsidiary colouring " (R1) : not more than 1%

"..." **[6]**

E104 - Quinoline Yellow

Products insoluble in water: not more than 0.2%

"..." **[6]**

E110 - Orange Yellow S, Sunset Yellow FCF

Products insoluble in water: not more than 0.2%

"..." **[6]**

E120 - Cochineal, carminic acid

Paper chromatography: with a solution of 2 g of trisodium citrate in 100 ml 5% ammonium hydroxide, cochineal gives only a single stain in the alkaline zone.

"..." **[6]**

E122 - " Azorubine, Carmoisine " (R1)

Products insoluble in water: not more than 0.2%
" Subsidiary colouring " (R1) : not more than 1%

E123 - Amaranth

Product insoluble in water: not more than 0.2%

E124 - Cochineal Red A, Ponceau 4 R

Products insoluble in water: not more than 0.2%

"..." **[6]**

"..." **[6]**

" E127 - Erythrosine

Products insoluble in water: not more than 0.2%
Mineral iodides: not more than 1000 mg/kg (assessed as sodium iodide)
" Subsidiary colourings: " (R3) not more than 3%
Fluorescein: no detectable trace. " **[2]**

"..." **[6]**

E131 - Patent Blue V

Products insoluble in water: not more than 0.5%
Chromium (estimated as CR): not more than 20 mg/kg
" Subsidiary colourings " (R1) : not more than 1%

E132 - Indigotin indigo carmine

Products insoluble in water: not more than 0.2%
" Subsidiary colourings " (R1) : not more than 1%
Isatinsulphonic acid: not more than 1%

E141 - Copper complexes of chlorophylls and chlorophyllins

A 1% solution of copper chlorophyll complex in turpentine should not be turbid and should not form a sediment.
Copper (free ionisable Cu): not more than 200 mg/kg

" E142 - Acid brilliant green BS

Products insoluble in water: not more than 0.2%
" Subsidiary colourings: " (R3) not more than 1%. " **[2]**

" E150 - Caramel

Ammonia-nitrogen: not more than 0.5% determined according to the Tillmans-Mildner method (2)
Sulphur dioxide: not more than 0.1% determined according to the Monier-Williams E. W. method (3)
pH: not less than 1.8
Phosphates: not more than 0.5% expressed as P2O5 " **[1]**

E151 - Brilliant Black BN, Black PN

Products insoluble in water: not more than 0.2%
" Subsidiary colourings " (R1) : not more than 15%. (The presence of " subsidiary colourings " (R1) among which the diacetylised compound has been identified is essential in order to obtain the precise shade.)
Intermediate products: not more than 1%

"..." **[6]**

E153 - Carbo medicinalis vegetalis (charcoal)

Higher aromatic hydrocarbons: extract 1 g of carbon black with 10 g of pure cyclohexane for two hours. The extract should be colourless. It should have little or no fluorescence in ultra-violet light; on evaporation it should leave no residue.
" Tar products " (R1) : boil 2 g of carbon black with 20 ml of N sodium hydroxide, then filter. The filtrate should be colourless.

E160 (a) - Alpha-, Beta-, Gamma-Carotene

Chromatography: By " adsorption " (R1) on alumina or silica gel, pure Beta-carotene shows only one zone.

E160 (b) - " Bixin and Norbixin (Annatto) " (R1)

Chromatography:

(a) Annatto: Dissolve a sufficient quantity of Annatto in benzene or dilute a benzene solution of Annatto to obtain a solution of the same colour as " a 0.1% solution " (R1) of potassium dichromate. Pour 3 ml of the solution on the top of an alumina column; elute slowly. Wash the column three times with benzene. The bixin is very heavily absorbed on the surface of the alumina and forms a brilliant orange-red zone (as distinct from crocetin saffron). A very pale yellow zone usually moves very rapidly across the column, even with crystallised pure bixin. The bixin cannot be eluted in benzene, " petroleum, ether, chloroform, acetone, ethanol " (R1) or methanol. But the ethanol and methanol cause the orange tint to turn into an orange yellow.

Carr-Price reaction: Remove the benzene from the column by washing three times with chloroform previously dehydrated by means of potassium carbonate. After elution of the last chloroform wash, add 5 ml of the Carr-Price reagent to the top of the column. The bixin zone immediately turns to blue-green (as distinct from crocetin).

(b) Bixin: Dissolve 1 to 2 mg of crystallised bixin in 20 ml of chloroform. Add 5 ml of this solution to the top of the prepared column. Rinse the solution with chloroform previously dehydrated with sodium carbonate and proceed as for (a) (Carr-Price reaction).

(c) Alkaline solutions of norbixin: Place 2 ml of an aqueous solution of Annatto in a 50 ml separating funnel. Add sufficient 2 N sulphuric acid to obtain a highly acid reaction. The norbixin will separate out as a red precipitate. Add 50 ml of benzene, then shake vigorously. After separation discard the aqueous layer and wash the benzene solution with 100 ml of water until the solution is no longer acid. Centrifuge the solution (usually emulsified) of norbixin in benzene for ten minutes at 2500 revolutions per minute. Decant the clear norbixin solution and dehydrate by means of anhydrous sodium sulphate. Pour 3-5 ml of this solution on the top of the alumina column. Norbixin like bixin will form an orange-red zone on the surface of the alumina. When eluted as in (a), it will behave like bixin and will also give the Carr-Price reaction.

E162 - Beetroot red, betanin

Paper Chromatography: With butanol saturated with 2 N hydrochloric acid as a solvent (ascending chromatography), betanin gives a single red spot with a brownish trail and little migration.

E171 - Titanium dioxide

Substances soluble in hydrochloric acid: Suspend 5 g of titanium dioxide in 100 ml of 0.5 N hydrochloric acid and heat for thirty minutes in a water bath, stirring from time to time. Filter in a Gooch crucible on the bottom of which three layers have been placed, the first of coarse asbestos the second of filter paper reduced to a pulp and the third of fine asbestos. Wash with three successive portions of 0.5 N hydrochloric acid each of 10 ml. Evaporate the filtrate to dryness in a platinum evaporating dish, then heat to a dull red until the weight is constant. The weight of the residue should not exceed 0.0175 g.

Antimony: not more than 100 mg/kg
Zinc: not more than 50 mg/kg
Soluble barium compounds: not more than 5 mg/kg

E172 - Iron oxides and hydroxides

Selenium: not more than 1 mg/kg
Mercury: not more than 1 mg/kg

"..." **[6]**

(R1) Corrigenda, Official Journal, English Special Edition, July 1975, p. 5.
(R2) Corrigenda, Official Journal, English Special Edition, July 1975, p. 13.
(R3) Corrigenda, Official Journal, English Special Edition, July 1975, p. 23.

(1) OJ No L 291, 19.11.1969, p. 9.
(2) Beythien-Diemair, Laboratoriumsbuch, 7th Edition, p. 151.
(3) "Determination of sulphur dioxide in foods", Dept. Public Health & Med. Subjects No 48, Ministry of Health, London 1927.

364L0054

64/54/EEC: COUNCIL DIRECTIVE OF 5 NOVEMBER 1963 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES CONCERNING THE PRESERVATIVES AUTHORIZED FOR USE IN FOODSTUFFS INTENDED FOR HUMAN CONSUMPTION

OFFICIAL JOURNAL NO 12, 27/01/1964, P. 161; ENGLISH SPECIAL EDITION, 1963-1964, P. 99
DATE OF NOTIFICATION: 06/11/1963
DATE OF TRANSPOSITION: 06/11/1964; SEE ART. 11

AMENDED BY

365L0569
65/569/EEC: COUNCIL DIRECTIVE OF 23 DECEMBER 1965 [1]
OFFICIAL JOURNAL NO 222, 28/12/1965, P. 3263 (ACT NOT PUBLISHED IN THE ENGLISH SPECIAL EDITION OF THE OFFICIAL JOURNAL, UNOFFICIAL TRANSLATION)
DATE OF NOTIFICATION: 24/12/1965
DATE OF TRANSPOSITION: 31/12/1966

366L0722
66/722/EEC: COUNCIL DIRECTIVE OF 14 DECEMBER 1966 [2]
OFFICIAL JOURNAL NO 233, 20/12/1966, P. 3947 (ACT NOT PUBLISHED IN THE ENGLISH SPECIAL EDITION OF THE OFFICIAL JOURNAL, UNOFFICIAL TRANSLATION)
DATE OF NOTIFICATION: 16/12/1966

367L0427
67/427/EEC: COUNCIL DIRECTIVE OF 27 JUNE 1967 [3]
OFFICIAL JOURNAL NO 148, 11/07/1967, P. 1; ENGLISH SPECIAL EDITION, 1967, P. 169
DATE OF NOTIFICATION: 28/06/1967
DATE OF TRANSPOSITION: 01/07/1968; SEE ART. 3

368L0420
68/420/EEC: COUNCIL DIRECTIVE OF 20 DECEMBER 1968 [4]
OFFICIAL JOURNAL NO L 309, 24/12/1968, P. 25; ENGLISH SPECIAL EDITION, 1968 II, P. 598
DATE OF NOTIFICATION: 20/12/1968

370L0359
70/359/EEC: COUNCIL DIRECTIVE OF 13 JULY 1970 [5]
OFFICIAL JOURNAL NO L 157, 18/07/1970, P. 38; ENGLISH SPECIAL EDITION, 1970 II, P. 436
DATE OF NOTIFICATION: 16/07/1970

371L0160
71/160/EEC: COUNCIL DIRECTIVE OF 30 MARCH 1971 [6]
OFFICIAL JOURNAL NO L 87, 17/04/1971, P. 12; ENGLISH SPECIAL EDITION, 1971 I, P. 220
DATE OF NOTIFICATION: 01/04/1971
DATE OF TRANSPOSITION: 01/10/1971; SEE ART. 2

372L0002
72/2/EEC: COUNCIL DIRECTIVE OF 20 DECEMBER 1971 [7]
OFFICIAL JOURNAL NO L 2, 04/01/1972, P. 22; ENGLISH SPECIAL EDITION, 1972 I, P. 11
DATE OF NOTIFICATION: 21/12/1971

172B
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE KINGDOM OF DENMARK, IRELAND AND THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND AND THE ADJUSTMENTS TO THE TREATIES **[8]**
OFFICIAL JOURNAL NO L 73, 27/03/1972, P. 121; ENGLISH SPECIAL EDITION, 27/03/1972, P. 121

372L0444
72/444/EEC: COUNCIL DIRECTIVE OF 26 DECEMBER 1972 **[9]**
OFFICIAL JOURNAL NO L 298, 31/12/1972, P. 48; ENGLISH SPECIAL EDITION, 30-31/12/1972, P. 75
DATE OF NOTIFICATION: 30/12/1972

374L0062
74/62/EEC: COUNCIL DIRECTIVE OF 17 DECEMBER 1973 **[10]**
OFFICIAL JOURNAL NO L 38, 11/02/1974, P. 29
DATE OF NOTIFICATION: 20/12/1973
DATE OF TRANSPOSITION: 01/01/1974; SEE ART. 2

374L0394
74/394/EEC: COUNCIL DIRECTIVE OF 22 JULY 1974 **[11]**
OFFICIAL JOURNAL NO L 208, 30/07/1974, P. 25
DATE OF NOTIFICATION: 23/07/1974
DATE OF TRANSPOSITION: 01/01/1974; SEE ART. 2

376L0462
76/462/EEC: COUNCIL DIRECTIVE OF 4 MAY 1976 **[12]**
OFFICIAL JOURNAL NO L 126, 14/05/1976, P. 31
DATE OF NOTIFICATION: 05/05/1976
DATE OF TRANSPOSITION: 05/05/1977; SEE ART. 4

376L0629
76/629/EEC: COUNCIL DIRECTIVE OF 20 JULY 1976 **[13]**
OFFICIAL JOURNAL NO L 223, 16/08/1976, P. 3
DATE OF NOTIFICATION: 29/07/1976
DATE OF TRANSPOSITION: 01/07/1976; SEE ART. 2

378L0145
78/145/EEC: COUNCIL DIRECTIVE OF 30 JANUARY 1978 **[14]**
OFFICIAL JOURNAL NO L 44, 15/02/1978, P. 23
DATE OF NOTIFICATION: 01/02/1978
DATE OF TRANSPOSITION: 01/02/1979; SEE ART. 3

379L0040
79/40/EEC: COUNCIL DIRECTIVE OF 18 DECEMBER 1978 **[15]**
OFFICIAL JOURNAL NO L 13, 19/01/1979, P. 50
DATE OF NOTIFICATION: 21/12/1978
DATE OF TRANSPOSITION: 31/12/1978; SEE ART. 2

179H
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE HELLENIC REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES **[16]**
OFFICIAL JOURNAL NO L 291, 19/11/1979, P. 110

381L0214
81/214/EEC: COUNCIL DIRECTIVE OF 16 MARCH 1981 **[17]**
OFFICIAL JOURNAL NO L 101, 11/04/1981, P. 10
DATE OF NOTIFICATION: 20/03/1981
DATE OF TRANSPOSITION: 01/07/1981; SEE ART. 4

383L0585
83/585/EEC: COUNCIL DIRECTIVE OF 25 NOVEMBER 1983 **[18]**
OFFICIAL JOURNAL NO L 335, 30/11/1983, P. 38
DATE OF NOTIFICATION: 01/12/1983
DATE OF TRANSPOSITION: 01/07/1984; SEE ART. 2

383L0636
83/636/EEC: COUNCIL DIRECTIVE OF 13 DECEMBER 1983 **[19]**
OFFICIAL JOURNAL NO L 357, 21/12/1983, P. 40
DATE OF NOTIFICATION: 21/12/1983

384L0086
84/86/EEC: COUNCIL DIRECTIVE OF 6 FEBRUARY 1984 **[20]**
OFFICIAL JOURNAL NO L 40, 11/02/1984, P. 29
DATE OF NOTIFICATION: 09/02/1984

384L0223
84/223/EEC: COUNCIL DIRECTIVE OF 10 APRIL 1984 **[21]**
OFFICIAL JOURNAL NO L 104, 17/04/1984, P. 25
DATE OF NOTIFICATION: 13/04/1984

384L0261
84/261/EEC: COUNCIL DIRECTIVE OF 7 MAY 1984 **[22]**
OFFICIAL JOURNAL NO L 129, 15/05/1984, P. 28
DATE OF NOTIFICATION: 14/05/1984

384L0458
84/458/EEC: COUNCIL DIRECTIVE OF 18 SEPTEMBER 1984 **[23]**
OFFICIAL JOURNAL NO L 256, 26/09/1984, P. 19
DATE OF TRANSPOSITION: 16/09/1984; SEE ART. 2

385L0007
85/7/EEC: COUNCIL DIRECTIVE OF 19 DECEMBER 1984 **[24]**
OFFICIAL JOURNAL NO L 2, 03/01/1985, P. 22
DATE OF NOTIFICATION: 27/12/1984

385L0172
85/172/EEC: COUNCIL DIRECTIVE OF 28 FEBRUARY 1985 **[25]**
OFFICIAL JOURNAL NO L 65, 06/03/1985, P. 22
DATE OF NOTIFICATION: 04/03/1985

185I
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE KINGDOM OF SPAIN AND THE PORTUGUESE REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES **[26]**
OFFICIAL JOURNAL NO L 302, 15/11/1985, P. 215

385L0585
85/585/EEC: COUNCIL DIRECTIVE OF 20 DECEMBER 1985 **[27]**
OFFICIAL JOURNAL NO L 372, 31/12/1985, P. 43
DATE OF NOTIFICATION: 24/12/1985
DATE OF TRANSPOSITION: 31/12/1986; SEE ART. 2

ARTICLE 1

SHALL BE SUBSTITUTED FOR THE DATE THE USE, FOR THE PROTECTION OF FOODSTUFFS INTENDED FOR HUMAN CONSUMPTION (HEREINAFTER CALLED "FOODSTUFFS") AGAINST DETERIORATION CAUSED BY MICRO-ORGANISMS, OF ANY PRESERVATIVES OTHER THAN THOSE LISTED IN THE ANNEX TO THIS DIRECTIVE.

ARTICLE 2

1. MEMBER STATES SHALL TAKE ALL MEASURES NECESSARY TO ENSURE THAT THE PRESERVATIVES FOR WHOSE USE THE ANNEX LAYS DOWN CERTAIN CONDITIONS ARE USED SOLELY IN ACCORDANCE WITH THOSE CONDITIONS.

2. SAVE AS OTHERWISE PROVIDED IN PARAGRAPH 1, THIS DIRECTIVE SHALL NOT AFFECT PROVISIONS OF NATIONAL LAWS SPECIFYING THE FOODSTUFFS TO WHICH THE PRESERVATIVES LISTED IN THE ANNEX MAY BE ADDED AND THE CONDITIONS GOVERNING THE ADDITION OF SUCH PRESERVATIVES; " HOWEVER, THE LAWS OF A MEMBER STATE MAY TOTALLY EXCLUDE THE USE OF ANY OF THE PRESERVATIVES LISTED IN THE ANNEX ONLY WHERE THERE IS NO TECHNOLOGICAL REASON FOR USING SUCH PRESERVATIVE FOODSTUFFS PRODUCED AND CONSUMED IN ITS OWN TERRITORY. " **[3]**

" ARTICLE 3

MEMBER STATES MAY AUTHORIZE THE SMOKING OF CERTAIN FOODSTUFFS ONLY IN SMOKE, OR LIQUID SOLUTIONS OF SMOKE, PRODUCED FROM WOOD OR WOODY PLANTS IN THE NATURAL STATE, EXCLUDING WOOD OR PLANTS WHICH HAVE BEEN IMPREGNATED, COLOURED, GUMMED OR PAINTED OR TREATED IN A SIMILAR MANNER AND PROVIDED THAT SUCH SMOKING DOES NOT CREATE ANY RISK TO HUMAN HEALTH. " **[17]**

ARTICLE 4

1. WHERE THE USE IN FOODSTUFFS OF ONE OF THE PRESERVATIVES LISTED IN THE ANNEX, OR THE LEVEL OF ONE OR MORE OF THE COMPONENTS REFERRED TO IN ARTICLE 7 CONTAINED IN SUCH PRESERVATIVE, MIGHT ENDANGER HUMAN HEALTH, A MEMBER STATE MAY, FOR A MAXIMUM PERIOD OF ONE YEAR, SUSPEND THE AUTHORIZATION TO USE THAT PRESERVATIVE OR REDUCE THE MAXIMUM AUTHORIZED LEVEL OF ONE OR MORE OF THE COMPONENTS IN QUESTION. IT SHALL INFORM THE OTHER MEMBER STATES AND THE COMMISSION THEREOF WITHIN ONE MONTH.

2. THE COUNCIL, ACTING UNANIMOUSLY ON A PROPOSAL FROM THE COMMISSION, SHALL DECIDE WITHOUT DELAY WHETHER THE LIST GIVEN IN THE ANNEX SHOULD BE AMENDED AND, IF SO, ADOPT BY DIRECTIVE THE NECESSARY AMENDMENTS. THE COUNCIL, ACTING BY A QUALIFIED MAJORITY ON A PROPOSAL FROM THE COMMISSION, MAY ALSO, IF NECESSARY,

EXTEND FOR A MAXIMUM OF ONE YEAR THE PERIOD SET IN THE FIRST SENTENCE OF PARAGRAPH 1.

ARTICLE 5

" 1. NOTWITHSTANDING ARTICLE 2 (1), MEMBER STATES MAY AUTHORIZE THE USE OF HEXAMETHYLENETETRAMINE

(a) IN SEMI-PRESERVED FISH AND FISHERY PRODUCTS WHOSE PH IS MORE THAN 4.5, PROVIDED THAT, WHEN THE PRODUCT IS MARKETED, THE LEVEL OF THIS SUBSTANCE DOES NOT EXCEED 50 mg/kg;

(b) IN CAVIAR (STURGEON EGGS) AND OTHER FISH EGGS, NOT SMOKED, PROVIDED THAT, WHEN THE PRODUCT IS MARKETED, THE LEVEL OF THIS SUBSTANCE DOES NOT EXCEED 1 g/kg. " **[10]**

" 2. " **[17]** " BY WAY OF DEROGATION FROM ARTICLE 1, MEMBER STATES MAY MAINTAIN THE PROVISIONS OF THEIR NATIONAL LAWS RELATING TO THE USE OF FORMALDEHYDE IN GRANO PADANO CHEESE PROVIDED THAT WHEN THE FINAL PRODUCT IS MARKETED, THE LEVEL OF FORMALDEHYDE, FREE AND/OR COMBINED, SHALL NOT EXCEED 0.5 MILLIGRAM PER KILOGRAM. " **[14]** [the paragraph was inserted by **[14]**; **[17]** deletes 5 (2) and 5 (3) (b), 5 (3) (a) becomes 5 (2)]

3. "..." **[17]**

ARTICLE 6

THIS DIRECTIVE SHALL NOT AFFECT THE PROVISIONS OF NATIONAL LAWS CONCERNING:

(a) PRODUCTS USED AS FOODSTUFFS BUT WHICH MAY ALSO HAVE PRESERVATIVE PROPERTIES, FOR EXAMPLE VINEGAR, SODIUM CHLORIDE, ETHANOL, EDIBLE OILS, AND SUGARS IN PARTICULAR;

(b) NISIN;

(c) PRODUCTS USED FOR COATING FOODSTUFFS;

(d) PRODUCTS USED TO PROTECT PLANTS AND PLANT PRODUCTS AGAINST HARMFUL ORGANISMS;

(e) ANTI-MICROBIAL PRODUCTS USED FOR THE TREATMENT OF DRINKING WATER;

(f) ANTIOXIDANTS.

ARTICLE 7

MEMBER STATES SHALL TAKE ALL MEASURES NECESSARY TO ENSURE THAT THE PRESERVATIVES LISTED IN THE ANNEX AND INTENDED FOR USE IN FOODSTUFFS SATISFY:

" (a) THE FOLLOWING GENERAL CRITERIA OF PURITY:

- THEY SHALL NOT CONTAIN A TOXICOLOGICALLY DANGEROUS AMOUNT OF ANY ELEMENT, IN PARTICULAR HEAVY METALS,
- THEY SHALL NOT CONTAIN MORE THAN 3 mg/kg OF ARSENIC OR MORE THAN 10 mg/kg OF LEAD,
- THEY SHALL NOT CONTAIN MORE THAN 50 mg/kg OF COPPER AND ZINC TAKEN TOGETHER OF WHICH THE ZINC CONTENT MUST IN NO CASE EXCEED 25 mg/kg, SUBJECT TO ANY EXCEPTION DERIVING FROM THE SPECIFIC CRITERIA OF PURITY REFERRED TO IN (b); " **[12]**

(b) THE SPECIFIC CRITERIA OF PURITY LAID DOWN WHERE APPROPRIATE AND IN ACCORDANCE WITH ARTICLE 8 (1).

ARTICLE 8

1. THE COUNCIL SHALL, ACTING UNANIMOUSLY ON A PROPOSAL FROM THE COMMISSION, LAY DOWN BY DIRECTIVE THE SPECIFIC CRITERIA OF PURITY REFERRED TO IN ARTICLE 7 (b).

2. " THE PROCEDURE LAID DOWN IN ARTICLE 8A SHALL BE USED TO ESTABLISH:

- THE METHODS OF ANALYSIS NEEDED TO VERIFY THAT THE GENERAL AND SPECIFIC CRITERIA OF PURITY REFERRED TO IN ARTICLE 7 OF THIS DIRECTIVE ARE SATISFIED;
- THE PROCEDURE FOR TAKING SAMPLES AND THE METHODS FOR THE QUALITATIVE AND QUANTITATIVE ANALYSIS OF PRESERVATIVES IN AND ON FOODSTUFFS. " **[5]**

" ARTICLE 8a

1. WHERE THE PROCEDURE LAID DOWN IN THIS ARTICLE IS TO BE FOLLOWED, MATTERS SHALL BE REFERRED BY THE CHAIRMAN, EITHER ON HIS OWN INITIATIVE OR AT THE REQUEST OF THE REPRESENTATIVE OF A MEMBER STATE, TO THE STANDING COMMITTEE FOR FOODSTUFFS (HEREINAFTER CALLED THE "COMMITTEE") SET UP BY THE COUNCIL DECISION OF 13 NOVEMBER 1969 (1).

2. THE REPRESENTATIVE OF THE COMMISSION SHALL SUBMIT TO THE COMMITTEE A DRAFT OF THE MEASURES TO BE ADOPTED. THE COMMITTEE SHALL DELIVER ITS OPINION ON THE DRAFT WITHIN A TIME LIMIT SET BY THE CHAIRMAN ACCORDING TO THE URGENCY OF THE MATTER. OPINIONS SHALL BE DELIVERED BY A MAJORITY OF " fifty-four " **[26]** VOTES, THE VOTES OF THE MEMBER STATES BEING WEIGHTED AS PROVIDED IN ARTICLE 148 (2) OF THE TREATY. THE CHAIRMAN SHALL NOT VOTE.

3. (a) THE COMMISSION SHALL ADOPT THE MEASURES ENVISAGED WHERE THEY ARE IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE.

(b) WHERE THE MEASURES ENVISAGED ARE NOT IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE OR IF NO OPINION IS DELIVERED, THE COMMISSION SHALL WITHOUT DELAY PROPOSE TO THE COUNCIL THE MEASURES TO BE ADOPTED. THE COUNCIL SHALL ACT BY A QUALIFIED MAJORITY.

(c) IF, WITHIN THREE MONTHS OF THE PROPOSAL BEING SUBMITTED TO IT, THE COUNCIL HAS NOT ACTED, THE PROPOSED MEASURES SHALL BE ADOPTED BY THE COMMISSION.

ARTICLE 8b

THE PROVISIONS OF ARTICLE 8a SHALL APPLY " FOR A PERIOD OF TWO YEARS FROM THE DATE ON WHICH THE MATTER WAS FIRST REFERRED TO THE COMMITTEE AFTER 1 JANUARY 1985 " **[24]** EITHER UNDER ARTICLE 8a (1) OR UNDER ANY OTHER CORRESPONDING PROVISION. " **[5]**

ARTICLE 9

1. THE MEMBER STATES SHALL TAKE ALL MEASURES NECESSARY TO ENSURE THAT THE PRESERVATIVES LISTED IN THE ANNEX AND INTENDED FOR USE IN FOODSTUFFS ARE PLACED ON THE MARKET ONLY IF THEIR PACKAGINGS OR CONTAINERS BEAR THE FOLLOWING INFORMATION:

(a) THE NAME AND ADDRESS OF THE MANUFACTURER, OR OF A SELLER RESPONSIBLE WITHIN THE MEANING OF THE LAWS OF THE MEMBER STATE IN WHICH HE IS RESIDENT; A PERSON IMPORTING A PRODUCT FROM A THIRD COUNTRY SHALL BE TREATED AS THE MANUFACTURER;

(b) THE NUMBER AND NAME OF THE PRESERVATIVE AS THEY ARE GIVEN IN THE ANNEX;

(c) THE WORDS "FOR FOODSTUFFS (RESTRICTED USE)";

(d) IN THE CASE OF A MIXTURE COMPOSED OF PRESERVATIVES AND OTHER PRODUCTS, THE PERCENTAGE OF THE PRESERVATIVE AND THE NAME OF THE MIXTURE.

" 2. Member States shall not prohibit the preservatives listed in the Annex from entering their territory and from being placed on sale therein on the ground that they consider the labelling inadequate if the particulars required under paragraph 1 appear on the packages or containers, and if the particulars required under subparagraphs (b), (c) and (d) are expressed in at least one official language of the Community.
However, any importing Member State may require that the latter particulars be expressed in its official language or languages. " **[8]**

ARTICLE 10

1. THIS DIRECTIVE SHALL ALSO APPLY TO PRESERVATIVES INTENDED FOR USE IN FOODSTUFFS AND TO FOODSTUFFS IMPORTED INTO THE COMMUNITY.

2. THIS DIRECTIVE SHALL NOT APPLY TO PRESERVATIVES AND FOODSTUFFS INTENDED FOR EXPORTATION FROM THE COMMUNITY.

ARTICLE 11

1. MEMBER STATES SHALL, WITHIN A PERIOD OF ONE YEAR FOLLOWING NOTIFICATION OF THIS DIRECTIVE, AMEND THEIR LAWS IN ACCORDANCE WITH THE ABOVE PROVISIONS AND SHALL FORTHWITH INFORM THE COMMISSION THEREOF. THE LAWS THUS AMENDED SHALL APPLY TO PRESERVATIVES AND FOODSTUFFS PLACED ON THE MARKET IN MEMBER STATES NOT LATER THAN TWO YEARS AFTER THAT NOTIFICATION.

2. WHERE ARTICLE 5 (a) IS APPLICABLE THE DATE OF EXPIRY OF THE PERIOD SET IN THAT ARTICLE SHALL BE SUBSTITUTED FOR THE DATE OF NOTIFICATION REFERRED TO IN PARAGRAPH 1.
" However, in the case of formic acid and its salts, boric acid and its salts and hexamethylenetetramine, application of the amended laws may be deferred until 1 January 1974. " **[9]**

ARTICLE 12

THIS DIRECTIVE SHALL ALSO APPLY IN THE FRENCH OVERSEAS DEPARTMENTS.

ARTICLE 13

THIS DIRECTIVE IS ADDRESSED TO THE MEMBER STATES.

ANNEX

EEC No	Name	Conditions of use
	I. *Preservatives*	
E 200	Sorbic acid	
E 201	Sodium sorbate (sodium salt of sorbic acid)	
E 202	Potassium sorbate (potassium salt of sorbic acid)	
E 203	Calcium sorbate (calcium salt of sorbic acid)	
E 210	Benzoic acid	
E 211	Sodium benzoate (sodium salt of benzoic acid)	
E 212	Potassium benzoate (potassium salt of benzoic acid)	
E 213	Calcium benzoate (calcium salt of benzoic acid)	
E 214	Ethyl p-hydroxybenzoate (ethyl ester of p-hydroxybenzoic acid)	
E 215	Sodium ethyl p-hydroxybenzoate	
E 216	Propyl p-hydroxybenzoate (propyl ester of p-hydroxybenzoic acid)	
E 217	Sodium propyl p-hydroxybenzoate	
" E 218	Methyl p-hydroxybenzoate (methyl ester of p-hydroxybenzoic acid) " **[8]**	
" E 219	Sodium derivative of methyl p-hydroxybenzoate " **[12]**	
E 220	Sulphur dioxide	
E 221	Sodium sulphite	
E 222	Sodium bisulphite (acid sodium sulphite)	
E 223	Sodium metabisulphite (sodium pyrosulphite or sodium disulphite)	
E 224	Potassium metabisulphite (potassium pyrosulphite or potassium disulphite)	
E 225	" ... " **[6]**	
" E 226	Calcium sulphite " **[6]**	
" E 227	Calcium bisulphite (calcium hydrogen sulphite) " **[8]**	
" E 228	Potassium acid sulphite (Potassium bisulphite) " **[27]**	

EEC No	Name	Conditions of use
" E 230 E 231 E 232	Biphenyl (Diphenyl) Orthophenylphenol Sodium orthophenylphenate	(a) Exclusively for surface treatment of citrus fruit (b) At the time of marketing the citrus fruit (i) the residual amount per kg of citrus fruit (whole fruit) must not be greater than: for biphenyl: 70 mg, and for orthophenylphenol and sodium orthophenylphenate, used separately or together, expressed as orthophenylphenol: 12 mg (ii) the treatment must be indicated — in the wholesale trade, on invoices and on one external surface of the packaging, by the words: "Preserved with..." giving the name of the substances used — in the retail trade, by some visible indication giving the consumer clear information " **[3]**
" E 233	2-(4'-thiazolyl)-benzimidazole (thiabendazole)	(a) only for surface treatment of — citrus fruits — bananas (b) at the time when the fruit is placed on the market: (i) the residual content per "kg of whole fruit" (R1) must not exceed: — citrus fruit: 6mg — bananas: 3 mg " **[6]** "(ii) as regards citrus fruit: — in the wholesale trade, the treatment shall be indicated on the invoices and on one external surface of the packaging by the words. "Treated with thiabendazole" — in the retail trade, Member States may require a visible indication ensuring beyond doubt that the consumer is made aware that the fruit been treated " **[11]** (c) " ... " **[27]** (With effect from 1 January 1986)

EEC No	Name	Conditions of use
" E 236	Formic acid	
E 237	Sodium formate (sodium salts of formic acid)	
E 238	Calcium formate (calcium salts of formic acid)	
E 239	Hexamethylenetetramine	(a) Solely in "Provolone" cheese (b) When the product is marketed, the level of this substance, expressed as formaldehyde, must not exceed 25 mg/kg for "Provolone" " **[10]**
	II. *Substances intended mainly for other purposes but which may have a subsidiary preservative property*	
" E 249	Potassium nitrite	Solely in a mixture with sodium chloride " **[12]**
E 250	Sodium nitrite	Solely in a mixture with sodium chloride
E 251	Sodium nitrate	Alone or in mixture with sodium chloride
E 252	Potassium nitrate	Alone or in mixture with sodium chloride
E 260	Acetic acid	
E 261	Potassium acetate	
E 262	Sodium diacetate	
E 263	Calcium acetate	
E 270	Lactic acid	
E 280	Propionic acid	
E 281	Sodium propionate (sodium salt of propionic acid)	
E 282	Calcium propionate (calcium salt of propionic acid)	
" E 283	Potassium propionate (potassium salt of propionic acid) " **[12]**	
E 290	Carbon dioxide	

(1) OJ No L 291, 19/11/1969, p. 9..

365L0066

65/66/EEC: COUNCIL DIRECTIVE OF 26 JANUARY 1965 LAYING DOWN SPECIFIC CRITERIA OF PURITY FOR PRESERVATIVES AUTHORIZED FOR USE IN FOODSTUFFS INTENDED FOR HUMAN CONSUMPTION

OFFICIAL JOURNAL NO 22, 09/02/1965, P. 373; ENGLISH SPECIAL EDITION, 1965-1966, P. 25
DATE OF NOTIFICATION: 03/02/1965
DATE OF TRANSPOSITION: 01/06/1966; SEE ART. 2

AMENDED BY

367L0428
67/428/EEC: COUNCIL DIRECTIVE OF 27 JUNE 1967 **[1]**
OFFICIAL JOURNAL NO 148, 11/07/1967, P. 10; ENGLISH SPECIAL EDITION, 1967, P. 178
DATE OF NOTIFICATION: 28/06/1967
DATE OF TRANSPOSITION: 01/07/1968; SEE ART. 2

376L0463
76/463/EEC: COUNCIL DIRECTIVE OF 4 MAY 1976 **[2]**
OFFICIAL JOURNAL NO L 126, 14/05/1976, P. 33
DATE OF NOTIFICATION: 05/05/1976
DATE OF TRANSPOSITION: 05/05/1977; SEE ART. 2
DATE OF TRANSPOSITION: 04/05/1978

386L0604
86/604/EEC: COUNCIL DIRECTIVE OF 8 DECEMBER 1986 **[3]**
OFFICIAL JOURNAL NO L 352, 13/12/1986, P. 45
DATE OF NOTIFICATION: 11/12/1986
DATE OF TRANSPOSITION: 01/01/1988; SEE ART. 2

ARTICLE 1

THE SPECIFIC CRITERIA OF PURITY REFERRED TO IN ARTICLE 7 (b) OF THE DIRECTIVE OF 5 NOVEMBER 1963 ARE GIVEN IN THE ANNEX TO THIS DIRECTIVE (1).

ARTICLE 2

MEMBER STATES SHALL SO AMEND THEIR LAWS IN ACCORDANCE WITH THE PROVISIONS OF ARTICLE 1 THAT BY 1 JUNE 1966 THE NEW MEASURES APPLY TO PRESERVATIVES PLACED ON THE MARKET.

ARTICLE 3

THIS DIRECTIVE IS ADDRESSED TO THE MEMBER STATES.

ANNEX

SPECIFIC CRITERIA OF PURITY

General observations

(a) Save as otherwise stated, quantities and percentages are calculated by weight on the anhydrous product.

(b) Where the relevant product is not initially anhydrous and 'volatile substances' are involved, water is included among these substances.

(c) Where the drying period is not specified, this means 'dried till constant weight'.

(d) Where interpretation of the criteria set out below requires the definition of certain technical terms such as 'vacuum', reference should be made to the methods of analysis established pursuant to Article 8 (2) of the Directive of 5 November 1963.

	E 200 Sorbic acid
Appearance	White crystalline powder showing no change in colour after heating for 90 mins at 105 °C
Melting range	133–135 °C, after vacuum drying for 4 hours in a sulphuric acid desiccator
Content	Not less than 99%, after vacuum drying for 4 hours in a sulphuric acid desiccator
Volatile substances	Not more than 3%, determined by drying for 24 hours in a sulphuric acid desiccator
Sulphated ash	Not more than 0·2%
Aldehydes	Not more than 0·1% calculated as formaldehyde

	E 201 Sodium sorbate
Appearance	White crystalline powder showing no change in colour after heating for 90 mins at 105 °C
Melting range of sorbic acid isolated by acidification and not recrystallised	133–135 °C, after vacuum drying in a sulphuric acid desiccator
Content	Not less than 99%, after vacuum drying for 4 hours in a sulphuric acid desiccator
Volatile substances	Not more than 1%, determined by vacuum drying in a sulphuric acid desiccator
Aldehydes	Not more than 0·1% calculated as formaldehyde

" E 202 - Potassium sorbate " (R1)

Appearance	White crystalline powder showing no change in colour after heating for 90 mins at 105 °C
Melting range of sorbic acid isolated by acidification and not recrystallised	133–135 °C, after vacuum drying in a sulphuric acid desiccator
Content	Not less than 99%, after vacuum drying for 4 hours in a sulphuric acid desiccator
Volatile substances	Not more than 1%, determined by vacuum drying in a sulphuric acid desiccator
Aldehydes	Not more than 0·1%, calculated as formaldehyde

E 203 Calcium sorbate

Appearance	Fine white crystalline powder showing no change in colour after heating for 90 mins at 105 °C
Melting range of sorbic acid isolated by acidification and not recrystallised	133–135 °C, after vacuum drying in a sulphuric acid desiccator
Content	Not less than 98%, after vacuum drying for 4 hours in a sulphuric acid desiccator
Volatile substances	Not more than 2%, determined by vacuum drying in a sulphuric acid desiccator
Aldehydes	Not more than 0·1%, calculated as formaldehyde

E 210 Benzoic acid

Appearance	White crystalline powder
Melting range	121·5–123·5 °C, after vacuum drying in a sulphuric acid desiccator
Content	Not less than 99·5%
Sulphated ash	Not more than 0·05%
Polycyclic acids	On fractional acidification of a neutralised solution of benzoic acid, the first precipitate must not have a different melting point from that of the benzoic acid
Organic chlorine	Not more than 0·07%, corresponding to 0·3% expressed as mono-chlorobenzoic acids
Readily oxidisable substances	Pink colour maintained with not more than 0·5 ml of $KMnO_4$ (0·1 N) per g in sulphuric acid solution (0·1 N) after 1 hour, at room temperature
Sulphuric acid test	Cold solution of 0·5 g of benzoic acid in 5 ml of 94·5–95·5% sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0·2 ml of cobalt chloride TSC,[2] 0·3 ml of ferric chloride STC,[3] 0·1 ml of copper sulphate TSC[4] add 4·4 ml of water

E 211 Sodium benzoate

Appearance	White crystalline powder
Melting range of benzoic acid isolated by acidification and not recrystallised	121·5–123·5 °C, after vacuum drying in a sulphuric acid desiccator
Content	Not less than 99·5%, after drying for 4 hours at 105 °C
Volatile substances	Not more than 1%, determined by drying for 4 hours at 105 °C

Polycyclic acids	On fractional acidification of a (neutralised) solution of sodium benzoate, the first precipitate must not have a different melting range from that of benzoic acid
Organic chlorine	Not more than 0·06%, corresponding to 0·25% expressed as monochlorobenzoic acids
Readily oxidisable substances	Pink colour maintained with not more than 0·5 ml of $KMnO_4$ (0·1 N) per g in sulphuric acid solution (0·1 N) after 1 hour, at room temperature
Degree of acidity or alkalinity	Neutralisation of 1 g of sodium benzoate, in the presence of phenolphthalein, must not require more than 0·25 ml of NaOH (0·1 N) or HCl (0·1 N)

E 212 Potassium benzoate

Appearance	White crystalline powder
Melting range of benzoic acid isolated by acidification and not recrystallised	121·5–123·5 °C, after vacuum drying in a sulphuric acid desiccator
Content	Not less than 99%, after drying at 105 °C
Volatile substances	Not more than 26·5%, determined by drying at 105 °C
Polycyclic acids	On fractional acidification of a (neutralised) solution of potassium benzoate, the first precipitate must not have a different melting range from that of benzoic acid
Organic chlorine	Not more than 0·06%, corresponding to 0·25% expressed as monochlorobenzoic acids
Readily oxidisable substances	Pink colour maintained with not more than 0·5 ml of $KMnO_4$ (0·1 N) per g in sulphuric acid solution (0·1 N) after 1 hour, at room temperature
Degree of acidity or alkalinity	Neutralisation of 1 g of potassium benzoate, in the presence of phenolphthalein, must not require more than 0·25 ml of NaOH (0·1 N) or HCl (0·1 N)

E 213 Calcium benzoate

Appearance	White crystalline powder
Melting range of benzoic acid isolated by acidification and not recrystallised	121·5–123·5 °C, after vacuum drying in a sulphuric acid desiccator
Content	Not less than 99%, after drying at 105 °C
Volatile substances	Not more than 17·5%, determined by drying at 105 °C
Polycyclic acids	On fractional acidification of a (neutralised) solution of calcium benzoate, the first precipitate must not have a different melting range from that of benzoic acid
Organic chlorine	Not more than 0·06%, corresponding to 0·25% expressed as monochlorobenzoic acids
Readily oxidisable substances	Pink colour maintained with not more than 0·5 ml of $KMnO_4$ (0·1 N) per g in sulphuric acid solution (0·1 N) after 1 hour, at room temperature
Degree of acidity or alkalinity	Neutralisation of 1 g of calcium benzoate, in the presence of phenolphthalein, must not require morethan 0·25 ml of NaOH (0·1 N) or HCl (0·1 N)

	E 214 Ethyl ester of p-hydroxybenzoic acid
Appearance	White crystalline powder
Melting range	115–118 °C
Content	Not less than 99·5%, after drying for 2 hours at 80 °C
Sulphated ash	Not more than 0·05%
Free acids	Not more than 0·35% expressed as p-hydroxybenzoic acid
Salicylic acid	Not more than 0·1%

	E 215 Sodium ethyl p-hydroxybenzoate
Appearance	White crystalline hygroscopic powder
Melting range of ester isolated by acidification and not recrystallised	115–118 °C, after vacuum drying in a sulphuric acid desiccator
Content: ethyl ester of p-hydroxybenzoic acid	Not less than 83%, after vacuum drying in a sulphuric acid desiccator
Volatile substances	Not more than 5%, determined by vacuum drying in a sulphuric acid desiccator
Sulphated ash	37–39%
pH	pH of 0·1% aqueous solution must be between 9·9 and 10·3
Salicylic acid	Not more than 0·1%

	E 216 n-propyl p-hydroxybenzoate
Appearance	White crystalline powder
Melting point	95–97 °C, after drying for 2 hours at 80 °C
Content	Not less than 99·5%, after drying for 2 hours at 80 °C
Sulphated ash	Not more than 0·05%
Free acids	Not more than 0·35%, expressed as p-hydroxybenzoic acid
Salicylic acid	Not more than 0·1%

	E 217 Sodium n-propyl p-hydroxybenzoate
Appearance	White, or almost white, crystalline hygroscopic powder
Melting range of ester isolated by acidification and not recrystallised	94–97 °C, after vacuum drying in a sulphuric acid desiccator
Content: propyl ester of p-hydroxybenzoic acid	Not less than 85%, after vacuum drying in a sulphuric acid desiccator
Volatile substances	Not more than 5%, determined by vacuum drying in a sulphuric acid desiccator
Sulphated ash	34–36%
pH	pH of 0·1% aqueous solution must be between 9·8 and 10·2
Salicylic acid	Not more than 0·1%

" *E 218 p-hydroxybenzoate*

Appearance :	White, almost odourless, crystalline powder
Melting range :	125 to 128 °C
Content :	Not less than 99·0 % expressed as $C_8H_8O_3$ after drying for two hours at 80 °C
Sulphated ash :	Not more than 0·05 %
Free acidity :	Not more than 0·7 % expressed as p-hydroxybenzoic acid
Salicylic acid :	Not more than 0·1 %
Loss on drying :	Not more than 0·5 % after drying for two hours at 80 °C

E 219 Sodium derivative of methyl p-hydroxybenzoate

Appearance :	White hygroscopic powder
Melting range of methyl ester :	The white precipitate formed by acidifying with hydrochloric acid a 10 % (w/v) aqueous solution of the sodium derivative of methyl p-hydroxybenzoate (using litmus paper as indicator) shall, when washed with water and dried at 80 °C for two hours, have a melting range of 125 to 128°C.
Content :	Not less than 99·5 % of $C_8H_7O_3Na$ calculated on the dry matter
Moisture :	Not more than 5·0 % (Karl-Fischer)
Sulphated ash :	40·0 to 44·5 % calculated on the dry matter
pH (0·1 % solution in carbon dioxide-free water) :	Not less than 9·7 and not more than 10·3
Salicylic acid :	Not more than 0·1 % " **[2]**

	E 220 **Sulphur dioxide**
Appearance	Colourless gas
Content	Not less than 99%
Non-volatile substances	Not more than 0·01%
Sulphur trioxide	Not more than 0·1%
Other gases not normally present in the air	No trace
Selenium	Not more than 10 mg/kg

	E 221 **Sodium sulphite (anhydrous or heptahydrate)**
Appearance	White crystalline powder or colourless crystals
Content: anhydrous	Not less than 95% of Na_2SO_3 and not less than 48% of SO_2
heptahydrate	Not less than 48% of Na_2SO_3 and not less than 24% of SO_2
Thiosulphate	Not more than 0·1% of $Na_2S_2O_3$ based on the SO_2 content
Iron	Not more than 50 mg/kg of N_2SO_3 based on the SO_2 content
Selenium	Not more than 10 mg/kg based on the SO_2 content

	E 222 **Acid sodium sulphite**
Appearance	White crystalline powder
Content	Not less than 95% of $NaHSO_3$ and not less than 58·4% of SO_2
Iron	Not more than 30 mg/kg of $NaHSO_3$
Selenium	Not more than 10 mg/kg based on the SO_2 content

	E 223 Sodium metabisulphite
Appearance	Colourless crystals or white crystalline powder
Content	Not less than 95% of $Na_2S_2O_5$ and not less than 64% of SO_2
Iron	Not more than 35 mg/kg of $Na_2S_2O_5$
Selenium	Not more than 10 mg/kg based on the SO_2 content

	E 224 Potassium metabisulphite
Appearance	Colourless crystals or white crystalline powder
Content	" Not less than 90% of $K_2S_2O_5$ and not less than 51·8% of SO_2, the remainder being composed almost entirely of potassium sulphate " **[1]**
Iron	Not more than 30 mg/kg of $K_2S_2O_5$
Selenium	Not more than 10 mg/kg based on the SO_2 content

	E 225 Calcium metabisulphite
Appearance	White powder or yellowish lumps
Content	Not less than 95% of CaS_2O_5 and not less than 66% of SO_2
Iron	Not more than 35 mg/kg of CaS_2O_5
Selenium	Not more than 10 mg/kg based on the SO_2 content

"*E 226 Calcium sulphite*

Appearance :	White crystals or white crystalline powder
Content :	Not less than 95 % of $CaSO_3 \cdot 2H_2O$ and not less than 39 % of SO_2
Sulphates :	Not more than 0·1 %, expressed as SO_4
Chlorides :	Not more than 0·05 % expressed as Cl
Iron :	Not more than 0·005 %
Selenium :	Not more than 10 mg/kg of the SO_2 content

E 227 Calcium hydrogen sulphite

Appearance :	Clear greenish-yellow aqueous solution having a distinct odour of sulphur dioxide
Content :	6 to 8 % (w/v) of sulphur dioxide and 2·5 to 3·5 % (w/v) of calcium oxide corresponding to 10 to 14 % (w/v) of calcium bisulphite $[Ca(HSO_3)_2]$
Iron :	Not more than 30 mg/kg
Selenium :	Not more than 10 mg/kg of the SO_2 content " **[2]**

"**E 228 — Potassium acid sulphite** (potassium bisulphite)

Appearance :	**Clear colourless solution prepared by bubbling sulphur dioxide (SO_2) (E 220) in an aqueous solution of potassium hydroxide (KOH) as used in foodstuffs**
Chemical formula :	**$KHSO_3$ in aqueous solution (5)**
Content :	**Not less than 280 g $KHSO_3$ per litre (or 150 g SO_2 per litre)**
Sodium :	**Not more than 1 % of the SO_2 content**
Selenium :	**Not more than 10 mg/kg of the SO_2 content**
Chloride :	**Not more than 1 000 mg/kg expressed as Cl. " [3]**

" E 230 Biphenyl

Appearance	White crystalline powder
Melting range	68·5-70·5 °C
Content	Not less than 99·8%
Benzene	Not more than 10 mg/kg
Aromatic amines	Not more than 2 mg/kg expressed as aniline
Phenol derivatives	Not more than 5 mg/kg expressed as phenol
Terphenyl and higher polyphenyl derivatives	Not more than 0·2%
Polycyclic aromatic hydrocarbons	Absent
Sulphuric acid test	1 g of biphenyl and 5 ml of concentrated sulphuric acid mixed cold produces no colouring

E 231 Orthophenylphenol

Appearance	White or slightly yellowish crystalline powder
Melting range	56-58 °C
Content	Not less than 99%
Diphenylether	Not more than 0·3%
P-phenylphenol	Not more than 0·1%
1-naphthol	Not more than 0·01%
Sulphated ash	Not more than 0·05%

E 232 Sodium orthophenylphenate

Appearance	White or slightly yellowish crystalline powder
Melting range of orthophenylphenol isolated by acidification and not recrystallised	56-58 °C after drying in a sulphuric acid dessicator
pH	pH of 2% aqueous solution must be between 11·1 and 11·8
Content	Not less than 95% or $C_{12}H_9ONa.\ 4H_2O$
Diphenylether	Not more than 0·3%
P-phenylphenol	Not more than 0·1%
1-naphthol	Not more than 0·01% " **[1]**

"*E 233 2-(4-thiazolyl) benzimidazole* (thiabendazole)

Appearance :	White, or almost white, odourless powder
Melting range :	296 to 303 °C
Content :	98 to 101 % $C_{10}H_7N_3S$ calculated on the anhydrous product
Sulphated ash :	Not more than 0·2 %
Moisture :	Not more than 0·5 % (Karl-Fischer)
UV Absorption (0·0005 % w/v in 0·1 N HCl) :	$E\ \frac{1\ \%}{1\ cm}$ at 302 ± 2 nm = 1 230 approximately
	$E\ \frac{1\ \%}{1\ cm}$ at 258 ± 2 nm = 200 approximately
	$E\ \frac{1\ \%}{1\ cm}$ at 243 ± 2 nm = 620 approximately
	Ratio of $\frac{\text{absorption at 241 to 245 nm}}{\text{absorption at 300 to 304 nm}}$ = 0·47 to 0·53
	Ratio of $\frac{\text{absorption at 256 to 260 nm}}{\text{absorption at 300 to 304 nm}}$ = 0·14 to 0·18
Selenium :	10 mg/kg

E 236 Formic acid

Appearance :	Clear, colourless, highly corrosive liquid with a characteristic pungent odour
Content :	Not less than 98·0 % of CH_2O_2
Acetic acid :	Not more than 0·5 %
Sulphates :	Not more than 40 mg/kg, expressed as SO_4
Sulphites :	Dilute 25 ml of formic acid with 25 ml of water. Add 0·1 ml of 0·1 N iodine solution. The solution should retain a distinct yellow colour
Chlorides :	Not more than 50 mg/kg, expressed as Cl
Specific gravity :	1·216 to 1·220 (20/20 °C)
Non-volatile matter :	Not more than 0·05 %
Aldehydes :	A slightly alkaline 5 % solution, on heating must not give off a sharp or burnt smell
Formaldehyde :	Not more than 0·1 % of the formic acid content, determined using chromotropic acid
Oxalic acid :	Not more than 0·5 % of the formic acid content determined as calcium oxalate, expressed as oxalic acid

E 237 Sodium formate

Appearance :	White crystalline powder
Content :	Not less than 98 % $NaCHO_2$ after drying for two hours at 105 °C
Volatile matter :	Not more than 2 % by drying for two hours at 105 °C
Degree of acidity or alkalinity :	Neutralization of 1 g of sodium formate in the presence of phenolphthalein must not require more than 0·5 ml of 0·1 N HCl or 0·1 N NaOH
Aldehydes :	A 5 % solution on heating must not give off a sharp or burnt smell
Formaldehyde :	Not more than 0·1 % of the sodium formate content, determined using chromotropic acid
Oxalic acid :	Not more than 0·5 % of the sodium formate content, determined as calcium oxalate, expressed as oxalic acid

E 238 Calcium formate

Appearance :	White crystalline powder
Content :	Not less than 98 % $CaC_2H_2O_4$ after drying for two hours at 105 °C
Volatile matter :	Not more than 2 % after drying for two hours at 105 °C
Water-insoluble matter :	Not more than 0·5 %
Degree of acidity or alkalinity :	Neutralization of 1 g of calcium formate in the presence of phenolphthalein must not require more than 0·5 ml of 0·1 N HCl or 0·1 N NaOH
Aldehydes :	A 5 % solution on heating must not give off a sharp or burnt smell
Formaldehyde :	Not more than 0·1 % of the calcium formate content, determined using chromotropic acid
Oxalic acid :	Not more than 0·3 % of the calcium formate content, determined as calcium oxalate, expressed as oxalic acid

E 239 Hexamethylenetetramine

Appearance :	Colourless, or white, crystalline powder
Content :	Not less than 99 % $C_6H_{12}N_4$
Loss on drying :	Not more than 0·5 % after drying at 105 °C in vacuum over phosphorus pentoxide for two hours
Sublimation point :	Sublimes at about 260 °C
Sulphated ash :	Not more than 0·05 %
Sulphates :	Not more than 0·005 %, expressed as SO_4
Chlorides :	Not more than 0·005 % expressed as Cl

E 249 Potassium nitrite

Appearance :	White, or slightly yellow, deliquescent granules
Content :	Not less than 95 % after drying for four hours over silica gel
pH (5 % solution in carbon dioxide-free and ammonia-free water) :	Not less than 6·0 and not more than 9·0 " [2]

	E 250 Sodium nitrite
Appearance	White crystalline powder or yellowish lumps
Content	Not less than 98%, after vacuum drying in a sulphuric acid desiccator; the remainder must consist practically entirely of sodium nitrate
Water	Not more than 1%

	E 251 Sodium nitrate
Appearance	White crystalline slightly hygroscopic powder
Content	Not less than 99% after drying at 105 °C
Volatile substances	Not more than 1%, determined by drying at 105 °C
Nitrates	Not more than 30 mg/kg, expressed as $NaNO_2$

	E 252 Potassium nitrate
Appearance	White crystalline powder
Content	Not less than 99% after drying at 105 °C
Volatile substances	Not more than 1%, determined after drying at 105 °C
Nitrites	Not more than 30 mg/kg, expressed as $NaNO_2$

	E 260 Acetic acid[6]
Appearance	Clear colourless liquid
Content	Not less than 99·4%
Boiling point	118 °C at 760 mm pressure (of Mercury)
Non-volatile substances	Not more than 0·005%
Formic acid, formates and other oxidisable impurities	Not more than 0·2%, expressed as formic acid, determined by titration with potassium permanganate

	E 261 Potassium acetate
Appearance	Colourless deliquescent crystals
Content	Not less than 99%, after drying at 200 °C
Formic acid, formates and other oxidisable impurities	Not more than 0·2%, expressed as formic acid, determined by titration with potassium permanganate

	E 262 Sodium diacetate[7]
Appearance	Colourless crystals or white crystalline powder
Water insolubles	10% aqueous solution must be clear
Formic acid, formates and other oxidisable impurities	Not more than 0·2%, expressed as formic acid, determined by titration with potassium permanganate
Acetic acid, sodium acetate and water	Totalling not less than 99·7% including not less than 40% acetic acid

	E 263 Calcium acetate
Appearance	White crystalline powder
Content	Not less than 99%, after drying at 200 °C
Volatile substances	Not more than 10·5%, determined by drying at 200 °C
pH	pH of 10% aqueous solution must be between 7·0 and 9·0
Formic acid, formates and other oxidisable impurities	Not more than 0·2%, expressed as formic acid, determined by titration with potassium permanganate

	E 270 Lactic acid[8]
Appearance	Clear, slightly viscous liquid, colourless or slightly yellowish
Content	Not less than 80%
Fatty acids	No measurable trace
Calcium	Not more than 0·05%
Sulphates	Not more than 0·05%, expressed as SO_4
Chlorides	Not more than 0·02%, expressed as Cl
Sulphated ash	Not more than 0·3%
Iron	Not more than 20 mg/kg
Barium	No measurable trace
Oxalic acid	Not more than 0·15%

Ferrocyanides	No trace
Reducing substances	No reduction of Fehlings solution

E 280 **Propionic acid**[9]

Appearance	Colourless or slightly yellowish liquid
Content	Not less than 99%
Non-volatile substances	Not more than 0·05%
Aldehydes	Not more than 0·1%, expressed as formaldehyde
Iron	Not more than 30 mg/kg

E 281 **Sodium propionate**

Appearance	White crystalline powder
Content	Not less than 99%, after drying for 2 hours at 105 °C
Volatile substances	Not more than 4%, determined by drying for 2 hours at 105 °C
Water insolubles	Not more than 0·3%
Readily oxidisable substances	No trace
Iron	Not more than 30 mg/kg

E 282 **Calcium propionate**

Appearance	White crystalline powder
Content	Not less than 99%, after drying for 2 hours at 105 °C
Volatile substances	Not more than 4%, determined by drying for 2 hours at 105 °C
Water insolubles	Not more than 0·3%
Readily oxidisable substances	No trace
Iron	Not more than 30 mg/kg

"*E 283 Potassium propionate*

Appearance :	White crystalline powder
Content :	Not less than 99 % after drying for two hours at 105 °C
Volatile substances :	Not more than 4 % after drying for two hours at 105 °C
Water-insoluble substances :	Not more than 0·3 %
Readily oxidizable substances :	No trace
Iron :	Not more than 30 mg/kg" **[2]**

E 290 Carbon dioxide

Appearance	Colourless gas
Content	Not less than 99% CO_2 by volume
Acidity	915 ml of gas bubbled through 50 ml of freshly boiled water must not render the latter more acid to methylorange than is 50 ml freshly boiled water to which has been added 1 ml of hydrochloric acid (0·01 N)

Reducing substances, hydrogen phosphide and sulphide	915 ml of gas bubbled through 25 ml of ammoniacal silver nitrate reagent to which has been added 3 ml of ammonia must not cause clouding or blackening of this solution
Carbon monoxide	A dilute solution of blood, after stirring with 915 ml of gas and adding a mixture of pyrogallol and tannic acid, must not be pink in colour but of a grey comparable to the colour produced in the same conditions by an equal volume of carbon dioxide obtained by decomposition of sodium bicarbonate with hydrochloric acid

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(R1) Corrigenda, Official Journal, English Special Edition, July 1975, p. 13.

(1) OJ No 12, 27/01/1964, p. 161/64.

(2) COBALT CHLORIDE TSC: DISSOLVE APPROX. 65 g OF COBALT CHLORIDE CoCl2.6H2O IN A SUFFICIENT QUANTITY OF A MIXTURE OF 25 ml HYDROCHLORIC ACID AND 975 ml OF WATER TO GIVE A TOTAL VOLUME OF 1 LITRE. PLACE EXACTLY 5 ml OF THIS SOLUTION IN A ROUND-BOTTOMED FLASK CONTAINING 250 ml OF IODINE SOLUTION, ADD 5 ml OF 3 % HYDROGEN PEROXIDE, THEN 15 ml OF A 20 % SOLUTION OF SODIUM HYDROXIDE. BOIL FOR 10 MINS, ALLOW TO COOL, ADD 2 g OF POTASSIUM IODIDE AND 20 ml OF 25 % SULPHURIC ACID. AFTER THE PRECIPITATE IS COMPLETELY DISSOLVED, TITRATE THE LIBERATED IODINE WITH SODIUM THIOSULPHATE (0.1 N) IN THE PRESENCE OF STARCH TS. (*) 1 ml OF SODIUM THIOSULPHATE (0.1 N) CORRESPONDS TO 23.80 mg OF CoCl2.6H2O. ADJUST FINAL VOLUME OF SOLUTION BY THE ADDITION OF A SUFFICIENT QUANTITY OF THE HYDROCHLORIC ACID/WATER MIXTURE TO GIVE A SOLUTION CONTAINING 59.5 mg OF CoCl2.6H2O PER ml.

(3) FERRIC CHLORIDE TSC: DISSOLVE APPROX. 55 g OF FERRIC CHLORIDE IN A SUFFICIENT QUANTITY OF A MIXTURE OF 25 ml OF HYDROCHLORIC ACID AND 975 ml OF WATER TO GIVE A TOTAL VOLUME OF 1 LITRE. PLACE 10 ml OF THIS SOLUTION IN A ROUND-BOTTOMED FLASK CONTAINING 250 ml OF IODINE SOLUTION, ADD 15 ml OF WATER AND 3 g OF POTASSIUM IODIDE; LEAVE THE MIXTURE TO STAND FOR 15 mins. DILUTE WITH 100 ml OF WATER THEN TITRATE THE LIBERATED IODINE WITH SODIUM THIOSULPHATE (0.1 N) IN THE PRESENCE OF STARCH TS. (*) 1 ml OF SODIUM THIOSULPHATE (0.1 N) CORRESPONDS TO 27.03 mg OF FeCl3.6H2O. ADJUST FINAL VOLUME OF SOLUTION BY THE ADDITION OF A SUFFICIENT QUANTITY OF THE HYDROCHLORIC ACID/WATER MIXTURE TO GIVE A SOLUTION CONTAINING 45.0 mg OF FeCl3.6H2O PER ml.

(4) COPPER SULPHATE TSC: DISSOLVE APPROX. 65 g OF COPPER SULPHATE CuSO4.5H2O IN A SUFFICIENT QUANTITY OF A MIXTURE OF 25 ml OF HYDROCHLORIC ACID AND 975 ml OF WATER TO GIVE A TOTAL VOLUME OF 1 LITRE. PLACE 10 ml OF THIS SOLUTION IN A ROUND-BOTTOMED FLASK CONTAINING 250 ml OF IODINE SOLUTION, ADD 40 ml OF WATER, 4 ml OF ACETIC ACID AND 3 g OF POTASSIUM IODIDE. TITRATE THE LIBERATED IODINE WITH SODIUM THIOSULPHATE (0.1 N) IN THE PRESENCE OF STARCH TS. (*) 1 ml OF SODIUM THIOSULPHATE (0.1 N) CORRESPONDS TO 24.97 mg OF CuSO4.5H2O. ADJUST FINAL VOLUME OF SOLUTION BY THE ADDITION OF A SUFFICIENT QUANTITY OF THE HYDROCHLORIC ACID/WATER MIXTURE TO GIVE A SOLUTION CONTAINING 62.4 mg OF CuSO4.5H2O PER ml.

(5) OTHER POTASSIUM SALTS OF SULPHUR DIOXIDE MAY BE PRESENT FOLLOWING DETERIORATION DUE TO STORAGE IN OPEN CONTAINERS.

(6) THE SPECIFICATION REFERS TO GLACIAL ACETIC ACID (CRYSTALLISABLE); FOR AQUEOUS SOLUTIONS, CALCULATE VALUES CORRESPONDING TO THEIR GLACIAL ACETIC ACID CONTENT.

(7) MAY CONTAIN A SLIGHT EXCESS OF ACETIC ACID OR SODIUM ACETATE.

(8) THE SPECIFICATION REFERS TO AN 80 - 85 % AQUEOUS SOLUTION; FOR WEAKER AQUEOUS SOLUTIONS, CALCULATE VALUES CORRESPONDING TO THEIR LACTIC ACID CONTENT.

(9) THE SPECIFICATION REFERS TO ANHYDROUS PROPIONIC ACID; FOR AQUEOUS SOLUTIONS, CALCULATE VALUES CORRESPONDING TO THEIR PROPIONIC ACID CONTENT.

(*) STARCH TS: TRITURATE 0.5 g STARCH (POTATO STARCH, MAIZE STARCH OR SOLUBLE STARCH) WITH 5 ml OF WATER; TO THE RESULTING PASTE ADD A SUFFICIENT QUANTITY OF WATER TO GIVE A TOTAL VOLUME OF 100 ml, STIRRING ALL THE TIME. BOIL FOR A FEW MINUTES, ALLOW TO COOL, FILTER. THE STARCH MUST BE FRESHLY PREPARED.

11.7.67 OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITIES No 148/1

COUNCIL DIRECTIVE

of 27 June 1967

on the use of certain preservatives for the surface treatment of citrus fruit and on the control measures to be used for the qualitative and quantitative analysis of preservatives in and on citrus fruit

(67/427/EEC)

THE COUNCIL OF THE EUROPEAN ECONOMIC COMMUNITY,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof;

Having regard to the proposal from the Commission;

Having regard to the Opinion of the European Parliament[1];

Having regard to the Opinion of the Economic and Social Committee[2];

Whereas, under Article 5 of the Council Directive of 5 November 1963[3] on the approximation of the laws of the Member States concerning the preservatives authorised for use in foodstuffs intended for human consumption, as last amended by Article 1 of the Council Directive of 14 December 1966,[4] Member States may, until 30 June 1967, maintain in force the provisions of their national laws relating to the surface treatment of citrus fruit with biphenyl (diphenyl), orthophenylphenol and sodium orthophenylphenate;

Whereas the use of those substances for the surface treatment of citrus fruit does not constitute a danger to health where the residual amount per kilogramme of whole fruit does not exceed 70 milligrammes of biphenyl and 12 milligrammes of orthophenylphenol and sodium orthophenylphenate, expressed as orthophenylphenol;

Whereas, moreover, the treatment carried out should be indicated in an appropriate manner at all stages of marketing;

Whereas, if the three substances in question are to be authorised at Community level, common rules must be laid down for the official control of treated citrus fruit;

Whereas a transitional period is necessary before the provisions of this Directive can be implemented by the Member States; whereas the provisions of national laws relating to the surface treatment of citrus fruit with the three preservatives in question should therefore be maintained in force until the end of that period;

Whereas a Member State should not be required to authorise the use of a preservative in foodstuffs produced and consumed in its own territory when there is no technological reason to justify such use;

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Council Directive of 5 November 1963 on the approximation of the laws of the Member States Concerning the preservatives authorised for use in foodstuffs for human consumption is hereby amended as follows:

1. In Article 2 (2), for the second sentence there shall be substituted the following:

> 'However, the laws of a Member State may totally exclude the use of any of the preservatives listed in the Annex only where there is no technological reason for using such preservative foodstuffs produced and consumed in its own territory.'

2. The following preservatives shall be added to those listed in Section I of the Annex:

[1] OJ No 63, 3.4.1967, p. 990/67.
[2] OJ No 64, 5.4.1967, p. 1005/67.
[3] OJ No 12, 27.1.1964, p. 161/64.
[4] OJ No 233, 20.12.1966, p. 3947/66

EEC No	Name	Conditions of use
E 230	Biphenyl (Diphenyl)	(a) Exclusively for surface treatment of citrus fruit; (b) At the time of marketing the citrus fruit (i) the residual amount per kg of citrus fruit (whole fruit) must not be greater than: for biphenyl: 70 mg, and for orthophenylphenol and sodium orthophenylphenate, used separately or together, expressed as orthophenylphenol: 12 mg;
E 231	Orthophenylphenol	(ii) the treatment must be indicated — in the wholesale trade, on invoices and on one external surface of the packaging, by the words: 'Preserved with...' giving the name of the substances used; — in the retail trade, by some visible indication giving the consumer clear information.
E 232	Sodium orthophenyl phenate	

3. Subparagraph (b) of Article 5 shall be deleted.

Article 2

The Member States shall take all measures necessary to ensure that the taking of samples and the qualitative and quantitative analysis of biphenyl, orthophenylphenol and sodium orthophenylphenate in and on citrus fruit are carried out in accordance with the provisions of Annexes I, II, III and IV to this Directive.

Article 3

1. Member States shall, not later than 1 July 1968, bring into force the measures necessary to comply with this Directive and shall forthwith inform the Commission thereof.

2. Until 1 July 1968 Member States may maintain in force the provisions of their national laws relating to the surface treatment of citrus fruit with biphenyl, orthophenylphenol and sodium orthophenylphenate.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 27 June 1967.

For the Council

The President

R. VAN ELSLANDE

ANNEX I

PROCEDURE FOR TAKING SAMPLES OF CITRUS FRUIT FOR PRESERVATIVE CONTROL

A. Taking of samples

I. Samples shall be taken using scientific methods which ensure that the samples are representative of the lot to be analysed.

II. The samples must satisfy at least the following requirements:

1. *Packaged goods* (crates, paperboard boxes, and similar containers)

Number of containers in the lot	Up to 20	From 21 to 500	From 501 to 1000	Above 1000
Minimum number of containers to be sampled	1	2	3	4
Mass, in kg, of fruit to be sampled per container	2	2	2	2

2. *Goods in bulk*

Mass of batch in kg	Up to 20	From 21 to 500	Above 500
Mass, in kg, to be sampled	2	4	8

III. By 'lot' is meant: a part of a consignment, which part has the same characteristics, such as variety, degree of ripeness, type of packaging.

B. Packaging and delivery of samples

1. The samples shall be placed in air-tight containers;
2. The containers shall be sealed;
3. The samples thus packaged shall be delivered as quickly as possible to the test laboratories.

ANNEX II

QUALITATIVE ANALYSIS FOR RESIDUES OF BIPHENYL, ORTHOPHENYLPHENOL AND SODIUM ORTHOPHENYLPHENATE IN CITRUS FRUIT PEEL

1. Purpose and scope

The method described below enables the presence of residues of biphenyl, orthophenylphenol (OPP) or sodium orthophenylphenate in the *peel* of citrus fruit to be detected. The sensitivity limit of this method, in absolute terms, is approximately 5 µg for biphenyl and 1 milligramme for OPP or sodium orthophenylphenate, which is the equivalent of 5 µg of biphenyl (5 ppm) and 1 milligramme of OPP (1 ppm) respectively in the peel of 1 kilogramme of citrus fruit.

When citrus fruit is treated with the above-mentioned products the residues deposited are found largely in the peel of the fruit. Quantitative analysis of such residues in the whole fruit therefore seems necessary only if they are found in the peel.

2. **Principle**

An extract is prepared from the peel using dichloromethane in an acid medium. The extract is concentrated and separated by thin layer chromatography using silica gel. The presence of biphenyl, orthophenylphenol or sodium orthophenylphenate is shown by fluorescence and colour tests.

3. **Reagents**

cyclohexane A.R.

dichloromethane A.R.

hydrochloric acid 25% (w/v)

silica gel GF 254 Merck or equivalent

0·5% solution of 2,4,7-trinitrofluorenone (Fluka, B.D.H or equivalent) (TNF) in acetone

0·1% solution of 2,6-dibromo-benzoquinone-4-chloroimide in ethanol (stable for up to one week if kept in the refrigerator)

concentrated solution of ammonia, S.G. : 0·9

standard 1% solution of pure biphenyl in cyclohexane

standard 1% solution of pure orthophenylphenol in cyclohexane

4. **Apparatus**

mixer

250 ml flask with ground glass joint and with a cooled reflux condenser

reduced pressure evaporator

micropipettes

thin layer chromatographic apparatus with plates measuring 20 × 20 cm

U.V. lamp (254 nm): the intensity should be such that a spot of 5 µg of biphenyl is visible

equipment for pulverising reagents

oven

5. **Method**

(a) *Preparation of the sample and extraction*

All the fruit in the sample for testing is cut in half. Half of each piece of fruit is kept for quantitative determination of residues of biphenyl and/or orthophenylphenol. Pieces of peel are taken from the other halves to give a sample of about 80 grammes. These pieces are chopped, crushed in the mixer and placed in the 250 ml flask; to this is added 1 ml of 25% hydrochloric acid and 100 ml of dichloromethane. The mixture is heated under reflux for ten minutes. After cooling and rinsing of the condenser with about 5 ml of dichloromethane, the mixture is filtered through a fluted filter. The solution is transferred to the evaporator and some porous granules are added. The solution is concentrated at reduced pressure at a temperature of 60 °C to a final volume of about 10 ml. If a rotary evaporator is used, the flask should be kept in a fixed position to avoid loss of biphenyl through the formation of a film of the product on the upper wall of the flask.

(b) *Chromatography*

30 grammes of silica gel and 60 ml of water are placed in a mixer and mixed for one minute. The mixture is then poured on to 5 chromatographic plates and spread to form a layer approximately 0·250 mm thick. The plates covered with this layer are subjected for fifteen minutes to a stream of hot air and then placed in an oven where they are kept for thirty minutes at a temperature of 110 °C.

After cooling each plate is divided into strips 2 cm wide, by parallel lines penetrating the covering layer down to the surface of the plate. 50 µl of the extract to be analysed are put, as a row of drops, close together on to each strip, approximately 1·5 cm from the edge. At least one strip is kept for the controls consisting of a deposit of 1 µl (that is, 10 µg) of the standard solutions of biphenyl and orthophenylphenol.

The chromatographic plates are developed in a mixture of cyclohexane and dichloromethane (25 : 95) in dishes previously lined with filter paper.

(c) *Detection and identification*

The presence of biphenyl and orthophenylphenol is shown by the appearance of spots in U.V. light (254 nm). The sodium orthophenylphenate has changed into orthophenylphenol during the extraction in an acid medium, and its presence can not therefore be distinguished from that of orthophenylphenol. The products are identified in the following manner:

(i) *biphenyl* gives a yellow spot in daylight when sprayed with the TNF solution;

(ii) *orthophenylphenol* gives a blue spot when sprayed with the solution of 2,6-dibromobentoquinone-4-chlorimide, followed by rapid passage through a stream of hot air and exposure to an ammonia-saturated atmosphere.

ANNEX III

QUANTITATIVE ANALYSIS OF THE RESIDUES OF BIPHENYL IN CITRUS FRUIT

1. Purpose and scope

The method described below gives a quantitative analysis of the residues of biphenyl in citrus fruit (whole fruit). The accuracy of the method is ± 10% for a biphenyl content greater than 10 milligrammes per kilogramme of fruit (10 ppm).

2. Principle

After distillation in an acid medium and extraction by cyclohexane, the extract is chromatographed in a thin layer on silica gel. The chromatogram is developed and the biphenyl is eluted and determined spectrophotometrically at 248 nm.

3. Reagents

concentrated sulphuric acid solution

silicone-based anti-foaming emulsion

cyclohexane A.R.

hexane A.R.

ethanol A.R.

anhydrous sodium sulphate

silica gel GF 254 Merck or equivalent

standard 1% solution of pure biphenyl in cyclohexane: dilute with cyclohexane to obtain the following three solutions:

(a) 0·6 µg/µl (b) 1 µg/µl (c) 1·4 µg/µl

4. Apparatus

1 mixer (1 litre capacity)

2-litre distillation flask with modified Clevenger-type separator[1] and cooled reflux condenser

10 ml graduated flask

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[1] See figure on page 180.

50 µl micropipettes

thin layer chromatographic apparatus with 20×20 cm plates

oven

centrifuge with 15 ml conical tubes

U.V. spectrophotometer

5. **Method**

(a) *Preparation of the sample and extraction*

All the fruit in the sample for testing is cut in half.

Half of each piece of fruit is kept for qualitative analysis for residues of biphenyl, OPP or sodium orthophenylphenate. The other halves are put all together and shredded in a mill or crushed until a homogeneous mixture is obtained. From this at least two sub-samples of 200 grammes are taken for analysis in the following manner. Each sub-sample is placed in a mixer with 100 ml of water and mixed at slow speed for several seconds. Water is added until the volume of the mixture reaches three-quarters of the capacity of the mixer, and the mixture is then mixed for five minutes at full speed. The resulting purée is transferred to the 2-litre distillation flask. The mixer is rinsed with water and the rinsings added to the contents of the flask. (The total quantity of water to be used in the mixing and rinsing is 1 l). To the mixture are added 2 ml sulphuric acid, 1 ml anti-foaming emulsion and several porous granules. The separator and reflux condenser are fitted on to the flask. Distilled water is poured into the separator until the water level is well past the lower arm of the lateral return tube, followed by 7 ml of cyclohexane. This is distilled for about two hours. The contents of the separator are then collected in the 10 ml graduated flask, the separator is rinsed with about 1·5 ml of cyclohexane and the rinsings added to the contents of the flask, which are then brought up to volume with cyclohexane. Finally a little anhydrous socium sulphate is added and the mixture is shaken.

(b) *Chromatography*

30 grammes of silica gel and 60 ml of water are placed in a mixer and mixed for one minute. The mixture is then poured on to 5 chromatographic plates and spread to form a layer approximately 0·250 mm thick. The plates covered with this layer are subjected for fifteen minutes to a stream of hot air and then placed in an oven where they are kept for thirty minutes at a temperature of 110 °C. After cooling each plate is divided into four strips 4·5 cm wide, by parallel lines penetrating the covering layer down to the surface of the plate. 50 µl of the extract to be analysed are put, as a row of drops, close together on to one of the strips approximately 1·5 cm from the egde of the plate. On to each of the three other strips are put in the same way 50 µl of the standard solutions (a), (b) and (c), corresponding respectively to 30, 50 and 70 µl levels of biphenyl.

If the analyses are made in series, standard solutions need not be put on to each plate and a standard curve may be produced from the average of the values obtained *from at least five plates,* with the same standard amounts.

(c) *Development of chromatograms and elution*

The chromatograms are developed with hexane to a height of 17 cm in dishes previously lined with filter paper. The plates are air dried. The areas in which the biphenyl is localised are picked out in U.V. light (254 nm), and marked off in rectangles of equal areas.

The areas thus marked off are immediately scraped clean with a spatula, through the full thickness of the supporting layer. The biphenyl is extracted from this by 10 ml of ethanol, for ten minutes, shaking several times. The mixture is transferred to the centrifuge tubes and centrifuged for five minutes at 2500 r.p.m.

A sample control area of the same size is taken by the same method. If the analyses are made in series, this control area is taken from an unused strip of the plate; if the analyses are made individually, it is taken from one of the strips containing a standard solution located below the area containing the biphenyl.

(d) *Spectrophotometric determination*

The supernatant liquid is decanted into the spectrophotometer cells and the extinction determined at 248 nm and compared with a control extract from a chromatographic area free from biphenyl.

6. **Calculation of results**

A standard curve is drawn, plotting the biphenyl values of 30, 50 and 70 µg against the corresponding extinctions, as determined on the spectrophotometer. This gives a straight line which passes through the origin. This graph allows the biphenyl content of the samples to be read directly in ppm from the extinction value of their extracts.

ANNEX IV

QUANTITATIVE ANALYSIS OF THE RESIDUES ORTHOPHENYLPHENOL AND SODIUM ORTHOPHENYLPHENATE IN CITRUS FRUIT

1. **Purpose and scope**

The method described below enables a quantitative analysis of the residues of orthophenylphenol (OPP) and sodium orthophenylphenate in citrus fruit (whole fruit) to be made. The method gives results which for an OPP or sodium orthophenylphenate content of the order of 12 ppm are low by an average value of between 10% and 20%.

2. **Principle**

After distillation in an acid medium and extraction by di-isopentyl ether, the extract is purified and treated with a solution of 4-amino-2,3-dimethyl-1-phenyl-3-pyrazolin-5-one (= 4-aminoantipyrine). A red colour develops the intensity of which is measured by spectrophotometry at 510 nm.

3. **Reagents**

70% orthophosphoric acid

silicone-based anti-foaming emulsion

di-isopentyl ether A.R.

purified cyclohexane; shake three times with a 4% solution of sodium hydroxide, wash three times with distilled water

4% sodium hydroxide solution

buffer solution at pH 10·4: into a 2-litre graduated flask put 6·64 grammes of boric acid, 8·00 grammes of potassium chloride and 93·1 ml of N sodium hydroxide solution: mix and bring up to calibration mark with distilled water

reagent I: dissolve 1·0 grammes of 4-amino-2,3-dimethyl-1-phenyl-3-pyrazolin-5-one (= 4-aminotipyrine) in 100 ml of distilled water

reagent II: dissolve 2·0 grammes of potassium ferrocyanide in 100 ml of distilled water. Reagents I and II must be kept in brown glass flasks and are only stable for approximately fourteen days

silica gel

standard solution: dissolve 10 milligrammes of pure OPP in 1 ml of 0·1 N NaOH; dilute to 100 ml with a 0·2 m sodium borate solution (1 ml = 100 µg). For the standard solution, dilute 1 : 10 with the buffer solution.

4. **Apparatus**

shredding or crushing mill

mixer

1-litre distillation flask with modified Clevenger type separator[1] and reflux condenser

infra-red bath

200 ml separating funnel

graduated cylinders of 25 and 100 ml

graduated flasks of 25 and 100 ml

1 to 10 ml pipettes

0·5 ml graduated pipettes

spectrophotometer with 5 cm cells

5. **Method**

All the fruit in the sample for checking is cut in half. Half of each piece of fruit is kept for qualitative analysis for residues of biphenyl, OPP or sodium orthophenylphenate. The other halves are put all together and shredded in a mill or crushed until a homogeneous mixture is obtained. From this at least two sub-samples of 250 grammes are taken for analysis in the following manner.

Each sub-sample is placed in a mixer with 500 ml of water and mixed until a very fine homogeneous mixture is obtained in which the oily cells are no longer perceptible. A sample of 150 to 300 grammes of the purée is taken, depending on the presumed OPP content and placed in the 1-litre distillation flask with a quantity of water sufficient to dilute the mixture to 500 grammes in the flask. After the addition of 10 ml of 70% orthophosphoric acid, several porous granules and 0·5 ml of anti-foaming emulsion, the separator and the reflux condenser are fitted on to the flask. 10 ml of di-isopentyl ether is put into the separator and the flask is heated gently in the infra-red bath, without allowing the purée to boil or foam. After distilling for about six hours, the contents of the separator are poured into the 200 ml separating funnel, and the separator and the condenser are rinsed with 60 ml of cyclohexane and then with 60 ml of water. The rinsings are added to the contents of the separating funnel. The mixture is shaken vigorously and when the phases have separated the aqueous phase is discarded.

To extract the OPP, the organic phase is shaken vigorously five times, each time for three minutes, with 10 ml of 4% sodium hydroxide. The alkaline solutions are combined, neutralised to pH 9-10 with orthophosphoric acid in the presence of phenolphthalein paper, and diluted to 100 ml with distilled water. A pinch of silica gel is added in order to clarify the solution which will have a slightly cloudy appearance. The solution is then shaken and filtered through a dry, fine-grain filter. Since the colouring is developed with the maximum of accuracy and precision using quantities of OPP of between 10 and 70 µg, an aliquot sample of between 0·5 and 10 ml of solution is taken with a pipette, taking into account the quantities of OPP which might be expected to be found. The sample is placed in a 25 ml graduated flask; to this are added 0·5 ml of reagent I, 10 ml of the buffer solution and then 0·5 ml of reagent II. The mixture is made up to the calibration mark with the buffer solution and shaken vigorously.

After five minutes the extinction of the red colouring at 510 nm is measured with the spectrophotometer in comparison with a control containing no extract. The colour does not lose intensity within thirty minutes. Evaluation is made by referring to a standard curve drawn under the same conditions using the standard OPP solution.

6. **Observations**

For each analysis it is recommended that the spectrophotometric determination be made in duplicate with different volumes of the neutralised alkaline extract.

Non-treated citrus fruit give by this method a 'blank' reading of up to 0·5 ppm for oranges and 0·8 ppm for lemons.

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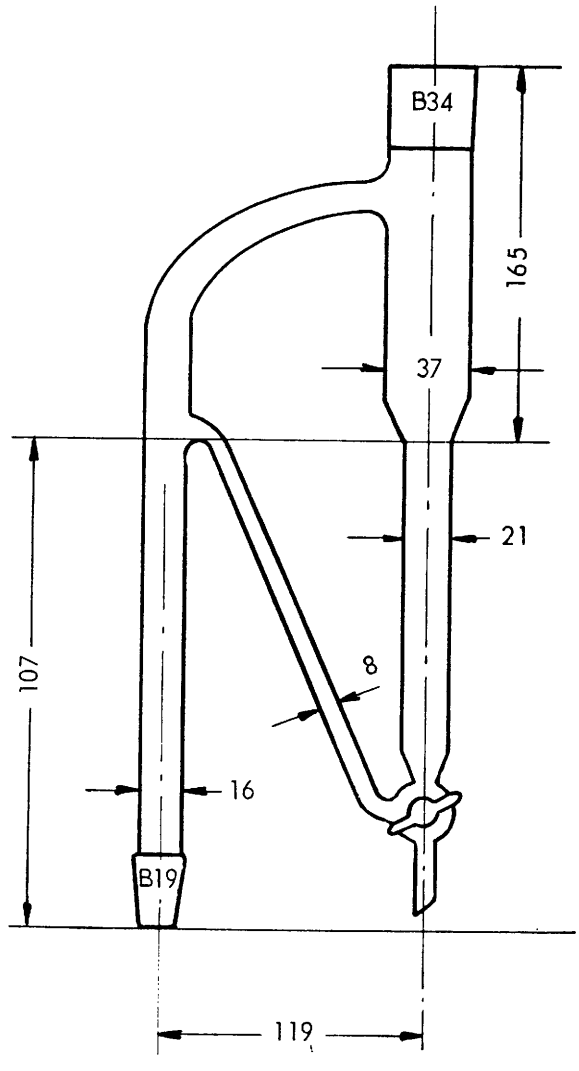
[1] See figure on page 180.

CLEVENGER

(Annex III, Chapter 4;

Annex IV, Chapter 4)



370L0357

70/357/EEC: COUNCIL DIRECTIVE OF 13 JULY 1970 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES CONCERNING THE ANTIOXIDANTS AUTHORIZED FOR USE IN FOODSTUFFS INTENDED FOR HUMAN CONSUMPTION

OFFICIAL JOURNAL NO L 157, 18/07/1970, P. 31; ENGLISH SPECIAL EDITION, 1970 II, P. 429
DATE OF NOTIFICATION: 13/07/1970
DATE OF TRANSPOSITION: 13/07/1971; SEE ART. 11

AMENDED BY

172B
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE KINGDOM OF DENMARK, IRELAND AND THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND AND THE ADJUSTMENTS TO THE TREATIES **[1]**
OFFICIAL JOURNAL NO L 73, 27/03/1972, P.121; ENGLISH SPECIAL EDITION, 27/03/1972, P. 121

374L0412
74/412/EEC: COUNCIL DIRECTIVE OF 1 AUGUST 1974 **[2]**
OFFICIAL JOURNAL NO L 221, 12/08/1974, P. 18
DATE OF NOTIFICATION: 05/08/1974

378L0143
78/143/EEC: COUNCIL DIRECTIVE OF 30 JANUARY 1978 **[3]**
OFFICIAL JOURNAL NO L 44, 15/02/1978, P. 18
DATE OF NOTIFICATION: 01/02/1978
DATE OF TRANSPOSITION: 01/02/1979; SEE ART. 4

179H
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE HELLENIC REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES **[4]**
OFFICIAL JOURNAL NO L 291, 19/11/1979, P. 110

381L0962
81/962/EEC: COUNCIL DIRECTIVE OF 24 NOVEMBER 1981 **[5]**
OFFICIAL JOURNAL NO L 354, 09/12/1981, P. 22
DATE OF NOTIFICATION: 01/12/1981
DATE OF TRANSPOSITION: 01/12/1982; SEE ART. 3

385L0007
85/7/EEC: COUNCIL DIRECTIVE OF 19 DECEMBER 1984 **[6]**
OFFICIAL JOURNAL NO L 2, 03/01/1985, P. 22
DATE OF NOTIFICATION: 27/12/1984

185I
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE KINGDOM OF SPAIN AND THE PORTUGUESE REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES **[7]**
OFFICIAL JOURNAL NO L 302, 15/11/1985, P. 215

387L0055
87/55/EEC: COUNCIL DIRECTIVE OF 18 DECEMBER 1986 [8]
OFFICIAL JOURNAL NO L 24, 27/01/1987, P. 41
DATE OF NOTIFICATION: 24/12/1986

ARTICLE 1

MEMBER STATES SHALL NOT AUTHORIZE THE USE, FOR THE PROTECTION OF FOODSTUFFS INTENDED FOR HUMAN CONSUMPTION (HEREINAFTER CALLED "FOODSTUFFS") AGAINST DETERIORATION CAUSED BY OXIDATION, SUCH AS FAT DETERIORATION AND COLOUR CHANGES IN FOODSTUFFS CAUSED BY AUTOXIDATION, OF ANY SUBSTANCES OTHER THAN THOSE LISTED IN PARTS I TO III OF THE ANNEX TO THIS DIRECTIVE WHICH MAY, IF NECESSARY, BE DISSOLVED IN OR DILUTED WITH THE SUBSTANCES LISTED IN PART IV OF THE ANNEX.

" ARTICLE 2

1. BY WAY OF DEROGATION FROM ARTICLE 1, MEMBER STATES MAY AUTHORIZE IN THEIR TERRITORY THE USE OF CALCIUM DISODIUM ETHYLENE DIAMINE TETRA-ACETATE IN FOODSTUFFS UNTIL " 31 DECEMBER 1988 " **[8]**.

2. BEFORE THAT DATE THE COMMISSION SHALL RE-EXAMINE THE PROVISIONS OF PARAGRAPH 1 AND PROPOSE ANY NECESSARY AMENDMENTS TO THE COUNCIL. " **[5]**

ARTICLE 3

1. WHERE THE USE IN FOODSTUFFS OF ONE OF THE SUBSTANCES LISTED IN THE ANNEX, OR THE LEVEL OF ONE OR MORE OF THE COMPONENTS REFERRED TO IN ARTICLE 4 CONTAINED IN SUCH SUBSTANCES, MIGHT ENDANGER HUMAN HEALTH, A MEMBER STATE MAY, FOR A MAXIMUM PERIOD OF ONE YEAR, SUSPEND THE AUTHORIZATION TO USE THAT SUBSTANCE OR REDUCE THE MAXIMUM AUTHORIZED LEVEL OF ONE OR MORE OF THE COMPONENTS IN QUESTION. IT SHALL INFORM THE COMMISSION THEREOF FORTHWITH AND THE COMMISSION SHALL CONSULT THE MEMBER STATES.

2. THE COUNCIL, ACTING UNANIMOUSLY ON A PROPOSAL FROM THE COMMISSION, SHALL DECIDE WITHOUT DELAY WHETHER THE LIST IN THE ANNEX SHOULD BE AMENDED, AND, IF SO, ADOPT BY DIRECTIVE THE NECESSARY AMENDMENTS. THE COUNCIL, ACTING BY A QUALIFIED MAJORITY, ON A PROPOSAL FROM THE COMMISSION, MAY ALSO, IF NECESSARY, EXTEND FOR A MAXIMUM OF ONE YEAR THE PERIOD SET IN THE FIRST SENTENCE OF PARAGRAPH 1.

ARTICLE 4

THE MEMBER STATES SHALL TAKE ALL MEASURES NECESSARY TO ENSURE THAT THE SUBSTANCES LISTED IN THE ANNEX AND INTENDED FOR USE IN FOODSTUFFS SATISFY:

(a) THE FOLLOWING GENERAL CRITERIA OF PURITY:

" - THEY MUST NOT CONTAIN MORE THAN 3 MILLIGRAMMES PER KILOGRAMME OF ARSENIC OR MORE THAN 10 MILLIGRAMMES PER KILOGRAMME OF LEAD; " (R1)
" - THEY MUST NOT CONTAIN MORE THAN 50 MILLIGRAMMES PER KILOGRAMME OF COPPER AND ZINC TAKEN TOGETHER, OF WHICH THE ZINC CONTENT MUST NOT BE HIGHER THAN 25

MILLIGRAMMES PER KILOGRAMME " (R1), ALWAYS SUBJECT HOWEVER TO ANY EXCEPTIONS IMPLICIT IN THE SPECIFIC CRITERIA REFERRED TO IN SUBPARAGRAPH (b);
- THEY MUST NOT CONTAIN ANY MEASURABLE TRACE OF TOXICOLOGICALLY DANGEROUS ELEMENTS, IN PARTICULAR OTHER HEAVY METALS, ALWAYS SUBJECT HOWEVER TO ANY EXCEPTIONS IMPLICIT IN THE SPECIFIC CRITERIA REFERRED TO IN SUBPARAGRAPH (b);

(b) THE SPECIFIC CRITERIA OF PURITY LAID DOWN IN ACCORDANCE WITH ARTICLE 5 (1).

ARTICLE 5

1. THE COUNCIL SHALL, ACTING UNANIMOUSLY ON A PROPOSAL FROM THE COMMISSION, LAY DOWN BY DIRECTIVE THE SPECIFIC CRITERIA OF PURITY FOR THE SUBSTANCES LISTED IN PARTS I TO III OR IV (4) TO (7) OF THE ANNEX TO THIS DIRECTIVE.

2. THE PROCEDURE LAID DOWN IN ARTICLE 6 SHALL BE USED TO DETERMINE:

- THE METHODS OF ANALYSIS NEEDED TO VERIFY THAT THE GENERAL AND SPECIFIC CRITERIA OF PURITY REFERRED TO IN ARTICLE 4 ARE SATISFIED;
- THE PROCEDURE FOR TAKING SAMPLES AND THE METHODS FOR THE QUALITATIVE AND QUANTITATIVE ANALYSIS OF ANTIOXIDANTS IN AND ON FOODSTUFFS.

ARTICLE 6

1. WHERE THE PROCEDURE LAID DOWN IN THIS ARTICLE IS TO BE FOLLOWED, MATTERS SHALL BE REFERRED BY THE CHAIRMAN EITHER ON HIS OWN INITIATIVE OR AT THE REQUEST OF THE REPRESENTATIVE OF A MEMBER STATE, TO THE STANDING COMMITTEE FOR FOODSTUFFS (HEREINAFTER CALLED THE "COMMITTEE") SET UP BY COUNCIL DECISION OF 13 NOVEMBER 1969 (1).

2. THE REPRESENTATIVE OF THE COMMISSION SHALL SUBMIT TO THE COMMITTEE A DRAFT OF THE MEASURES TO BE ADOPTED. THE COMMITTEE SHALL DELIVER ITS OPINION ON THE DRAFT WITHIN A TIME LIMIT SET BY THE CHAIRMAN ACCORDING TO THE URGENCY OF THE MATTER. OPINIONS SHALL BE DELIVERED BY A MAJORITY OF " fifty-four " **[7]** VOTES, THE VOTES OF THE MEMBER STATES BEING WEIGHTED AS PROVIDED IN ARTICLE 148 (2) OF THE TREATY. THE CHAIRMAN SHALL NOT VOTE.

" 3. (a) " (R1) THE COMMISSION SHALL ADOPT THE MEASURES ENVISAGED WHERE THEY ARE IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE.

(b) WHERE THE MEASURES ENVISAGED ARE NOT IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE, OR IF NO OPINION IS DELIVERED, THE COMMISSION SHALL WITHOUT DELAY PROPOSE TO THE COUNCIL THE MEASURES TO BE ADOPTED. THE COUNCIL SHALL ACT BY A QUALIFIED MAJORITY.

(c) IF WITHIN THREE MONTHS OF THE PROPOSAL BEING SUBMITTED TO IT, THE COUNCIL HAS NOT ACTED, THE PROPOSED MEASURES SHALL BE ADOPTED BY THE COMMISSION.

ARTICLE 7

THE PROVISIONS OF " ARTICLE 6 " (R1) SHALL APPLY " FOR A PERIOD OF TWO YEARS FROM THE DATE ON WHICH THE MATTER WAS FIRST REFERRED TO THE COMMITTEE AFTER 1 JANUARY 1985 " **[6]**, EITHER UNDER ARTICLE 6 (1) OR UNDER ANY OTHER CORRESPONDING PROVISION.

ARTICLE 8

1. MEMBER STATES SHALL TAKE ALL MEASURES NECESSARY TO ENSURE THAT THE SUBSTANCES LISTED IN PARTS I TO III OF THE ANNEX AND INTENDED FOR USE IN FOODSTUFFS FOR THE PURPOSES MENTIONED IN ARTICLE 1 ARE PLACED ON THE MARKET ONLY IF THEIR PACKAGINGS OR CONTAINERS BEAR THE FOLLOWING INFORMATION:

(a) THE NAME AND ADDRESS OF THE MANUFACTURER, OR OF A SELLER RESPONSIBLE WITHIN THE MEANING OF THE LAWS OF THE MEMBER STATE IN WHICH HE IS RESIDENT; A PERSON IMPORTING A PRODUCT FROM A THIRD COUNTRY SHALL BE TREATED AS THE MANUFACTURER;

(b) THE NUMBER AND NAME OF THE SUBSTANCE AS THEY ARE GIVEN IN THE ANNEX TO THIS DIRECTIVE;

(c) THE WORDS "FOR FOODSTUFFS (RESTRICTED USE)";

(d) IN THE CASE OF A MIXTURE COMPOSED OF SUBSTANCES LISTED IN THE ANNEX OR INCLUDING OTHER SUBSTANCES:

- THE NAME OF EACH COMPONENT OR, WHERE APPROPRIATE, ITS NUMBER AS GIVEN IN THE ANNEX TO THIS DIRECTIVE;
- PERCENTAGES OF THE COMPONENTS, WHERE THERE IS ONE OR MORE OF THE SUBSTANCES LISTED IN PARTS I TO III OR IV (7) OF THE ANNEX TO THIS DIRECTIVE, OR WHERE THIS REQUIREMENT IS LAID DOWN IN PROVISIONS RELATING TO OTHER CATEGORIES OF ADDITIVES.

" 2. Member States shall not prohibit the substances listed in the Annex from entering their territory and being placed on sale therein on the ground that they consider the labelling inadequate, if the particulars required under paragraph 1 appear on the packages or containers, and if the particulars required under paragraph 1 (b), (c) and (d) are expressed in at least one official language of the Community.
However, any importing Member State may require that the latter particulars be expressed in its official language or languages. " **[1]**

ARTICLE 9

THIS DIRECTIVE SHALL NOT AFFECT NATIONAL LAWS SPECIFYING THE FOODSTUFFS TO WHICH THE SUBSTANCES LISTED IN PARTS I TO III OF THE ANNEX TO THIS DIRECTIVE MAY BE ADDED AND THE CONDITIONS GOVERNING THE ADDITION OF SUCH SUBSTANCES. HOWEVER, SUCH LAWS MUST NOT HAVE THE EFFECT OF TOTALLY EXCLUDING THE USE IN FOODSTUFFS OF ANY OF THE SUBSTANCES LISTED IN THE ANNEX TO THIS DIRECTIVE.

" ARTICLE 10

1. THIS DIRECTIVE SHALL APPLY TO SUBSTANCES LISTED IN THE ANNEX TO THIS DIRECTIVE WHICH ARE INTENDED FOR USE IN FOODSTUFFS, AND ALSO TO FOODSTUFFS IMPORTED INTO THE COMMUNITY.

2. WHERE THE SUBSTANCES OR FOODSTUFFS ARE INTENDED FOR EXPORTATION FROM THE COMMUNITY, THIS DIRECTIVE SHALL APPLY NEITHER TO SUBSTANCES LISTED IN THE ANNEX, NOR TO FOODSTUFFS. " (R1)

ARTICLE 11

1. THE MEMBER STATES SHALL, WITHIN A PERIOD OF ONE YEAR FOLLOWING NOTIFICATION OF THIS DIRECTIVE, AMEND THEIR LAWS IN ACCORDANCE WITH THE ABOVE PROVISIONS AND SHALL FORTHWITH INFORM THE COMMISSION THEREOF. THE LAWS THUS AMENDED SHALL APPLY NOT LATER THAN TWO YEARS AFTER THAT NOTIFICATION.

2. WHERE THE FIRST PARAGRAPH OF ARTICLE 2 IS APPLICABLE, THE PERIODS SET IN THE ABOVE PARAGRAPH SHALL RUN FROM THE DATE OF EXPIRY OF THE PERIOD REFERRED TO IN THAT PARAGRAPH.

ARTICLE 12

THIS DIRECTIVE SHALL ALSO APPLY IN THE FRENCH OVERSEAS DEPARTMENTS.

ARTICLE 13

THIS DIRECTIVE IS ADDRESSED TO THE MEMBER STATES.

ANNEX

PART I

ANTIOXIDANTS

EEC NO / NAME

E 300 L-ASCORBIC ACID

E 301 SODIUM L-ASCORBATE (SODIUM SALT OF L-ASCORBIC ACID)

E 302 CALCIUM L-ASCORBATE (CALCIUM SALT OF L-ASCORBIC ACID)

E 303 "..." **[5]**

E 304 6-PALMITYL-L-ASCORBIC ACID (ASCORBYL PALMITATE)

E 306 TOCOPHEROL-RICH EXTRACTS OF NATURAL ORIGIN

E 307 SYNTHETIC " alpha " (R1) -TOCOPHEROL

E 308 SYNTHETIC " gamma " (R1) -TOCOPHEROL

E 309 SYNTHETIC " delta " (R1) -TOCOPHEROL

" E 310 PROPYL GALLATE " **[3]**

E 311 OCTYL GALLATE

E 312 " DODECYL " (R1) GALLATE

E 320 BUTYLATED HYDROXYANISOLE (BHA)

E 321 BUTYLATED " HYDROXYTOLUENE " (R1) (BHT)

PART II

SUBSTANCES HAVING AN ANTIOXIDANT EFFECT AND ALSO OTHER FUNCTIONS

EEC NO / NAME

E 220 SULPHUR DIOXIDE

E 221 SODIUM SULPHITE

E 222 " SODIUM HYDROGEN SULPHITE (SODIUM BISULPHITE) " (R1)

E 223 SODIUM " METABISULPHITE " (R1) (SODIUM PYROSULPHITE OR SODIUM DISULPHITE)

E 224 POTASSIUM METABISULPHITE (POTASSIUM PYROSULPHITE OR POTASSIUM DISULPHITE)

E 226 CALCIUM SULPHITE

E 322 LECITHINS

PART III

SUBSTANCES CAPABLE OF INCREASING THE ANTIOXIDANT EFFECT OF OTHER SUBSTANCES

EEC NO / NAME

E 270 LACTIC ACID

E 325 SODIUM LACTATE (SODIUM SALT OF LACTIC ACID)

E 326 POTASSIUM LACTATE (POTASSIUM SALT OF LACTIC ACID)

E 327 CALCIUM LACTATE (CALCIUM SALT OF LACTIC ACID)

E 330 CITRIC ACID

E 331 SODIUM CITRATES (SODIUM SALTS OF CITRIC ACID)

E 332 POTASSIUM CITRATES (POTASSIUM SALTS OF CITRIC ACID)

E 333 CALCIUM CITRATES (CALCIUM SALTS OF CITRIC ACID)

E 334 TARTARIC ACID

E 335 SODIUM TARTRATES (SODIUM SALTS OF TARTARIC ACID)

E 336 POTASSIUM TARTRATES (POTASSIUM SALTS OF TARTARIC ACID)

E 337 SODIUM POTASSIUM TARTRATE

E 338 ORTHOPHOSPHORIC ACID

E 339 SODIUM ORTHOPHOSPHATES (SODIUM SALTS OF ORTHOPHOSPHORIC ACID)

E 340 POTASSIUM ORTHOPHOSPHATES (POTASSIUM SALTS OF ORTHOPHOSPHORIC ACID)

E 341 CALCIUM ORTHOPHOSPHATES (CALCIUM SALTS OF ORTHOPHOSPHORIC ACID)

E 372c CITRIC ACID ESTER OF MONO AND DI-GLYCERIDES OF FOOD FATTY ACIDS (CITROGLYCERIDES)

PART IV

SUBSTANCES IN WHICH THE SUBSTANCES LISTED IN PARTS I TO III MAY BE DISSOLVED OR DILUTED

NAME

1. DRINKING WATER, DEMINERALIZED WATER, DISTILLED WATER

2. EDIBLE OILS

3. EDIBLE FATS

4. ETHYL ALCOHOL

5. GLYCEROL

6. SORBITOL

7. PROPYLENE GLYCOL (1, 2- " propanediol " (R1))

(R1) Corrigenda, Official Journal, English Special Edition, July 1975, p. 74.

(1) OJ No L 291, 19/11/1969, p. 9.

378L0664

78/664/EEC: COUNCIL DIRECTIVE OF 25 JULY 1978 LAYING DOWN SPECIFIC CRITERIA OF PURITY FOR ANTIOXIDANTS WHICH MAY BE USED IN FOODSTUFFS INTENDED FOR HUMAN CONSUMPTION

OFFICIAL JOURNAL NO L 223, 14/08/1978, P. 30
DATE OF NOTIFICATION: 31/07/1978
DATE OF TRANSPOSITION: 01/02/1980; SEE ART. 3

AMENDED BY

382L0712
82/712/EEC: COUNCIL DIRECTIVE OF 18 OCTOBER 1982 **[1]**
OFFICIAL JOURNAL NO L 297, 23/10/1982, P. 31
DATE OF NOTIFICATION: 29/10/1982
DATE OF TRANSPOSITION: 30/06/1984; SEE ART. 2

ARTICLE 1

THE SPECIFIC CRITERIA OF PURITY REFERRED TO IN ARTICLE 5 (1) OF DIRECTIVE 70/357/EEC (1) ARE SET OUT IN THE ANNEX TO THIS DIRECTIVE.

ARTICLE 2

" 1. THIS DIRECTIVE DOES NOT AFFECT NATIONAL MEASURES IN EXISTENCE AT THE TIME OF ITS NOTIFICATION UNDER WHICH SPECIFIC CRITERIA OF PURITY ARE SET FOR DL-TARTARIC ACID AND SALTS THEREOF.

2. THE COUNCIL, ACTING UNANIMOUSLY ON A PROPOSAL FROM THE COMMISSION, SHALL DECIDE BEFORE 1 JANUARY 1985 ON THE CRITERIA OF PURITY REFERRED TO IN PARAGRAPH 1. " **[1]**

ARTICLE 3

MEMBER STATES SHALL BRING INTO FORCE THE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS NECESSARY TO COMPLY WITH THIS DIRECTIVE NOT LATER THAN 18 MONTHS AFTER NOTIFICATION OF THIS DIRECTIVE. THEY SHALL FORTHWITH INFORM THE COMMISSION THEREOF.

ARTICLE 4

THIS DIRECTIVE IS ADDRESSED TO THE MEMBER STATES.

ANNEX

SPECIFIC CRITERIA OF PURITY FOR ANTIOXIDANTS WHICH MAY BE USED IN FOODSTUFFS INTENDED FOR HUMAN CONSUMPTION

General remarks

(a) Except where otherwise stated, the quantities and percentages shall be calculated by mass on the basis of the anhydrous form of the substance.

(b) Where the substance in question is not anhydrous at the outset and where 'volatile matter' is involved, the latter shall include all moisture, including water of crystallization.

(c) Where the drying temperature and time are not stated, the latter shall be understood to mean 'to constant weight' and the former shall be 105 °C.

(d) Where the interpretation of the criteria set out below require that certain technical data such as 'vacuum' data be defined, the methods of analysis established pursuant to Article 5 (2) of the Directive concerning antioxidants shall be referred to.

(e) Where the concentration of a solution is given, this shall be taken to mean mass/volume except where otherwise stated.

(f) Temperatures shall always be stated in degrees centigrade (Celsius).

(g) The specific criteria of purity applicable to substances E 220 to E 224, E 226 and E 270 are laid down by Directive 65/66/EEC.(2)

(h) The specific criteria of purity applicable to sorbitol, glycerol and to substance E 472 (c) are laid down by Council Directive 78/663/EEC.(3)

E 300 — L-ascorbic acid

Chemical description	(+)-L-ascorbic acid; 3-oxo-L-gulofuranolactone; $C_6H_8O_6$.
Appearance	White or pale yellow crystalline powder.
Melting range	189 to 193 °C with slight decomposition.
Content	Not less than 99 % $C_6H_8O_6$ on a volatile matter-free basis.
Specific optical rotatory power	$[\alpha]_D^{20}$ = + 20·5 to + 21·5° (C = 10 % aqueous).
Volatile matter	Not more than 0·4 % determined by drying at room temperature for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide.
Sulphated ash	Not more than 0·1 % on a volatile matter-free basis determined by calcination at 800 ± 25 °C.
pH	2·4 to 2·8 in 2 % aqueous solution.

E 301 — Sodium L-ascorbate

Chemical description	Sodium salt of (+)-L-ascorbic acid; 3-oxo-L-gulofuranolactone; sodium enolate; $C_6H_7O_6Na$.

Appearance	White or pale yellow crystalline powder.
Content	Not less than 99 % $C_6H_7O_6Na$ on a volatile matter-free basis.
Specific optical rotatory power	$[\alpha]_D^{20}$ = + 103 to + 106° (C = 5 % aqueous).
Volatile matter	Not more than 0·3 % determined by drying at room temperature for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide.
pH	6·0 to 8·0 in 10 % aqueous solution.

E 302 — Calcium L-ascorbate

Chemical description	Calcium salt of (+)-L-ascorbic acid; $(C_6H_7O_6)_2Ca \cdot 2H_2O$.
Appearance	White or very pale grey crystalline powder.
Content	Not less than 99 % $(C_6H_7O_6)_2Ca \cdot 2H_2O$ on a volatile matter-free basis.
Specific optical rotatory power	$[\alpha]_D^{20}$ = + 95 to + 97° (C = 5 % aqueous)
Volatile matter	Not more than 0·3 % (4) determined by drying at room temperature for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide.
pH	6·0 to 7·5 in 10 % aqueous solution.

E 303 — 5,6-Diacetyl-L-ascorbic acid

Chemical description	Ascorbyl diacetate, derivative of (+)-L-ascorbic acid; $C_{10}H_{12}O_8$.
Appearance	White or pale yellow crystalline powder.
Melting range	155 to 158 °C.
Content	Not less than 99 % $C_{10}H_{12}O_8$ on a volatile matter-free basis.
Specific optical rotatory power	$[\alpha]_D^{20}$ = − 77 to − 79° (C = 2 % in methanol).
Volatile matter	Not more than 1 % determined by drying at room temperature for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide.
Sulphated ash	Not more than 0·1 % of the volatile matter-free substance determined by calcination at 800 ± 25 °C.

E 304 — 6-Palmitoyl-L-ascorbic acid

Chemical description	Ascorbyl palmitate; derivative of (+)-L-ascorbic acid; L-ascorbyl palmitate; 6-0-palmitoyl-3-oxo-L-gulofuranolactone.

Appearance	Impalpable white or yellowish-white powder or yellowish-white crystals.
Content	Not less than 98 % $C_{22}H_{38}O_7$ on a volatile matter-free basis.
Melting range	111 to 113 °C (changes to viscous state without completely melting).
Specific optical rotatory power	$[\alpha]_D^{20}$ = + 21 to +24° (C = 5 % in methanol).
Volatile matter	Not more than 1 % determined by drying at room temperature for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide.
Sulphated ash	Not more than 0·2 % of the volatile matter-free substance after calcination at 800 ± 25 °C.

E 306 — Tocopherol-rich extracts of natural origin

Chemical description	Mixed tocopherols concentrate obtained from edible vegetable oils or their derivatives.
Appearance	Clear, viscous, red to brownish-red oil.
Content	Not less than 34 % total tocopherols (5).
Relative density d_4^{20}	Not less than 0·928 and not more than 0·951 (5).
Free fatty acids	Not more than 3 % expressed in terms of oleic acid (5).

E 307 — Synthetic alpha-tocopherol

Chemical description	Synthetic dl-α-tocopherol; 2,5,7,8-tetramethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol; $C_{29}H_{50}O_2$.
Appearance	Clear, viscous, yellowish oil which darkens on exposure to air or light.
Content	Not less than 96 % $C_{29}H_{50}O_2$ (5).
Refractive index n_D^{20}	Not less than 1·503 and not more than 1·507 (5).
Relative density d_4^{20}	Not less than 0·947 and not more than 0·958 (5).
Specific absorption $E_{1\,cm}^{1\,\%}$ *in ethanol*	Absorption at 292 nm: $E_{1\,cm}^{1\,\%}$ (292 nm): not less than 72 and not more than 76. Absorption at 255 nm: $E_{1\,cm}^{1\,\%}$ (255 nm): not less than 6·0 and not more than 8·0.
Sulphated ash	Not more than 0·1 % after calcination at 800 ± 25 °C (5).

E 308 — Synthetic gamma-tocopherol

Chemical description	Synthetic dl-γ-tocopherol, 2,7,8-trimethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol; $C_{28}H_{48}O_2$.
Appearance	Clear, viscous, pale yellow oil which darkens on exposure to air or light.
Content	Not less than 97 % $C_{28}H_{48}O_2$ (5).
Refractive index n_D^{20}	Not less than 1·503 and not more than 1·507 (5).
Relative density d_4^{20}	Not less than 0·948 and not more than 0·959 (5).
Specific absorption in ethanol $E_{1\,cm}^{1\,\%}$	Absorption at 298 nm: $E_{1\,cm}^{1\,\%}$ (298 nm): not less than 91 and not more than 97. Absorption at 257 nm: $E_{1\,cm}^{1\,\%}$ (257 nm): not less than 5·0 and not more than 8·0.
Sulphated ash	Not more than 0·1 % after calcination at 800 ± 25 °C (5).

E 309 — Synthetic delta-tocopherol

Chemical description	Synthetic dl-δ-tocopherol; 2,8-dimethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol; $C_{28}H_{48}O_2$.
Appearance	Clear, viscous, pale yellowish or orange oil which darkens on exposure to air or light.
Content	Not less than 97 % $C_{27}H_{46}O_2$ (5).
Refractive index n_D^{20}	Not less 1·500 and not more than 1·504 (5).
Relative density d_4^{20}	Not less than 0·952 and not more than 0·962 (5).
Specific absorption in ethanol $E_{1\,cm}^{1\,\%}$	Absorption at 298 nm: $E_{1\,cm}^{1\,\%}$ (298 nm): not less than 89 and not more than 95. Absorption at 257 nm: $E_{1\,cm}^{1\,\%}$ (257 nm): not less than 3·0 and not more than 6·0.
Sulphated ash	Not more than 0·1 % after calcination at 800 ± 25 °C (5).

E 310 — Propyl gallate

Chemical description	Propyl gallate; n-propyl ester of 3,4,5-trihydroxybenzoic acid; $C_{10}H_{12}O_5$.
Appearance	White or pale cream crystalline powder.

Content	Not less than 99 % $C_{10}H_{12}O_5$ on a volatile matter-free basis.
Melting range	146 to 150 °C after drying at 110 °C for four hours.
Specific absorption E $\frac{1\ \%}{1\ cm}$ *in ethanol*	Absorption at 275 nm: $E\ \frac{1\ \%}{1\ cm}$ (275 nm): not less than 485 and not more than 505.
Volatile matter	Not more than 1·0 % determined by drying at 110 °C for four hours.
Sulphated ash	Not more than 0·05 % of the volatile matter-free substances after calcination at 800 ± 25 °C.
Free acids	Not more than 0·5 % expressed as gallic acid (8·506 mg gallic acid corresponding to 1 ml 0·05 N sodium hydroxide).
Chlorinated organic compounds	Not more than 100 mg/kg expressed as chlorine.

E 311 — Octyl gallate

Chemical description	Octyl gallate; n-octyl ester of 3,4,5-trihydroxybenzoic acid, $C_{15}H_{22}O_5$.
Appearance	White or very pale yellowish crystalline powder.
Melting range	99 to 102·5 °C after drying at 90 °C for six hours.
Content	Not less than 98·5 % $C_{15}H_{22}O_5$ on a volatile matter-free basis.
Specific absorption E $\frac{1\ \%}{1\ cm}$ *in ethanol*	Absorption at 275 nm: $E\ \frac{1\ \%}{1\ cm}$ (275 nm): not less than 375 and not more than 390.
Volatile matter	Not more than 0·5 % determined by drying at 90 °C for six hours.
Sulphated ash	Not more than 0·05 % of the volatile matter-free substance after calcination at 800 ± 25 °C.
Free acids	Not more than 0·5 % expressed as gallic acid (8·506 mg gallic acid corresponding to 1 ml 0·05 N sodium hydroxide).
Chlorinated organic compounds	Not more than 100 mg/kg expressed as chlorine.

E 312 — Dodecyl gallate

Chemical description	Dodecyl gallate; lauryl gallate; n-dodecyl ester of 3,4,5-trihydroxybenzoic acid; $C_{19}H_{30}O_5$.
Appearance	White or pale cream crystalline powder.
Melting range	95 to 98 °C after drying at 90 °C for six hours.
Content	Not less than 98·5 % $C_{19}H_{30}O_5$ on a volatile matter-free basis.

Specific absorption E $\frac{1\ \%}{1\ cm}$ *in ethanol*	Absorption at 275 nm: E $\frac{1\ \%}{1\ cm}$ (275 nm): not less than 300 and not more than 325.
Volatile matter	Not more than 0·5 % determined by drying at 90 °C for six hours.
Sulphated ash	Not more than 0·05 % of the volatile matter-free substance after calcination at 800 ± 25 °C.
Free acids	Not more than 0·5 % expressed as gallic acid (8·506 mg gallic acid corresponding to 1 ml 0·05 N sodium hydroxide).
Chlorinated organic compounds	Not more than 100 mg/kg expressed as chlorine.

E 320 — Butylated hydroxyanisole (BHA)

Chemical description	Mixture of 3- and 2-tertiarybutyl-4-hydroxyanisole; 2- and 3-tertiarybutyl-4-methoxy-phenol; $C_{11}H_{16}O_2$.
Appearance	White or pale yellowish powder or large crystals with waxy appearance and slight aromatic smell.
Content	Not less than 98·5 % $C_{11}H_{16}O_2$ and not less than 85 % of the 3-tertiary+butyl-4-hydroxyanisole isomer (5).
Specific absorption E $\frac{1\ \%}{1\ cm}$ *in ethanol*	Absorption at 290 nm: E $\frac{1\ \%}{1\ cm}$ (290 nm): not less than 190 and not more than 210.
	Absorption at 228 nm: E $\frac{1\ \%}{1\ cm}$ (228 nm): not less than 326 and not more than 345.
4-hydroxyanisole content	Not more than 0·5 %.
Sulphated ash	Not more than 0·05 % after calcination at 800 ± 25 °C (5).

E 321 — Butylated hydroxy toluene (BHT)

Chemical description	2,6-ditert-butyl-p-cresol; 4-methyl-2,6-ditert-butyl phenol; $C_{15}H_{24}O$.
Appearance	White crystalline or powdery crystalline substance.
Content	Not less than 99 % $C_{15}H_{24}O$.
Melting range	69 to 70 °C.
Specific absorption E $\frac{1\ \%}{1\ cm}$ *in ethanol*	Absorption at 278 nm: E $\frac{1\ \%}{1\ cm}$ (278 nm): not less than 81 and not more than 88.
Sulphated ash	Not more than 0·005 % after calcination at 800 ± 25 °C (5).

" **E 322 — Lecithins**

Description	Lecithins are mixtures or fractions of phosphatides obtained by physical procedures from animal or vegetable foodstuffs; they also include hydrolyzed products obtained through the use of harmless and appropriate enzymes. The final product must not show any signs of residual enzyme activity. The lecithins may be slightly bleached in aquaeous medium by means of hydrogen peroxide. This oxidation must not chemically modify the lecithin phosphatides.
Appearance	**— Lecithins : brown liquid or viscous semi-liquid or powder.** **— Hydrolyzed lecithins : light brown to brown viscous liquid or paste.**
Content	**— Lecithins : not less than 60 % of substances insoluble in acetone** (5). **— Hydrolyzed lecithins : not less than 56 % of substances insoluble in acetone.**
Volatile matter	**Not more than 2 % determined by drying at 105 °C for one hour** (5).
Substances insoluble in toluene	**Not more than 0·3 %** (5).
Acid number	**— Lecithins : not more than 35 mg of potassium hydroxide per gram** (5). **— Hydrolyzed lecithins : not more than 45 mg of potassium hydroxide per gram.**
Peroxide number	**Equal to or less than 10, expressed as milli-equivalents per kilogram. " [1]**

E 325 — Sodium lactate

Chemical description	Sodium salt of lactic acid; $C_3H_5O_3Na$.
Appearance	White hygroscopic mass. Solutions are practically colourless and odourless.
Description	The substance is usually available commercially in the form of an aqueous solution containing 50 to 80 % mass/mass of anhydrous sodium lactate.
Content	Not less than 98 % $C_3H_5O_3Na$ after drying.
Acidity	Not more than 0·5 % after drying expressed as lactic acid.
Reducing substances	No reduction of Fehling's solution.

E 326 — Potassium lactate

Chemical description	Potassium salt of lactic acid; $C_3H_5O_3K$.
Description	The substance is usually available commercially in the form of an aqueous, slightly syrupy, clear, almost odourless solution containing about 60 % mass/mass of anhydrous potassium lactate.

Content	Not less than 98 % $C_3H_5O_3K$ after drying.
Acidity	Not more than 0·5 % after drying expressed as lactic acid.
Reducing substances	No reduction of Fehling's solution.

E 327 — Calcium lactate

Chemical description	Calcium salt of lactic acid; calcium dilactate; $(C_3H_5O_2)_2Ca$; also available commercially in hydrated forms (one, three or four-and-a-half molecules of water).
Appearance	Almost odourless, white crystalline powder or granules.
Content	Not less than 98 % $(C_3H_5O_3)_2Ca$ on a volatile matter-free basis.
Volatile matter	Determined by drying at 120 °C for four hours: — anhydrous: not more than 3 %, — with one molecule of water: not more than 8 %, — with three molecules of water: not more than 20 %, — with four-and-a-half molecules of water: not more than 27 %.
Acidity	Not more than 0·5 % of the dry matter expressed as lactic acid.
Fluorides	Not more than 30 mg/kg expressed as fluorine.
Reducing substances	No reduction of Fehling's solution.

E 330 — Citric acid

Chemical description	2-hydroxy-1,2,3-propane tricarboxylic acid; $C_6H_8O_7$; available commercially in anhydrous or monohydrate form.
Appearance	Colourless or translucent crystalline solid or white crystalline powder.
Content	Not less than 99·5 % $C_6H_8O_7$ after drying.
Volatile matter	Anhydrous: not more than 0·5 %. Monohydrate: not more than 8·8 %.
Oxalates	Not more than 0·05 %, expressed as oxalic acid, after drying.
Sulphated ash	Not more than 0·05 % of the dry matter after calcination at 800 ± 25 °C.
Sulphuric acid test	1 g sample dissolved in 10 ml 95 % sulphuric acid and heated for 60 minutes at 90° shall not show a darker colouration than a solution containing 0·5 part of a $CoCl_2 \cdot 6H_2O$ solution (59·5 mg/ml) and 4·5 parts of a $FeCl_3 \cdot 6H_2O$ solution (45·0 mg/ml).

E 331 — Sodium citrates

(i) Monosodium citrate

Chemical description	Monosodium salt of citric acid; $C_6H_5O_7H_2Na$; in anhydrous form or as the monohydrate.
Appearance	Crystalline white powder or colourless crystals.
Content	Not less than 99 % $C_6H_5O_7H_2Na$ on a volatile matter-free basis.

Volatile matter	Determined by drying at 120 °C for two hours: — anhydrous: not more than 1·0 %, — monohydrate: not more than 8·8 %.
Oxalates	Not more than 0·05 % expressed as oxalic acid.
pH	Determined in a 1 % solution, not less than 3·5 and not more than 3·8.

(ii) Disodium citrate

Chemical description	Disodium salt of citric acid with one-and-a-half molecules of water; $C_6H_5O_7HNa_2$, 1·5 H_2O.
Appearance	Crystalline white powder or colourless crystals.
Content	Not less than 99 % $C_6H_5O_7HNa_2$ on a volatile matter-free basis.
Volatile matter	Determined by drying at 180 °C for two hours, not more than 13 %.
Oxalates	Not more than 0·05 % expressed as oxalic acid.
pH	Determined in a 1 % solution, not less than 4·9 and not more than 5·2.

(iii) Trisodium citrate

Chemical description	Trisodium salt of citric acid, in anhydrous, dihydrate or pentahydrate form; $C_6H_5O_7Na_3$.
Appearance	Crystalline white powder or colourless crystals.
Content	Not less than 99 % $C_6H_5O_7Na_3$ on a volatile matter-free basis.
Volatile matter	Determined by drying at 180 °C for two hours: — anhydrous: not more than 1·0 %, — dihydrate: not more than 13·5 %, — pentahydrate: not more than 30·3 %.
Oxalates	Not more than 0·05 % expressed as oxalic acid.
pH	Determined in a 1 % solution, not less than 7·0 and not more than 9·0.

E 332 — Potassium citrates

(i) Monopotassium citrate

Chemical description	Anhydrous monopotassium salt of citric acid; $C_6H_5O_7H_2K$.

Appearance	White, hygroscopic, granular powder or transparent crystals.
Content	Not less than 99 % $C_6H_5O_7H_2K$ on a volatile matter-free basis.
Volatile matter	Not more than 1 % determined by drying at 120 °C for four hours.
Oxalates	Not more than 0·05 % expressed as oxalic acid.
pH	Determined in a 1 % solution, not less than 3·5 and not more than 3·8.

(ii) Tripotassium citrate

Chemical description	Monohydrated tripotassium salt of citric acid; $C_6H_5O_7K_3$, 1 H_2O.
Appearance	White hygroscopic granular powder or transparent crystals.
Content	Not less than 99 % $C_6H_5O_7K_3$ on a volatile matter-free basis.
Volatile matter	Not more than 6 % determined by drying at 180 °C for four hours.
Oxalates	Not more than 0·05 % expressed as oxalic acid.
pH	Determined in a 1 % solution, not less than 7·0 and not more than 9·0.

E 333 — Calcium citrates

(i) Monocalcium citrate

Chemical description	Monohydrate monocalcium salt of citric acid; $(C_6H_5O_7)_2$ H_4Ca, 1 H_2O.
Appearance	Fine white powder.
Content	Not less than 97·5 % $(C_6H_5O_7)_2$ H_4Ca on a volatile matter-free basis.
Volatile matter	Not more than 7 % determined by drying at 120 °C for four hours.
Carbonates	Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles.
Oxalates	Not more than 0·05 % expressed as oxalic acid.
Fluorides	Not more than 30 mg/kg expressed as fluorine.

(ii) Dicalcium citrate

Chemical description	Trihydrated dicalcium salt of citric acid; $(C_6H_5O_7)_2$ H_2Ca_2, 3 H_2O.

Appearance	Fine white powder.
Content	Not less than 97·5 % $(C_6H_5O_7)_2\ H_2Ca_2$ on a volatile matter-free basis.
Volatile matter	Not more than 20 % determined by drying at 120 °C for four hours.
Carbonates	Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles.
Oxalates	Not more than 0·05 % expressed as oxalic acid.
Fluorides	Not more than 30 mg/kg expressed as fluorine.

(iii) Tricalcium citrate

Chemical description	Tetrahydrated tricalcium salt of citric acid; $(C_6H_5O_7)_2\ Ca_3,\ 4\ H_2O$.
Appearance	Fine white powder.
Content	Not less than 97·5 % $(C_6H_5O_7)_2\ Ca_3$ on a volatile matter-free basis.
Volatile matter	Not more than 14 % determined by drying at 150 °C for four hours.
Carbonates	Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles.
Oxalates	Not more than 0·05 % expressed as oxalic acid.
Fluorides	Not more than 30 mg/kg expressed as fluorine.

E 334 — Tartaric acid

Chemical description	L-(+)-tartaric acid; 2,3-dihydroxysuccinic acid; $C_4H_6O_6$.
Appearance	Colourless or translucent crystalline solid or white crystalline powder.
Content	Not less than 99·5 % $C_4H_6O_6$.
Volatile matter	Not more than 0·5 %.
Sulphated ash	Not more than 0·1 % of the dry matter after calcination at 800 ± 25 °C.
Oxalates	Not more than 0·05 % expressed as oxalic acid.
Melting range	168 to 170 °C.
Specific optical rotatory power	$[\alpha]_D^{20}$ from + 11·5 to + 13·5° (C = 20 % aqueous).

E 335 — Sodium tartrates

(i) Monosodium tartrate

Chemical description	Monohydrated monosodium salt of L-(+)-tartaric acid; $C_4H_4O_6$ H Na, H_2O.
Description	Transparent, colourless crystals.
Content	Not less than 99 % $C_4H_4O_6$ H Na on a volatile matter-free basis.
Volatile matter	Not more than 10 % determined by drying at 105 °C for four hours.
Oxalates	Not more than 0·05 % expressed as oxalic acid.

(ii) Disodium tartrate

Chemical description	Dihydrated disodium salt of L-(+)-tartaric acid, $C_4H_4O_6$ Na_2, 2 H_2O.
Description	Transparent, colourless crystals.
Content	Not less than 99 % $C_4H_4O_6$ Na_2 on a volatile matter-free basis.
Volatile matter	Not more than 17 % determined by drying at 150 °C for four hours.
Oxalates	Not more than 0·05 % expressed as oxalic acid.

E 336 — Potassium tartrates

(i) Monopotassium tartrate

Chemical description	Anhydrous monopotassium salt of L-(+)-tartaric acid; $C_4H_4O_6$ HK.
Description	White crystalline or granulated powder.
Content	Not less than 98 % $C_4H_4O_6$ HK on a volatile matter-free basis.
Volatile matter	Not more than 1 % determined by drying at 105 °C for four hours.
Oxalates	Not more than 0·05 % expressed as oxalic acid.

(ii) Dipotassium tartrate

Chemical description	Dipotassium salt with half a molecule of water of L-(+)-tartaric acid; $C_4H_4O_6$ K_2, $^1/_2$ H_2O.
Description	White crystalline or granulated powder.

Content	Not less than 99 % $C_4H_4O_6K_2$ on a volatile matter-free basis.
Volatile matter	Not more than 4 % determined by drying at 150 °C for four hours.
Oxalates	Not more than 0·05 % expressed as oxalic acid.

E 337 — Potassium sodium tartrate

Chemical description	Derivate of L-(+)-tartaric acid; potassium sodium L (+) tartrate; Available commercially in the form of potassium sodium tartrate with four molecules of water of crystallization; $C_4H_4O_6K$ Na, 4 H_2O.
Description	Colourless crystals or white crystalline powder.
Content	Not less than 99 % $C_4H_4O_6K$ Na on a volatile matter-free basis.
Volatile matter	Not more than 21 % determined by drying at 150 °C for three hours.
Oxalates	Not more than 0·05 % expressed as oxalic acid.

E 338 — Orthophosphoric acid

Chemical description	Orthophosphoric acid H_3PO_4 in concentrated aqueous solution.
Appearance	Clear, colourless, viscous liquid.
Content	Not less than 85 % H_3PO_4 (5).
Chlorides	Not more than 200 mg/kg expressed as chlorine (5).
Nitrates	Not more than 5 mg/kg expressed as $NaNO_3$ (5).
Sulphates	Not more than 1 500 mg/kg expressed as $CaSO_4$·(5).
Fluorides	Not more than 10 mg/kg expressed as fluorine (5).
Volatile acids	Not more than 10 mg/kg expressed as acetic acid (5).

E 339 — Sodium orthophosphates

(i) Monosodium orthophosphate

Chemical description	Monosodium monophosphate; acid monosodium monophosphate; monosodium orthophosphate; monobasic sodium phosphate; Na H_2PO_4. The substance is available commercially in anhydrous or hydrated form with one or two molecules of water.
Appearance	Slightly deliquescent white powder, crystals or granules.
Content	Not less than 97 % Na H_2PO_4 on a volatile matter-free basis.

Volatile matter	Determined by drying at 60 °C for one hour and then at 105 °C for four hours: — anhydrous: not more than 2 %, — with one molecule of water: not more than 15 %, — with two molecules of water: not more than 25 %.
Water insoluble substances	Not more than 0·2 % of the volatile matter-free substance.
Fluorides	Not more than 10 mg/kg expressed as fluorine.

(ii) Disodium orthophosphate

Chemical description	Disodium monophosphate; secondary sodium phosphate; disodium orthophosphate; acid disodium phosphate; $Na_2H\ PO_4$. The substance is available commercially in anhydrous form or as a hydrate with two, seven or 12 molecules of water.
Appearance	Anhydrous: white hygroscopic powder. With two molecules of water: white crystalline solid. With seven molecules of water: granular powder or white efflorescent crystals. With 12 molecules of water: white efflorescent powder or crystals.
Content	Not less than 98 % $Na_2H\ PO_4$ on a volatile matter-free basis.
Volatile matter	Determined by drying at 60 °C for one hour and at 105 °C for four hours: — anhydrous: not more than 5 %, — with one molecule of water: not more than 21 %, — with seven molecules of water: not more than 50 %, — with 12 molecules of water: not more than 61 %.
Water insoluble substances	Not more than 0·2 % of the volatile matter-free substance.
Fluorides	Not more than 10 mg/kg expressed as fluorine.

(iii) Trisodium orthophosphates

Chemical description	Trisodium monophosphate; trisodium orthophosphate; Na_3PO_4. The substance is available commercially in anhydrous form or as a hydrate with one or 12 molecules of water.
Appearance	White powder, crystals or granules.
Content	Not less than 97 % Na_3PO_4 on a volatile matter-free basis.
Volatile matter	Determined by drying at 105 °C for one hour, followed by calcination at 800 ± 25 °C for 30 minutes: — anhydrous: not more than 2 %, — with one molecule of water: not more than 9 %, — with 12 molecules of water: not more than 55 %.

Water insoluble substances	Not more than 0·2 % of the volatile matter-free substance.
Fluorides	Not more than 10 mg/kg expressed as fluorine.

E 340 — Potassium orthophosphates

(i) Monopotassium orthophosphate

Chemical description	Monopotassium monophosphate; acid monopotassium monophosphate; KH_2PO_4.
Appearance	Colourless crystals or white granular or crystalline powder, hygroscopic.
Content	Not less than 98 % KH_2PO_4 on a volatile matter-free basis.
Volatile matter	Not more than 2 % determined by drying at 105 °C for four hours.
Water insoluble substances	Not more than 0·2 % of the volatile matter-free substance.
Fluorides	Not more than 10 mg/kg expressed as fluorine.

(ii) Dipotassium orthophosphate

Chemical description	Dipotassium monophosphate; secondary potassium phosphate; acid dipotassium orthophosphate; dipotassium phosphate; $K_2H\ PO_4$.
Appearance	Colourless or white granular deliquescent substance.
Content	Not less than 98 % $K_2H\ PO_4$ on a volatile matter-free basis.
Volatile matter	Not more than 2 % determined by drying at 105 °C for four hours.
Water insoluble substances	Not more than 0·2 % of the volatile matter-free substance.
Fluorides	Not more than 10 mg/kg expressed as fluorine.

(iii) Tripotassium orthophosphate

Chemical description	Tripotassium monophosphate; tripotassium orthophosphate; K_3PO_4. The substance is available commercially in anhydrous form or hydrated form, the most common being that with one molecule of water of crystallization.
Appearance	White hygroscopic crystals or granules.
Content	Not less than 97 % K_3PO_4 on a volatile matter-free basis.
Volatile matter	Determined by drying at 105 °C for one hour followed by calcination at 800 ± 25 °C for 30 minutes: — anhydrous: not more than 3 %, — with one molecule of water: not more than 20 %.

Water insoluble substances	Not more than 0·2 % of the volatile matter-free substance.
Fluorides	Not more than 10 mg/kg expressed as fluorine.

E 341 – Calcium orthophosphates

(i) Monocalcium orthophosphate

Chemical description	Monocalcium phosphate; $CaH_4(PO_4)_2$. Available commercially in anhydrous form or as the monohydrate.
Appearance	Granular powder or white, deliquescent crystals or granules.
Calcium content	Anhydrous: not less than 23 % and not more than 25 % expressed as CaO (5). With one molecule of water: not less than 22·2 % and not more than 24·7 % expressed as CaO (5).
Volatile matter	Anhydrous: not less than 14 % and not more than 15·5 % determined after calcination at 800 ± 25 °C for 30 minutes. With one molecule of water: not more than 0·6 % determined by drying at 60 °C for three hours.
Fluorides	Not more than 30 mg/kg expressed as fluorine.

(ii) Dicalcium orthophosphate

Chemical description	Dibasic calcium phosphate; dicalcium phosphate; Ca H PO_4. Available commercially in anhydrous and dihydrate form.
Appearance	Impalpable white powder.
Calcium content	Anhydrous: not less than 39 % and not more than 42 % expressed as CaO (5). With two molecules of water: not less than 31·9 % and not more than 33·5 % expressed as CaO (5).
Volatile matter	Determined by calcination at 800 ± 25 °C to constant weight. Anhydrous: not less than 7 % and not more than 8·5 %. Dihydrate: not less than 24·5 % and not more than 26·5 %.
Fluorides	Not more than 50 mg/kg expressed as fluorine.

Propylene glycol (1,2-propanediol)

Chemical description	Propane-1,2-diol; 1,2-dihydroxypropane; methyl glycol; $C_3H_8O_2$.
Appearance	Clear, colourless, almost odourless, viscous, hygroscopic liquid with a slightly bitter-sweet flavour.
Content	Not less than 98·5 % by weight propane-1,2-diol (5).
Distillation range	Not less than 185 °C and not more than 189 °C.
Relative density d_4^{20}	Not less than 1·035 and not more than 1·037.
Refractive index n_D^{20}	Not less than 1·431 and not more than 1·433.
Sulphated ash	Not more than 0·07 % of the dry matter after calcination at 800 ± 25 °C (5).
Total content of dimer, trimer and higher polymers of propane-1,2-diol	Not more than 0·1 % (5).
Propane-1,3-diol content	Not more than 100 mg/kg (5).
Chlorinated organic compounds	Not more than 1 mg/kg expressed as chlorine (5).

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(1) OJ No L 157, 18/07/1970, p. 31.
(2) OJ No 22, 09/02/1965, p. 373/65.
(3) OJ No L 223, 14/08/1978, p. 7.
(4) THIS PERCENTAGE VALUE DOES NOT RELATE TO THE WATER OF CRYSTALLIZATION BUT TO THE ATMOSPHERIC WATER VAPOUR (MOISTURE IN THE SUBSTANCE) DETERMINED UNDER THESE CONDITIONS.
(5) THESE CRITERIA APPLY TO THE PRODUCT AS IT IS.

374L0329

74/329/EEC: COUNCIL DIRECTIVE OF 18 JUNE 1974 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO EMULSIFIERS, STABILIZERS, THICKENERS AND GELLING AGENTS FOR USE IN FOODSTUFFS

OFFICIAL JOURNAL NO L 189, 12/07/1974, P. 1
DATE OF NOTIFICATION: 20/06/1974
DATE OF TRANSPOSITION: 20/06/1975; SEE ART. 13

AMENDED BY

378L0612
78/612/EEC: COUNCIL DIRECTIVE OF 29 JUNE 1978 **[1]**
OFFICIAL JOURNAL NO L 197, 22/07/1978, P. 22
DATE OF NOTIFICATION: 05/07/1978
DATE OF TRANSPOSITION: 05/07/1979; SEE ART. 6

179H
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE HELLENIC REBUBLIC AND THE ADJUSTMENTS TO THE TREATIES **[2]**
OFFICIAL JOURNAL NO L 291, 19/11/1979, P. 110

380L0597
80/597/EEC: COUNCIL DIRECTIVE OF 29 MAY 1980 **[3]**
OFFICIAL JOURNAL NO L 155, 23/06/1980, P. 23
DATE OF NOTIFICATION: 03/06/1980
DATE OF TRANSPOSITION: 03/06/1981; SEE ART. 3
DATE OF TRANSPOSITION: 03/06/1982; SEE ART. 3

385L0006
85/6/EEC: COUNCIL DIRECTIVE OF 19 DECEMBER 1984 **[4]**
OFFICIAL JOURNAL NO L 2, 03/01/1985, P. 21
DATE OF NOTIFICATION: 21/12/1984

385L0007
85/7/EEC: COUNCIL DIRECTIVE OF 19 DECEMBER 1984 **[5]**
OFFICIAL JOURNAL NO L 2, 03/01/1985, P. 22
DATE OF NOTIFICATION: 27/12/1984

185I
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE KINGDOM OF SPAIN AND THE PORTUGUESE REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES **[6]**
OFFICIAL JOURNAL NO L 302, 15/11/1985, P. 216

386L0102
86/102/EEC: COUNCIL DIRECTIVE OF 24 MARCH 1986 **[7]**
OFFICIAL JOURNAL NO L 88, 03/04/1986, P. 40
DATE OF NOTIFICATION: 27/03/1986
DATE OF TRANSPOSITION: 27/03/1987; SEE ART. 3

389L0393
89/393/EEC: COUNCIL DIRECTIVE OF 14 JUNE 1989 **[8]**
OFFICIAL JOURNAL NO L 186, 30/06/1989, P.13
DATE OF TRANSPOSITION: 01/01/1989; SEE ART. 2

ARTICLE 1

FOR THE PURPOSES OF THIS DIRECTIVE:

- EMULSIFIERS AND STABILIZERS MEAN THOSE SUBSTANCES WHICH, WHEN ADDED TO A FOODSTUFF, MAKE IT POSSIBLE TO FORM OR MAINTAIN A UNIFORM DISPERSION OF TWO OR MORE IMMISCIBLE SUBSTANCES;
- THICKENERS MEAN THOSE SUBSTANCES WHICH, WHEN ADDED TO A FOODSTUFF, INCREASE ITS VISCOSITY;
- GELLING AGENTS MEAN THOSE SUBSTANCES WHICH, WHEN ADDED TO A FOODSTUFF, GIVE IT THE CONSISTENCY OF A GEL.

ARTICLE 2

1. MEMBER STATES SHALL AUTHORIZE THE USE AS EMULSIFIERS, STABILIZERS, THICKENERS AND GELLING AGENTS IN FOODSTUFFS INTENDED FOR HUMAN CONSUMPTION, OF ONLY THOSE SUBSTANCES LISTED IN ANNEX I AND WHERE APPROPRIATE, ONLY UNDER THE CONDITIONS SPECIFIED THEREIN.

" 2. HOWEVER, AS REGARDS TRAGACANTH GUM REFERRED TO IN ANNEX I UNDER E 413, THE COMMISSION SHALL MAKE AN ENQUIRY AND, ON THE BASIS OF THE RESULTS OF THIS ENQUIRY, PROPOSE WHERE APPROPRIATE TO THE COUNCIL, THAT A DECISION BE TAKEN BY NOT LATER THAN 31 DECEMBER 1988, IN ACCORDANCE WITH THE PROCEDURE PROVIDED FOR IN ARTICLE 100 OF THE TREATY , TO DELETE IT FROM THE ANNEX OR OTHERWISE CHANGE ITS STATUS AS APPROPRIATE. " **[7]**

" ARTICLE 2a

1. NOTWITHSTANDING ARTICLE 2 (1), MEMBER STATES MAY AUTHORIZE THE USE IN FOODSTUFFS OF THE SUBSTANCES LISTED BELOW:

- AMMONIUM PHOSPHATIDES,
- POLYGLYCEROL POLYRICINOLEATE,
- SORBITAN MONOSTEARATE,
- SORBITAN TRISTEARATE,
- SORBITAN MONOLAURATE,
- SORBITAN MONOLEATE,
- SORBITAN MONOPALMITATE.

2. THE COUNCIL MAY, IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 100 OF THE TREATY, INCLUDE IN ANNEX I THE SUBSTANCES MENTIONED IN PARAGRAPH 1, AT THE SAME TIME STIPULATING THE CONDITIONS FOR THEIR USE IN FOODSTUFFS, PROVIDED THAT IN ACCORDANCE WITH ARTICLE 7 (1) THEIR PURITY CRITERIA ARE ESTABLISHED. " **[3]**

ARTICLE 3

" 1. By way of derogation from Article 2 (1), Member States may authorize, until 31 December 1991, the use in foodstuffs of the substances listed in Annex II. " **[8]**

" MEMBER STATES MAY AUTHORIZE UP TO 31 MARCH 1987 THE MARKETING OF FOODSTUFFS CONTAINING THE FOLLOWING SUBSTANCES:

- POLYOXYETHYLENE (8) STEARATE,
- POLYOXYETHYLENE (40) STEARATE,
- LACTYLATED FATTY ACID ESTERS OF GLYCEROL AND PROPYLENE GLYCOL,
- DIOCTYL SODIUM SULPHOSUCCINATE.

2. WHERE A MEMBER STATE EXERCISES THE OPTION UNDER PARAGRAPH 1 OTHER THAN BY MERELY RETAINING THE LEGISLATION IN FORCE AT THE TIME OF NOTIFICATION OF THIS DIRECTIVE, IT SHALL FORTHWITH INFORM THE OTHER MEMBER STATES AND THE COMMISSION OF THE MEASURES TAKEN AND SHALL FURNISH EVIDENCE WHICH IN ITS VIEW JUSTIFIES SUCH MEASURES.

3. WITHOUT PREJUDICE TO THE FIRST SUBPARAGRAPH OF PARAGRAPH 1 AND BEFORE THE END OF THE PERIOD PROVIDED THEREIN, THE COUNCIL MAY, IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 100 OF THE TREATY, INCLUDE IN ANNEX I THE SUBSTANCES REFERRED TO IN ANNEX II.
IN THE CASE REFERRED TO IN PARAGRAPH 2, THE COUNCIL MAY, IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 100 OF THE TREATY DECIDE ON ANY OTHER APPROPRIATE MEASURE. " **[7]**

ARTICLE 4

THE COUNCIL, IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 100 OF THE TREATY, SHALL DETERMINE AS SOON AS POSSIBLE THE FOODSTUFFS TO WHICH THE SUBSTANCES LISTED IN ANNEX I MAY BE ADDED AND THE CONDITIONS UNDER WHICH THEY MAY BE ADDED.

ARTICLE 5

1. WHERE THE USE IN FOODSTUFFS OF ANY SUBSTANCE LISTED IN ANNEX I OR THE LEVEL OF ONE OR MORE OF THE COMPONENTS REFERRED TO IN ARTICLE 6 CONTAINED IN SUCH SUBSTANCES MIGHT ENDANGER HUMAN HEALTH, A MEMBER STATE MAY, FOR A MAXIMUM PERIOD OF ONE YEAR, SUSPEND THE AUTHORIZATION TO USE THAT SUBSTANCE OR REDUCE THE MAXIMUM AUTHORIZED LEVEL OF ONE OR MORE OF THE COMPONENTS IN QUESTION. IT SHALL FORTHWITH INFORM THE COMMISSION THEREOF, WHICH SHALL CONSULT THE MEMBER STATES.

2. THE COUNCIL, ACTING UNANIMOUSLY ON A PROPOSAL FROM THE COMMISSION, SHALL DECIDE WITHOUT DELAY WHETHER THE LIST IN ANNEX I SHOULD BE AMENDED AND, IF APPROPRIATE, ADOPT THE NECESSARY AMENDMENTS BY MEANS OF A DIRECTIVE. THE COUNCIL, ACTING BY A QUALIFIED MAJORITY ON A PROPOSAL FROM THE COMMISSION, MAY ALSO IF NECESSARY EXTEND FOR A MAXIMUM OF ONE YEAR THE PERIOD REFERRED TO IN PARAGRAPH 1.

ARTICLE 6

1. MEMBER STATES SHALL TAKE ALL NECESSARY MEASURES TO ENSURE THAT THE SUBSTANCES LISTED IN ANNEX I AND INTENDED FOR USE IN FOODSTUFFS SATISFY:

(a) THE FOLLOWING GENERAL CRITERIA OF PURITY:

- THEY SHALL NOT CONTAIN A TOXICOLOGICALLY DANGEROUS AMOUNT OF ANY ELEMENT, IN PARTICULAR HEAVY METALS;
- THEY SHALL NOT CONTAIN MORE THAN 3 mg/kg OF ARSENIC OR MORE THAN 10 mg/kg OF LEAD;
" - THEY SHALL NOT CONTAIN MORE THAN 50 mg/kg OF COPPER AND ZINC TAKEN TOGETHER OF WHICH THE ZINC CONTENT MUST IN NO CASE EXCEED 25 mg/kg, SUBJECT TO ANY EXCEPTION DERIVING FROM THE SPECIFIC CRITERIA OF PURITY REFERRED TO IN (b); " **[1]**

" (b) THE SPECIFIC CRITERIA OF PURITY DETERMINED IN ACCORDANCE WITH ARTICLE 7 (1). " **[1]**

2. MEMBER STATES SHALL ALSO ENSURE THAT THE SUBSTANCES LISTED IN ANNEX I UNDER E 471, E 472 (b), E 473, E 474, E 475 AND E 477 DO NOT IN ADDITION CONTAIN MORE THAN 6 % OF THE SUBSTANCES LISTED IN ANNEX I, UNDER E 470, EXPRESSED AS SODIUM OLEATE.

" 3. MEMBER STATES SHALL ALSO PROVIDE THAT THE SUBSTANCES LISTED IN ANNEX I UNDER E 407 AND E 440 MAY, FOR THE PURPOSES OF STANDARDIZATION, CONTAIN ONE OR MORE SUGARS AS DEFINED IN DIRECTIVE 73/437/EEC (1). " **[1]**

ARTICLE 7

1. THE COUNCIL, ACTING UNANIMOUSLY ON A PROPOSAL FROM THE COMMISSION, SHALL LAY DOWN BY MEANS OF A DIRECTIVE THE SPECIFIC CRITERIA OF PURITY FOR THE SUBSTANCES LISTED IN ANNEX I.

2. THE FOLLOWING SHALL BE DETERMINED IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 10:

- THE METHODS OF ANALYSIS NECESSARY FOR THE CONTROL OF THE GENERAL AND SPECIFIC CRITERIA OF PURITY REFERRED TO IN ARTICLE 6 (1) AND THE LIMIT SPECIFIED IN ARTICLE 6 (2),
- THE PROCEDURE FOR TAKING OF SAMPLES AND THE METHODS FOR QUALITATIVE AND QUANTITATIVE ANALYSIS OF EMULSIFIERS, STABILIZERS, THICKENERS AND GELLING AGENTS IN AND ON FOODSTUFFS.

ARTICLE 8

1. MEMBER STATES SHALL TAKE ALL NECESSARY MEASURES TO ENSURE THAT THE SUBSTANCES LISTED IN ANNEX I AND INTENDED FOR USE IN FOODSTUFFS FOR THE PURPOSES LISTED IN ARTICLE 1 MAY BE MARKETED ONLY IF THEIR PACKAGINGS OR CONTAINERS BEAR THE FOLLOWING INFORMATION:

(a) THE NAME AND ADDRESS OF THE MANUFACTURER OR OF A SELLER RESPONSIBLE WITHIN THE MEANING OF THE LAW OF THE MEMBER STATE WHERE HE IS RESIDENT; A PERSON IMPORTING A PRODUCT FROM A THIRD COUNTRY SHALL BE REGARDED AS THE MANUFACTURER;

" (b) THE NUMBER AND DESIGNATION OF THE SUBSTANCE AS GIVEN IN ANNEX I, QUALIFIED IN THE CASE OF SUBSTANCES TO WHICH SUGARS HAVE BEEN ADDED FOR STANDARDIZATION IN ACCORDANCE WITH ARTICLE 6 (3) BY ADDING TO THE DESIGNATION THE STATEMENT "STANDARDIZED WITH SUGAR(S)"; " **[1]**

(c) THE STATEMENT "FOR FOODSTUFFS (RESTRICTED USE)";

" (d) APPROPRIATE WORDS FOR THE SUBSTANCE REFERRED TO IN ANNEX I UNDER E 420 (ii), WHERE IT CONTAINS AFTER HYDROLYSIS A LEVEL OF TOTAL SUGARS OF MORE THAN 1 %;

(e) IN THE CASE OF SUBSTANCES LISTED IN ANNEX I, WHETHER OR NOT STANDARDIZED WITH SUGARS IN ACCORDANCE WITH ARTICLE 6 (3), WHEN MIXED WITH EACH OTHER, WITH OTHER

ADDITIVES AND WHERE RELEVANT WITH SUBSTANCES IN WHICH SUCH OTHER ADDITIVES CAN BE DISSOLVED OR DILUTED:

- THE NUMBER OR THE DESIGNATION OF THE SUBSTANCE AS GIVEN IN ANNEX I, QUALIFIED AS NECESSARY IN ACCORDANCE WITH PARAGRAPH 1 (b);
- THE DESIGNATION OF EACH OTHER ADDITIVE AND WHERE RELEVANT THE SUBSTANCES IN WHICH SUCH ADDITIVES CAN BE DISSOLVED OR DILUTED;
- THE PERCENTAGE OF EACH COMPONENT WHERE THIS REQUIREMENT IS LAID DOWN IN PROVISIONS RELATING TO OTHER CATEGORIES OF ADDITIVES. " **[1]**

2. IN THE CASE OF MIXTURES DESCRIBED IN PARAGRAPH 1 (d) MEMBER STATES MAY ALSO MAKE OBLIGATORY AN INDICATION OF THE PERCENTAGE OF THOSE SUBSTANCES ENUMERATED IN ANNEX I FOR WHICH THEIR NATIONAL LEGISLATION PROVIDES A QUANTITATIVE LIMITATION IN FOODSTUFFS, EXCEPT WHEN THE SAME LIMIT APPLIES SINGLY OR IN COMBINATION TO ALL OF THE COMPONENTS IN THE MIXTURE. " IN THE CASE OF SUBSTANCES TO WHICH SUGARS HAVE BEEN ADDED IN ACCORDANCE WITH ARTICLE 6 (3), THIS PERCENTAGE INCORPORATES THE SUGAR USED FOR STANDARDIZATION. " **[1]**
THE MEMBER STATE SHALL INFORM THE OTHER MEMBER STATES AND THE COMMISSION OF ANY MEASURES TAKEN IN ACCORDANCE WITH THIS PARAGRAPH.

3. IN ADOPTING THE PROVISIONS PROVIDED FOR IN ARTICLE 4, THE COUNCIL SHALL ALSO FIX THE RULES WHICH WILL APPLY AT A LATER STAGE IN THE COMMUNITY RELATING TO THE LABELLING OF THE COMPOSITION OF THE MIXTURES DESCRIBED IN PARAGRAPH 1 (d).

4. MEMBER STATES MAY NOT PROHIBIT THE INTRODUCTION INTO THEIR TERRITORY AND THE MARKETING OF THE SUBSTANCES LISTED IN ANNEX I FOR THE SOLE REASON THAT THEY CONSIDER THE LABELLING INADEQUATE IF THE INFORMATION REQUIRED BY PARAGRAPH 1 IS GIVEN ON THE PACKAGINGS OR CONTAINERS AND IF THE DETAILS LISTED IN SUBPARAGRAPHS (b) AND (c) OF PARAGRAPH 1 ARE GIVEN IN AT LEAST ONE OF THE OFFICIAL LANGUAGES OF THE COMMUNITY. EACH RECIPIENT STATE MAY HOWEVER REQUIRE THE LATTER DETAILS TO BE GIVEN IN ITS OFFICIAL LANGUAGE OR LANGUAGES.

ARTICLE 9

ARTICLE 2 SHALL NOT APPLY TO:

(a) FOODSTUFFS WHICH HAVE EMULSIFYING, STABILIZING, THICKENING OR GELLING PROPERTIES , SUCH AS, FOR EXAMPLE, EGGS, FLOUR AND STARCHES;

(b) EMULSIFIERS USED IN RELEASE AGENTS;

(c) ACIDS, BASES AND SALTS WHICH, WHEN ADDED TO A FOODSTUFF DURING MANUFACTURE, CHANGE OR STABILIZE THE PH;

(d) BLOOD PLASMA, MODIFIED STARCHES, EDIBLE GELATINE AND HYDROLYZED FOOD PROTEINS AND THEIR SALTS.

" (e) PRODUCTS CONTAINING PECTIN AND DERIVED FROM DRIED APPLE POMACE OR DRIED PEEL OF CITRUS FRUITS, OR FROM A MIXTURE OF BOTH, BY THE ACTION OF DILUTE ACID FOLLOWED BY PARTIAL NEUTRALIZATION WITH SODIUM OR POTASSIUM SALTS. " **[1]**

ARTICLE 10

1. WHERE THE PROCEDURE LAID DOWN IN THIS ARTICLE IS TO BE FOLLOWED, MATTERS SHALL BE REFERRED BY THE CHAIRMAN, EITHER ON HIS OWN INITIATIVE OR AT THE REQUEST OF THE REPRESENTATIVE OF A MEMBER STATE, TO THE STANDING COMMITTEE ON FOODSTUFFS, HEREINAFTER CALLED THE "COMMITTEE".

2. THE REPRESENTATIVE OF THE COMMISSION SHALL SUBMIT TO THE COMMITTEE A DRAFT OF THE MEASURES TO BE ADOPTED. THE COMMITTEE SHALL DELIVER ITS OPINION ON THE DRAFT WITHIN A TIME LIMIT SET BY THE CHAIRMAN ACCORDING TO THE URGENCY OF THE MATTER. OPINIONS SHALL BE DELIVERED BY A MAJORITY OF " FIFTY-FOUR " **[6]** VOTES, THE VOTES OF THE MEMBER STATES BEING WEIGHTED AS PROVIDED IN ARTICLE 148 (2) OF THE TREATY. THE CHAIRMAN SHALL NOT VOTE.

3. (a) THE COMMISSION SHALL ADOPT THE MEASURES ENVISAGED WHERE THEY ARE IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE.

(b) WHERE THE MEASURES ENVISAGED ARE NOT IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE, OR IF NO OPINION IS DELIVERED, THE COMMISSION SHALL WITHOUT DELAY PROPOSE TO THE COUNCIL THE MEASURES TO BE ADOPTED. THE COUNCIL SHALL ACT BY A QUALIFIED MAJORITY.

(c) IF, WITHIN THREE MONTHS OF THE PROPOSAL BEING SUBMITTED TO IT, THE COUNCIL HAS NOT ACTED, THE PROPOSED MEASURES SHALL BE ADOPTED BY THE COMMISSION.

ARTICLE 11

ARTICLE 10 SHALL APPLY " FOR A PERIOD OF TWO YEARS FROM THE DATE ON WHICH THE MATTER WAS FIRST REFERRED TO THE COMMITTEE AFTER 1 JANUARY 1985 " **[5]** UNDER ARTICLE 10 (1).

ARTICLE 12

1. THIS DIRECTIVE SHALL APPLY EQUALLY TO EMULSIFIERS, STABILIZERS, THICKENERS AND GELLING AGENTS INTENDED FOR USE IN FOODSTUFFS AND TO FOODSTUFFS IMPORTED INTO THE COMMUNITY.

2. THIS DIRECTIVE SHALL APPLY NEITHER TO EMULSIFIERS, STABILIZERS, THICKENERS AND GELLING AGENTS, NOR TO FOODSTUFFS INTENDED FOR EXPORT OUTSIDE THE COMMUNITY.

ARTICLE 13

MEMBER STATES SHALL, WITHIN ONE YEAR FROM THE NOTIFICATION OF THIS DIRECTIVE, AMEND THEIR LAWS IN ACCORDANCE WITH THE PRECEDING PROVISIONS AND SHALL FORTHWITH INFORM THE COMMISSION THEREOF. THE LAWS THUS AMENDED SHALL BE IMPLEMENTED AT THE LATEST TWO YEARS AFTER NOTIFICATION OF THIS DIRECTIVE.

ARTICLE 14

THIS DIRECTIVE SHALL ALSO APPLY TO THE FRENCH OVERSEAS DEPARTMENTS.

ARTICLE 15

THIS DIRECTIVE IS ADDRESSED TO THE MEMBER STATES.

" ANNEX I

EMULSIFIERS, STABILIZERS, THICKENERS AND GELLING AGENTS WHICH MAY BE USED IN FOODSTUFFS

EEC No - DESIGNATION (CONDITIONS OF USE)

E 322 - LECITHINS

E 339 - SODIUM ORTHOPHOSPHATES

E 340 - POTASSIUM ORTHOPHOSPHATES

E 341 - CALCIUM ORTHOPHOSPHATES

E 400 - ALGINIC ACID

E 401 - SODIUM ALGINATE

E 402 - POTASSIUM ALGINATE

E 403 - AMMONIUM ALGINATE

E 404 - CALCIUM ALGINATE

E 405 - PROPANE-1,2-DIOL ALGINATE

E 406 - AGAR

E 407 - CARRAGEENAN

E 410 - LOCUST BEAN GUM

E 412 - GUAR GUM

E 413 - TRAGACANTH

E 414 - ACACIA OR GUM ARABIC

" E 415 - XANTHAN GUM " **[3]**

E 420 -

(i) SORBITOL
(ii) SORBITOL SYRUP

E 421 - MANNITOL

E 422 - GLYCEROL

" E 440 -

(i) PECTIN
(ii) AMIDATED PECTIN " **[7]**

E 450 (a) -

(i) DISODIUM DIHYDROGEN DIPHOSPHATE
(ii) TRISODIUM DIPHOSPHATE
(iii) TETRASODIUM DIPHOSPHATE
(iv) TETRAPOTASSIUM DIPHOSPHATE

E 450 (b) -

(i) PENTASODIUM TRIPHOSPHATE
(ii) PENTAPOTASSIUM TRIPHOSPHATE

E 450 (c) -

(i) SODIUM POLYPHOSPHATES
(ii) POTASSIUM POLYPHOSPHATES

" E 460 -

(i) MICROCRYSTALLINE CELLULOSE
(ii) POWDERED CELLULOSE " **[3]**

E 461 - METHYLCELLULOSE

E 463 - HYDROXYPROPYLCELLULOSE

E 464 - HYDROXYPROPYLMETHYLCELLULOSE

E 465 - ETHYLMETHYLCELLULOSE

E 466 - CARBOXYMETHYLCELLULOSE

E 470 - SODIUM, POTASSIUM AND CALCIUM SALTS OF FATTY ACIDS (EXCLUSIVELY IN THE MANUFACTURE OF "DUTCH" TYPE RUSKS UP TO A LEVEL SINGLY OR IN COMBINATION OF NOT MORE THAN 1.5 % OF FLOUR USED)

E 471 - MONO- AND DIGLYCERIDES OF FATTY ACIDS

E 472 (a) - ACETIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS

E 472 (b) - LACTIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS

E 472 (c) - CITRIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS

E 472 (d) - TARTARIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS

E 472 (e) - MONO- AND DIACETYLTARTARIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS

E 472 (f) - MIXED ACETIC AND TARTARIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS

E 473 - SUCROSE ESTERS OF FATTY ACIDS (THESE SUBSTANCES MAY NOT BE USED IN BREAD UNLESS PERMITTED UNDER NATIONAL LAW)

E 474 - SUCROGLYCERIDES (THESE SUBSTANCES MAY NOT BE USED IN BREAD UNLESS PERMITTED UNDER NATIONAL LAW)

E 475 - POLYGLYCEROL ESTERS OF FATTY ACIDS

E 477 - PROPANE-1,2-DIOL ESTERS OF FATTY ACIDS

E 481 - SODIUM STEAROYL-2-LACTYLATE (THESE SUBSTANCES MAY NOT BE USED IN BREAD UNLESS PERMITTED UNDER NATIONAL LAW)

E 482 - CALCIUM STEAROYL-2-LACTYLATE (THESE SUBSTANCES MAY NOT BE USED IN BREAD UNLESS PERMITTED UNDER NATIONAL LAW)

E 483 - STEARYL TARTRATE (THESE SUBSTANCES MAY NOT BE USED IN BREAD UNLESS PERMITTED UNDER NATIONAL LAW) " **[1]**

" ANNEX II

DENOMINATIONS

KARAYA GUM (SYNONYM: STERCULIA GUM),

POLYOXYETHYLENE (20) SORBITAN MONOLAURATE (SYNONYM: POLYSORBATE 20),

POLYOXYETHYLENE (20) SORBITAN MONOPALMITATE (SYNONYM: POLYSORBATE 40),

POLYOXYETHYLENE (20) SORBITAN MONOSTEARATE (SYNONYM: POLYSORBATE 60),

POLYOXYETHYLENE (20) SORBITAN TRISTEARATE (SYNONYM: POLYSORBATE 65),

POLYOXYETHYLENE (20) SORBITAN MONOOLEATE (SYNONYM: POLYSORBATE 80),

THERMALLY OXIDIZED SOYA BEAN OIL INTERACTED WITH MONO- AND DI-GLYCERIDES OF FATTY ACIDS " **[7]**

(1) OJ No L 356, 27/12/1973, p. 71.

378L0663

78/663/EEC: COUNCIL DECISION OF 25 JULY 1978 LAYING DOWN SPECIFIC CRITERIA OF PURITY FOR EMULSIFIERS, STABILIZERS, THICKENERS AND GELLING AGENTS FOR USE IN FOODSTUFFS

OFFICIAL JOURNAL NO L 223, 14/08/1978, P. 7
DATE OF NOTIFICATION: 31/07/1978
DATE OF TRANSPOSITION: 31/01/1980; SEE ART. 3

AMENDED BY

382L0504
82/504/EEC: COUNCIL DIRECTIVE OF 12 JULY 1982 **[1]**
OFFICIAL JOURNAL NO L 230, 05/08/1982, P. 35
DATE OF NOTIFICATION: 19/07/1982
DATE OF TRANSPOSITION: 01/01/1984; SEE ART. 2

390L0612
90/612/EEC: COMMISSION DIRECTIVE OF 26 OCTOBER 1990 **[2]**
OFFICIAL JOURNAL NO L 326, 24/11/1990, P. 58
DATE OF TRANSPOSITION: 12/11/1991; SEE ART. 2

392L0004
92/4/EEC: COMMISSION DIRECTIVE OF 10 FEBRUARY 1992 **[3]**
OFFICIAL JOURNAL NO L 55, 29/02/1992, P. 96
DATE OF TRANSPOSITION: 01/06/1993; SEE ART. 2

ARTICLE 1

THE SPECIFIC CRITERIA OF PURITY REFERRED TO IN ARTICLE 6 (1) (b) OF DIRECTIVE 74/329/EEC (1) ARE GIVEN IN THE ANNEX TO THIS DIRECTIVE.

ARTICLE 2

" AS REGARDS THE SUBSTANCES REFERRED TO IN THE ANNEX UNDER E 477, MEMBER STATES MAY, UNTIL 31 DECEMBER 1984, AUTHORIZE FOR USE IN FOODSTUFFS A PRODUCT CONTAINING NOT MORE THAN 4 % DIMER AND TRIMER OF PROPANE-1,2-DIOL. " **[1]**

ARTICLE 3

MEMBER STATES SHALL BRING INTO FORCE THE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS NECESSARY TO COMPLY WITH THIS DIRECTIVE NOT LATER THAN 18 MONTHS AFTER THE NOTIFICATION OF THIS DIRECTIVE. THEY SHALL FORTHWITH INFORM THE COMMISSION THEREOF.

ARTICLE 4

THIS DIRECTIVE IS ADDRESSED TO THE MEMBER STATES.

ANNEX

SPECIFIC CRITERIA OF PURITY FOR EMULSIFIERS, STABILIZERS, THICKENERS AND GELLING AGENTS FOR USE IN FOODSTUFFS

GENERAL OBSERVATIONS

(a) WHERE INTERPRETATION OF THE CRITERIA SET OUT BELOW REQUIRES THE DEFINITION OF CERTAIN TECHNICAL DETAILS, REFERENCE SHOULD BE MADE TO THE METHODS OF ANALYSIS ESTABLISHED PURSUANT TO ARTICLE 7 (2) OF DIRECTIVE 74/329/EEC.

(b) UNLESS OTHERWISE STATED, THE QUANTITIES AND PERCENTAGES SHALL BE CALCULATED IN TERMS OF WEIGHT OF THE PRODUCT AS SUCH.

(c) THE SPECIFIC CRITERIA OF PURITY APPLICABLE TO SUBSTANCES E 322, E 339 (i), (ii) AND (iii), E 340 (i), (ii) AND (iii) AND E 341 (i) AND (ii) ARE LAID DOWN BY COUNCIL DIRECTIVE 78/664/EEC OF 25 JULY 1978 LAYING DOWN SPECIFIC CRITERIA OF PURITY FOR ANTIOXIDANTS WHICH MAY BE USED IN FOODSTUFFS INTENDED FOR HUMAN CONSUMPTION (2). THE REGIME APPLICABLE TO HYDROLYSED LECITHINS IS SET OUT IN THE SAME DIRECTIVE.

E 341 - (iii) TRICALCIUM ORTHOPHOSPHATE

CHEMICAL DESCRIPTION:

- TRICALCIUM DIORTHOPHOSPHATE; Ca3(PO4)2,
- HYDROXYAPATITE; Ca5(PO4)3OH.

APPEARANCE: IMPALPABLE WHITE POWDER.

CONTENT: NOT LESS THAN 90 % EXPRESSED AS Ca3(PO4)2 AFTER CALCINATION AT 800 ± 25 °C TO CONSTANT WEIGHT.

VOLATILE MATTER: NOT MORE THAN 10 % DETERMINED BY CALCINATION AT 800 ± 25 °C TO CONSTANT WEIGHT.

FLUORIDE: NOT MORE THAN 50 mg/kg EXPRESSED AS FLUORINE.

E 400 - ALGINIC ACID

CHEMICAL DESCRIPTION: LINEAR GLYCURONOGLYCAN CONSISTING MAINLY OF BETA (1-4) LINKED D-MANNURONIC AND ALPHA (1-4) LINKED L-GULURONIC ACID UNITS IN PYRANOSE RING FORM. HYDROPHILIC COLLOIDAL CARBOHYDRATE EXTRACTED BY THE USE OF DILUTE ALKALI FROM VARIOUS SPECIES OF BROWN SEAWEEDS.

DESCRIPTION: NEARLY ODOURLESS, TASTELESS WHITE TO YELLOWISH FIBROUS POWDER.

CONTENT: YIELDS, ON A VOLATILE MATTER-FREE BASIS, NOT LESS THAN 20 % AND NOT MORE THAN 23 % OF CARBON DIOXIDE CORRESPONDING TO NOT LESS THAN 91.0 % AND NOT MORE THAN 104.5 % OF ALGINIC ACID (EQUIVALENT WEIGHT 200).

ASH: NOT MORE THAN 4 % ON A VOLATILE MATTER-FREE BASIS DETERMINED AT 600 °C AFTER DRYING AT 105 °C FOR FOUR HOURS.

"..." **[1]**

VOLATILE MATTER: NOT MORE THAN 15 % DETERMINED BY DRYING AT 105 °C FOR FOUR HOURS.

ACID-INSOLUBLE ASH (INSOLUBLE IN APPROXIMATELY 3 N HYDROCHLORIC ACID): " NOT MORE THAN 2 %. " **[1]**

E 401 - SODIUM ALGINATE

CHEMICAL NAME: SODIUM SALT OF ALGINIC ACID.

DESCRIPTION: NEARLY ODOURLESS, TASTELESS WHITE TO YELLOWISH FIBROUS OR GRANULAR POWDER.

CONTENT: YIELDS, ON A VOLATILE MATTER-FREE BASIS, NOT LESS THAN 18 % AND NOT MORE THAN 21 % OF CARBON DIOXIDE CORRESPONDING TO NOT LESS THAN 90.8 % AND NOT MORE THAN 106.0 % OF SODIUM ALGINATE (EQUIVALENT WEIGHT 222).

ASH: NOT LESS THAN 18.0 % AND NOT MORE THAN 27.0 % ON A VOLATILE MATTER-FREE BASIS DETERMINED AT 600 °C AFTER DRYING AT 105 °C FOR FOUR HOURS.

"..." **[1]**

VOLATILE MATTER: NOT MORE THAN 15 % DETERMINED BY DRYING AT 105 °C FOR FOUR HOURS.

ACID-INSOLUBLE ASH (INSOLUBLE IN APPROXIMATELY 3 N HYDROCHLORIC ACID): " NOT MORE THAN 2 %. " **[1]**

E 402 - POTASSIUM ALGINATE

CHEMICAL NAME: POTASSIUM SALT OF ALGINIC ACID.

DESCRIPTION: NEARLY ODOURLESS, TASTELESS WHITE TO YELLOWISH FIBROUS OR GRANULAR POWDER.

CONTENT: YIELDS, ON A VOLATILE MATTER-FREE BASIS, NOT LESS THAN 16.5 % AND NOT MORE THAN 19.5 % OF CARBON DIOXIDE CORRESPONDING TO NOT LESS THAN 89.2 % AND NOT MORE THAN 105.5 % OF POTASSIUM ALGINATE (EQUIVALENT WEIGHT 238).

ASH: NOT LESS THAN 23 % AND NOT MORE THAN 32 % ON A VOLATILE MATTER-FREE BASIS DETERMINED AT 600 °C AFTER DRYING AT 105 °C FOR FOUR HOURS.

"..." **[1]**

VOLATILE MATTER: NOT MORE THAN 15 % DETERMINED BY DRYING AT 105 °C FOR FOUR HOURS.

ACID-INSOLUBLE ASH (INSOLUBLE IN APPROXIMATELY 3 N HYDROCHLORIC ACID): " NOT MORE THAN 2 %. " **[1]**

E 403 - AMMONIUM ALGINATE

CHEMICAL NAME: AMMONIUM SALT OF ALGINIC ACID.

DESCRIPTION: WHITE TO YELLOWISH FIBROUS OR GRANULAR POWDER.

CONTENT: YIELDS, ON A VOLATILE MATTER-FREE BASIS, NOT LESS THAN 18 % AND NOT MORE THAN 21 % OF CARBON DIOXIDE CORRESPONDING TO NOT LESS THAN 88.7 % AND NOT MORE THAN 103.6 % OF AMMONIUM ALGINATE (EQUIVALENT WEIGHT 217).

ASH: NOT MORE THAN 4 % ON A VOLATILE MATTER-FREE BASIS DETERMINED AT 600 °C AFTER DRYING AT 105 °C FOR FOUR HOURS.

"..." **[1]**

VOLATILE MATTER: NOT MORE THAN 15 % DETERMINED BY DRYING AT 105 °C FOR FOUR HOURS.

ACID-INSOLUBLE ASH (INSOLUBLE IN APPROXIMATELY 3 N HYDROCHLORIC ACID): " NOT MORE THAN 2 %. " **[1]**

E 404 - CALCIUM ALGINATE

CHEMICAL NAME: CALCIUM SALT OF ALGINIC ACID.

DESCRIPTION: NEARLY ODOURLESS, TASTELESS WHITE TO YELLOWISH FIBROUS OR GRANULAR POWDER.

CONTENT: YIELDS, ON A VOLATILE MATTER-FREE BASIS, NOT LESS THAN 18 % AND NOT MORE THAN 21 % OF CARBON DIOXIDE CORRESPONDING TO NOT LESS THAN 89.6 % AND NOT MORE THAN 104.5 % OF CALCIUM ALGINATE (EQUIVALENT WEIGHT 219).

ASH: NOT LESS THAN 15 % AND NOT MORE THAN 24 % ON A VOLATILE MATTER-FREE BASIS DETERMINED AT 600 °C AFTER DRYING AT 105 °C FOR FOUR HOURS.

"..." **[1]**

VOLATILE MATTER: NOT MORE THAN 15 % DETERMINED BY DRYING AT 105 °C FOR FOUR HOURS.

ACID-INSOLUBLE ASH (INSOLUBLE IN APPROXIMATELY 3 N HYDROCHLORIC ACID): " NOT MORE THAN 2 %. " **[1]**

E 405 - PROPANE-1,2-DIOL ALGINATE

CHEMICAL DESCRIPTION: PROPANE-1,2-DIOL ESTER OF ALGINIC ACID; VARIES IN COMPOSITION ACCORDING TO ITS DEGREE OF ESTERIFICATION AND THE PERCENTAGE OF FREE AND NEUTRALIZED CARBOXYL GROUPS IN THE MOLECULE.

DESCRIPTION: NEARLY ODOURLESS AND TASTELESS, WHITE TO YELLOWISH FIBROUS OR GRANULAR POWDER.

CONTENT: YIELDS, ON A VOLATILE MATTER-FREE BASIS, NOT LESS THAN 16 % AND NOT MORE THAN 20 % OF CARBON DIOXIDE.

ASH: NOT MORE THAN 10 % ON A VOLATILE MATTER-FREE BASIS DETERMINED AT 600 °C AFTER DRYING AT 105 °C FOR FOUR HOURS.

TOTAL PROPANE-1,2-DIOL CONTENT: NOT LESS THAN 15 % AND NOT MORE THAN 36 %.

FREE PROPANE-1,2-DIOL CONTENT: NOT MORE THAN 12 %.

"..." **[1]**

VOLATILE MATTER: NOT MORE THAN 20 % DETERMINED BY DRYING AT 105 °C FOR FOUR HOURS.

ACID-INSOLUBLE ASH (INSOLUBLE IN APPROXIMATELY 3 N HYDROCHLORIC ACID): " NOT MORE THAN 2 %. " **[1]**

E 406 - AGAR

CHEMICAL DESCRIPTION: A HYDROPHILIC COLLOIDAL POLYGALACTOSIDE, ABOUT 90 % OF THE GALACTOSE MOLECULES BEING OF THE D-FORM AND 10 % OF THE L-FORM. ON ABOUT EVERY TENTH D-GALACTOPYRANOSE UNIT ONE OF THE HYDROXYL GROUPS IS ESTERIFIED WITH SULPHURIC ACID WHICH IS NEUTRALIZED BY CALCIUM, MAGNESIUM, POTASSIUM OR SODIUM. IT IS EXTRACTED FROM CERTAIN MARINE ALGAE OF THE FAMILIES GELIDIACEAE AND SPHAEROCOCCACEAE AND RELATED RED ALGAE OF THE CLASS RHODOPHYCEAE.

DESCRIPTION: IT OCCURS AS WHITE TO PALE YELLOW POWDER, FIBRES OR FLAKES AND IS EITHER ODOURLESS, OR HAS A SLIGHT CHARACTERISTIC ODOUR AND A MUCILAGINOUS TASTE.

ASH: NOT MORE THAN 6.5 % DETERMINED AT 550 °C ON A VOLATILE MATTER-FREE BASIS.

ACID-INSOLUBLE ASH (INSOLUBLE IN APPROXIMATELY 3 N HYDROCHLORIC ACID): NOT MORE THAN 0.5 % DETERMINED AT 550 °C ON A VOLATILE MATTER-FREE BASIS.

GELATIN AND OTHER PROTEINS: DISSOLVE ABOUT 1 g OF AGAR IN 100 ml OF BOILING WATER AND ALLOW TO COOL TO ABOUT 50 °C. TO 5 ml OF THE SOLUTION ADD 5 ml OF TRINITROPHENOL SOLUTION (1 g OF ANHYDROUS TRINITROPHENOL/100 ml OF HOT WATER). NO TURBIDITY APPEARS WITHIN 10 MINUTES.

INSOLUBLE MATTER (IN HOT WATER): NOT MORE THAN 1 %.

VOLATILE MATTER: NOT MORE THAN 20 % DETERMINED BY DRYING AT 105 °C FOR FIVE HOURS.

STARCH AND DEXTRINS: BOIL 100 mg OF AGAR IN 100 ml OF WATER. COOL AND ADD A FEW DROPS OF IODINE SOLUTION (14 g I2 IN A SOLUTION OF 36 g KI IN 100 ml H2O, ADD THREE DROPS OF HCl AND DILUTE TO 1 000 ml). NO BLUE OR RED COLOUR IS PRODUCED.

WATER ABSORPTION: PLACE 5 g OF AGAR IN A 100 ml GRADUATED CYLINDER, FILL TO THE MARK WITH WATER, MIX AND ALLOW TO STAND AT ABOUT 25 °C FOR 24 HOURS. POUR THE CONTENTS OF THE CYLINDER THROUGH MOISTENED GLASS WOOL, ALLOWING THE WATER TO DRAIN INTO A SECOND 100 ml GRADUATED CYLINDER. NOT MORE THAN 75 ml OF WATER IS OBTAINED.

E 407 - CARRAGEENAN

CHEMICAL DESCRIPTION: CARRAGEENAN IS OBTAINED BY AQUEOUS EXTRACTION OF SEAWEEDS OF GIGARTINACEAE, SOLIERIACEAE, HYPNEACEAE AND FURCELLARIACEAE, FAMILIES OF THE CLASS RHODOPHYCEAE (RED SEAWEEDS). NO ORGANIC PRECIPITANTS SHALL BE USED OTHER THAN METHANOL, ETHANOL AND ISOPROPANOL. CARRAGEENAN CONSISTS CHIEFLY OF THE POTASSIUM, SODIUM, MAGNESIUM AND CALCIUM SALTS OF POLYSACCHARIDE SULPHATE ESTERS WHICH, ON HYDROLYSIS, YIELD GALACTOSE AND 3,6-ANHYDROGALACTOSE. CARRAGEENAN SHALL NOT BE HYDROLYSED OR OTHERWISE CHEMICALLY DEGRADED.

DESCRIPTION: YELLOWISH TO COLOURLESS, COARSE TO FINE POWDER WHICH IS PRACTICALLY ODOURLESS AND HAS A MUCILAGINOUS TASTE.

VOLATILE MATTER: NOT MORE THAN 12 % DETERMINED BY DRYING AT 105 °C FOR FOUR HOURS.

SULPHATE: NOT LESS THAN 15 % AND NOT MORE THAN 40 % ON A VOLATILE MATTER-FREE BASIS, EXPRESSED AS SO4.

" acid-insoluble ash (insoluble in 10 % w/v hydrochloric acid): not more than 1 % dry matter

acid-insoluble matter (insoluble in 1 % v/v sulphuric acid): not more than 2 % dry matter. " **[2]**

ASH: NOT LESS THAN 15 % AND NOT MORE THAN 40 % DETERMINED AT 550 °C ON A VOLATILE MATTER-FREE BASIS.

METHANOL, ETHANOL, ISOPROPANOL CONTENT: NOT MORE THAN 1 % SINGLY OR IN COMBINATION.

VISCOSITY OF A 1.5 % SOLUTION AT 75 °C: NOT LESS THAN FIVE CENTIPOISES.

E 410 - LOCUST BEAN GUM

CHEMICAL DESCRIPTION: CONSISTS MAINLY OF A HIGH MOLECULAR WEIGHT HYDROCOLLOIDAL POLYSACCHARIDE, COMPOSED OF GALACTOPYRANOSE AND MANNOPYRANOSE UNITS COMBINED THROUGH GLYCOSIDIC LINKAGES, WHICH MAY BE DESCRIBED CHEMICALLY AS GALACTOMANNAN.

DESCRIPTION: LOCUST BEAN GUM IS THE GROUND ENDOSPERM OF THE SEEDS OF THE CAROB TREE, CERATIONIA SILIQUA (L.) TAUB. (FAM. LEGUMINOSAE). IT IS A WHITE TO YELLOWISH-WHITE, NEARLY ODOURLESS POWDER.

GALACTOMANNAN CONTENT: NOT LESS THAN 75 %.

INSOLUBLE MATTER (IN 0.4 N SULPHURIC ACID): NOT MORE THAN 4 % AFTER DIGESTION FOR SIX HOURS.

ASH: NOT MORE THAN 1.2 % DETERMINED AT 800 °C.

VOLATILE MATTER: NOT MORE THAN 14 % DETERMINED BY DRYING TO CONSTANT WEIGHT AT 102 TO 105 °C (THREE TO FIVE HOURS).

PROTEIN (N TIMES 6.25): NOT MORE THAN 7 %.

E 412 - GUAR GUM

CHEMICAL DESCRIPTION: CONSISTS MAINLY OF A HIGH MOLECULAR WEIGHT HYDROCOLLOIDAL POLYSACCHARIDE COMPOSED OF GALACTOPYRANOSE AND MANNOPYRANOSE UNITS COMBINED THROUGH GLYCOSIDIC LINKAGES, WHICH MAY BE DESCRIBED CHEMICALLY AS GALACTOMANNAN.

DESCRIPTION: GUAR GUM IS THE GROUND ENDOSPERM OF THE SEEDS OF THE GUAR PLANT, CYAMOPSIS TETRAGONOLOBUS (L.) TAUB. (FAM. LEGUMINOSAE). IT IS A WHITE TO YELLOWISH-WHITE, NEARLY ODOURLESS POWDER.

GALACTOMANNAN CONTENT: NOT LESS THAN 75 %.

INSOLUBLE MATTER (IN 0.4 N SULPHURIC ACID): NOT MORE THAN 4 % AFTER DIGESTION FOR SIX HOURS.

ASH: NOT MORE THAN 1.5 % DETERMINED AT 800 °C.

VOLATILE MATTER: NOT MORE THAN 14 % DETERMINED BY DRYING TO CONSTANT WEIGHT AT 102 TO 105 °C (THREE TO FIVE HOURS).

PROTEIN (N TIMES 6.25): NOT MORE THAN 7 %.

E 413 - TRAGACANTH

CHEMICAL DESCRIPTION: CONSISTS MAINLY OF HIGH MOLECULAR WEIGHT POLYSACCHARIDES COMPOSED OF GALACTO-ARABANS AND ACIDIC POLYSACCHARIDES CONTAINING GALACTURONIC ACID GROUPS.

DESCRIPTION: TRAGACANTH IS A DRIED GUMMY EXUDATE OBTAINED FROM ASTRAGALUS GUMMIFER LABILLARDIERE, OR OTHER ASIATIC SPECIES OF ASTRAGALUS (FAM. LEGUMINOSAE).

UNGROUND TRAGACANTH OCCURS AS FLATTENED, LAMELLATED, FREQUENTLY CURVED FRAGMENTS OR STRAIGHT OR SPIRALLY TWISTED LINEAR PIECES FROM 0.5 TO 2.5 mm IN THICKNESS. IT IS WHITE TO PALE YELLOW IN COLOUR. IT IS ODOURLESS AND HAS AN INSIPID, MUCILAGINOUS TASTE.
POWDERED TRAGACANTH IS WHITE TO YELLOWISH-WHITE IN COLOUR.

VISCOSITY OF A 1 % SOLUTION AT 25 °C: NOT LESS THAN 250 CENTIPOISES.

ASH: NOT MORE THAN 3.5 % DETERMINED AT 550 °C.

ACID-INSOLUBLE ASH (INSOLUBLE IN APPROXIMATELY 3 N HYDROCHLORIC ACID): NOT MORE THAN 0.5 % DETERMINED AT 550 °C.

KARAYA GUM: BOIL 1 g WITH 20 ml OF WATER UNTIL A MUCILAGE IS FORMED. ADD 5 ml OF HYDROCHLORIC ACID AND AGAIN BOIL THE MIXTURE FOR FIVE MINUTES. NO PERMANENT PINK OR RED COLOUR DEVELOPS.

E 414 - ACACIA

CHEMICAL DESCRIPTION: CONSISTS MAINLY OF HIGH MOLECULAR WEIGHT POLYSACCHARIDES AND THEIR CALCIUM, POTASSIUM AND MAGNESIUM SALTS, WHICH ON HYDROLYSIS YIELD ARABINOSE, GALACTOSE, RHAMNOSE AND GLUCURONIC ACID. IT IS OBTAINED AS A DRIED GUMMY EXUDATE FROM THE STEMS AND BRANCHES OF ACACIA SENEGAL (L) WILLD. OR OF RELATED SPECIES OF ACACIA (FAM. LEGUMINOSAE).

DESCRIPTION: UNGROUND ACACIA OCCURS AS WHITE, YELLOWISH-WHITE OR PALE PINKISH SPHEROIDAL TEARS OF VARYING SIZES OR IN ANGULAR FRAGMENTS. IT IS ALSO AVAILABLE COMMERCIALLY IN THE FORM OF WHITE OR YELLOWISH -WHITE FLAKES, GRANULES OR POWDER.

ASH: NOT MORE THAN 4 % DETERMINED AT 550 °C.

ACID-INSOLUBLE ASH (INSOLUBLE IN APPROXIMATELY 3 N HYDROCHLORIC ACID): NOT MORE THAN 0.5 % DETERMINED AT 550 °C.

INSOLUBLE MATTER (IN APPROXIMATELY 3 N HYDROCHLORIC ACID): NOT MORE THAN 1 %.

VOLATILE MATTER: NOT MORE THAN 15 % DETERMINED BY DRYING AT 105 °C FOR FIVE HOURS.

STARCH OR DEXTRIN: BOIL A 1 IN 50 SOLUTION OF THE GUM AND COOL. TO 5 ml ADD ONE DROP OF IODINE SOLUTION (14 g OF IODINE IN A SOLUTION OF 36 g OF POTASSIUM IODIDE IN 100 ml OF WATER, ADD THREE DROPS OF HYDROCHLORIC ACID AND DILUTE TO 1 000 ml). NO BLUISH OR REDDISH COLOUR IS PRODUCED.

TANNIN: TO 10 ml OF A 1 IN 50 SOLUTION ADD ABOUT 0.1 ml OF FERRIC CHLORIDE SOLUTION (9 g FeCl3.6H2O MADE UP TO 100 ml WITH WATER). NO BLACKISH COLOURATION OR BLACKISH PRECIPITATE IS FORMED.

" E 415 - XANTHAN GUM

CHEMICAL DESCRIPTION: XANTHAN GUM IS A HIGH MOLECULAR WEIGHT POLYSACCHARIDE GUM PRODUCED BY PURE-CULTURE FERMENTATION OF A CARBOHYDRATE WITH XANTHOMONAS CAMPESTRIS, PURIFIED BY RECOVERY WITH ETHANOL OR ISOPROPANOL, DRIED AND MILLED. IT CONTAINS D-GLUCOSE AND D-MANNOSE AS THE DOMINANT HEXOSE UNITS, ALONG WITH D-GLUCURONIC ACID AND PYRUVIC ACID, AND IS PREPARED AS THE SODIUM, POTASSIUM OR CALCIUM SALT. ITS SOLUTIONS ARE NEUTRAL.

DESCRIPTION: CREAM-COLOURED POWDER.

CONTENT: XANTHAN GUM YIELDS, ON A VOLATILE MATTER-FREE BASIS, NOT LESS THAN 4.2 % AND NOT MORE THAN 5.0 % OF CARBON DIOXIDE.

VOLATILE MATTER: NOT MORE THAN 15 % DETERMINED BY DRYING AT 105 °C FOR 2 1/2 HOURS.

ASH: NOT MORE THAN 16 % ON A VOLATILE-MATTER-FREE BASIS DETERMINED AT 600 °C AFTER DRYING AT 105 °C FOR FOUR HOURS.

PYRUVIC ACID: NOT LESS THAN 1.5 %.

NITROGEN: NOT MORE THAN 1.5 %.

ISOPROPANOL: NOT MORE THAN 750 mg/kg.

MICROBIOLOGICAL CRITERIA: VIABLE CELLS OF XANTHOMONAS CAMPESTRIS SHALL BE ABSENT. " **[1]**

E 420 - (i) SORBITOL

CHEMICAL NAME: D-SORBITOL.

DESCRIPTION: WHITE HYGROSCOPIC CRYSTALLINE POWDER, FLAKES OR GRANULES, HAVING A SWEET TASTE.

CONTENT: SORBITOL CONTAINS NOT LESS THAN 98 % OF GLYCITOLS AND NOT LESS THAN 91 % OF D-SORBITOL, ON A DRY-MATTER BASIS IN EACH CASE. GLYCITOLS ARE COMPOUNDS WITH THE STRUCTURAL FORMULA CH2OH (CHOH) n CH2OH WHERE "n" IS AN INTEGER. THAT PART OF THE PRODUCT WHICH IS NOT D-SORBITOL IS COMPOSED MAINLY OF MANNITOL, TOGETHER WITH SMALL QUANTITIES OF OTHER GLYCITOLS, WHERE $n \leq 4$, AND MINOR QUANTITIES OF HYDROGENATED OLIGOSACCHARIDES.

WATER: NOT MORE THAN 1 % (KARL FISCHER).

REDUCING SUGARS: NOT MORE THAN 0.3 % ON A DRYWEIGHT BASIS, EXPRESSED AS DEXTROSE.

TOTAL SUGARS: NOT MORE THAN 1 % ON A DRYWEIGHT BASIS, EXPRESSED AS DEXTROSE.

SULPHATED ASH: NOT MORE THAN 0.1 % AT 800 ± 25 °C ON A DRYWEIGHT BASIS.

SULPHATE: NOT MORE THAN 0.01 % ON A DRYWEIGHT BASIS, EXPRESSED AS SO4.

CHLORIDE: NOT MORE THAN 0.005 % ON A DRYWEIGHT BASIS, EXPRESSED AS Cl.

NICKEL: NOT MORE THAN 2 mg/kg, EXPRESSED AS Ni.

E 420 - (ii) SORBITOL SYRUP

DESCRIPTION: CLEAR, COLOURLESS AND SWEET-TASTING AQUEOUS SOLUTION OF SORBITOL AND HYDROGENATED OLIGOSACCHARIDES. THAT PART OF THE PRODUCT WHICH IS NOT D-SORBITOL IS COMPOSED MAINLY OF HYDROGENATED OLIGOSACCHARIDES FORMED BY THE HYDROGENATION OF GLUCOSE SYRUP USED AS RAW MATERIAL (IN WHICH CASE THE SYRUP IS NON-CRYSTALLIZING) OR MANNITOL. MINOR QUANTITIES OF GLYCITOLS WHERE $n \leq 4$ MAY BE PRESENT. GLYCITOLS ARE COMPOUNDS WITH THE STRUCTURAL FORMULA CH2OH (CHOH) n CH2OH, WHERE "n" IS AN INTEGER.

CONTENT: NOT LESS THAN 69 % TOTAL SOLIDS AND NOT LESS THAN 50 % OF D-SORBITOL.

REDUCING SUGARS: NOT MORE THAN 0.3 % ON A DRYWEIGHT BASIS, EXPRESSED AS DEXTROSE.

SULPHATED ASH: NOT MORE THAN 0.1 % ON A DRYWEIGHT BASIS (AFTER IGNITION AT 800 ± 25 °C).

SULPHATE: NOT MORE THAN 0.01 % ON A DRYWEIGHT BASIS, EXPRESSED AS SO4.

CHLORIDE: NOT MORE THAN 0.005 % ON A DRYWEIGHT BASIS, EXPRESSED AS Cl.

NICKEL: NOT MORE THAN 2 mg/kg, EXPRESSED AS Ni.

E 421 - MANNITOL

CHEMICAL NAME: D-MANNITOL.

DESCRIPTION: WHITE CRYSTALLINE SOLID WHICH IS ODOURLESS AND HAS A SWEET TASTE.

CONTENT: NOT LESS THAN 98 % OF D-MANNITOL (C6H14O6) ON A VOLATILE MATTER-FREE BASIS.

MELTING RANGE: 165 TO 169 °C.

SPECIFIC ROTATION /α/ 25:D : NOT LESS THAN + 23.0° AND NOT MORE THAN + 24.3°.

VOLATILE MATTER: NOT MORE THAN 0.3 % DETERMINED BY DRYING AT 105 °C FOR FOUR HOURS.

REDUCING SUGARS: NOT MORE THAN 0.05 %, EXPRESSED AS DEXTROSE.

SULPHATE: NOT MORE THAN 0.01 %, EXPRESSED AS SO4.

CHLORIDE: NOT MORE THAN 0.007 %, EXPRESSED AS Cl.

ASH: NOT MORE THAN 0.1 % DETERMINED AT 800 ± 25 °C.

NICKEL: NOT MORE THAN 2 mg/kg, EXPRESSED AS Ni.

E 422 - GLYCEROL

DESCRIPTION: CLEAR, COLOURLESS HYGROSCOPIC SYRUPY LIQUID WITH A SWEET TASTE ACCOMPANIED BY A SENSATION OF HEAT TO THE TONGUE.

CONTENT: NOT LESS THAN 98 % OF GLYCEROL (C3H8O3).

SPECIFIC GRAVITY (25/25 °C): NOT LESS THAN 1.257.

REFRACTIVE INDEX /n/ 20:D : 1.471 TO 1.474.

ACROLEIN, GLUCOSE AND AMMONIUM COMPOUNDS: HEAT A MIXTURE OF 5 ml OF GLYCEROL AND 5 ml OF POTASSIUM HYDROXIDE SOLUTION (1 IN 10) AT 60 °C FOR FIVE MINUTES. IT NEITHER BECOMES YELLOW NOR EMITS AN ODOUR OF AMMONIA.

BUTANETRIOLS: NOT MORE THAN 0.2 %.

CHLORINATED COMPOUNDS (EXPRESSED AS Cl): NOT MORE THAN 0.003 %.

FATTY ACIDS AND ESTERS: NOT MORE THAN 0.1 % CALCULATED AS BUTYRIC ACID.

SULPHATED ASH: NOT MORE THAN 0.01 % DETERMINED AT 800 ± 25 °C.

E 440 (a) - PECTIN

CHEMICAL DESCRIPTION: PECTIN CONSISTS MAINLY OF THE PARTIAL METHYL ESTERS OF POLYGALACTURONIC ACID AND THEIR SODIUM, POTASSIUM, CALCIUM AND AMMONIUM SALTS. PECTIN IS OBTAINED BY AQUEOUS EXTRACTION OF APPROPRIATE EDIBLE PLANT MATERIAL, USUALLY CITRUS FRUITS OR APPLES. NO ORGANIC PRECIPITANTS SHALL BE USED OTHER THAN METHANOL, ETHANOL AND ISOPROPANOL.

DESCRIPTION: WHITE, LIGHT YELLOW, LIGHT GREY OR LIGHT BROWN POWDER.

GALACTURONIC ACID: NOT LESS THAN 65 % CALCULATED ON AN ASH AND VOLATILE MATTER-FREE BASIS AFTER WASHING WITH ACID AND ALCOHOL.

" Volatile matter: not more than 12 % determined by drying at 105 °C for two hours. " (R1)

ACID-INSOLUBLE ASH (INSOLUBLE IN APPROXIMATELY 3 N HYDROCHLORIC ACID): NOT MORE THAN 1 %.

FREE METHANOL, ETHANOL AND ISOPROPANOL CONTENT NOT MORE THAN 1 %, SINGLY OR IN COMBINATION, ON A VOLATILE MATTER-FREE BASIS.

SULPHUR DIOXIDE RESIDUE: NOT MORE THAN 50 mg/kg ON A VOLATILE MATTER-FREE BASIS.

NITROGEN CONTENT: NOT MORE THAN 0.5 % DETERMINED AFTER WASHING WITH ACID AND ALCOHOL (KJELDAHL).

E 440 (b) - AMIDATED PECTIN

CHEMICAL DESCRIPTION: AMIDATED PECTIN CONSISTS MAINLY OF THE PARTIAL METHYL ESTERS AND AMIDES OF POLYGALACTURONIC ACID AND THEIR AMMONIUM, SODIUM, POTASSIUM AND CALCIUM SALTS. IT IS OBTAINED BY AQUEOUS EXTRACTION OF APPROPRIATE EDIBLE PLANT MATERIAL, USUALLY CITRUS FRUITS OR APPLES AND TREATMENT WITH AMMONIA UNDER ALKALINE CONDITIONS. NO ORGANIC PRECIPITANTS SHALL BE USED OTHER THAN METHANOL, ETHANOL AND ISOPROPANOL.

DESCRIPTION: WHITE, LIGHT YELLOW, LIGHT GREY OR LIGHT BROWN POWDER.

DEGREE OF AMIDATION: NOT MORE THAN 25 % OF TOTAL CARBOXYL GROUPS.

GALACTURONIC ACID: NOT LESS THAN 65 % CALCULATED ON AN ASH AND VOLATILE MATTER-FREE BASIS DETERMINED AFTER WASHING WITH ACID AND ALCOHOL.

" Volatile matter: not more than 12 % determined by drying at 105 °C for two hours. " (R1)

ACID-INSOLUBLE ASH (INSOLUBLE IN APPROXIMATELY 3 N HYDROCHLORIC ACID): NOT MORE THAN 1 %.

FREE METHANOL, ETHANOL AND ISOPROPANOL CONTENT: NOT MORE THAN 1 %, SINGLY OR IN COMBINATION, ON A VOLATILE MATTER-FREE BASIS.

SULPHUR DIOXIDE RESIDUE: NOT MORE THAN 50 mg/kg ON A VOLATILE MATTER-FREE BASIS.

NITROGEN CONTENT: NOT MORE THAN 2.5 % AFTER WASHING WITH ACID AND ALCOHOL (KJELDAHL).

E 450 (a) - (i) DISODIUM DIHYDROGEN DIPHOSPHATE

DESCRIPTION: WHITE POWDER OR GRAINS.

CONTENT: NOT LESS THAN 95.0 % OF Na2H2P2O7.

CONTENT IN P2O5: NOT LESS THAN 63.0 % AND NOT MORE THAN 64.0 %.

VOLATILE MATTER: NOT MORE THAN 0.5 % DETERMINED BY DRYING AT 105 °C FOR FOUR HOURS.

PH OF 1 % SOLUTION: NOT LESS THAN 3.7 AND NOT MORE THAN 4.4.

WATER INSOLUBLE MATTER: NOT MORE THAN 0.6 %.

FLUORIDE: NOT MORE THAN 10 mg/kg EXPRESSED AS FLUORINE.

E 450 (a) - (ii) TRISODIUM DIPHOSPHATE

DESCRIPTION: WHITE POWDER OR GRAINS. OCCURS ANHYDROUS OR AS A MONOHYDRATE.

CONTENT: NOT LESS THAN 95.0 % OF Na3HP2O7 OR OF Na3HP2O7.H2O.

CONTENT IN P2O5: NOT LESS THAN 57.5 % AND NOT MORE THAN 58.5 % FOR THE ANHYDROUS SALT. NOT LESS THAN 53.6 % AND NOT MORE THAN 54.6 % FOR THE MONOHYDRATE.

PH OF A 1 % SOLUTION: NOT LESS THAN 6.7 AND NOT MORE THAN 7.3.

VOLATILE MATTER: NOT MORE THAN 0.5 % DETERMINED BY DRYING AT 105 °C FOR FOUR HOURS.

WATER INSOLUBLE: MATTER NOT MORE THAN 0.2 %.

FLUORIDE: NOT MORE THAN 10 mg/kg EXPRESSED AS FLUORINE.

E 450 (a) - (iii) TETRASODIUM DIPHOSPHATE

DESCRIPTION: WHITE, CRYSTALLINE OR GRANULAR POWDER. OCCURS ANHYDROUS OR AS A DECAHYDRATE.

CONTENT: NOT LESS THAN 95.0 % OF Na4P2O7 OR OF Na4P2O7.10H2O.

CONTENT IN P2O5: NOT LESS THAN 52.5 % AND NOT MORE THAN 54.0 % FOR THE ANHYDROUS SALT. NOT LESS THAN 31.5 % AND NOT MORE THAN 32.5 % FOR THE DECAHYDRATE.

LOSS ON IGNITION: NOT MORE THAN 0.5 % FOR THE ANHYDROUS SALT, NOT LESS THAN 38 % AND NOT MORE THAN 42 % FOR THE DECAHYDRATE, IN BOTH CASES DETERMINED AFTER DRYING AT 105 % °C FOR FOUR HOURS, FOLLOWED BY IGNITION AT 550 °C FOR 30 MINUTES.

PH OF A 1 % SOLUTION: NOT LESS THAN 9.9 AND NOT MORE THAN 10.7.

WATER INSOLUBLE MATTER: NOT MORE THAN 0.2 %.

FLUORIDE: NOT MORE THAN 10 mg/kg EXPRESSED AS FLUORINE.

E 450 (a) - (iv) TETRAPOTASSIUM DIPHOSPHATE

DESCRIPTION: COLOURLESS CRYSTALS OR WHITE, VERY HYGROSCOPIC POWDER.

CONTENT: NOT LESS THAN 95.0 % OF K4P2O7.

CONTENT IN P2O5: NOT LESS THAN 42.0 % AND NOT MORE THAN 43.7 %.

LOSS ON IGNITION: NOT MORE THAN 2 % AFTER DRYING AT 105 °C FOR FOUR HOURS FOLLOWED BY IGNITION AT 550 °C FOR 30 MINUTES.

PH OF A 1 % SOLUTION: NOT LESS THAN 10.0 AND NOT MORE THAN 10.7.

WATER INSOLUBLE MATTER: NOT MORE THAN 0.2 %.

FLUORIDE (EXPRESSED AS F): NOT MORE THAN 10 mg/kg.

E 450 (b) - (i) PENTASODIUM TRIPHOSPHATE

DESCRIPTION: WHITE, SLIGHTLY HYGROSCOPIC GRANULES OR POWDER. OCCURS ANHYDROUS OR AS A HEXAHYDRATE.

CONTENT: NOT LESS THAN 85.0 % OF Na5P3O10 OR OF Na5P3O10.6H2O, THE REMAINDER BEING PRINCIPALLY OTHER SODIUM PHOSPHATES (E 450).

CONTENT IN P2O5: NOT LESS THAN 56.0 % AND NOT MORE THAN 58.0 % FOR THE ANHYDROUS SALT. NOT LESS THAN 43.0 % AND NOT MORE THAN 45.0 % FOR THE HEXAHYDRATE.

LOSS ON IGNITION: NOT MORE THAN 0.5 % FOR THE ANHYDROUS SALT AND NOT MORE THAN 23.5 % FOR THE HEXAHYDRATE, IN BOTH CASES DETERMINED AFTER DRYING AT 105 °C FOR FOUR HOURS FOLLOWED BY IGNITION AT 550 °C FOR 30 MINUTES.

PH OF A 1 % SOLUTION: NOT LESS THAN 9.3 AND NOT MORE THAN 10.1.

WATER INSOLUBLE MATTER: NOT MORE THAN 0.2 %.

FLUORIDE (EXPRESSED AS F): NOT MORE THAN 10 mg/kg.

E 450 (b) - (ii) PENTAPOTASSIUM TRIPHOSPHATE

DESCRIPTION: WHITE, VERY HYGROSCOPIC POWDER.

CONTENT: NOT LESS THAN 85.0 % OF K5P3O10, THE REMAINDER BEING PRINCIPALLY OTHER POTASSIUM PHOSPHATES (E 450).

CONTENT IN P2O5: NOT LESS THAN 46.5 % AND NOT MORE THAN 48.0 %.

LOSS ON IGNITION: NOT MORE THAN 0.5 % CALCULATED ON THE P2O5 CONTENT AFTER DRYING AT 105 °C FOR FOUR HOURS, FOLLOWED BY IGNITION AT 550 °C FOR 30 MINUTES.

PH OF A 1 % SOLUTION: NOT LESS THAN 9.3 AND NOT MORE THAN 10.1.

WATER INSOLUBLE MATTER: NOT MORE THAN 2 %.

FLUORIDE (EXPRESSED AS F): NOT MORE THAN 10 mg/kg.

E 450 (c) - (i) SODIUM POLYPHOSPHATES

CHEMICAL DESCRIPTION: HETEROGENEOUS MIXTURES OF SODIUM SALTS OF LINEAR CONDENSED POLYPHOSPHORIC ACIDS OF GENERAL FORMULA H(n+2) PnO(3n+1) WHERE "n" IS NOT LESS THAN 2.

DESCRIPTION: FINE WHITE POWDERS OR CRYSTALS OR COLOURLESS GLASSY PLATELETS.

CONTENT IN P2O5: NOT LESS THAN 59.5 % AND NOT MORE THAN 70.0 %, CALCULATED ON THE IGNITED BASIS.

LOSS ON IGNITION: NOT MORE THAN 0.5 % AFTER DRYING AT 105 °C FOR FOUR HOURS FOLLOWED BY IGNITION AT 550 °C FOR 30 MINUTES.

PH OF A 1 % SOLUTION: NOT LESS THAN 3.6 AND NOT MORE THAN 9.0.

WATER INSOLUBLE MATTER: NOT MORE THAN 0.2 %.

FLUORIDE: NOT MORE THAN 10 mg/kg EXPRESSED AS FLUORINE.

CYCLIC PHOSPHATES: NOT MORE THAN 8 %.

E 450 (c) - (ii) POTASSIUM POLYPHOSPHATES

CHEMICAL DESCRIPTION: HETEROGENEOUS MIXTURES OF POTASSIUM SALTS OF LINEAR CONDENSED POLYPHOSPHORIC ACIDS OF GENERAL FORMULA H(n+2) PNO(3n+1) WHERE "n" IS NOT LESS THAN 2.

DESCRIPTION: FINE WHITE POWDERS OR CRYSTALS OR COLOURLESS GLASSY PLATELETS.

CONTENT IN P2O5: NOT LESS THAN 53.5 % AND NOT MORE THAN 61.5 %, CALCULATED ON THE IGNITED BASIS.

LOSS ON IGNITION: NOT MORE THAN 2 % AFTER DRYING AT 105 °C FOR FOUR HOURS FOLLOWED BY IGNITION AT 550 °C FOR 30 MINUTES.

PH OF A 1 % SOLUTION: NOT MORE THAN 7.8 (3).

WATER INSOLUBLE MATTER: NOT MORE THAN 0.2 % (3).

FLUORIDE: NOT MORE THAN 10 mg/kg EXPRESSED AS FLUORINE.

CYCLIC PHOSPHATES: NOT MORE THAN 8 %.

" E 460 - (i) " **[1]** MICROCRYSTALLINE CELLULOSE

CHEMICAL DESCRIPTION: MICROCRYSTALLINE CELLULOSE IS PURIFIED PARTIALLY DEPOLYMERIZED CELLULOSE PREPARED BY ACID HYDROLYSIS OF ALPHA-CELLULOSE OBTAINED DIRECTLY FROM FIBROUS PLANT MATERIAL. IT HAS A MOLECULAR WEIGHT OF ABOUT 36 000.

DESCRIPTION: A FINE WHITE OR ALMOST WHITE ODOURLESS POWDER.

VOLATILE MATTER: NOT MORE THAN 5 % DETERMINED BY DRYING TO CONSTANT WEIGHT AT 105 °C.

PH: SHAKE ABOUT 5 g WITH 40 ml OF CARBON DIOXIDE-FREE WATER FOR 20 MINUTES AND CENTRIFUGE. THE PH OF THE SUPERNATANT LIQUID IS BETWEEN 5.5 AND 7.

SULPHATED ASH: NOT MORE THAN 0.1 % DETERMINED AT 800 ± 25 °C.

WATER SOLUBLE SUBSTANCES: NOT MORE THAN 0.16 %.

DIETHYL ETHER EXTRACTABLE MATTER: NOT MORE THAN 200 mg/kg.

CHLORIDE: NOT MORE THAN 350 mg/kg EXPRESSED AS Cl.

SULPHATE: NOT MORE THAN 600 mg/kg EXPRESSED AS SO4.

" E 460 - (ii) POWDERED CELLULOSE

CHEMICAL DESCRIPTION: POWDERED CELLULOSE IS PURIFIED MECHANICALLY DISINTEGRATED CELLULOSE PREPARED BY PROCESSING ALPHA-CELLULOSE OBTAINED DIRECTLY FROM FIBROUS PLANT MATERIAL. IT HAS A MOLECULAR WEIGHT OF 1.6 TIMES 10 to the power of 5 OR GREATER.

DESCRIPTION: A WHITE, ODOURLESS POWDER.

CONTENT: NOT LESS THAN 92 % (C12H20O10)n.

VOLATILE MATTER: NOT MORE THAN 7 % DETERMINED BY DRYING AT 105 °C FOR THREE HOURS.

PH: SHAKE ABOUT 5 g WITH 40 ml OF CARBON-DIOXIDE-FREE WATER FOR 20 MINUTES AND CENTRIFUGE. THE PH OF THE SUPERNATANT LIQUID IS BETWEEN 5.0 AND 7.5.

SULPHATED ASH: NOT MORE THAN 0.3 % DETERMINED AT 800 ± 25 °C.

WATER-SOLUBLE SUBSTANCES: NOT MORE THAN 1 %. " **[1]**

E 461 - METHYLCELLULOSE

CHEMICAL DESCRIPTION: METHYLCELLULOSE IS CELLULOSE OBTAINED DIRECTLY FROM FIBROUS PLANT MATERIAL AND PARTIALLY ETHERIFIED WITH METHYL GROUPS.

DESCRIPTION: SLIGHTLY HYGROSCOPIC WHITE OR SLIGHTLY YELLOWISH OR GREYISH ODOURLESS AND TASTELESS, GRANULAR OR FIBROUS POWDER.

CHEMICAL FORMULA: THE POLYMERS CONTAIN SUBSTITUTED ANHYDROGLUCOSE UNITS WITH THE FOLLOWING GENERAL FORMULA:

C6H7O2 (OR1) (OR2) (OR3) WHERE R1, R2, R3 EACH MAY BE

- H,
- CH3, OR
- CH2 CH2 OH.

MOLECULAR WEIGHT: FROM ABOUT 20 000 TO 380 000.

CONTENT OF SUBSTITUTED GROUPS: NOT LESS THAN 25 % AND NOT MORE THAN 33 % OF METHOXYL GROUPS (-OCH3). NOT MORE THAN 5 % OF HYDROXYETHOXYL GROUPS (-OCH2CH2OH).

VOLATILE MATTER: NOT MORE THAN 10 % DETERMINED BY DRYING TO CONSTANT WEIGHT AT 105 °C.

SULPHATED ASH: NOT MORE THAN 1.5 % DETERMINED AT 800 ± 25 °C.

PH OF A 1 % SOLUTION: NOT LESS THAN 5 AND NOT MORE THAN 8.

E 463 - HYDROXYPROPYLCELLULOSE

CHEMICAL DESCRIPTION: HYDROXYPROPYLCELLULOSE IS CELLULOSE OBTAINED DIRECTLY FROM FIBROUS PLANT MATERIAL AND PARTIALLY ETHERIFIED WITH HYDROXYPROPYL GROUPS.

DESCRIPTION: SLIGHTLY HYGROSCOPIC WHITE OR SLIGHTLY YELLOWISH OR GREYISH ODOURLESS AND TASTELESS, GRANULAR OR FIBROUS POWDER.

CHEMICAL FORMULA: THE POLYMERS CONTAIN SUBSTITUTED ANHYDROGLUCOSE UNITS WITH THE FOLLOWING GENERAL FORMULA:

C6H7O2 (OR1) (OR2) (OR3) WHERE R1, R2, R3 EACH MAY BE ANY ONE OF THE FOLLOWING:

- H,
- CH2CHOHCH3,
- CH2CHO (CH2CHOHCH3) CH3,
- CH2CHO (CH2CHO (CH2CHOHCH3) CH3) CH3.

MOLECULAR WEIGHT: FROM ABOUT 30 000 TO 1 000 000.

CONTENT OF SUBSTITUTED GROUPS: NOT MORE THAN 80.5 % OF HYDROXYPROPOXYL GROUPS (-OCH2CHOHCH3) ON A VOLATILE MATTER-FREE BASIS, EQUIVALENT TO NOT MORE THAN 4.6 HYDROXYPROPYL GROUPS PER ANHYDROGLUCOSE UNIT.

PH OF A 1 % SOLUTION: NOT LESS THAN 5.0 AND NOT MORE THAN 8.0.

VOLATILE MATTER: NOT MORE THAN 10 % DETERMINED BY DRYING TO CONSTANT WEIGHT AT 105 °C.

SULPHATED ASH: NOT MORE THAN 0.5 % DETERMINED AT 800 ± 25 °C.

E 464 - HYDROXYPROPYLMETHYLCELLULOSE

CHEMICAL DESCRIPTION: HYDROXYPROPYLMETHYLCELLULOSE IS CELLULOSE OBTAINED DIRECTLY FROM FIBROUS PLANT MATERIAL AND PARTIALLY ETHERIFIED WITH METHYL GROUPS AND CONTAINING A SMALL DEGREE OF HYDROXYPROPYL SUBSTITUTION.

DESCRIPTION: SLIGHTLY HYGROSCOPIC WHITE OR SLIGHTLY YELLOWISH OR GREYISH ODOURLESS AND TASTELESS, GRANULAR OR FIBROUS POWDER.

CHEMICAL FORMULA: THE POLYMERS CONTAIN SUBSTITUTED ANHYDROGLUCOSE UNITS WITH THE FOLLOWING GENERAL FORMULA:

C6H7O2 (OR1) (OR2) (OR3) WHERE R1, R2 AND R3 EACH MAY BE ANY ONE OF THE FOLLOWING:

- H,
- CH3,
- CH2CHOHCH3,
- CH2CHO (CH2CHOHCH3) CH3,
- CH2CHO (CH2CHO (CH2CHOHCH3) CH3) CH3.

MOLECULAR WEIGHT: FROM ABOUT 13 000 TO 200 000.

CONTENT OF SUBSTITUTED GROUPS: NOT LESS THAN 19 % AND NOT MORE THAN 30 % OF METHOXYL GROUPS (-OCH3) AND NOT LESS THAN 3 % AND NOT MORE THAN 12 % HYDROXYPROPOXYL GROUPS (-OCH2CHOHCH3) ON A VOLATILE MATTER-FREE BASIS.

PH OF A 1 % SOLUTION: NOT LESS THAN 5.0 AND NOT MORE THAN 8.0.

VOLATILE MATTER: NOT MORE THAN 10 % DETERMINED BY DRYING TO CONSTANT WEIGHT AT 105 °C.

SULPHATED ASH: NOT MORE THAN 1.5 % FOR PRODUCTS WITH VISCOSITIES GREATER THAN 50 cP AND NOT MORE THAN 3.0 % FOR PRODUCTS WITH VISCOSITIES OF 50 cP OR LESS, DETERMINED AT 800 ± 25 °C.

E 465 - ETHYLMETHYLCELLULOSE

CHEMICAL DESCRIPTION: ETHYLMETHYLCELLULOSE IS CELLULOSE OBTAINED DIRECTLY FROM FIBROUS PLANT MATERIAL AND PARTIALLY ETHERIFIED WITH METHYL AND ETHYL GROUPS.

DESCRIPTION: SLIGHTLY HYGROSCOPIC WHITE OR SLIGHTLY YELLOWISH OR GREYISH ODOURLESS AND TASTELESS, GRANULAR OR FIBROUS POWDER.

CHEMICAL FORMULA: THE POLYMERS CONTAIN SUBSTITUTED ANHYDROGLUCOSE UNITS WITH THE FOLLOWING GENERAL FORMULA:

C6H7O2 (OR1) (OR2) (OR3) WHERE R1, R2 AND R3 EACH MAY BE ANY ONE OF THE FOLLOWING:

- H,
- CH3,
- CH2CH3.

MOLECULAR WEIGHT: FROM ABOUT 30 000 TO 40 000.

CONTENT OF SUBSTITUTED GROUPS: NOT LESS THAN 14.5 % AND NOT MORE THAN 19.0 % OF ETHOXYL GROUPS (-OC2H5) AND NOT LESS THAN 3.5 % AND NOT MORE THAN 6.5 % OF METHOXYL GROUPS (-OCH3) ON A VOLATILE MATTER-FREE BASIS.

VOLATILE MATTER:

- FIBROUS FORM: NOT MORE THAN 15 %.

- POWDERED FORM: NOT MORE THAN 10 %. DETERMINED BY DRYING TO CONSTANT WEIGHT AT 105 °C IN EACH CASE.

SULPHATED ASH: NOT MORE THAN 0.6 % DETERMINED AT 800 ± 25 °C.

PH OF A 1 % SOLUTION: NOT LESS THAN 5 AND NOT MORE THAN 8.

E 466 - CARBOXYMETHYLCELLULOSE

CHEMICAL DESCRIPTION: CARBOXYMETHYLCELLULOSE IS THE PARTIAL SODIUM SALT OF A CARBOXYMETHYL ETHER OF CELLULOSE, THE CELLULOSE BEING OBTAINED DIRECTLY FROM FIBROUS PLANT MATERIAL.

DESCRIPTION: SLIGHTLY HYGROSCOPIC WHITE OR SLIGHTLY YELLOWISH OR GREYISH ODOURLESS AND TASTELESS, GRANULAR OR FIBROUS POWDER.

CHEMICAL FORMULA: THE POLYMERS CONTAIN SUBSTITUTED ANHYDROGLUCOSE UNITS WITH THE FOLLOWING GENERAL FORMULA:

C6H7O2 (OR1) (OR2) (OR3) WHERE R1, R2 AND R3 EACH MAY BE ANY ONE OF THE FOLLOWING:

- H,
- CH2COONa,
- CH2COOH.

MOLECULAR WEIGHT: " higher than approximately 17 000 (degree of polymerization approximately 100). " **[2]**

CONTENT: NOT LESS THAN 99.5 % OF CARBOXYMETHYLCELLULOSE CALCULATED ON A VOLATILE MATTER-FREE BASIS.

SODIUM CHLORIDE AND SODIUM GLYCOLATE: NOT MORE THAN 0.5 % TOTAL, AND NOT MORE THAN 0.4 % OF SODIUM GLYCOLATE.

DEGREE OF SUBSTITUTION: NOT LESS THAN 0.2 AND NOT MORE THAN 1.0 CARBOXYMETHYL GROUPS (-CH2COOH) PER ANHYDROGLUCOSE UNIT.

SODIUM: NOT MORE THAN 9.7 % ON A VOLATILE MATTER-FREE BASIS.

VOLATILE MATTER: NOT MORE THAN 12 % DETERMINED BY DRYING TO CONSTANT WEIGHT AT 105 °C.

PH OF A 1 % SOLUTION: NOT LESS THAN 6 AND NOT MORE THAN 8.5.

E 470 - SODIUM, POTASSIUM AND CALCIUM SALTS OF FATTY ACIDS

CHEMICAL DESCRIPTION: SODIUM, POTASSIUM AND CALCIUM SALTS OF FATTY ACIDS OCCURRING IN FOOD OILS AND FATS, THESE SALTS BEING OBTAINED EITHER FROM EDIBLE FATS OR FROM DISTILLED FOOD FATTY ACIDS.

DESCRIPTION: WHITE OR CREAMY WHITE LIGHT POWDERS, FLAKES, OR SEMI-SOLIDS.

UNSAPONIFIABLE MATTER: NOT MORE THAN 2 %.

FREE FATTY ACIDS: NOT MORE THAN 3 % ESTIMATED AS OLEIC ACID.

TOTAL GLYCEROL (COMBINED AND FREE): NOT MORE THAN 10 %.

FREE ALKALI: NOT MORE THAN 0.1 % EXPRESSED AS NaOH.

MATTER INSOLUBLE IN ALCOHOL: NOT MORE THAN 0.2 % (SODIUM AND POTASSIUM SALTS ONLY).

VOLATILE MATTER: NOT MORE THAN 3 %. CONTENT OF SODIUM, OR POTASSIUM, OR CALCIUM SODIUM NOT LESS THAN 9.0 % AND NOT MORE THAN 14.0 % EXPRESSED AS Na2O.

POTASSIUM: NOT LESS THAN 13.0 % AND NOT MORE THAN 21.5 % EXPRESSED AS K2O.

CALCIUM: NOT LESS THAN 8.5 % AND NOT MORE THAN 13.0 % EXPRESSED AS CaO.

E 471 - MONO- AND DIGLYCERIDES OF FATTY ACIDS

CHEMICAL DESCRIPTION: MONO- AND DIGLYCERIDES OF FATTY ACIDS CONSIST OF MIXTURES OF GLYCEROL MONO-, DI- AND TRI-ESTERS OF FATTY ACIDS OCCURRING IN FOOD FATS. THEY MAY CONTAIN SMALL AMOUNTS OF FREE FATTY ACIDS AND GLYCEROL.

DESCRIPTION: THE PRODUCT VARIES FROM A PALE YELLOW TO PALE BROWN OILY LIQUID TO A WHITE OR SLIGHTLY OFF-WHITE HARD WAXY SOLID. THE SOLIDS MAY BE IN THE FORM OF FLAKES, POWDERS OR SMALL BEADS.

MONO- AND DI-ESTER CONTENT: NOT LESS THAN 70 %.

FREE FATTY ACIDS: NOT MORE THAN 3 % ESTIMATED AS OLEIC ACID.

FREE GLYCEROL: NOT MORE THAN 7 %.

TOTAL GLYCEROL: NOT LESS THAN 16 % AND NOT MORE THAN 33 %.

POLYGLYCEROLS: NOT MORE THAN 4 % DIGLYCEROL AND NOT MORE THAN 1 % HIGHER POLYGLYCEROLS BOTH BASED ON TOTAL GLYCEROL CONTENT.

WATER: NOT MORE THAN 2 % (KARL FISCHER).

SULPHATED ASH: NOT MORE THAN 0.5 % DETERMINED AT 800 ± 25 °C.

NOTE: THESE CRITERIA ARE BASED ON THE PRODUCT WITHOUT E 470.

E 472 (a) - ACETIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS

CHEMICAL DESCRIPTION: ESTERS OF GLYCEROL WITH ACETIC ACID AND FATTY ACIDS OCCURRING IN FOOD FATS. THEY MAY CONTAIN SMALL AMOUNTS OF FREE GLYCEROL, FREE FATTY ACIDS, FREE ACETIC ACID AND FREE GLYCERIDES.

DESCRIPTION: CLEAR, MOBILE LIQUIDS TO SOLIDS, FROM WHITE TO PALE YELLOW IN COLOUR.

TOTAL ACETIC ACID CONTENT: NOT LESS THAN 9 % AND NOT MORE THAN 32 %.

FREE FATTY ACIDS (AND ACETIC ACID): NOT MORE THAN 3 % ESTIMATED AS OLEIC ACID.

FREE GLYCEROL: NOT MORE THAN 2 %.

TOTAL GLYCEROL: NOT LESS THAN 14 % AND NOT MORE THAN 31 %.

SULPHATED ASH: NOT MORE THAN 0.5 % DETERMINED AT 800 ± 25 °C.

E 472 (b) - LACTIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS

CHEMICAL DESCRIPTION: ESTERS OF GLYCEROL WITH LACTIC ACID AND FATTY ACIDS OCCURRING IN FOOD FATS. THEY MAY CONTAIN SMALL AMOUNTS OF FREE GLYCEROL, FREE FATTY ACIDS, FREE LACTIC ACID AND FREE GLYCERIDES.

DESCRIPTION: SOFT TO HARD WAXY SOLIDS.

TOTAL LACTIC ACID CONTENT: NOT LESS THAN 13 % AND NOT MORE THAN 45 %.

FREE FATTY ACIDS: NOT MORE THAN 3 % ESTIMATED AS OLEIC ACID.

FREE GLYCEROL: NOT MORE THAN 2 %.

TOTAL GLYCEROL: NOT LESS THAN 13 % AND NOT MORE THAN 30 %.

SULPHATED ASH: NOT MORE THAN 0.5 % DETERMINED AT 800 ± 25 °C.

NOTE: THESE CRITERIA ARE BASED ON THE PRODUCT WITHOUT E 470.

E 472 (c) - CITRIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FOOD FATTY ACIDS

CHEMICAL DESCRIPTION: ESTERS OF GLYCEROL WITH CITRIC ACID AND FATTY ACIDS OCCURRING IN FOOD OILS AND FATS. THEY MAY CONTAIN SMALL AMOUNTS OF FREE GLYCEROL, FREE FATTY ACIDS, FREE CITRIC ACID AND FREE GLYCERIDES. THEY MAY BE PARTIALLY OR WHOLLY NEUTRALIZED WITH SODIUM HYDROXIDE OR WITH POTASSIUM HYDROXIDE.

DESCRIPTION: YELLOWISH OR LIGHT BROWN LIQUIDS TO WAXY SOLIDS OR SEMI-SOLIDS.

TOTAL CITRIC ACID CONTENT: NOT LESS THAN 13 % AND NOT MORE THAN 50 %.

FREE FATTY ACIDS: NOT MORE THAN 3 % ESTIMATED AS OLEIC ACID.

FREE GLYCEROL: NOT MORE THAN 2 %.

TOTAL GLYCEROL: NOT LESS THAN 11 % AND NOT MORE THAN 29 %.

SULPHATED ASH: NOT MORE THAN 0.5 % FOR THE NON-NEUTRALIZED PRODUCTS AND NOT MORE THAN 10.0 % FOR THE PARTIALLY OR WHOLLY NEUTRALIZED PRODUCTS DETERMINED AT 800 ± 25 °C.

PH OF A 1 % SOLUTION: NOT LESS THAN 3 AND NOT MORE THAN 7.3.

E 472 (d) - TARTARIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FOOD FATTY ACIDS

CHEMICAL DESCRIPTION: ESTERS OF GLYCEROL WITH TARTARIC ACID (E 334) AND FATTY ACIDS OCCURRING IN FOOD FATS. THEY MAY CONTAIN SMALL AMOUNTS OF FREE GLYCEROL, FREE FATTY ACIDS, FREE TARTARIC ACID AND FREE GLYCERIDES.

DESCRIPTION: STICKY VISCOUS YELLOWISH LIQUIDS TO HARD YELLOW WAXES.

TOTAL TARTARIC ACID CONTENT: NOT LESS THAN 15 % AND NOT MORE THAN 50 %.

FREE FATTY ACIDS: NOT MORE THAN 3 % ESTIMATED AS OLEIC ACID.

FREE GLYCEROL: NOT MORE THAN 2 %.

TOTAL GLYCEROL: NOT LESS THAN 12 % AND NOT MORE THAN 29 %.

SULPHATED ASH: NOT MORE THAN 0.5 % DETERMINED AT 800 ± 25 °C.

E 472 (e) - MONO- AND DIACETYL TARTARIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS

CHEMICAL DESCRIPTION: ESTERS OF GLYCEROL WITH MONO- AND DIACETYL TARTARIC ACIDS (OBTAINED FROM E 334 TARTARIC ACID) AND FATTY ACIDS OCCURRING IN FOOD FATS. THEY MAY

CONTAIN SMALL AMOUNTS OF FREE GLYCEROL, FREE FATTY ACIDS, FREE TARTARIC AND ACETIC ACIDS AND THEIR COMBINATIONS, AND FREE GLYCERIDES.

DESCRIPTION: STICKY VISCOUS LIQUIDS THROUGH A FAT-LIKE CONSISTENCY TO YELLOW WAXES WHICH HYDROLYSE IN MOIST AIR TO LIBERATE ACETIC ACID.

TOTAL TARTARIC ACID CONTENT: NOT LESS THAN 10 % AND NOT MORE THAN 40 %.

TOTAL ACETIC ACID CONTENT: NOT LESS THAN 8 % AND NOT MORE THAN 32 %.

FREE FATTY ACIDS: NOT MORE THAN 3 % ESTIMATED AS OLEIC ACID.

FREE GLYCEROL: NOT MORE THAN 2 %.

TOTAL GLYCEROL: NOT LESS THAN 11 % AND NOT MORE THAN 28 %.

SULPHATED ASH: NOT MORE THAN 0.5 % DETERMINED AT 800 ± 25 °C.

E 472 (f) - MIXED ACETIC AND TARTARIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS

CHEMICAL DESCRIPTION: ESTERS OF GLYCEROL WITH ACETIC AND TARTARIC (E 334) ACIDS AND FATTY ACIDS OCCURRING IN FOOD FATS. THEY MAY CONTAIN SMALL AMOUNTS OF FREE GLYCEROL, FREE FATTY ACIDS, FREE ACETIC AND TARTARIC ACIDS, AND FREE GLYCERIDES.

DESCRIPTION: CLEAR MOBILE LIQUIDS TO SOLIDS, FROM WHITE TO PALE YELLOW IN COLOUR.

TOTAL ACETIC ACID: NOT LESS THAN 10 % AND NOT MORE THAN 20 %.

TOTAL TARTARIC ACID: NOT LESS THAN 20 % AND NOT MORE THAN 40 %.

FREE ACETIC ACID: NOT LESS THAN 5.5 % AND NOT MORE THAN 8.5 %.

FREE TARTARIC ACID: NOT MORE THAN 1 %.

FREE FATTY ACIDS: NOT MORE THAN 3 % ESTIMATED AS OLEIC ACID.

FREE GLYCEROL: NOT MORE THAN 2 %.

TOTAL GLYCEROL: NOT LESS THAN 12 % AND NOT MORE THAN 27 %.

SULPHATED ASH: NOT MORE THAN 0.5 % DETERMINED AT 800 ± 25 °C.

E 473 - SUCROSE ESTERS OF FATTY ACIDS

CHEMICAL DESCRIPTION: ESSENTIALLY THE MONO- AND DI-ESTERS OF SUCROSE WITH FATTY ACIDS OCCURRING IN FOOD FATS. THEY MAY BE PREPARED FROM SUCROSE AND THE METHYL AND ETHYL ESTERS OF FOOD FATTY ACIDS OR BY EXTRACTION FROM SUCROGLYCERIDES. " No organic solvent other than dimethylsulphoxide, dimethylformamide, ethyl acetate, isopropanol, isobutanol and methylethylketon may be used in their preparation. " **[3]**

DESCRIPTION: SOFT SOLIDS, STIFF GELS OR WHITE TO GREYISH-WHITE POWDERS.

TOTAL SUCROSE FATTY ACID ESTER CONTENT: NOT LESS THAN 80 %.

TOTAL GLYCERIDE CONTENT: NOT MORE THAN 20 %.

FREE SUCROSE CONTENT: NOT MORE THAN 5 %.

FREE FATTY ACID CONTENT: NOT MORE THAN 3 % ESTIMATED AS OLEIC ACID.

SULPHATED ASH: NOT MORE THAN 2 % DETERMINED AT 800 ± 25 °C.

" Dimethylsulphoxide content: not more than 2 mg/kg. " **[2]**

DIMETHYLFORMAMIDE CONTENT: NOT MORE THAN 1 mg/kg.

METHANOL CONTENT: NOT MORE THAN 10 mg/kg.

" Isobutanol content: not more than 10 mg/kg. " **[2]**

" Methylethylketon content: not more than 10 mg/kg. " **[3]**

TOTAL ETHYL ACETATE AND ISOPROPANOL CONTENT: NOT MORE THAN 350 mg/kg SINGLY OR IN COMBINATION.

NOTE: THESE CRITERIA ARE BASED ON THE PRODUCT WITHOUT E 470.

E 474 - SUCROGLYCERIDES

CHEMICAL DESCRIPTION: SUCROGLYCERIDES ARE PRODUCED BY REACTING SUCROSE WITH AN EDIBLE FAT OR OIL TO PRODUCE A MIXTURE OF ESSENTIALLY MONO- AND DI-ESTERS OF SUCROSE AND FATTY ACIDS TOGETHER WITH RESIDUAL MONO-, DI- AND TRI-GLYCERIDES FROM THAT FAT OR OIL. " NO ORGANIC SOLVENTS SHALL BE USED IN THEIR PREPARATION OTHER THAN CYCLOHEXANE, DIMETHYLFORMAMIDE, ETHYL ACETATE, ISOBUTANOL AND ISOPROPANOL. " **[1]**

DESCRIPTION: SOFT SOLID MASSES, STIFF GELS OR WHITE TO OFF-WHITE POWDERS.

TOTAL SUCROSE FATTY ACID ESTER CONTENT: NOT LESS THAN 40 % AND NOT MORE THAN 60 %.

TOTAL GLYCERIDE CONTENT: NOT LESS THAN 40 % AND NOT MORE THAN 60 %.

FREE SUCROSE CONTENT: NOT MORE THAN 5 %.

FREE FATTY ACID CONTENT: NOT MORE THAN 3 % ESTIMATED AS OLEIC ACID.

SULPHATED ASH: NOT MORE THAN 2 % DETERMINED AT 800 ± 25 °C.

DIMETHYLFORMAMIDE CONTENT: NOT MORE THAN 1 mg/kg.

METHANOL CONTENT: NOT MORE THAN 10 mg/kg.

TOTAL ETHYL ACETATE AND ISOPROPANOL CONTENT: NOT MORE THAN 350 mg/kg SINGLY OR IN COMBINATION.

" TOTAL CYCLOHEXANE AND ISOBUTANOL CONTENT: NOT MORE THAN 10 mg/kg SINGLY OR IN COMBINATION. " **[1]**

NOTE: THESE CRITERIA ARE BASED ON THE PRODUCT WITHOUT E 470.

E 475 - POLYGLYCEROL ESTERS OF NON-POLYMERIZED FATTY ACIDS

CHEMICAL DESCRIPTION: POLYGLYCEROL ESTERS OF FATTY ACIDS ARE PRODUCED BY THE ESTERIFICATION OF POLYGLYCEROL WITH FOOD FATS OR WITH FATTY ACIDS OCCURRING IN FOOD FATS. THE POLYGLYCEROL MOIETY IS PREDOMINANTLY DI-, TRI- AND TETRA-GLYCEROL AND CONTAINS NOT MORE THAN 10 % OF POLYGLYCEROLS EQUAL TO OR HIGHER THAN HEPTAGLYCEROL.

DESCRIPTION: YELLOW OR LIGHT BROWN LIQUIDS OR SEMI-SOLIDS.

TOTAL FATTY ACID ESTER CONTENT: NOT LESS THAN 90 %.

FREE FATTY ACIDS: NOT MORE THAN 6 % ESTIMATED AS OLEIC ACID.

TOTAL GLYCEROL AND POLYGLYCEROL: NOT LESS THAN 18 % AND NOT MORE THAN 60 %.

FREE GLYCEROL AND POLYGLYCEROL: NOT MORE THAN 7 %.

SULPHATED ASH: NOT MORE THAN 0.5 % DETERMINED AT 800 ± 25 °C.

NOTE: THESE CRITERIA ARE BASED ON THE PRODUCT WITHOUT E 470.

E 477 - PROPANE-1,2-DIOL ESTERS OF FATTY ACIDS

CHEMICAL DESCRIPTION: CONSISTS CHIEFLY OF MIXTURES OF PROPANE-1,2-DIOL MONO- AND DI-ESTERS OF FATTY ACIDS OCCURRING IN FOOD FATS. THE ALCOHOL MOIETY IS EXCLUSIVELY PROPANE-1,2-DIOL TOGETHER WITH DIMER AND TRACES OF TRIMER. ORGANIC ACIDS OTHER THAN FOOD FATTY ACIDS ARE ABSENT.

DESCRIPTION: WAXY WHITE FLAKES, BEADS OR SOLIDS.

TOTAL FATTY ACID ESTER CONTENT: NOT LESS THAN 85 %.

FREE PROPANE-1,2-DIOL: NOT MORE THAN 5 %.

DIMER AND TRIMER OF PROPANE-1,2-DIOL: " NOT MORE THAN 0.5 %. " **[1]**

FREE FATTY ACIDS: NOT MORE THAN 6 % ESTIMATED AS OLEIC ACID.

SULPHATED ASH: NOT MORE THAN 0.5 % DETERMINED AT 800 ± 25 °C.

TOTAL PROPANE-1,2: NOT LESS THAN 11 % AND NOT MORE THAN 31 %.

NOTE: THESE CRITERIA ARE BASED ON THE PRODUCT WITHOUT E 470.

E 481 - SODIUM STEAROYL-2-LACTYLATE

CHEMICAL DESCRIPTION: A MIXTURE OF THE SODIUM SALTS OF STEAROYL LACTYLIC ACIDS AND MINOR AMOUNTS OF SODIUM SALTS OF OTHER RELATED ACIDS, MANUFACTURED BY THE REACTION OF STEARIC ACID AND LACTIC ACID. OTHER FOOD FATTY ACIDS MAY ALSO BE PRESENT, FREE OR ESTERIFIED, DUE TO THEIR PRESENCE IN THE STEARIC ACID USED.

DESCRIPTION: CREAM COLOURED POWDER OR BRITTLE SOLID WITH A CHARACTERISTIC ODOUR.

SODIUM CONTENT: NOT LESS THAN 2.5 % AND NOT MORE THAN 5 %.

ESTER VALUE: NOT LESS THAN 90 AND NOT MORE THAN 190 mg KOH/g.

TOTAL LACTIC ACID (FREE AND COMBINED): NOT LESS THAN 15 % AND NOT MORE THAN 40 %.

ACID VALUE: NOT LESS THAN 60 AND NOT MORE THAN 130 mg KOH/g.

E 482 - CALCIUM STEAROYL-2-LACTYLATE

CHEMICAL DESCRIPTION: A MIXTURE OF CALCIUM SALTS OF STEAROYL LACTYLIC ACIDS WITH MINOR AMOUNTS OF CALCIUM SALTS OF OTHER RELATED ACIDS, MANUFACTURED BY THE REACTION OF STEARIC ACID AND LACTIC ACID. OTHER FOOD FATTY ACIDS MAY ALSO BE PRESENT, FREE OR ESTERIFIED DUE TO THEIR PRESENCE IN THE STEARIC ACID USED.

DESCRIPTION: WHITE OR SLIGHTLY YELLOWISH POWDER OR BRITTLE SOLID WITH A CHARACTERISTIC ODOUR.

CALCIUM CONTENT: NOT LESS THAN 1.0 % AND NOT MORE THAN 5.2 %.

ESTER VALUE: NOT LESS THAN 125 AND NOT MORE THAN 190 mg KOH/g.

TOTAL LACTIC ACID (FREE AND COMBINED): NOT LESS THAN 15 % AND NOT MORE THAN 40 %.

ACID VALUE: NOT LESS THAN 50 AND NOT MORE THAN 130 mg KOH/g.

E 483 - STEARYL TARTRATE

CHEMICAL DESCRIPTION: STEARYL TARTRATE IS PRODUCED BY THE ESTERIFICATION OF TARTARIC ACID (E 334) WITH STEARYL ALCOHOL. IT CONSISTS CHIEFLY OF THE DI-ESTER WITH MINOR AMOUNTS OF MONO-ESTER, TARTARIC ACID AND STEARYL ALCOHOL. OTHER ESTERS MAY ALSO BE PRESENT DUE TO THE PRESENCE IN THE STEARYL ALCOHOL USED OF ALCOHOLS DERIVED FROM FOOD FATTY ACIDS OTHER THAN STEARIC ACID.

DESCRIPTION: CREAM COLOURED UNCTUOUS SOLID (AT 25 °C).

TOTAL ESTER CONTENT: NOT LESS THAN 90 %.

TOTAL TARTARIC ACID CONTENT: NOT LESS THAN 18 % AND NOT MORE THAN 35 %.

UNSAPONIFIABLE MATTER: NOT LESS THAN 77 % AND NOT MORE THAN 83 %.

MELTING RANGE: 67 TO 77 °C.

ESTER VALUE: NOT LESS THAN 163 AND NOT MORE THAN 180 mg KOH/g.

IODINE VALUE: NOT MORE THAN 4 (Wijs).

ACID VALUE: NOT MORE THAN 6 mg KOH/g.

SULPHATED ASH: NOT MORE THAN 0.5 % DETERMINED AT 800 ± 25 °C.

(R1) Corrigenda, OJ No L 91, 10/04/1979, p. 7.

(1) OJ No L 189, 12/07/1974, p. 1.
(2) OJ No L 223, 14/08/1978, p. 30.
(3) A SPECIAL METHOD OF ANALYSIS IS REQUIRED TO DETERMINE THIS.

388L0388

88/388/EEC: COUNCIL DIRECTIVE OF 22 JUNE 1988 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO FLAVOURINGS FOR USE IN FOODSTUFFS AND TO SOURCE MATERIALS FOR THEIR PRODUCTION

OFFICIAL JOURNAL NO L 184, 15/07/1988, P. 61
DATE OF TRANSPOSITION: 21/12/1989; SEE ART. 13

AMENDED BY

391L0071
91/71/EEC: COMMISSION DIRECTIVE OF 16 JANUARY 1991 [1]
OFFICIAL JOURNAL NO L 42, 15/02/1991, P. 25
DATE OF NOTIFICATION: 07/02/1991
DATE OF TRANSPOSITION: 30/06/1992; SEE ART. 2
DATE OF TRANSPOSITION: 01/01/1994; SEE ART. 2

ARTICLE 1

1. THIS DIRECTIVE SHALL APPLY TO "FLAVOURINGS" USED OR INTENDED FOR USE IN OR ON FOODSTUFFS TO IMPART ODOUR AND/OR TASTE, AND TO SOURCE MATERIALS USED FOR THE PRODUCTION OF FLAVOURINGS.

2. FOR THE PURPOSES OF THIS DIRECTIVE:

(a) "FLAVOURING" MEANS FLAVOURING SUBSTANCES, FLAVOURING PREPARATIONS, PROCESS FLAVOURINGS, SMOKE FLAVOURINGS OR MIXTURES THEREOF;

(b) "FLAVOURING SUBSTANCE" MEANS A DEFINED CHEMICAL SUBSTANCE WITH FLAVOURING PROPERTIES WHICH IS OBTAINED:

(i) BY APPROPRIATE PHYSICAL PROCESSES (INCLUDING DISTILLATION AND SOLVENT EXTRACTION) OR ENZYMATIC OR MICROBIOLOGICAL PROCESSES FROM MATERIAL OF VEGETABLE OR ANIMAL ORIGIN EITHER IN THE RAW STATE OR AFTER PROCESSING FOR HUMAN CONSUMPTION BY TRADITIONAL FOOD-PREPARATION PROCESSES (INCLUDING DRYING, TORREFACTION AND FERMENTATION),

(ii) BY CHEMICAL SYNTHESIS OR ISOLATED BY CHEMICAL PROCESSES AND WHICH IS CHEMICALLY IDENTICAL TO A SUBSTANCE NATURALLY PRESENT IN MATERIAL OF VEGETABLE OR ANIMAL ORIGIN AS DESCRIBED IN (i),

(iii) BY CHEMICAL SYNTHESIS BUT WHICH IS NOT CHEMICALLY IDENTICAL TO A SUBSTANCE NATURALLY PRESENT IN MATERIAL OF VEGETABLE OR ANIMAL ORIGIN AS DESCRIBED IN (i);

(c) "FLAVOURING PREPARATION" MEANS A PRODUCT, OTHER THAN THE SUBSTANCES DEFINED IN (b) (i), WHETHER CONCENTRATED OR NOT, WITH FLAVOURING PROPERTIES, WHICH IS OBTAINED BY APPROPRIATE PHYSICAL PROCESSES (INCLUDING DISTILLATION AND SOLVENT EXTRACTION) OR BY ENZYMATIC OR MICROBIOLOGICAL PROCESSES FROM MATERIAL OF VEGETABLE OR ANIMAL ORIGIN, EITHER IN THE RAW STATE OR AFTER PROCESSING FOR HUMAN CONSUMPTION BY TRADITIONAL FOOD-PREPARATION PROCESSES (INCLUDING DRYING, TORREFACTION AND FERMENTATION);

(d) "PROCESS FLAVOURING" MEANS A PRODUCT WHICH IS OBTAINED ACCORDING TO GOOD MANUFACTURING PRACTICES BY HEATING TO A TEMPERATURE NOT EXCEEDING 180 °C FOR A

PERIOD NOT EXCEEDING 15 MINUTES A MIXTURE OF INGREDIENTS, NOT NECESSARILY THEMSELVES HAVING FLAVOURING PROPERTIES, OF WHICH AT LEAST ONE CONTAINS NITROGEN (AMINO) AND ANOTHER IS A REDUCING SUGAR;

(e) "SMOKE FLAVOURING" MEANS A SMOKE EXTRACT USED IN TRADITIONAL FOODSTUFFS SMOKING PROCESSES.

3. FLAVOURINGS MAY CONTAIN FOODSTUFFS AS WELL AS OTHER SUBSTANCES AS DESCRIBED IN ARTICLE 6 (1).

ARTICLE 2

THIS DIRECTIVE SHALL NOT APPLY TO:

- EDIBLE SUBSTANCES AND PRODUCTS INTENDED TO BE CONSUMED AS SUCH, WITH OR WITHOUT RECONSTITUTION,
- SUBSTANCES WHICH HAVE EXCLUSIVELY A SWEET, SOUR OR SALT TASTE,
- MATERIAL OF VEGETABLE OR ANIMAL ORIGIN, HAVING INHERENT FLAVOURING PROPERTIES, WHERE THEY ARE NOT USED AS FLAVOURING SOURCES.

ARTICLE 3

MEMBER STATES SHALL TAKE THE NECESSARY MEASURES TO ENSURE THAT FLAVOURINGS MAY NOT BE MARKETED OR USED IF THEY DO NOT COMPLY WITH THE RULES LAID DOWN IN THIS DIRECTIVE.

ARTICLE 4

MEMBER STATES SHALL TAKE ALL MEASURES NECESSARY TO ENSURE THAT:

(a) - FLAVOURINGS DO NOT CONTAIN ANY ELEMENT OR SUBSTANCE IN A TOXICOLOGICALLY DANGEROUS QUANTITY;
- SUBJECT TO ANY EXCEPTIONS PROVIDED FOR IN THE SPECIFIC CRITERIA OF PURITY REFERRED TO IN ARTICLE 6 (2), THIRD INDENT, THEY DO NOT CONTAIN MORE THAN 3 mg/kg OF ARSENIC, 10 mg/kg OF LEAD, 1 mg/kg OF CADMIUM AND 1 mg/kg OF MERCURY;

(b) THE USE OF FLAVOURINGS DOES NOT RESULT IN THE PRESENCE IN FOODSTUFFS AS CONSUMED OF UNDESIRABLE SUBSTANCES LISTED IN ANNEX I IN QUANTITIES GREATER THAN THOSE SPECIFIED THEREIN;

(c) THE USE OF FLAVOURINGS AND OF OTHER FOOD INGREDIENTS WITH FLAVOURING PROPERTIES DOES NOT RESULT IN THE PRESENCE OF SUBSTANCES LISTED IN ANNEX II IN QUANTITIES GREATER THAN THOSE SPECIFIED THEREIN.

ARTICLE 5

THE COUNCIL, ACTING IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 100a OF THE TREATY, SHALL ADOPT:

1. APPROPRIATE PROVISIONS CONCERNING:

- FLAVOURING SOURCES COMPOSED OF FOODSTUFFS, AND OF HERBS AND SPICES NORMALLY CONSIDERED AS FOODS,
- FLAVOURING SOURCES COMPOSED OF VEGETABLE OR ANIMAL RAW MATERIALS NOT NORMALLY CONSIDERED AS FOODS,
- FLAVOURING SUBSTANCES OBTAINED BY APPROPRIATE PHYSICAL PROCESSES OR BY ENZYMATIC OR MICROBIOLOGICAL PROCESSES FROM VEGETABLE OR ANIMAL RAW MATERIALS,
- CHEMICALLY SYNTHESIZED OR CHEMICALLY ISOLATED FLAVOURING SUBSTANCES CHEMICALLY IDENTICAL TO FLAVOURING SUBSTANCES NATURALLY PRESENT IN FOODSTUFFS OR IN HERBS AND SPICES NORMALLY CONSIDERED AS FOODS,
- CHEMICALLY SYNTHESIZED OR CHEMICALLY ISOLATED FLAVOURING SUBSTANCES CHEMICALLY IDENTICAL TO FLAVOURING SUBSTANCES NATURALLY PRESENT IN VEGETABLE OR ANIMAL RAW MATERIALS NOT NORMALLY CONSIDERED AS FOODS,
- CHEMICALLY SYNTHESIZED OR CHEMICALLY ISOLATED FLAVOURING SUBSTANCES OTHER THAN THOSE REFERRED TO IN THE FOURTH AND FIFTH INDENTS,
- SOURCE MATERIALS USED FOR THE PRODUCTION OF SMOKE FLAVOURINGS OR PROCESS FLAVOURINGS, AND THE REACTION CONDITIONS UNDER WHICH THEY ARE PREPARED;

2. ANY SPECIAL PROVISIONS WHICH MAY BE NECESSARY, FOR THE PROTECTION OF PUBLIC HEALTH OR TRADE, CONCERNING:

- THE USE AND METHODS OF PRODUCTION OF FLAVOURINGS, INCLUDING PHYSICAL PROCESSES OR ENZYMATIC OR MICROBIOLOGICAL PROCESSES FOR THE PRODUCTION OF FLAVOURING PREPARATIONS AND FLAVOURING SUBSTANCES AS REFERRED TO IN ARTICLE 1 (2) (b) (i) AND (c),
- THE CONDITIONS FOR THE USE OF THE SUBSTANCES AND MATERIALS REFERRED TO IN ARTICLE 6 (1);

3. AMENDMENTS CONCERNING THE MAXIMUM LIMITS LAID DOWN IN THE ANNEXES.

ARTICLE 6

THE FOLLOWING SHALL BE ADOPTED IN ACCORDANCE WITH THE PROCEDURE SET OUT IN ARTICLE 10:

1. THE LIST OF SUBSTANCES OR MATERIALS AUTHORIZED IN THE COMMUNITY AS:

- ADDITIVES NECESSARY FOR THE STORAGE AND USE OF FLAVOURINGS,
- PRODUCTS USED FOR DISSOLVING AND DILUTING FLAVOURINGS,
- ADDITIVES NECESSARY FOR THE PRODUCTION OF FLAVOURINGS (PROCESSING AIDS) WHERE SUCH ADDITIVES ARE NOT COVERED BY OTHER COMMUNITY PROVISIONS;

2. WHERE NECESSARY:

- THE METHODS OF ANALYSIS NEEDED TO VERIFY COMPLIANCE WITH THE LEVELS REFERRED TO IN ARTICLE 4,
- THE PROCEDURE FOR TAKING SAMPLES AND THE METHODS FOR QUALITATIVE AND, WHERE APPROPRIATE, QUANTITATIVE ANALYSIS OF FLAVOURINGS IN OR ON FOODSTUFFS,
- THE SPECIFIC CRITERIA OF PURITY FOR GIVEN FLAVOURINGS;

3. - THE MICROBIOLOGICAL CRITERIA APPLICABLE TO FLAVOURINGS,
- THE DESIGNATION CRITERIA GIVEN TO THE MORE SPECIFIC NAMES REFERRED TO IN ARTICLE 9 (1) (b);

4. THE APPROPRIATE STEPS, TO BE TAKEN BY 1 JULY 1990 TO SUPPLEMENT THIS DIRECTIVE WITH LABELLING RULES FOR FLAVOURINGS INTENDED FOR SALE TO THE FINAL CONSUMER.

ARTICLE 7

PROVISIONS THAT MAY HAVE EFFECTS ON PUBLIC HEALTH SHALL BE ADOPTED ONLY AFTER CONSULTING THE SCIENTIFIC COMMITTEE FOR FOOD.

ARTICLE 8

1. WHERE, AS A RESULT OF NEW INFORMATION OR OF A RE-ASSESSMENT OF EXISTING INFORMATION MADE SINCE THIS DIRECTIVE OR ONE OF THE DIRECTIVES PROVIDED FOR IN ARTICLE 5 WAS ADOPTED, A MEMBER STATE HAS DETAILED EVIDENCE:

- THAT THE PRESENCE OF ONE OF THE SUBSTANCES LISTED IN THE ANNEXES TO THIS DIRECTIVE OR THE MAXIMUM LEVELS STIPULATED, WHILE COMPLYING WITH THE PROVISIONS OF THIS DIRECTIVE, OR
- THAT THE USE OF A FLAVOURING, WHILE COMPLYING WITH THE RELEVANT DIRECTIVE OR WITH THIS DIRECTIVE, OR
- THAT THE PRESENCE OF A SUBSTANCE SIMILAR TO THOSE REFERRED TO IN THE ANNEXES

CONSTITUTES A DANGER TO HUMAN HEALTH, THAT MEMBER STATE MAY TEMPORARILY SUSPEND OR RESTRICT APPLICATION OF THE PROVISIONS IN QUESTION WITHIN ITS TERRITORY. IT SHALL IMMEDIATELY INFORM THE OTHER MEMBER STATES AND THE COMMISSION THEREOF AND GIVE REASONS FOR ITS DECISION.

2. THE COMMISSION SHALL EXAMINE AS SOON AS POSSIBLE THE EVIDENCE GIVEN BY THE MEMBER STATE AND CONSULT THE STANDING COMMITTEE FOR FOODSTUFFS, AND SHALL THEN DELIVER ITS OPINION FORTHWITH AND TAKE THE APPROPRIATE MEASURES, WHICH MAY REPLACE THE MEASURES REFERRED TO IN PARAGRAPH 1.

3. IF THE COMMISSION CONSIDERS THAT AMENDMENTS TO THIS DIRECTIVE OR TO ONE OF THE DIRECTIVES REFERRED TO IN ARTICLE 5 ARE NECESSARY IN ORDER TO ALLEVIATE THE DIFFICULTIES MENTIONED IN PARAGRAPH 1 AND TO ENSURE THE PROTECTION OF HUMAN HEALTH, IT SHALL INITIATE THE PROCEDURE LAID DOWN IN ARTICLE 10, WITH A VIEW TO ADOPTING THESE AMENDMENTS; THE MEMBER STATE WHICH HAS ADOPTED SAFEGUARD MEASURES MAY IN THAT EVENT RETAIN THEM UNTIL THE AMENDMENTS ENTER INTO FORCE.

ARTICLE 9

1. FLAVOURINGS NOT INTENDED FOR SALE TO THE FINAL CONSUMER MAY NOT BE MARKETED UNLESS THEIR PACKAGINGS OR CONTAINERS BEAR THE FOLLOWING INFORMATION, WHICH SHOULD BE EASILY VISIBLE, CLEARLY LEGIBLE AND INDELIBLE:

(a) THE NAME OR BUSINESS NAME AND ADDRESS OF THE MANUFACTURER OR PACKER, OR OF A SELLER ESTABLISHED WITHIN THE COMMUNITY;

(b) THE SALES DESCRIPTION: EITHER THE WORD "FLAVOURING" OR A MORE SPECIFIC NAME OR DESCRIPTION OF THE FLAVOURING.
MEMBER STATES MAY MAINTAIN FOR A PERIOD OF THREE YEARS FOLLOWING THE ADOPTION OF THIS DIRECTIVE, MORE SPECIFIC NAMES TO DESIGNATE FLAVOURINGS COMPOSED OF MIXTURES OF FLAVOURING PREPARATIONS AND FLAVOURING SUBSTANCES.
BEFORE THIS PERIOD EXPIRES, IT SHALL BE DECIDED ACCORDING TO THE PROCEDURE PROVIDED FOR IN ARTICLE 10 WHETHER OR NOT THESE NAMES SHALL BE INCLUDED IN THIS DIRECTIVE;

(c) EITHER THE STATEMENT "FOR FOODSTUFFS" OR A MORE SPECIFIC REFERENCE TO THE FOODSTUFF FOR WHICH THE FLAVOURING IS INTENDED;

(d) A LIST IN DESCENDING ORDER OF WEIGHT OF THE CATEGORIES OF FLAVOURING SUBSTANCES AND FLAVOURING PREPARATIONS PRESENT CLASSIFIED AS FOLLOWS:

- NATURAL FLAVOURING SUBSTANCES IN THE CASE OF FLAVOURING SUBSTANCES DEFINED IN ARTICLE 1 (2) (b) (i),
- FLAVOURING SUBSTANCES IDENTICAL TO NATURAL SUBSTANCES IN THE CASE OF FLAVOURING SUBSTANCES DEFINED IN ARTICLE 1 (2) (b) (ii),
- ARTIFICIAL FLAVOURING SUBSTANCES IN THE CASE OF FLAVOURING SUBSTANCES DEFINED IN ARTICLE 1 (2) (b) (iii),
- FLAVOURING PREPARATIONS IN THE CASE OF PREPARATIONS DEFINED IN ARTICLE 1 (2) (c),
- PROCESS FLAVOURINGS IN THE CASE OF FLAVOURINGS DEFINED IN ARTICLE 1 (2) (d),
- SMOKE FLAVOURINGS IN THE CASE OF FLAVOURINGS DEFINED IN ARTICLE 1 (2) (e);

(e) IN THE CASE OF A MIXTURE OF FLAVOURINGS WITH OTHER SUBSTANCES OR MATERIALS REFERRED TO IN THE FIRST AND SECOND INDENTS OF ARTICLE 6 (1), A LIST IN DESCENDING ORDER OF WEIGHT IN THE MIXTURE OF:

- THE CATEGORIES OF FLAVOURINGS CLASSIFIED AS IN (d) OF THIS PARAGRAPH,
- THE NAMES OF EACH OF THE OTHER SUBSTANCES OR MATERIALS OR, WHERE APPROPRIATE, THEIR "EEC" NUMBERS;

(f) AN INDICATION OF THE MAXIMUM QUANTITY OF EACH COMPONENT OR GROUP OF COMPONENTS SUBJECT TO QUANTITATIVE LIMITATION IN A FOODSTUFF OR APPROPRIATE INFORMATION ENABLING THE PURCHASER TO COMPLY WITH THE COMMUNITY PROVISIONS OR, WHERE THERE ARE NONE, NATIONAL PROVISIONS APPLYING TO THAT FOODSTUFF;

(g) AN INDICATION IDENTIFYING THE CONSIGNMENT;

(h) THE NOMINAL QUANTITY EXPRESSED IN UNITS OF MASS OR VOLUME.

2. WITHOUT PREJUDICE TO PARAGRAPH 1 (d), THE WORD "NATURAL", OR ANY OTHER WORD HAVING SUBSTANTIALLY THE SAME MEANING, MAY BE USED ONLY FOR FLAVOURINGS IN WHICH THE FLAVOURING COMPONENT CONTAINS EXCLUSIVELY " FLAVOURING SUBSTANCES AS DEFINED IN ARTICLE 1 (2) (b) (i) AND/OR " (R1) FLAVOURING PREPARATIONS AS DEFINED IN ARTICLE 1 (2) (c).
IF THE SALES DESCRIPTION OF THE FLAVOURING CONTAINS A REFERENCE TO A FOODSTUFF OR A FLAVOURING SOURCE, THE WORD "NATURAL", OR ANY OTHER WORD HAVING SUBSTANTIALLY THE SAME MEANING, MAY NOT BE USED UNLESS THE FLAVOURING COMPONENT HAS BEEN ISOLATED BY APPROPRIATE PHYSICAL PROCESSES, ENZYMATIC OR MICROBIOLOGICAL PROCESSES OR TRADITIONAL FOOD-PREPARATION PROCESSES SOLELY OR ALMOST SOLELY FROM THE FOODSTUFF OR THE FLAVOURING SOURCE CONCERNED.

3. BY WAY OF DEROGATION FROM PARAGRAPH 1, THE INFORMATION REQUIRED IN PARAGRAPH 1 (d), (e) AND (f) MAY APPEAR MERELY ON THE TRADE DOCUMENTS RELATING TO THE CONSIGNMENT WHICH ARE TO BE SUPPLIED WITH OR PRIOR TO THE DELIVERY, PROVIDED THE INDICATION "INTENDED FOR THE MANUFACTURE OF FOODSTUFFS AND NOT FOR RETAIL" APPEARS IN A CONSPICUOUS PART OF THE PACKAGING OR CONTAINER OF THE PRODUCTS IN QUESTION.

4. MEMBER STATES SHALL REFRAIN FROM LAYING DOWN REQUIREMENTS MORE DETAILED THAN THOSE CONTAINED IN THIS ARTICLE CONCERNING THE MANNER IN WHICH THE PARTICULARS PROVIDED FOR ARE TO BE SHOWN.
THE PARTICULARS PROVIDED FOR IN THIS ARTICLE SHALL BE GIVEN IN TERMS EASILY UNDERSTOOD BY PURCHASERS UNLESS OTHER MEASURES HAVE BEEN TAKEN TO ENSURE THAT THE PURCHASER IS INFORMED. THIS PROVISION SHALL NOT PREVENT SUCH PARTICULARS FROM BEING INDICATED IN VARIOUS LANGUAGES.

" ARTICLE 9a

1. Flavourings intended for sale to the final consumer may not be marketed unless their labels indicate the following obligatory information, which should be easily visible, clearly legible and indelible:

(a) either the word "flavouring" or a more specific name or description of the flavouring;

(b) either the words "for foodstuffs" or a more specific reference to the foodstuff for which the flavouring is intended;

(c) the date of minimum durability in conformity with Article 3 (1) No 4 and Article 9 of Council Directive 79/112/EEC (1);

(d) where necessary, the special conditions for storage and use;

(e) the instructions for use if omission thereof would prevent appropriate use of the flavouring;

(f) the net quantity expressed in units of mass or volume;

(g) the name or business name and address of the manufacturer or packer, or of a seller established within the Community;

(h) an indication or mark identifying the batch in conformity with Council Directive 89/396/EEC (2);

(i) in the case of a mixture of flavouring(s) with other substances a list in descending order of weight in the mixture of:

- the flavouring or flavourings in question, in conformity with (a) above;
- the names of each of the other substances or materials or, where appropriate, their E numbers.

2. the word "natural", or any other word having substantially the same meaning, may be used only for flavourings in which the flavouring component contains exclusively flavouring substances as defined in Article 1 (2) (b) (i) and/or flavouring preparations as defined in Article 1 (2) (c). If the sales description of the flavourings contains a reference to a foodstuff or a flavouring source, the word "natural" or any other word having substantially the same meaning, may not be used unless the flavouring component has been isolated by appropriate physical processes, enzymatic or microbiological processes or traditional food-preparation processes solely or almost solely from the foodstuff or the flavouring source concerned.

3. The particulars required in this Article shall be given in a language easily understood by the purchaser unless other measures have been taken to ensure that the purchaser is informed. This provision shall not prevent such particulars from being indicated in various languages. " **[1]**

ARTICLE 10

1. WHERE THE PROCEDURE LAID DOWN IN THIS ARTICLE IS TO BE FOLLOWED, THE CHAIRMAN SHALL REFER THE MATTER TO THE STANDING COMMITTEE FOR FOODSTUFFS EITHER ON HIS OWN INITIATIVE OR AT THE REQUEST OF THE REPRESENTATIVE OF A MEMBER STATE.

2. THE COMMISSION REPRESENTATIVE SHALL SUBMIT TO THE COMMITTEE A DRAFT OF MEASURES TO BE TAKEN. THE COMMITTEE SHALL DELIVER ITS OPINION ON THE DRAFT WITHIN A TIME LIMIT WHICH THE CHAIRMAN MAY LAY DOWN ACCORDING TO THE URGENCY OF THE MATTER. THE OPINION SHALL BE DELIVERED BY THE QUALIFIED MAJORITY LAID DOWN IN ARTICLE 148 (2) OF THE TREATY. THE CHAIRMAN SHALL NOT VOTE.

3. (a) THE COMMISSION SHALL ADOPT THE INTENDED MEASURES WHEN THEY ARE IN ACCORDANCE WITH THE COMMITTEE'S OPINION.

(b) WHERE THE INTENDED MEASURES ARE NOT IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE, OR IN THE ABSENCE OF ANY OPINION, THE COMMISSION SHALL FORTHWITH SUBMIT TO THE COUNCIL A PROPOSAL RELATING TO THE MEASURES TO BE TAKEN. THE COUNCIL SHALL ACT ON A QUALIFIED MAJORITY.

IF, ON THE EXPIRY OF THREE MONTHS FROM THE DATE ON WHICH THE MATTER WAS REFERRED TO IT, THE COUNCIL HAS NOT ADOPTED ANY MEASURES, THE COMMISSION SHALL ADOPT THE PROPOSED MEASURES.

ARTICLE 11

1. THIS DIRECTIVE SHALL ALSO APPLY TO FLAVOURING INTENDED FOR USE IN FOODSTUFFS, AND TO FOODSTUFFS, IMPORTED INTO THE COMMUNITY.

2. THIS DIRECTIVE SHALL APPLY NEITHER TO FLAVOURINGS, NOR TO FOODSTUFFS, INTENDED FOR EXPORT OUTSIDE THE COMMUNITY.

ARTICLE 12

1. THE MEMBER STATES MAY NOT INVOKE REASONS OF COMPOSITION OR LABELLING OF FLAVOURINGS OR THEIR BEHAVIOUR IN FOODSTUFFS TO PROHIBIT, RESTRICT, OR HAMPER THE MARKETING OR USE OF FLAVOURINGS WHICH COMPLY WITH THIS DIRECTIVE AND WITH THE DIRECTIVES REFERRED TO IN ARTICLE 5.

2. PARAGRAPH 1 SHALL NOT AFFECT NATIONAL PROVISIONS WHICH ARE APPLICABLE IN THE ABSENCE OF THE DIRECTIVES AS REFERRED TO IN ARTICLE 5.

ARTICLE 13

1. MEMBER STATES SHALL TAKE THE MEASURES NECESSARY TO COMPLY WITH THIS DIRECTIVE WITHIN 18 MONTHS OF ITS ADOPTION. THEY SHALL FORTHWITH INFORM THE COMMISSION THEREOF. THE MEASURES TAKEN SHALL:

- AUTHORIZE, TWO YEARS AFTER ADOPTION OF THIS DIRECTIVE, THE MARKETING AND USE OF FLAVOURINGS COMPLYING WITH THIS DIRECTIVE,
- PROHIBIT, THREE YEARS AFTER ADOPTION OF THIS DIRECTIVE, THE MARKETING AND USE OF FLAVOURINGS WHICH DO NOT COMPLY WITH THIS DIRECTIVE.

2. PARAGRAPH 1 SHALL NOT AFFECT THOSE NATIONAL PROVISIONS WHICH, IN THE ABSENCE OF THE DIRECTIVES REFERRED TO IN ARTICLE 5, APPLY TO CERTAIN GROUPS OF FLAVOURINGS OR SPECIFY THE FOODSTUFFS IN OR ON WHICH FLAVOURINGS COMPLYING WITH THE DIRECTIVE MAY BE USED.

ARTICLE 14

THE DIRECTIVE IS ADDRESSED TO THE MEMBER STATES.

ANNEX I

Maximum limits for certain undesirable substances present in foodstuffs as consumed as a result of the use of flavourings

Substance	Foodstuffs	Beverages
3,4 benzopyrene	0,03 µg/kg	0,03 µg/kg

ANNEX II

Maximum limits for certain substances obtained from flavourings and other food ingredients with flavouring properties present in foodstuffs as consumed in which flavourings have been used

Substances	Foodstuffs mg/kg	Beverages mg/kg	Exceptions and/or special restrictions
Agaric acid (3)	20	20	100 mg/kg in alcoholic beverages and foodstuffs containing mushrooms
Aloin (3)	0,1	0,1	50 mg/kg in alcoholic beverages
Beta asarone (3)	0,1	0,1	1 mg/kg in alcoholic beverages and seasonings used in snack foods
Berberine (3)	0,1	0,1	10 mg/kg in alcoholic beverages
Coumarin (3)	2	2	10 mg/kg in certain types of caramel confectionery 50 mg/kg in chewing gum 10 mg/kg in alcoholic beverages
Hydrocyanic acid (3)	1	1	50 mg/kg in nougat, marzipan or its substitutes or similar products 1 mg/ % volume of alcohol in alcoholic beverages 5 mg/kg in canned stone fruit
Hypericine (3)	0,1	0,1	10 mg/kg in alcoholic beverages 1 mg/kg in confectionery
Pulegone (3)	25	100	250 mg/kg in mint or peppermint-flavoured beverages 350 mg/kg in mint confectionery
Quassine (3)	5	5	10 mg/kg in confectionery in pastille form 50 mg/kg in alcoholic beverages
Safrole and isosafrole (3)	1	1	2 mg/kg in alcoholic beverages with not more than 25 % volume of alcohol 5 mg/kg in alcoholic beverages with more than 25 % volume of alcohol 15 mg/kg in foodstuffs containing mace and nutmeg
Santonin (3)	0,1	0,1	1 mg/kg in alcoholic beverages with more than 25 % volume of alcohol
Thuyone (alpha and beta) (3)	0,5	0,5	5 mg/kg in alcoholic beverages with not more than 25 % volume of alcohol 10 mg/kg in alcoholic beverages with more than 25 % volume of alcohol 25 mg/kg in foodstuffs containing preparations based on sage 35 mg/kg in bitters

(R1) Corrigenda, OJ No L 345, 14/12/1988, p. 29.

(1) OJ No L 33, 08/02/1979, p. 1.
(2) OJ No L 186, 30/06/1989, p. 21.
(3) MAY NOT BE ADDED AS SUCH TO FOODSTUFFS OR TO FLAVOURINGS. MAY BE PRESENT IN A FOODSTUFF EITHER NATURALLY OR FOLLOWING THE ADDITION OF FLAVOURINGS PREPARED FROM NATURAL RAW MATERIALS.

COUNCIL DECISION

of 22 June 1988

on the establishment, by the Commission, of an inventory of the source materials and substances used in the preparation of flavourings

(88/389/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 213 thereof,

Whereas the Council adopted on 22 June 1988 Directive 87/388/EEC on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production (1);

Whereas it became apparent that the acquisition of data on source materials and substances used in the preparation of flavourings was desirable with a view to assessing, on the one hand, all questions relating to flavourings and to source materials for their production and, on the other hand, the resulting action to be taken at Community level;

Whereas acquisition of the data concerned may be made easier by the preparation by the Commission of an inventory of the source materials and substances concerned,

HAS DECIDED AS FOLLOWS:

Article 1

1. The Commission shall, within 24 months of adoption of this Decision and after consultation of the Member States, establish an inventory of:

— flavouring sources composed of foodstuffs, and of herbs and spices normally considered as foods,

— flavouring sources composed of vegetable or animal raw materials not normally considered as foods,

— flavouring substances obtained by appropriate physical processes or by enzymatic or microbiological processes from vegetable or animal raw materials,

— chemically synthesized or chemically isolated flavouring substances chemically identical to flavouring substances naturally present in foodstuffs or in herbs and spices normally considered as foods,

— chemically synthesized or chemically isolated flavouring substances chemically identical to flavouring substances naturally present in vegetable or animal raw materials not normally considered as foods,

— chemically synthesized or chemically isolated flavouring substances other than those referred to in the fourth and fifth indents,

— source materials used for the production of smoke flavourings and process flavourings and the reaction conditions under which they are prepared.

2. The inventory referred to in paragraph 1 shall be regularly updated by the Commission.

Done at Luxembourg, 22 June 1988.

For the Council

The President

M. BANGEMANN

(1) See page 61 of this Official Journal.

MATERIALS AND ARTICLES IN CONTACT

COUNCIL DIRECTIVE

of 21 December 1988

on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs

(89/109/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission,

In cooperation with the European Parliament (1),

Having regard to the opinion of the Economic and Social Committee (2),

Whereas Council Directive 76/893/EEC of 23 November 1976 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs (3), as last amended by the act of Accession of Spain and Portugal (4), has been substantially amended on a number of occasions; whereas on making the new amendments to the said Directive, the opportunity should be taken to consolidate the provisions of the existing relevant texts with a view to ensuring legal clarity;

Whereas Directive 76/893/EEC was adopted on the grounds that the differences that existed at that time between the national laws relating to the aforesaid materials and articles impeded the free movement thereof, could create unequal conditions of competition and could thereby directly affect the establishment or functioning of the common market;

Whereas those laws had to be approximated if free movement was to be achieved for the aforesaid materials and articles, taking account primarily of human health requirements but also, within the limits required for the protection of health, of economic and technological needs;

Whereas the chosen method was to lay down, in the first place, in a framework directive, general principles on the basis of which legal differences between certain groups of materials and articles had been and could subsequently be eliminated by means of specific directives; whereas this method has proved itself and should therefore be retained;

Whereas covering or coating substances, all or part of which form part of foodstuffs, could not be considered to be simply in contact with these foodstuffs; whereas, in that case, account had to be taken of possible direct consumption by consumers; whereas the rules laid down in this Directive are therefore inappropriate in such circumstances;

Whereas the principle underlying this Directive should be that any material or article intended to come into contact or which is intentionally in contact either directly or indirectly with foodstuffs, must be sufficiently stable not to transfer substances to the foodstuffs in quantities which could endanger human health or bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic properties thereof;

Whereas, in order to achieve this objective, it may prove necessary to lay down various types of limitations, alone or in combination; whereas it is appropriate to retain in specific directives those limitations which are most appropriate to the desired objective, having regard to the technological characteristics peculiar to each group of materials and articles;

Whereas, in order to allow the informed use of the materials and articles, appropriate labelling should be provided for; whereas the methods used for such labelling may vary according to the user;

Whereas this Directive does not apply to the labelling of products which, by reason of their behaviour in the presence of foodstuffs, must not be designed to come into contact or be in contact with them;

Whereas the drafting of specific directives implementing the basic principles and of amendments thereto constitute technical implementing measures; whereas, in order to simplify and expedite the procedure, the adoption of these measures should be entrusted to the Commission;

Whereas the Scientific Committee for Food, set up by Commission Decision 74/234/EEC (5), should be asked for its opinion before provisions liable to affect public health are adopted under specific directives;

(1) OJ No C 99, 13. 4. 1987, p. 65 and OJ No C 12, 16. 1. 1989.
(2) OJ No C 328, 22. 12. 1986, p. 5.
(3) OJ No L 340, 9. 12. 1976, p. 19.
(4) OJ No L 302, 15. 11. 1985, p. 216.
(5) OJ No L 136, 20. 5. 1974, p. 1.

Whereas it is desirable that in all cases where the Council empowers the Commission to implement rules relating to foodstuffs, provision should be made for a procedure establishing close cooperation between the Member States and the Commission within the Standing Committee on Foodstuffs set up by Council Decision 69/414/EEC (1),

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to materials and articles which, in their finished state, are intended to be brought into contact with foodstuffs or which are brought into contact with foodstuffs and are intended for that purpose, hereinafter referred to as 'materials and articles'.

Covering or coating substances, such as the substances covering cheese rinds, prepared meat products or fruit, which form part of foodstuffs and may be consumed together with those foodstuffs, shall not be subject to this Directive.

2. This Directive shall apply to materials and articles which are in contact with water which is intended for human consumption. It shall not, however, apply to fixed public or private water supply equipment.

3. This Directive shall not apply to antiques.

Article 2

Materials and articles must be manufactured in compliance with good manufacturing practice so that, under their normal or foreseeable conditions of use, they do not transfer their constituents to foodstuffs in quantities which could:

— endanger human health,

— bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof.

Article 3

1. The groups of materials and articles listed in Annex I and, where appropriate, combinations of these materials and articles shall be subject to specific directives.

2. The specific directives, including amendments to existing specific directives, shall be adopted in accordance with the procedure laid down in Article 8.

3. The specific directives may include:

(a) a list of the substances the use of which is authorized to the exclusion of all others (positive list);

(b) purity standards for such substances;

(c) special conditions of use for these substances and/or the materials and articles in which they are used;

(d) specific limits on the migration of certain constituents or groups of constituents into or onto foodstuffs;

(e) an overall limit on the migration of constituents into or onto foodstuffs;

(f) if necessary, provisions aimed at protecting human health against any hazards which might arise through oral contact with materials and articles;

(g) other rules to ensure compliance with Article 2;

(h) the basic rules necessary for checking compliance with the provisions of points (d), (e), (f) and (g);

(i) detailed rules concerning sample taking and the methods of analysis required to check compliance with the provisions of points (a) to (g).

Provisions liable to affect public health shall be adopted after consulting the Scientific Committee for Food. They must fulfill the criteria set out in Annex II.

Article 4

1. Notwithstanding Article 3, a Member State may, where a list of substances has been drawn up in accordance with paragraph 3 (a) of that Article, authorize the use within its territory of a substance not included in the list, subject to compliance with the following conditions:

(a) the authorization must be limited to a maximum period of two years;

(b) the Member State must carry out an official check on materials and articles manufactured from a substance of which it has authorized the use;

(c) materials and articles thus manufactured must bear a distinctive indication which will be defined in the authorization.

2. The Member State shall forward to the other Member States and to the Commission the text of any authorization drawn up pursuant to paragraph 1 within two months of the date of its taking effect.

3. Before the expiry of the two-year period provided for in paragraph 1 (a), the Member State may submit to the Commission a request for the inclusion in the list referred to

(1) OJ No L 291, 19. 11. 1969, p. 9.

in Article 3 (3) (a) of the substance given national authorization in accordance with paragraph 1 of this Article. At the same time, it shall supply supporting documents setting out the grounds on which it deems such inclusion justified and shall indicate the uses for which this substance is intended.

Within 18 months of the submission of the request, a decision shall be taken on the basis of information relating to public health, after consulting the Scientific Committee for Food and in accordance with the procedure laid down in Article 9 as to whether the substance in question may be included in the list referred to in Article 3 (a) or whether the national authorization should be revoked. If provisions prove necessary pursuant to Article 3 (3) (b), (c) and (d), these shall be adopted in accordance with the same procedure. Notwithstanding paragraph 1 (a) of this Article, the national authorization shall remain in force until a decision is taken on the request for inclusion in the list.

Should it be decided pursuant to the preceding subparagraph that the national authorization should be revoked, this decision shall apply to any other national authorization in respect of the substance in question. The decision may stipulate that the ban on the use of this substance shall extend to uses other than those referred to in the request for inclusion in the list.

Article 5

1. Where a Member State, as a result of new information or of a reassessment of existing information made since one of the specific directives was adopted, has detailed grounds for establishing that the use of a material or article endangers human health although it complies with the relevant specific directive, that Member State may temporarily suspend or restrict application of the provisions in question within its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

2. The Commission shall examine as soon as possible within the Standing Committee on Foodstuffs the grounds adduced by the Member State referred to in paragraph 1 and shall deliver its opinion without delay and take the appropriate measures.

3. If the Commission considers that amendments to the specific directives in question are necessary in order to remedy the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure laid down in Article 9 with a view to adopting those amendments; the Member State which has adopted safeguard measures may in that event retain them until the amendments have been adopted.

Article 6

1. Without prejudice to any exceptions provided for in the specific directives, materials and articles not already in contact with foodstuffs must, when placed on the market, be accompanied by:

(a) — the words 'for food use',

— or a specific indication as to their use, such as coffee-machine, wine bottle, soup spoon,

— or a symbol determined in accordance with the procedure laid down in Article 9;

(b) where appropriate, any special conditions to be observed when they are being used;

(c) — either the name or trade name and the address or registered office,

— or the registered trade mark,

of the manufacturer or processor, or of a seller established within the Community.

2. The particulars listed in paragraph 1 must be conspicuous, clearly legible and indelible:

(a) at the retail stage:

— on the materials and articles or on the packaging,

— or on labels affixed to the materials and articles or to their packaging,

— or on a notice in the immediate vicinity of the materials and articles and clearly visible to purchasers; in the case mentioned in paragraph 1 (c), however, the latter option shall only be open if these particulars or a label bearing them cannot, for technical reasons, be affixed to the said materials and articles at either the manufacturing or the marketing stage;

(b) at the marketing stages other than the retail stage:

— on the accompanying documents,

— on the labels or packaging,

— or on the materials and articles themselves.

3. However, the particulars provided for in paragraph 1 shall not be compulsory for materials and articles which by their nature are clearly intended to come into contact with foodstuffs.

4. The particulars provided for in paragraph 1 (a) and (b) shall be confined to materials and articles which comply:

(a) with the criteria laid down in Article 2;

(b) with the specific directives, in the absence of such directives, with any national provisions.

5. The specific directives shall require that such materials and articles be accompanied by a written declaration attesting that they comply with the rules applicable to them.

In the absence of specific directives, Member States may retain existing provisions or adopt provisions to this effect.

6. Member States shall ensure that retail trade in materials and articles is prohibited if the particulars required under paragraph 1 (a) and (b) are not given in a language easily understood by purchasers, unless the purchaser is informed by other means. This provision shall not preclude such particulars appearing in several languages.

Article 7

1. Member States shall not, for reasons relating to composition, behaviour in the presence of foodstuffs or labelling, prohibit or restrict either trade in or the use of materials and articles complying with this Directive or with the specific directives.

2. Paragraph 1 shall not affect national provisions which are applicable in the absence of the specific directives.

Article 8

Amendments made to existing specific directives in order to bring them into line with this Directive shall be adopted in accordance with the procedure laid down in Article 9.

Article 9

1. Where the procedure laid down in this Article is to be followed, the chairman shall refer the matter to the Standing Committee on Foodstuffs either on his own initiative or at the request of the representative of a Member State.

2. The Commission representative shall submit to the committee a draft of measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the qualified majority laid down in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the intended measures when they are in accordance with the committee's opinion;

(b) where the intended measures are not in accordance with the opinion of the committee, or in the absence of any opinion, the Commission shall forthwith submit to the Council a proposal relating to the measures to be taken. The Council shall act on a qualified majority.

If, on the expiry of three months from the date on which the matter was referred to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures and apply them immediately.

Article 10

1. Directive 76/893/EEC is hereby repealed.

2. References to the Directive repealed under paragraph 1 shall be construed as references to this Directive.

References to the Articles of the repealed Directive should be read in accordance with the correlation table appearing in Annex III.

Article 11

1. Member States shall take all measures necessary to comply with this Directive. They shall forthwith inform the Commission thereof. The measures taken shall:

— permit, not later than 18 months after notification (1), trade in and use of materials and articles complying with this Directive, without prejudice to the application of national provisions which, in the absence of specific directives, apply to certain groups of materials and articles;

— prohibit not later than 36 months after notification trade in and use of materials and articles which do not comply with this Directive.

2. Paragraph 1 shall not affect those national provisions which, in the absence of the specific directives, apply to certain groups of materials and articles intended to come into contact with foodstuffs.

Article 12

This Directive shall not apply to materials and articles intended for export outside the Community.

Article 13

This Directive is addressed to the Member States.

Done at Brussels, 21 December 1988.

For the Council

The President

V. PAPANDREOU

(1) This Directive was notified to the Member States on 10 January 1989.

ANNEX I

List of groups of materials and articles covered by specific directives

Plastics, including varnish and coatings
Regenerated cellulose
Elastomers and rubber
Paper and board
Ceramics
Glass
Metals and alloys
Wood, including cork
Textile products
Paraffin waxes and micro-crystalline waxes

ANNEX II

Health criteria to be applied in the drafting of specific directives

1. Where appropriate, positive lists of substances shall be established for materials and articles intended to come into contact with foodstuffs. The acceptability of a substance for inclusion in a positive list shall be determined by considering both the quantity of the substance which is liable to migrate into foodstuffs and the toxicity of the substance.

2. A substance shall only be included in a positive list where, under normal or foreseeable conditions of use of any material or article of which it forms a part, the substance is not liable to migrate into foodstuffs in a quantity likely to constitute a danger to human health.

3. For certain materials it may be inappropriate to establish a positive list because such a list would offer no tangible benefit in terms of safeguarding human health. In such circumstances, any substances for which specific migration limits need to be established in order to prevent their being transferred to foodstuffs in quantities likely to constitute a danger to health shall be identified. The criteria set out in paragraphs 1 and 2 shall also apply to these substances.

4. All substances shall be kept under review and reassessed whenever this is justified by fresh scientific data or a re-evaluation of existing scientific data.

5. Where an acceptable daily intake or a tolerable daily intake is established for a particular substance, the need to establish a specific migration limit in order that this intake is not exceeded shall be considered. Where such a specific migration limit is established for a substance, due regard shall be paid to other possible sources of exposure to the substance.

6. In certain circumstances, a specific migration limit on a substance may not be the most valid means of safeguarding human health. In such circumstances, the need to protect human health shall be the primary consideration in determining what action might be appropriate.

ANNEX III

CORRELATION TABLE

Directive 76/893/EEC	Present Directive
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3
Article 4	Article 4
Article 5	Article —
Article 6	Article 5
Article 7	Article 6
Article 8	Article 7
Article —	Article 8
Article 9	Article —
Article 10	Article 9
Article —	Article 10
Article 11	Article —
Article 12	Article 12
Article 13	Article 11
Article 14	Article —
Article 15	Article 13

380L0590

80/590/EEC: COMMISSION DIRECTIVE OF 9 JUNE 1980 DETERMINING THE SYMBOL THAT MAY ACCOMPANY MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

OFFICIAL JOURNAL NO L 151, 19/06/1980, P. 21
DATE OF NOTIFICATION: 10/06/1980
DATE OF TRANSPOSITION: 01/01/1981; SEE ART. 2

AMENDED BY

185I
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE KINGDOM OF SPAIN AND THE PORTUGUESE REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES **[1]**
OFFICIAL JOURNAL NO L 302, 15/11/1985, P. 217

ARTICLE 1

THE SYMBOL REFERRED TO IN THE LAST INDENT OF ARTICLE 7 (1) (a) OF DIRECTIVE 76/893/EEC SHALL BE THAT REPRODUCED IN THE ANNEX HERETO (1).

ARTICLE 2

THE MEMBER STATES SHALL TAKE THE MEASURES NECESSARY TO AUTHORIZE WITH EFFECT FROM 1 JANUARY 1981 THE USE OF THE SYMBOL REFERRED TO IN ARTICLE 1.

ARTICLE 3

THIS DIRECTIVE IS ADDRESSED TO THE MEMBER STATES.

ANNEX

BILAG - ANHANG - ANNEX - ANNEXE - ALLEGATO - BIJLAGE - " ANEXO " **[1]**

[see drawing of the symbol reproduced in OJ No L 151, 19/06/1980, p. 22]

SYMBOL - SYMBOLE - SIMBOLO - SYMBOOL - " SÍMBOLO " **[1]**

(1) OJ No L 340, 09/12/1976, p. 19.

COUNCIL DIRECTIVE

of 30 January 1978

on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs

(78/142/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to Council Directive 76/893/EEC of 23 November 1976 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs (1), and in particular Article 3 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas Article 2 of Directive 76/893/EEC provides that materials and articles must not transfer any constituents to foodstuffs in quantities which could endanger human health;

Whereas Article 3 of the same Directive provides that the Council, under the procedure provided for in Article 100 of the Treaty, shall adopt by means of Directives special provisions applicable to certain groups of materials and articles (specific Directives); whereas these provisions may include specific limits on the migration of certain constituents into or onto foodstuffs as well as other rules to ensure compliance with Article 2 of the said Directive;

Whereas the administration of large doses of vinyl chloride monomer to experimental animals has been shown to produce harmful effects; whereas such effects could also occur in man;

Whereas the Scientific Committee for Food has given the opinion that the levels of vinyl chloride monomer in polyvinyl chloride and related polymers should be reduced as far as possible and at the same time recommended that no trace of vinyl chloride should be detectable in food or potable water by a method which can be generally applied to the majority of foodstuffs by most laboratories;

Whereas further research is at present being conducted on vinyl chloride monomer, but as a precaution the ingestion of vinyl chloride monomer should be restricted until the results are known;

Whereas the appropriate instrument for attaining this objective is a specific Directive within the meaning of Article 3 of Directive 76/893/EEC, the general provisions of which also become applicable in this particular case;

Whereas, however, this Directive does not concern all aspects of materials and articles prepared from vinyl chloride polymers or copolymers and the Member States should therefore be authorized not to require that labels carry the particulars laid down in Article 7 of Directive 76/893/EEC, in accordance with the opinions provided for in paragraphs 4 and 5 of that Article,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific Directive within the meaning of Article 3 of Directive 76/893/EEC.

2. This Directive concerns the presence of vinyl chloride monomer in, and possible migration from, materials and articles prepared with vinyl chloride polymers or copolymers, hereinafter called 'materials and articles', which in their finished state are intended to come into contact with foodstuffs, or which are in contact with foodstuffs and are intended for that purpose.

Article 2

1. Materials and articles must not contain vinyl chloride monomer in a quantity exceeding that laid down in Annex I.

2. Materials and articles must not pass on to foodstuffs which are in or have been brought into contact with such materials and articles any vinyl chloride detectable by the method which complies with the criteria laid down in Annex II.

(1) OJ No L 340, 9. 12. 1976, p. 19.
(2) OJ No C 118, 16. 5. 1977, p. 70.
(3) OJ No C 114, 11. 5. 1977, p. 13.

Article 3

The method of analysis necessary for checking compliance with Article 2 shall be adopted in accordance with the procedure laid down in Article 10 of Directive 76/893/EEC and shall comply with the criteria laid down in Annex II.

Article 4

The Council shall review this Directive on the basis of reports from the Commission drawn up in the light of scientific and technical knowledge becoming available after adoption of the Directive and accompanied, where appropriate, by suitable proposals. The first report from the Commission shall be forwarded to the Council not later than 1 January 1979.

Article 5

This Directive shall not affect national provisions relating to other possible rules provided for in Article 3 of Directive 76/893/EEC or the options afforded to Member States under Article 7 (4) and (5) of that Directive.

Article 6

1. Member States shall bring into force the laws, regulations and administrative provisions needed in order to comply with this Directive not later than 26 November 1979. They shall forthwith inform the Commission thereof.

2. Member States may defer the introduction of Article 2 (2) and Annex II until such time as a Community method of analysis, as required by Article 3, has been adopted.

Article 7

This Directive is addressed to the Member States.

Done at Brussels, 30 January 1978.

For the Council

The President

P. DALSAGER

ANNEX I

Maximum vinyl chloride monomer level in materials and articles

One milligram per kilogram in the final product.

ANNEX II

Criteria applicable to the method of determining the level of vinyl chloride in materials and articles and of determining vinyl chloride released by materials and articles

1. The level of vinyl chloride in materials and articles and the level of vinyl chloride released by materials and articles to foodstuffs are determined by means of gas-phase chromatography using the 'headspace' method.
2. For the purposes of determining vinyl chloride released by materials and articles to foodstuffs, the detection limit shall be 0·01 mg/kg.
3. Vinyl chloride released by materials and articles to foodstuffs is in principle determined in the foodstuffs. When the determination in certain foodstuffs is shown to be impossible for technical reasons, Member States may permit determination by simulants for these particular foodstuffs.

COMMISSION DIRECTIVE

of 8 July 1980

laying down the Community method of analysis for the official control of the vinyl chloride monomer level in materials and articles which are intended to come into contact with foodstuffs

(80/766/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Communities,

Having regard to Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs [1], and in particular Article 3 thereof,

Whereas Article 2 of Directive 78/142/EEC lays down that such materials and articles must not contain vinyl chloride monomer in a quantity exceeding 1 milligram per kilogram in the final product and Article 3 that this limit must be controlled by a Community analysis method;

Whereas, on the basis of a series of inter-laboratory collaborative trials, the method described in the Annex has proved to be sufficiently accurate and reproducible to be adopted as a Community method;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Member States shall require that the analysis necessary for official control of the vinyl chloride monomer level in materials and articles intended to come into contact with foodstuffs, referred to in the Annex as 'materials and articles', shall be performed according to the method described in the Annex.

Article 2

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 18 months following its notification. They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 8 July 1980.

For the Commission

Etienne DAVIGNON

Member of the Commission

[1] OJ No L 44, 15. 2. 1978, p. 15.

ANNEX

DETERMINATION OF THE VINYL CHLORIDE MONOMER LEVEL IN MATERIALS AND ARTICLES

1. SCOPE AND FIELD OF APPLICATION

The method determines the vinyl chloride monomer level in materials and articles.

2. PRINCIPLE

The level of vinyl chloride monomer level (VC) in materials or articles is determined by means of gas-chromatography using the 'headspace' method after dissolution or suspension of the sample in N,N-dimethylacetamide.

3. REAGENTS

3.1. Vinyl chloride (VC), of purity greater than 99·5 % (v/v).

3.2. N,N-dimethylacetamide (DMA), free from any impurity with the same retention time as VC or as the internal standard (3.3) under the conditions of the test.

3.3. Diethyl ether or cis-2-butene, in DMA (3.2) as the internal standard solution. These internal standards must not contain any impurity with the same retention time as VC, under the conditions of the test.

4. APPARATUS

N.B.

An instrument or piece of apparatus is mentioned only if it is special or made to particular specifications. Usual laboratory apparatus is assumed to be available.

4.1. Gas-chromatograph fitted with automatic head-space sampler or with facilities for manual sample injection.

4.2. Flame ionization detector or other detectors mentioned in point 7.

4.3. Gas-chromatographic column.

The column must permit the separation of the peaks of air, of VC and of the internal standard, if used.

Furthermore, the combined 4.2 and 4.3 system must allow the signal obtained with a solution containing 0·02 mg VC/litre DMA or 0·02 mg VC/kg DMA to be equal to at least five times the background noise.

4.4. Sample phials or flasks fitted with silicon or butyl rubber septa.

When using manual sampling techniques the taking of a sample from the headspace with a syringe may cause a partial vacuum to form inside the phial or flask. Hence, for manual techniques where the phials are not pressurized before the sample is taken, the use of large phials is recommended.

4.5. Micro-syringes.

4.6. Gas-tight syringes for manual headspace sampling.

4.7. Analytical balance accurate to 0·1 mg.

5. PROCEDURE

CAUTION: VC is a hazardous substance and a gas at ambient temperature, therefore the preparation of solutions should be carried out in a well-ventilated fume cupboard.

N.B.

— Take all the necessary precautions to ensure that no VC or DMA is lost;

— When employing manual sampling techniques an internal standard (3.3) should be used;

— When using an internal standard, the same solution must be utilized throughout the procedure.

5.1. **Preparation of concentrated standard VC solution at approximately 2 000 mg/kg**

Accurately weigh to the nearest 0·1 mg a suitable glass vessel and place in it a quantity (e.g. 50 ml) of DMA (3.2). Re-weigh. Add to the DMA a quantity (e.g. 0·1 g) of VC (3.1) in liquid or gas form, injecting it slowly on to the DMA. The VC may also be added by bubbling it into the DMA, provided that a device is used which will prevent loss of DMA. Re-weigh to the nearest 0·1 mg. Wait two hours to allow equilibrium to be attained. Keep the standard solution in a refrigerator.

5.2. **Preparation of dilute standard VC solution**

Take a weighed amount of concentrated standard solution of VC (5.1) and dilute, to a known volume or a known weight, with DMA (3.2) or with internal standard solution (3.3). The concentration of the resultant dilute standard solution is expressed as mg/l or mg/kg respectively.

5.3. **Preparation of the calibration curve**

N.B. — the curve must comprise at least seven pairs of points,

— the repeatability of the responses [1] must be lower than 0·02 mg VC/l or kg of DMA,

— the curve must be calculated from these points by the least squares technique, i.e. the regression line must be calculated using the following equation

$$y = a_1 x + a_0$$

where: $$a_1 = \frac{n\sum xy - (\sum x)\cdot(\sum y)}{n\sum x^2 - (\sum x)^2}$$

and: $$a_0 = \frac{(\sum y)\cdot(\sum x^2) - (\sum x)\cdot(\sum xy)}{n\sum x^2 - (\sum x)^2}$$

where:
y = the height or area of peaks in any single determination,
x = the corresponding concentration on the regression line,
n = number of determinations carried out ($n \geq 14$),

— the curve must be linear, i.e. the standard deviation (s) of the differences between the measured responses (y_i) and the corresponding value of the responses calculated from the regression line (z_i) divided by the mean value ($\bar{y}$) of all the measured responses shall not exceed 0·07:

This shall be calculated from: $\frac{s}{\bar{y}} \leq 0{\cdot}07$

where: $$s = \sqrt{\frac{\sum_{i=1}^{n} (y_i - z_i)^2}{n-1}}$$

$$\bar{y} = \frac{1}{n}\sum_{i=1}^{n} y_i$$

y_i = each individual measured response,
z_i = the corresponding value of the response (y_i) on the calculated regression line,
$n \geq 14$.

[1] See recommendation ISO DIS 5725 : 1977.

Prepare two series of at least seven phials (4.4). Add to each phial volumes of dilute standard VC solution (5.2) and DMA (3.2) or internal standard solution in DMA (3.3) such that the final VC concentration of the duplicate solutions will be approximately equal to 0; 0·050; 0·075; 0·100; 0·125; 0·150; 0·200, etc. mg/l or mg/kg of DMA and that all the phials contain the same quantity of DMA that is to be used under point 5.5. Seal the phials and proceed as described under point 5.6. Construct a graph in which the ordinate values show the areas (or heights) of the VC peaks of the duplicate solutions or the ratio of these areas (or heights) to those of the relevant internal standard peaks and the abscissa values show the VC concentrations of the duplicate solutions.

5.4. **Validation of preparation of standard solutions obtained in points 5.1 and 5.2**

Repeat the procedure described under points 5.1 and 5.2 to obtain a second diluted standard solution with a concentration equal to 0·1 mg VC/1 or 0·1 mg/kg of DMA or internal standard solution. The average of two gas-chromatographic determinations of this solution must not differ by more than 5 % from the corresponding point of the calibration curve. If the difference is greater than 5 %, reject all the solutions obtained in points 5.1, 5.2, 5.3 and 5.4 and repeat the procedure from the beginning.

5.5. **Preparation of the samples of materials or articles**

Prepare two phials (4.4). Weigh into each phial not less than 200 mg, to the nearest 0·1 mg, of the sample obtained from a single material or article under investigation which has been reduced to small pieces. Try to ensure that an equal quantity is weighed into each phial. Close the phial immediately. Add to each phial for each gram of the sample 10 ml or 10 g of DMA (3.2) or 10 ml or 10 g of internal standard solution (3.3). Seal the phials and proceed as described under point 5.6.

5.6. **Gas-chromatographic determinations**

5.6.1. Agitate the phials avoiding contact between the contained liquid and the septum (4.4) to obtain a solution or suspension of the samples of material or article (5.5) as homogeneous as possible.

5.6.2. Put all the sealed phials (5.3, 5.4 and 5.5) in a waterbath for two hours at 60 ° ± 1 °C to allow equilibrium to be attained. Agitate again, if necessary.

5.6.3. Take a sample from the headspace in the phial. When utilizing manual sampling techniques care must be exercised in obtaining a reproducible sample (see point 4.4), in particular the syringe must be pre-warmed to the temperature of the sample. Measure the area (or height) of the peaks relating to the VC and to the internal standard if used.

5.6.4. Remove from the column (4.3) excess DMA using an appropriate method as soon as peaks of DMA appear on the chromatogram.

6. CALCULATION OF THE RESULTS

6.1. Find by interpolation on the curve, the unknown concentration of each of the two solutions of the sample taking account of the internal standard solution if used. Calculate the amount of VC in each of the two samples of material or article under investigation by applying the following formula:

$$X = \frac{C \times V}{M} 1000$$

where:

X = concentration of VC in the sample of the material or article expressed in mg/kg.

C = concentration of VC in the phial containing the sample of material or article (see under point 5.5) expressed in mg/l or mg/kg.

V = volume or mass of DMA in the phial containing the sample of material or article (see under point 5.5) expressed in litres or kg.

M = amount of the sample of the material or article, expressed in grams.

6.2. The concentration of VC in the material and article under investigation expressed in mg/kg shall be the average of the two concentrations of VC (mg/kg) determined in point 6.1 provided that the repeatability criterion in point 8 is satisfied.

7. CONFIRMATION OF THE VC LEVEL

In cases where the content of VC in materials and articles as calculated under point 6.2 exceeds the maximum permissible amount the results obtained by the analysis of each of the two samples (5.6 and 6.1) must be confirmed in one of three ways:

— by using at least one other column (4.3) having a stationary phase with a different polarity. This procedure should continue until a chromatogram is obtained with no evidence of overlap of the VC and/or internal standard peaks with constituents of the sample of the material or article,

— by using other detectors, e.g. the micro-electrolytic conductivity detector (1),

— by using mass-spectrometry. In this case, if molecular ions with parent masses (m/e) of 62 and 64 are found in the ratio of 3 : 1, it may be regarded with high probability as confirming the presence of VC. In case of doubt the total mass spectrum must be checked.

8. REPEATABILITY

The difference between the results of two determinations (6.1) carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, must not exceed 0·2 mg VC/kg of material or article.

(1) See Journal of Chromatographic Science, Vol. 12, March 1974, p. 152.

COMMISSION DIRECTIVE

of 29 April 1981

laying down the Community method of analysis for the official control of vinyl chloride released by materials and articles into foodstuffs

(81/432/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs (1), and in particular Article 3 thereof,

Whereas Article 2 of Directive 78/142/EEC lays down that materials and articles must not pass on to the foodstuffs which are in, or have been brought into, contact with such materials and articles any vinyl chloride detectable by a method having a limit of detection of 0·01 mg/kg, and Article 3 that this limit must be controlled by a Community method of analysis;

Whereas, on the basis of a series of inter-laboratory collaborative trials, the method described in the Annex has proved to be sufficiently accurate and reproducible to be adopted as a Community method;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The analysis necessary for official control of vinyl chloride released by materials and articles into foodstuffs shall be performed according to the method described in the Annex hereto.

Article 2

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 October 1982. They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 29 April 1981.

For the Commission

Karl-Heinz NARJES

Member of the Commission

(1) OJ No L 44, 15. 2. 1978, p. 15.

ANNEX

DETERMINATION OF VINYL CHLORIDE RELEASED BY MATERIALS AND ARTICLES INTO FOODSTUFFS

1. SCOPE AND FIELD OF APPLICATION

The method determines the level of vinyl chloride in foodstuffs.

2. PRINCIPLE

The level of vinyl chloride (VC) in foodstuffs is determined by means of gas-chromatography using the 'headspace' method.

3. REAGENTS

3.1. Vinyl chloride (VC), of purity greater than 99·5% (v/v).

3.2. *N, N*-dimethylacetamide (DMA), free from any impurity with the same retention time as VC or as the internal standard (3.3) under the conditions of the test.

3.3. Diethyl ether or cis-2-butene, in DMA (3.2) as the internal standard solution. These internal standards must not contain any impurity with the same retention time as VC, under the conditions of the test.

3.4. Distilled water or demineralized water of equivalent purity.

4. APPARATUS

NB:
An instrument or piece of apparatus is mentioned only if it is special, or made to particular specifications. Usual laboratory apparatus is assumed to be available.

4.1. Gas-chromatograph fitted with automatic headspace sampler or with facilities for manual sample injection.

4.2. Flame ionization detector or other detectors mentioned in point 7.

4.3. Gas-chromatographic column

The column must permit the separation of the peaks of air, of VC and of the internal standard, if used.

Furthermore, the combined 4.2 and 4.3 system must allow the signal obtained with a solution containing 0·005 mg VC/litre DMA or 0·005 mg VC/kg DMA to be equal to at least five times the background noise.

4.4. Sample phials or flasks fitted with silicon or butyl rubber septa

When using manual sampling techniques, the taking of a sample from the headspace with a syringe may cause a partial vacuum to form inside the phial or flask. Hence, for manual techniques where the phials are not pressurized before the sample is taken, the use of large phials is recommended.

4.5. Micro-syringes.

4.6. Gas-tight syringes for manual headspace sampling.

4.7. Analytical balance accurate to 0·1 mg.

5. PROCEDURE

CAUTION: VC is a hazardous substance and a gas at ambient temperature therefore, the preparation of solutions should be carried out in a well-ventilated fume cupboard.

NB:

Take all the necessary precautions to ensure that no VC or DMA is lost.

When employing manual sampling techniques, an internal standard (3.3) should be used.

When using an internal standard, the same solution must be utilized throughout the procedure.

5.1. **Preparation of standard VC solution (solution A)**

5.1.1. *Concentrated standard VC solution at approximately 2 000 mg/kg*

Accurately weigh to the nearest 0·1 mg a suitable glass vessel and place in it a quantity (e.g. 50 ml) of DMA (3.2). Re-weigh. Add to the DMA a quantity (e.g. 0·1 g) of VC (3.1) in liquid or gas form, injecting it slowly onto the DMA. The VC may also be added by bubbling it into the DMA, provided that a device is used which will prevent loss of DMA. Reweigh to the nearest 0·1 mg. Wait two hours to allow equilibrium to be attained. If an internal standard is to be employed, add internal standard so that the concentration of the internal standard in the concentrated standard VC solution is the same as in the internal standard solution prepared under point 3.3. Keep the standard solution in a refrigerator.

5.1.2. *Preparation of dilute standard VC solution*

Take a weighed amount of concentrated standard solution of VC (5.1.1) and dilute, to a known volume or a known weight, with DMA (3.2) or with internal standard solution (3.3). The concentration of the resultant dilute standard solution (solution A) is expressed as mg/litre or mg/kg respectively.

5.1.3. *Preparation of the response curve with solution A*

NB:

The curve must comprise at least seven pairs of points.

The repeatability of the responses (1) must be lower than 0·002 mg VC/litre or kg of DMA.

The curve must be calculated from these points by the least squares technique, i.e., the regression line must be calculated using the following equation:

$$y = a_1 x + a_0$$

where:

$$a_1 = \frac{n\Sigma x\, y - (\Sigma x) \cdot (\Sigma y)}{n\Sigma x^2 - (\Sigma x)^2}$$

and:

$$a_0 = \frac{(\Sigma y)\ (\Sigma x^2) - (\Sigma x)\ (\Sigma xy)}{n\Sigma x^2 - (\Sigma x)^2}$$

where:

y = the height or area of peaks in any single determination;

x = the corresponding concentration on the regression line;

n = number of determinations carried out ($n \geq 14$).

The curve must be linear, i.e., the standard deviation (s) of the differences between the measured responses (y_i) and the corresponding value of the responses calculated from the regression line (z_i) divided by the mean value ($\bar{y}$) of all the measured responses shall not exceed 0·07.

This shall be calculated from:

$$\frac{s}{\bar{y}} \leq 0{\cdot}07$$

(1) See recommendation ISO DIS 5725: 1977.

where:

$$s = \sqrt{\frac{\sum_{i=1}^{n} (y_i - z_i)^2}{n-1}}$$

and:

$$\bar{y} = \frac{1}{n} \sum_{i=1}^{n} y_i$$

where:
y_i = each individual measured response;
z_i = the corresponding value of the response (y_i) on the calculated regression line;
$n = \geqslant 14$.

Prepare two series of at least seven phials (4.4). Add to each phial volumes of dilute standard VC solution (5.1.2) and DMA (3.2) or internal standard solution in DMA (3.3) such that the final VC concentration of the duplicate solutions will be approximately equal to 0, 0·005, 0·010, 0·020, 0·030, 0·040, 0·050, etc., mg/litre or mg/kg of DMA, and that each phial contains the same total volume of solution. The quantity of dilute standard VC solution (5.1.2) must be such that the ratio between the total volume (µl) of added VC solution and quantity (g or ml) of DMA, or internal standard solution (3.3) does not exceed five. Seal the phials and proceed as described under points 5.4.2, 5.4.3 and 5.4.5. Construct a graph in which the ordinate values show the areas (or heights) of the VC peaks of the duplicate solutions, or the ratio of these areas (or heights) to those of the relevant internal standard peaks, and the abscissa values show the VC concentrations of the duplicate solutions.

5.2. **Validation of preparation of standard solutions obtained in point 5.1**

5.2.1. *Preparation of a second standard VC solution (solution B)*

Repeat the procedure described under points 5.1.1 and 5.1.2 to obtain a second dilute standard solution with, in this case, a concentration approximately equal to 0·02 mg VC: l, or 0·02 mg VC/kg of DMA or internal standard solution. Add this solution to two phials (4.4). Seal the phials and proceed as described under points 5.4.2, 5.4.3 and 5.4.5.

5.2.2. *Validation of solution A*

If the average of two gas-chromatographic determinations relating to the solution B (5.2.1) does not differ by more than 5% from the corresponding point of the response curve obtained in point 5.1.3, the solution A is validated. If the difference is greater than 5%, reject all the solutions obtained in points 5.1 and 5.2 and repeat the procedure from the beginning.

5.3. **Preparation of the 'addition' curve**

NB:

The curve must comprise at least seven pairs of points.

The curve must be calculated from these points by the least squares technique (5.1.3, third indent).

The curve must be linear, i.e., the standard deviation(s) of the differences between the measured responses (y_i) and the corresponding value of the responses calculated from the regression line (z_i) divided by the mean value ($\bar{y}$) of all the measured responses shall not exceed 0·07 (5.1.3, fourth indent).

5.3.1. *Preparation of sample*

The sample of foodstuff to be analyzed must be representative of the foodstuff presented for analysis. The foodstuff must, therefore, be mixed or reduced to small pieces and mixed before the sample is taken.

5.3.2. *Procedure*

Prepare two series of at least seven phials (4.4). Add to each phial a quantity, not less than 5 g, of sample obtained from the foodstuff under investigation (5.3.1). Ensure that an equal quantity is added to each phial. Close the phial immediately. Add to each phial for each gram of sample 1 ml, preferably of distilled water, or demineralized water of at least equivalent purity, or an appropriate solvent if necessary. (Note: for homogeneous foodstuffs, addition of distilled of demineralized water is not necessary.) Add to each phial volumes of dilute standard VC solution (5.1.2), containing the internal standard (3.3), if considered useful, such that concentrations of VC added to the phials equal to 0, 0·005, 0·010, 0·020, 0·030, 0·040 and 0·050, etc., mg/kg of foodstuffs. Ensure that the total volume of DMA or DMA containing internal standard (3.3) in each phial is the same. The quantity of dilute standard VC solution (5.1.2) and additional DMA where used, must be such that the ratio between the total volume (µl) of these solutions and the quantity (g) of foodstuff contained in the phial is as low as possible but not more than five and is the same in all phials. Seal the phials and proceed as described under point 5.4.

5.4. **Gas-chromatographic determinations**

5.4.1. Agitate the phials avoiding contact between the contained liquid and the septum (4.4) to obtain a solution or a suspension of the samples of foodstuff as homogeneous as possible.

5.4.2. Put all the sealed phials (5.2 and 5.3) in a waterbath for two hours at 60 ± 1 °C to allow equilibrium to be attained. Agitate again, if necessary.

5.4.3. Take a sample from the headspace in the phial. When utilizing manual sampling techniques care must be exercized in obtaining a reproducible sample (4.4) in particular the syringe must be pre-warmed to the temperature of the sample. Measure the area (or height) of the peaks relating to the VC and internal standard, if used.

5.4.4. Construct a graph in which the ordinate value shows the areas (or heights) of the VC peaks or the ratio of the areas (or heights) of VC peaks to the areas (or heights) of the internal standard peaks and the abscissa values show the quantities of VC added (mg) relating to the quantities of the sample of foodstuff weighed in each phial (kg). Measure the abscissa intercept from the graph. The value so obtained is the concentration of VC in the sample of the foodstuff under investigation.

5.4.5. Remove from the column (4.3) excess DMA using an appropriate method as soon as peaks of DMA appear on the chromatogram.

6. RESULTS

The VC released by materials and articles into the foodstuff under investigation expressed in mg/kg shall be defined as the average of the two determinations (5.4) provided that the repeatability criterion in point 8 is satisfied.

7. CONFIRMATION OF THE VC

In cases where the VC released by materials and articles into the foodstuffs as calculated under point 6, exceeds the criterion in Article 2 (2) of Council Directive 78/142/EEC of 30 January 1978, the values obtained in each of the two determinations (5.4) must be confirmed in one of three ways:

(i) by using at least one other column (4.3) having a stationary phase of different polarity. This procedure should continue until a chromatogram is obtained with no evidence of overlap of the VC and/or internal standard peaks with constituents of the sample of foodstuff,

(ii) by using other detectors, e.g. the micro-electrolytic conductivity detector (1),

(iii) by using mass spectrometry; in this case, if molecular ions with parent masses (m/e) of 62 and 64 are found in the ratio of 3 : 1 it may be regarded with high probability as

(1) See Journal of Chromatographic Science (volume 12), March 1974, page 152.

confirming the presence of VC. In case of doubt the total mass spectrum must be checked.

8. REPEATABILITY

The difference between the results of two determinations (5.4) carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, must not exceed 0·003 mg VC/kg of foodstuff.

382L0711

82/711/EEC: COUNCIL DIRECTIVE OF 18 OCTOBER 1982 LAYING DOWN THE BASIC RULES NECESSARY FOR TESTING MIGRATION OF THE CONSTITUENTS OF PLASTIC MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

OFFICIAL JOURNAL NO L 297, 23/10/1982, P. 26
DATE OF NOTIFICATION: 04/11/1982

AMENDED BY

393L0008
93/8/EEC: COMMISSION DIRECTIVE OF 15 MARCH 1993 [1]
OFFICIAL JOURNAL NO L 90, 14/04/1993, P. 22
DATE OF TRANSPOSITION: 01/04/1994; SEE ART. 2

ARTICLE 1

1. This Directive is a specific Directive within the meaning of Article 3 of Directive 76/893/EEC (1).

2. This Directive shall apply to plastic materials and articles, that is to say to materials and articles and parts thereof:

(a) consisting exclusively of plastics, or

(b) composed of two or more layers of materials, each consisting exclusively of plastics, which are bound together by means of adhesives or by any other means,

which, in the finished product state, are intended to come into contact or are brought into contact with foodstuffs and are intended for that purpose.

3. For the purposes of this Directive, "plastics" shall mean the organic macromolecular compounds obtained by polymerization, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromolecules. Silicones and other similar macromolecular compounds shall also be regarded as plastics. Other substances or matter may be added to such macromolecular compounds.
However, the following shall not be regarded as "plastics":

(i) varnished or unvarnished regenerated cellulose film;

(ii) elastomers and natural and synthetic rubber;

(iii) paper and paperboard, whether modified or not by the addition of plastics;

(iv) surface coatings obtained from:

- paraffin waxes, including synthetic paraffin waxes, and/or micro-crystalline waxes,

- mixtures of the waxes listed in the first indent with each other and/or with plastics.

4. This Directive shall not apply to materials and articles composed of two or more layers, one or more of which does not consist exclusively of plastics, even if the one intended to come into direct contact with foodstuffs does consist exclusively of plastics.
A decision on the application of this Directive to the materials and articles referred to in the first subparagraph and on any adaptations to the Directive that may become necessary shall be taken at a later date.

ARTICLE 2

" The overall and specific migration levels of constituents of the materials and articles referred to in Article 1 into or onto foodstuffs or food simulants must not exceed the limits laid down in Commission Directive 90/128/EEC (2) or in any other relevant specific directive. " **[1]**

ARTICLE 3

" 1. Verification of compliance of migration into foodstuffs with the migration limits shall be carried out under the most extreme conditions of time and temperature foreseeable in actual use.
Verification of compliance of migration into food simulants with the migration limits shall be carried out using conventional migration tests, the basic rules for which are laid down in the Annex to this Directive.

2. (a) However, where a Member State, as a result of new information or of a reassessment of existing information made since this Directive was adopted, has detailed grounds for establishing that for a given plastic material or article the basic rules laid down in the Annex for migration tests are technically unsuitable or because the actual conditions of use are basically different from the test conditions specified in the table in the Annex, that Member State may, within its territory and only for the particular case, temporarily suspend application of the basic rules referred to in the Annex and permit the use of more appropriate basic rules. It shall immediately inform the other Member States and the Commission thereof and give the reasons for its decision.

(b) The Commission shall examine, as soon as possible, the reasons given by the Member States concerned and shall consult the Member States within the Standing Committee for Foodstuffs and shall then deliver its opinion forthwith and amend this Directive, if necessary. In that case, the Member State which has adopted the more appropriate basic rules may retain them until the said amendments enter into force. " **[1]**

ARTICLE 4

Adaptations to be made to Chapter II of the Annex to this Directive in the light of progress in scientific and technical knowledge shall be adopted in accordance with the procedure laid down in Article 10 of Directive 76/893/EEC.

ARTICLE 5

This Directive shall not affect national provisions relating to the other rules provided for in Article 3 of Directive 76/893/EEC nor the options open to Member States under Article 7 (4) and (5) of that Directive.

ARTICLE 6

Member States shall comply with this Directive not later than such time as a specific directive laying down the limits referred to in Article 2 (1) is implemented.

ARTICLE 7

This Directive is addressed to the Member States.

" ANNEX

Basic rules for testing migration in food simulants

The determination of migration in food simulants shall be carried out using the food simulants laid down in Chapter I of Annex and under the test conditions specified in Chapter II of Annex. However the determination of migration shall be restricted to the food simulant(s) and to the condition(s) of test which, in the specific case under examination, may be considered to be the most severe on the basis of experience.

Chapter I

Food simulants

1. General case: plastic materials and articles intended to come into contact with foodstuffs of all types

The tests shall be carried out using the food simulants mentioned below, taking a fresh sample of the plastic material or article for each simulant:

- distilled water or water of equivalent quality (= simulant A),
- 3 % acetic acid (w/v) in aqueous solution (= simulant B),
- 15 % ethanol (v/v) in aqueous solution (= simulant C),
- rectified olive oil (3) (= simulant D); if for technical reasons connected with the method of analysis it is necessary to use different food simulants, olive oil shall be replaced by a mixture of synthetic triglycerides (4) or by sunflower oil. If all the food simulants provided in this indent are inappropriate, other food simulants and conditions of time and temperature may be used.

However, the simulant A shall be used only in the cases mentioned specifically in the Table of this Annex.

2. Special case: plastic materials and articles intended to come into contact with a single foodstuff or a specific group of foodstuffs

The tests shall be carried out:

- using only the food simulant(s) specified as appropriate for the foodstuff or group of foodstuffs in Directive 85/572/EEC (5),
- where the foodstuff or group of foodstuffs is not included in the list referred to in the first indent, selecting the food simulant(s) prescribed in Section 1 which correspond most closely to the extractive capacity of the foodstuff or group of foodstuffs.

Chapter II

Test conditions (times and temperatures)

1. The migration tests are to be carried out, selecting from the times and temperatures specified in the table those which correspond most closely to, but are not less than, the normal or foreseeable conditions of contact for the plastic materials or articles being studied.

2. Where a material or article passes a test at a given time and temperature, it need not be tested for a shorter time at the same temperature, nor for the same time at a lower temperature.

3. However if a plastic material or article is intended for a food contact application covered by two or more combinations of time and temperature taken from the Table, migration will be determined by subjecting that material or article successively to all the applicable test conditions, using the same aliquot of food simulant.

4. If a plastic material or article is intended to come into contact with foodstuffs at any condition of time, the conditions for testing will be the following:

(a) where the plastic material or article may in actual use be employed at any temperature up to and including 70 °C and that is indicated by an appropriate labelling or instructions, only the 10 day test(s) at 40 °C shall be carried out;

(b) where a plastic material or article may in actual use be employed at a temperature above 70 °C:

(i) where no labelling or instructions are given to indicate temperature expected in real use, simulants B and C shall be used at reflux temperature, if possible, or at two-hour test(s) at 100 °C and simulant D shall be used for two hours at 175 °C;

(ii) where labelling or instructions are given to indicate conditions expected in real use, time and temperatures from the Table shall be selected.

5. By derogation from the conditions provided in the Table and in paragraph 2, if the plastic material or article may in actual use be employed for periods of less than 15 minutes at temperatures between 70 °C and 100 °C and that is indicated by an appropriate labelling or instructions, only the two-hour test at 70 °C and the 10-day test at 40 °C shall be carried out. These tests shall be carried out separately taking different samples. For each of these two types of test, use a new sample of the same material or article to be examined.

6. If it is found that carrying out the tests under the conditions specified in the table causes physical or other changes in the plastic material or article which do not occur under normal or foreseeable conditions of use of that material or article, the migration tests shall be carried out under conditions more appropriate to the specific case.

7. For materials and articles intended for use in microwave ovens, migration testing shall use a conventional oven and appropriate time and temperature conditions selected from the Table.

Table

Conditions of contact in actual use	Test condition
Contact time	*Test time*
t ≤ 0,5 hour	0,5 hour
0,5 hour < t ≤ 1 hour	1 hour
1 hour < t ≤ 2 hours	2 hours
2 hours < t ≤ 24 hours	24 hours
t > 24 hours	10 days
Contact temperature	*Test temperature*
T ≤ 5 °C	5 °C
5 °C < T ≤ 20 °C	20 °C
20 °C < T ≤ 40 °C	40 °C
40 °C < T ≤ 70 °C	70 °C
70 °C < T ≤ 100 °C	100 °C or reflux temperature
100 °C < T ≤ 121 °C	121 °C (6)
121 °C < T ≤ 130 °C	130 °C (6)
130 °C < T ≤ 150 °C	150 °C (7)
T > 150 °C	175 °C (7)

" [1]

(1) OJ No L 340, 09/12/1976, p. 19.
(2) OJ No L 75, 21/03/1990, p. 19, corrected by OJ No L 349, 13/12/1990, p. 26.
(3) Characteristics of rectified olive oil:
- iodine index (Wijs) = 80 to 88,
- refraction index at 25 °C = 1,4665 to 1,4679,
- acidity (expressed in % of oleic acid) = 0,5 % maximum,
- peroxide index (expressed in milli-equivalents of oxygen per kg of oil) = 10 maximum.
(4) Characteristics of the standard synthetic triglycerides mixture as described in K. Figge's article, "Food Cosmet. Toxicol" 10 (1972) 81.5.
(5) OJ No L 372, 31/12/1985, p. 14.
(6) Use simulant C at reflux temperature.
(7) Use simulant D at 150 °C or 175 °C, in addition to simulants A, B and C used as appropriate at 100 °C or at reflux temperature.

COUNCIL DIRECTIVE

of 19 December 1985

laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs

(85/572/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 82/711/EEC of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs (1), and in particular Article 2 (3) thereof,

Having regard to the proposal from the Commission (2),

Having regard to the opinion of the European Parliament (3),

Having regard to the opinion of the Economic and Social Committee (4),

Whereas, by virtue of Article 2 (3) of, together with the first indent of Chapter 1 (2) of the Annex to Directive 82/711/EEC, appropriate simulants to carry out migration tests should be indicated for plastic materials and articles intended to come into contact with a single foodstuff or a specific group of foodstuffs;

Whereas the possibility should not be excluded, where necessary, of making use of methods for testing migration other than those laid down in this Directive;

Whereas, in determining appropriate simulants, account must be taken in particular of the chemical composition of the foodstuff and its physical properties;

Whereas, for some foodstuffs containing fat, the result obtained in migration tests with the simulant is higher than that obtained in migration tests with the foodstuff itself and whereas therefore the result should be corrected by applying a 'reduction factor' appropriate to the particular situation; whereas in certain specific cases, particularly that of materials and objects in contact with foodstuffs with fatty substances on the surface, the existence of appropriate methods of analysis is essential for implementation of this Directive;

Whereas the adaptation of this Directive to technical progress constitutes an implementing measure, the adoption of which, in order to simplify and accelerate the procedure, should in principle be the responsibility of the Commission;

Whereas in all cases in which the Council confers on the Commission authority to implement the provisions relating to plastic materials and articles intended to come into contact with foodstuffs, a procedure should be laid down establishing close cooperation between Member States and the Commission within the Standing Committee for Foodstuffs, set up under Decision 69/414/EEC (5),

HAS ADOPTED THIS DIRECTIVE:

Article 1

Pursuant to Article 2 (3) of Directive 82/711/EEC, the simulants to be used for testing migration of the constituents of plastic materials and articles intended to come into contact with a single foodstuff or specific group of foodstuffs and the concentration of these simulants shall be those indicated in the Annex.

Article 2

Notwithstanding Article 1, the list of substances or materials whose use is authorized to the exclusion of all others may lay down procedures testing migration of particular constituents of plastic materials and articles which differ from those laid down in the Annex where this is appropriate.

Article 3

Adaptations to be made to the Annex to this Directive in the light of progress in scientific and technical knowledge shall be adopted in accordance with the procedure laid down in Article 10 of Directive 76/893/EEC (6).

(1) OJ No L 297, 23. 10. 1982, p. 26.
(2) OJ No C 102, 14. 4. 1984, p. 4.
(3) OJ No C 175, 15. 7. 1985, p. 299.
(4) OJ No C 25, 28. 1. 1985, p. 6.
(5) OJ No L 291, 19. 11. 1969, p. 9.
(6) OJ No L 340, 9. 12. 1976, p. 19.

Article 4

Member States shall take all measures necessary to comply with this Directive not later than such time as they take the measures to implement Directive 82/711/EEC

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 19 December 1985.

For the Council

The President

M. FISCHBACH

ANNEX

LIST OF SIMULANTS

1. In the following tables, which make up a non-exhaustive list of foodstuffs, the simulants to be used in migration tests with a particular foodstuff or group of foodstuffs are identified by the letters shown:

   Simulant A:

   distilled water or water of equivalent quality;

   Simulant B:

   3 % acetic acid (w/v) in aqueous solution;

   Simulant C:

   15 % ethanol (v/v) in aqueous solution;

   Simulant D:

   rectified olive oil (1); if for technical reasons connected with the method of analysis it is necessary to use different simulants, olive oil must be replaced by a mixture of synthetic triglycerides (2), or by sunflower oil (3).

2. For each foodstuff or group of foodstuffs, only the simulant(s) indicated by an 'X' is (are) to be used, using for each simulant, a new sample of the materials and subject concerned. Where no 'X' appears, no migration test is required for the heading or subheading concerned.

3. When 'X' is followed by an oblique stroke and a figure, the result of the migration tests should be divided by the number indicated. In the case of certain types of fatty foodstuffs this figure, known as the 'reduction factor', is conventionally used to take account of the greater extractive capacity of the simulant for such foodstuffs.

4. Where the letter 'a' is shown in brackets after the 'X', only one of the two simulants given should be used:

   — if the pH value of the foodstuff is higher than 4,5, simulant A should be used,

   — if the pH value of the foodstuff is 4,5, or less, simulant B should be used.

5. Where a foodstuff is listed under both a specific and a general heading, only the simulant(s) indicated under the specific heading is (are) to be used.

---

(1) **Characteristics of rectified olive oil**

Iodine value (Wijs)	= 80 to 88
Refractive index at 25 °C	= 1,4665 to 1,4679
Acidity (expressed as % oleic acid)	= 0,5 % maximum
Peroxide number (expressed as oxygen milliequivalents per kg of oil)	= 10 maximum

(2) **Composition of the synthetic triglycerides mixture**

Fatty acid distribution

Number of C-atoms in fatty acid residue	6	8	10	12	14	16	18	others
GLC area [%]	~1	6 to 9	8 to 11	45 to 52	12 to 15	8 to 10	8 to 12	≤ 1

Purity

Content of monoglycerides (enzymatically)	≤ 0,2 %
Content of diglycerides (enzymatically)	≤ 2,0 %
Unsaponifiable matter	≤ 0,2 %
Iodine value (Wijs)	≤ 0,1 %
Acid value	≤ 0,1 %
Water content (K. Fischer)	≤ 0,1 %
Melting point	28 ± 2 °C

Typical absorption spectrum (thickness of layer : d = 1 cm; reference: water = 35 °C)

Wavelength (nm)	290	310	330	350	370	390	430	470	510
Transmittance (%)	~2	~15	~37	~64	~80	~88	~95	~97	~98

At least 10 % light transmittance at 310 nm (cell of 1 cm, reference: water 35 °C)

(3) **Characteristics of sunflower oil**

Iodine value (Wijs)	= 120 to 145
Refractive index at 20 °C	= 1,474 to 1,476
Saponification number	= 188 to 193
Relative density at 20 °C	= 0,918 to 0,925
Unsaponifiable matter	= 0,5 % to 1,5 %

TABLE

Reference number	Description of foodstuffs	Simulants to be used			
		A	B	C	D
01	**Beverages**				
01.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than 5 % vol.:				
	Waters, ciders, fruit or vegetable juices of normal strength or concentrated, musts, fruit nectars, lemonades and mineral waters, syrups, bitters, infusions, coffee, tea, liquid chocolate, beers and other	X (a)	X (a)		
01.02	Alcoholic beverages of an alcoholic strength equal to or exceeding 5 % vol.:				
	Beverages shown under heading 01.01 but with an alcoholic strength equal to or exceeding 5 % vol.:				
	Wines, spirits and liqueurs		X (*)	X (**)	
01.03	Miscellaneous: undenatured ethyl aclcohol		X (*)	X (**)	
02	**Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares**				
02.01	Starches				
02.02	Cereals, unprocessed, puffed, in flakes, (including popcorn, corn flakes and the like)				
02.03	Cereal flour and meal				
02.04	Macaroni, spaghetti and similar products				
02.05	Pastry, biscuits, cakes and, other bakers' wares, dry:				
	A. With fatty substances on the surface				X/5
	B. Other				
02.06	Pastry, cakes and other bakers' wares, fresh:				
	A. With fatty substances on the surface				X/5
	B. Other	X			
03	**Chocolate, sugar and products thereof Confectionery products**				
03.01	Chocolate, chocolate-coated products, substitutes and products coated with substitutes				X/5
03.02	Confectionery products:				
	A. In solid form:				
	I. With fatty substances on the surface				X/5
	II. Other				

(*) This test shall be carried out only in cases where the pH is 4,5 or less.

(**) This test may be carried out in the case of liquids or beverages of an alcoholic strength exceeding 15 % vol. with aqueous solutions of ethanol of a similar strength.

Reference number	Description of foodstuffs	Simulants to be used			
		A	B	C	D
03.02 *(continued)*	B. In paste form:				
	I. With fatty substances on the surface				X/3
	II. Moist	X			
03.03	Sugar and sugar products:				
	A. In solid form				
	B. Honey and the like	X			
	C. Molasses and sugar syrups	X			
04	**Fruit, vegetables and products thereof**				
04.01	Whole fruit, fresh or chilled				
04.02	Processed fruit:				
	A. Dried or dehydrated fruit, whole or in the form of flour or powder				
	B. Fruit in the form of chunks, purée or paste	X (a)	X (a)		
	C. Fruit preserves (jams and similar products — whole fruit or chunks or in the form of flour or powder, preserved in a liquid medium):				
	I. In an aqueous medium	X (a)	X (a)		
	II. In an oily medium	X (a)	X (a)		X
	III. In an alcoholic medium (≥ 5 % vol.)		X (*)	X	
04.03	Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and other):				
	A. Shelled, dried				
	B. Shelled and roasted				X/5 (**)
	C. In paste or cream form	X			X/3 (**)
04.04	Whole vegetables, fresh or chilled				
04.05	Processed vegetables:				
	A. Dried or dehydrated vegetables whole or in the form of flour or powder				
	B. Vegetables, cut, in the form of purées	X (a)	X (a)		
	C. Preserved vegetables:				
	I. In an aqueous medium	X (a)	X (a)		
	II. In an oily medium	X (a)	X (a)		X
	III. In an alcoholic medium (≥ 5 % vol.)		X (*)	X	
05	**Fats and oils**				
05.01	Animals and vegetable fats and oils, whether natural or treated (including cocoa butter, lard, resolidified butter)				X
05.02	Margarine, butter and other fats and oils made from water emulsions in oil				X/2

(*) This test is to be used only where the pH is 4,5 or less.

(**) If it can be demonstrated by means of an appropriate test that there is no 'fatty contact' with the plastic, the test with simulant D may be dispensed with.

Reference number	Description of foodstuffs	Simulants to be used			
		A	B	C	D
06	**Animal products and eggs**				
06.01	Fish:				
	A. Fresh, chilled, salted, smoked	X			X/3 (*)
	B. In the form of paste	X			X/3 (*)
06.02	Crustaceans and molluscs (including oysters, mussels, snails) not naturally protected by their shells	X			
06.03	Meat of all zoological species (including poultry and game):				
	A. Fresh, chilled, salted, smoked	X			X/4
	B. In the form of paste, creams	X			X/4
06.04	Processed meat products (ham, salami, bacon and other)	X			X/4
06.05	Preserved and part-preserved meat and fish:				
	A. In an aqueous medium	X (a)	X (a)		
	B. In an oily medium	X (a)	X (a)		X
06.06	Eggs not in shell:				
	A. Powdered or dried				
	B. Other	X			
06.07	Egg yolks:				
	A. Liquid	X			
	B. Powdered or frozen				
06.08	Dried white of egg				
07	**Milk products**				
07.01	Milk:				
	A. Whole	X			
	B. Partly dried	X			
	C. Skimmed or partly skimmed	X			
	D. Dried				
07.02	Fermented milk such as yoghourt, buttermilk and such products in association with fruit and fruit products		X		
07.03	Cream and sour cream	X (a)	X (a)		
07.04	Cheeses:				
	A. Whole, with rind				
	B. Processed cheeses	X (a)	X (a)		
	C. All others	X (a)	X (a)		X/3 (*)

(*) If it can be demonstrated by means of an appropriate test that there is no 'fatty contact' with the plastic, the test with simulant D may be dispensed with.

Reference number	Description of foodstuffs	Simulants to be used			
		A	B	C	D
07.05	Rennet:				
	A. In liquid or viscous form	X (a)	X (a)		
	B. Powdered or dried				
08	**Miscellaneous products**				
08.01	Vinegar		X		
08.02	Fried or roasted foods:				
	A. Fried potatoes, fritters and the like				X/5
	B. Of animal origin				X/4
08.03	Preparations for soups, broths, in liquid, solid or powder form (extracts, concentrates); homogenized composite food preparations, prepared dishes:				
	A. Powdered or dried:				
	I. With fatty substances on the surface				X/5
	II. Other				
	B. Liquid or paste:				
	I. With fatty substances on the surface	X (a)	X (a)		X/3
	II. Other	X (a)	X (a)		
08.04	Yeasts and raising agents:				
	A. In paste form	X (a)	X (a)		
	B. Dried				
08.05	Salt				
08.06	Sauces:				
	A. Without fatty substances on the surface	X (a)	X (a)		
	B. Mayonnaise, sauces derived from mayonnaise, salad creams and other oil in water emulsions	X (a)	X (a)		X/3
	C. Sauce containing oil and water forming two distinct layers	X (a)	X (a)		X
08.07	Mustard (except powdered mustard under heading 08.17)	X (a)	X (a)		X/3 (*)
08.08	Sandwiches, toasted bread and the like containing any kind of foodstuff:				
	A. With fatty substances on the surface				X/5
	B. Other				
08.09	Ice-creams	X			
08.10	Dried foods:				
	A. With fatty substances on the surface				X/5
	B. Other				

(*) If it can be demonstrated by means of an appropriate test that there is no 'fatty contact' with the plastic, the test with simulant D may be dispensed with.

Reference number	Description of foodstuffs	Simulants to be used			
		A	B	C	D
08.11	Frozen or deep-frozen foods				
08.12	Concentrated extracts of an alcoholic strength equal to or exceeding 5 % vol		X (**)	X	
08.13	Cocoa:				
	A. Cocoa powder				X/5 (*)
	B. Cocoa paste				X/3 (*)
08.14	Coffee, whether or not roasted, decaffeinated or soluble, coffee substitutes, granulated or powdered				
08.15	Liquid coffee extracts	X			
08.16	Aromatic herbs and other herbs: camomile, mallow, mint, tea, lime blossom and others				
08.17	Spices and seasonings in the natural state: cinnamon, cloves, powdered mustard, pepper, vanilla, saffron and other				

(*) If it can be demonstrated by means of an appropriate test that there is no 'fatty contact' with the plastic, the test with simulant D may be dispensed with.

(**) This test is to be used only where the pH is 4,5 or less.

390L0128

90/128/EEC: COMMISSION DIRECTIVE OF 23 FEBRUARY 1990 RELATING TO PLASTICS MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

OFFICIAL JOURNAL NO L 75, 21/03/1990, P. 19
DATE OF NOTIFICATION: 27/02/1990
DATE OF TRANSPOSITION: 31/12/1990; SEE ART. 7

AMENDED BY

392L0039
92/39/EEC: COMMISSION DIRECTIVE OF 14 MAY 1992 **[1]**
OFFICIAL JOURNAL NO L 168, 23/06/1992, P. 21
DATE OF TRANSPOSITION: 31/12/1992; SEE ART. 2

393L0009
93/9/EEC: COMMISSION DIRECTIVE OF 15 MARCH 1993 **[2]**
OFFICIAL JOURNAL NO L 90, 14/04/1993, P. 26
DATE OF TRANSPOSITION: 01/04/1994; SEE ART. 2

" ARTICLE 1

1. This Directive is a specific Directive within the meaning of Article 3 of Directive 89/109/EEC (1).

2. This Directive shall apply to plastics materials and articles and parts thereof:

(a) consisting exclusively of plastics, or

(b) composed of two or more layers of materials, each consisting exclusively of plastics, which are bound together by means of adhesives or by any other means,

which, in the finished product state, are intended to come into contact or are brought into contact with foodstuffs and are intended for that purpose.

3. For the purposes of this Directive, "plastics" shall mean the organic macromolecular compounds obtained by polymerization, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromolecules. Silicones and other similar macromolecular compounds shall also be regarded as plastics. Other substances or matter may be added to such macromolecular compounds.
However, the following shall not be regarded as "plastics":

(i) varnished or unvarnished regenerated cellulose film, covered by Council Directive 83/229/EEC (2), as amended by Directive 86/388/EEC (3);

(ii) elastomers and natural and synthetic rubber;

(iii) paper and paperboard, whether modified or not by the addition of plastics;

(iv) surface coatings obtained from:

- paraffin waxes, including synthetic paraffin waxes, and/or micro-crystalline waxes,
- mixtures of the waxes listed in the first indent with each other and/or with plastics;

(v) ion-exchange resins.

4. This Directive shall not apply, until further action by the Commission, to materials and articles composed of two or more layers, one or more of which does not consist exclusively of plastics, even if the one intended to come into direct contact with foodstuffs does consist exclusively of plastics.

ARTICLE 2

Plastics materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams per square decimetre of surface area of material or article (mg/dm^2) (overall migration limit). However, this limit shall be 60 milligrams of the constituents released per kilogram of foodstuff (mg/kg) in the following cases:

(a) articles which are containers or are comparable to containers or which can be filled, with a capacity of not less than 500 millilitres (ml) and not more than 10 litres (l);

(b) articles which can be filled and for which it is impracticable to estimate the surface area in contact with foodstuffs;

(c) caps, gaskets, stoppers or similar devices for sealing.

ARTICLE 3

1. Only those monomers and other starting substances listed in Annex II, Sections A and B may be used for the manufacture of plastics materials and articles subject to the restrictions specified.

2. From the date of notification of this Directive, the list in Annex II, Section A may be amended:

- either by adding substances listed in Annex II, Section B, according to the criteria in Annex II of Directive 89/109/EEC, or
- by including "new substances", i.e. substances which are listed neither in Section A nor in Section B of Annex II, according to Article 3 of Directive 89/109/EEC.

3. From the date of notification of this Directive no Member State shall authorize any new substance for use within its territory except under the procedure in Article 4 of Directive 89/109/EEC.

4. " As from 1 January 1997, only those monomers and other starting substances listed in Annex II, Section A, shall be used for the manufacture of plastic materials and articles, subject to the restrictions specified therein. However, the substances listed in Annex II, Section B may be deleted before the abovementioned date if the data requested for inclusion in Section A are not supplied in time to permit their evaluation by the Scientific Committee for Food. Moreover, before 1 January 1996 it may be decided that, in some justified cases, for certain substances listed in Annex II, Section B, this time-limit will be postponed. " **[1]**

5. However the lists appearing in Annex II, Sections A and B do not yet include monomers and other starting substances used only in the manufacture of:

- surface coatings obtained from resinous or polymerized products in liquid, powder or dispersion form, such as varnishes, lacquers, paints, etc.,
- silicones,
- epoxy resins,
- products obtained by means of bacterial fermentation,
- adhesives and adhesion promoters,
- printing inks.

ARTICLE 4

The specific migration limits in the list set out in Annex II are expressed in mg/kg. However, such limits are expressed in mg/dm² in the following cases:

(a) articles which are containers or are comparable to containers or which can be filled, with a capacity of less than 500 ml or more than 10 l;

(b) sheet, film or other materials which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of such materials and the quantity of foodstuff in contact therewith.

In these cases, the limits set out in Annex II, expressed in mg/kg shall be divided by the conventional conversion factor of 6 in order to express them in mg/dm².

ARTICLE 5

1. Verification of compliance with the migration limits shall be carried out in accordance with the rules laid down in Directives 82/711/EEC (4) and 85/572/EEC (5) and the further provisions set out in Annex I.

2. The verification of compliance with the specific migration limits provided for in paragraph 1 shall not be compulsory, if it can be established that compliance with the overall migration limit laid down in Article 2 implies that the specific migration limits are not exceeded.

" 3. The verification of compliance with the specific migration limits provided for in paragraph 1 shall not be compulsory, if it can be established that, by assuming complete migration of the residual substance in the material or article, it cannot exceed the specific limit of migration. " **[2]**

ARTICLE 6

1. At the marketing stages other than the retail stages, the plastics materials and articles which are intended to be placed in contact with foodstuffs shall be accompanied by a written declaration in accordance with Article 6 (5) of Directive 89/109/EEC.

2. Paragraph 1 does not apply to plastics materials and articles which by their nature are clearly intended to come into contact with foodstuffs.

ARTICLE 7

1. The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 December 1990. They shall forthwith inform the Commission thereof.

2. Member States shall:

- permit the trade in and use of plastics materials and articles complying with this Directive before 1 January 1991,
- prohibit trade in and use of plastics materials and articles intended to come into contact with foodstuffs and which do not comply with this Directive as from 1 January 1993.

ARTICLE 8

This Directive is addressed to the Member States.

ANNEX I

FURTHER PROVISIONS APPLICABLE WHEN CHECKING COMPLIANCE WITH THE MIGRATION LIMITS

General provisions

1. When comparing the results of the migration tests specified in the Annex to Directive 82/711/EEC, the specific gravity of all the simulants should conventionally be assumed to be 1. Milligrams of substance(s) released per litre of simulant (mg/l) will thus correspond numerically to milligrams of substance(s) released per kilogram of simulant and, taking into account the provisions laid down in Directive 85/572/EEC, to milligrams of substance(s) released per kilogram of foodstuff.

2. Where the migration tests are carried out on samples taken from the material or article or on samples manufactured for the purpose, and the quantities of foodstuff or simulant placed in contact with the sample differ from those employed in the actual conditions under which the material or article is used, the results obtained should be corrected by applying the following formula:

$M = (m \cdot a2) \cdot 1000 / (a1 \cdot q)$

Where:

M is the migration in mg/kg;
m is the mass in mg of substance released by the sample as determined by the migration test;
a1 is the surface area in dm^2 of the sample in contact with the foodstuff or simulant during the migration test;
a2 is the surface area in dm^2 of the material or article in real conditions of use;
q is the quantity in grams of foodstuff in contact with the material or article in real conditions of use.

3. The determination of migration is carried out on the material or article or, if that is impracticable, using either specimens taken from the material or article or, where appropriate, specimens representative of this material or article.
The sample shall be placed in contact with the foodstuff or simulant in a manner representing the contact conditions in actual use. For this purpose, the test shall be performed in such a way that only those parts of the sample intended to come into contact with foodstuffs in actual use will be in contact with the foodstuff or simulant. This condition is particularly important in the case of materials and articles comprising several layers, for closures, etc.
The migration testing of caps, gaskets, stoppers or similar devices for sealing must be carried out on these articles by applying them to the containers for which they are intended in a manner which corresponds to the conditions of closing in normal or foreseeable use.
It shall in all cases be permissible to demonstrate compliance with migration limits by the use of a more severe test.

4. In accordance with the provisions set out in Article 5 of the present Directive, the sample of the material or article is placed in contact with the foodstuff or appropriate simulant for a period and at a temperature which are chosen by reference to the contact conditions in actual use, in accordance with the rules laid down in Directives 82/711/EEC and 85/572/EEC. At the end of the prescribed time, the analytical determination of the total quantity of substances (overall migration) and/or the specific quantity of one or more substances (specific migration) released by the sample is carried out on the foodstuff or simulant.

5. Where a material or article is intended to come into repeated contact with foodstuffs, the migration test(s) shall be carried out three times on a single sample in accordance with the conditions laid down in Directive 82/711/EEC using another sample of the food or simulant(s) on each occasion. Its compliance shall be checked on the basis of the level of the migration found in the third test. However, if there is conclusive proof that the

level of the migration does not increase in the second and third tests and if the migration limit(s) is (are) not exceeded on the first test, no further test is necessary.

Special provisions relating to overall migration

6. If the aqueous simulants specified in Directives 82/711/EEC and 85/572/EEC are used, the analytical determination of the total quantity of substances released by the sample may be carried out by evaporation of the simulant and weighing of the residue.
If rectified olive oil or any of its substitutes is used, the procedure given below may be followed.
The sample of the material or article is weighed before and after contact with the simulant. The simulant absorbed by the sample is extracted and determined quantitatively. The quantity of simulant found is subtracted from the weight of the sample measured after contact with the simulant. The difference between the initial and corrected final weights represents the overall migration of the sample examined.
Where a material or article is intended to come into repeated contact with foodstuffs and it is technically impossible to carry out the test described in paragraph 5, modifications to that test are acceptable, provided that they enable the level of migration occurring during the third test to be determied. One of these possible modifications is described below.
The test is carried out on three identical samples of the material or article. One of these shall be subjected to the appropriate test and the overall migration determined (M1). The second and third samples shall be subjected to the same conditions of temperature but the period of contact shall be two and three times that specified and overall migration determined in each case (M2 and M3, respectively).
The material or article shall be deemed to be in compliance provided that either M1 or M3-M2 do not exceed the overall migration limit.

7. A material or article that exceeds the overall migration limit by an amount not greater than the analytical tolerance mentioned below should therefore be deemed to be in compliance with this Directive.
The following analytical tolerances have been observed.

- 20 mg/kg or 3 mg/dm² in migration tests using rectified olive oil or substitutes,
- 6 mg/kg or 1 mg/dm² in migration tests using the other simulants referred to in Directives 82/711/EEC and 85/572/EEC.

8. Without prejudice to the provisions of Article 3 (2) of Directive 82/711/EEC, migration tests using rectified olive oil or substitutes shall not be carried out to check compliance with the overall migration limit in cases where there is conclusive proof that the specified analytical method is inadequate from a technical standpoint.
In any such case, for substances exempt from specific migration limits or other restrictions in the list provided in Annex II, a generic specific migration limit of 60 mg/kg or 10 mg/dm², according to the case, is applied. However the sum of all specific migration determined shall not exceed the overall migration limit.

ANNEX II

LIST OF MONOMERS AND OTHER STARTING SUBSTANCES WHICH MAY BE USED IN THE MANUFACTURE OF PLASTIC MATERIALS AND ARTICLES

General introduction

1. This Annex contains the list of monomers or other starting substances. The list includes:

- substances undergoing polymerization, which includes polycondensation, polyaddition or any other similar process, to manufacture macromolecules,
- natural or synthetic macromolecular substances used in the manufacture of modified macromolecules, if the monomers or the other starting substances required to synthesize them are not included in the list,
- substances used to modify existing natural or synthetic macromolecular substances.

2. The list does not include the salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc of the authorized acids, phenols or alcohols which are also authorized. However, names containing "... acid(s), salts" appear in the lists if the corresponding free acid(s) is (are) not mentioned. In such cases the meaning of the term "salts" is "salts of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc".

3. The list also does not include the following substances although they may be present:

(a) substances which could be present in the finished product as:

- impurities in the substances used,
- reaction intermediates,
- decomposition products;

(b) oligomers and natural or synthetic macromolecular substances as well as their mixtures, if the monomers or starting substances required to synthesize them are included in the list.

(c) mixtures of the authorized substances.

The materials and articles which contain the substance indicated under (a), (b) and (c) shall comply with the requirements stated in Article 2 of Directive 89/109/EEC.

4. Substances shall be of good technical quality.

5. The list contains the following information:

- column 1 (PM/REF. No): the EEC packaging material references number of the list,
- column 2 (CAS No): the CAS (Chemical Abstracts Service) Registry number,
- column 3 (Name): the chemical name,
- column 4 (Restrictions). These may include:

-- specific migration limit (SML),
-- maximum permitted quantity of the "residual" substance in the material or article (QM),
-- any other restriction specifically mentioned.

6. If a substance appearing on the list as an individual compound is also covered by a generic term, the restrictions applying to this substance shall be those indicated for the individual compound.

7. Where there is any inconsistency between the CAS number and the chemical name, the chemical name shall take precedence over the CAS number. If there is an inconsistency between the CAS number reported in EINECS and the CAS Registry, the CAS number in the CAS Registry shall apply.

8. A number of abbreviations or expressions are used in column 4 of the table, the meanings of which are as follows:

DL = detection limit of the method of analysis;

FP = finished material or article;

NCO = isocyanate moiety;

" ND = not detectable.

For the purpose of this Directive "not detectable" means that the substance should not be detected by a validated method of analysis which should detect it at the detection limit (DL) specified.
If such a method does not currently exist, an analytical method with appropriate performance characteristics at the detection limit may be used, pending the development of a validated method. " **[1]**

QM = maximum permitted quantity of the "residual" substance in the material or article;

QM (T) = maximum permitted quantity of the "residual" substance in the material or article expressed as total of moiety or substance(s) indicated;

" For the purpose of this Directive "QM (T)" means that the maximum permitted quantity of the "residual" substance in the material or article should be determined by a validated method of analysis at the specified limit. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method. " **[2]**

SML = specific migration limit in food or in food simulant, unless it is specified otherwise;

" For the purpose of this Directive "SML" means that the specific migration of the substance should be determined by a validated method of analysis at the specified limit. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method. " **[1]**

SML (T) = specific migration limit in food or in food simulant expressed as total of moiety or substance(s) indicated.

" For the purpose of this Directive "SML (T)" means that the specific migration of the substances should be determined by a validated method of analysis at the specified limit. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method. " **[2]**

SECTION A

LIST OF AUTHORIZED MONOMERS AND OTHER STARTING SUBSTANCES

PM/REF. No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
10030	000514-10-3	Abietic Acid	
10060	000075-07-0	Acetaldehyde	
10090	000064-19-7	Acetic acid	
10120	000108-05-4	Acetic acid, vinyl ester	SML = 12 mg/kg
10150	000108-24-7	Acetic anhydride	
10210	000074-86-2	Acetylene	
" 10630	000079-06-1	Acrylamide	SML = ND (DL = 0,01 mg/kg) " [1]
10690	000079-10-7	Acrylic acid	
" 10750	002495-35-4	Acrylic acid, benzyl ester " [2]	
10780	000141-32-2	Acrylic acid, n-butyl ester	
10810	002998-08-5	Acrylic acid, sec-butyl ester	
10840	001663-39-4	Acrylic acid, tert-butyl ester	
11470	000140-88-5	Acrylic acid, ethyl ester	
	000818-61-1	Acrylic acid, hydroxyethyl ester	See "Acrylic acid, monoester with ethyleneglycol"
11590	00106-63-8	Acrylic acid, isobutyl ester	
11680	000689-12-3	Acrylic acid, isopropyl ester	
11710	000096-33-3	Acrylic acid, methyl ester	
11830	000818-61-1	Acrylic acid, monoester with ethyleneglycol	
" 11890	002499-59-4	Acrylic acid, n-octyl ester " [2]	
11980	000925-60-0	Acrylic acid, propyl ester	
12100	000107-13-1	Acrylonitrile	SML = not detectable (DL = 0,020 mg/kg analytical tolerance included)
12130	000124-04-9	Adipic acid	
" 12280	002035-75-8	Adipic anhydride " [1]	
12310		Albumin	
12340		Albumin, coagulated by formaldehyde	
12375		Alcohols, aliphatic, monohydric, saturated, linear, primary (C4-C22)	
" 12670	002855-13-2	1-Amino-3-aminomethyl-3,5,5-trimethylcyclohexane	SML = 6 mg/kg " [1]
" 12788	002432-99-7	11-Aminoundecanoic acid	" SML = 5 mg/kg " [2] " [1]
12820	000123-99-9	Azelaic acid	
" 12970	004196-95-6	Azelaic anhydride " [1]	
13000	001477-55-0	1,3-Benzenedimethanamine	SML = 0,05 mg/kg
13090	000065-85-0	Benzoic acid	

PM/REF. No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
13150	000100-51-6	Benzyl alcohol	
	000111-46-6	Bis(2-hydroxyethyl) ether	See "Diethyleneglycol"
	000077-99-6	2,2-Bis(hydroxymethyl)-1-butanol	See "1,1,1-Trimethylolpropane"
13390	000105-08-8	1,4-Bis(hydroxymethyl)cyclohexane	
13480	000080-05-7	2,2-Bis(4-hydroxyphenyl)propane	SML = 3 mg/kg
13510	001675-54-3	2,2-Bis(4-hydroxyphenyl)propane-bis(2,3-epoxypropyl) ether	QM = 1 mg/kg in FP or SML = not detectable (DL = 0,020 mg/kg, analytical tolerance included)
	000110-98-5	Bis(hydroxypropyl) ether	See "Dipropyleneglycol"
	005124-30-1	Bis(4-isocyanatocyclohexyl)methane	See "Dicyclohexylmethane-4,4'-diisocyanate"
" 13530	038103-06-9	2,2-Bis(4-hydroxyphenyl)propane bis(phtalic anhydride)	SML = 0,05 mg/kg " **[1]**
13600	047465-97-4	3,3-Bis(3-methyl-4-hydroxyphenyl)2-indolinone	SML = 1,8 mg/kg
	000080-05-7	Bisphenol A	See "2,2-Bis(4-hydroxyphenyl) propane"
	001675-54-3	Bisphenol A bis(2,3-epoxypropyl) ether	See "2,2-Bis(4-hydroxyphenyl) propane bis(2,3-epoxypropyl) ether"
" 13614	038103-06-9	Bisphenol A bis(phtalic anhydride)	See 13530 " **[1]**
13630	000106-99-0	Butadiene	QM = 1 mg/kg in FP or SML = not detectable (DL = 0,020 mg/kg, analytical tolerance included)
13690	000107-88-0	1,3-Butanediol	
13840	000071-36-3	1-Butanol	
13870	000106-98-9	1-Butene	
13900	000107-01-7	2-Butene	
14110	000123-72-8	Butyraldehyde	
14140	000107-92-6	Butyric acid	
14170	000106-31-0	Butyric anhydride	
14200	000105-60-2	Caprolactam	SML(T) = 15 mg/kg
14230	002123-24-2	Caprolactam, sodium salt	SML(T) = 15 mg/kg (expressed as caprolactam)
14320	000124-07-2	Caprylic acid	
14350	000630-08-0	Carbon monoxide	
14380	000075-44-5	Carbonyl chloride	QM = 1 mg/kg in FP
14410	008001-79-4	Castor oil (food grade quality)	
14500	009004-34-6	Cellulose	
14530	007782-50-5	Chlorine	
	000106-89-8	1-Chloro-2,3-epoxypropane	See "Epichlorohydrin"
14680	000077-92-9	Citric acid	
14710	000108-39-4	*m*-Cresol	
14740	000095-48-7	o-Cresol	
14770	00106-44-5	*p*-Cresol	

PM/REF. No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
	000105-08-8	1,4-Cyclohexanedimethanol	See "1,4-Bis(hydroxymethyl)cyclohexane"
14950	003173-53-3	Cyclohexyl isocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
" 15095	000334-48-5	Decanoic acid " **[2]**	
15100	000112-30-1	1-Decanol	
	000107-15-3	1,2-Diaminoethane	See "Ethylenediamine"
	000124-09-4	1,6-Diaminohexane	See "Hexamethylenediamine"
" 15250	000110-60-1	1,4-Diaminobutane " **[1]**	
" 15565	000106-46-7	1,4-Dichlorobenzene	SML = 12 mg/kg " **[2]**
15700	005124-30-1	Dicyclohexylmethane-4,4'-diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
15760	000111-46-6	Diethyleneglycol	SML(T) = 30 mg/kg alone or with ethyleneglycol
" 15790	000111-40-0	Diethylenetriamine	SML = 5 mg/kg " **[2]**
" 15820	000345-92-6	4,4'-Difluorobenzophenone	SML = 0,05 mg/kg " **[2]**
15880	000120-80-9	1,2-Dihydroxybenzene	SML = 6 mg/kg
15910	000108-46-3	1,3-Dihydroxybenzene	SML = 2,4 mg/kg
15940	000123-31-9	1,4-Dihydroxybenzene	SML = 0,6 mg/kg
15970	000611-99-4	4,4'-Dihydroxybenzophenone	SML = 6 mg/kg
16000	000092-88-6	4,4'-Dihydroxybiphenyl	SML = 6 mg/kg
16150	000108-01-0	Dimethylaminoethanol	SML = 18 mg/kg
16240	000091-97-4	3,3'-Dimethyl-4,4'-diisocyanatobiphenyl	QM(T) = 1 mg/kg in FP (expressed as NCO)
16480	000126-58-9	Dipentaerythritol	
16570	004128-73-8	Diphenyl ether 4,4'-diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
16600	005873-54-1	Diphenylmethane 2,4'-diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
16630	000101-68-8	Diphenylmethane 4,4'-diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
16660	000110-98-5	Dipropyleneglycol	
16750	000106-89-8	Epichlorohydrin	QM = 1 mg/kg in FP
16780	000064-17-5	Ethanol	
16950	000074-85-1	Ethylene	
16960	000107-15-3	Ethylenediamine	SML = 12 mg/kg
16990	000107-21-1	Ethyleneglycol	SML(T) = 30 mg/kg alone or with diethyleneglycol
17005	000151-56-4	Ethyleneimine	"SML = ND(DL = 0,01 mg/kg) " **[1]**
17020	000075-21-8	Ethylene oxide	QM = 1 mg/kg in FP
" 17160	000097-53-0	Eugenol	SML = 0,01 mg/kg " **[2]**
17170	061788-47-4	Fatty acids, coco	
17200	068308-53-2	Fatty acids, soya	
17230	061790-12-3	Fatty acids, tall oil	

PM/REF. No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
17260	000050-00-0	Formaldehyde	SML = 15 mg/kg
17290	000110-17-8	Fumaric acid	
17530	000050-99-7	Glucose	
18010	000110-94-1	Glutaric acid	
" 18070	000108-55-4	Glutaric anhydride " **[1]**	
18100	000056-81-5	Glycerol	
" 18250	000115-28-6	Hexachloroendomethyl enetetrahydrophthalic acid	SML = ND (DL = 0,01 mg/kg) " **[1]**
" 18280	000115-27-5	Hexachloroendomethyl enetetrahydrophthalic anhydride	SML = ND (DL = 0,01 mg/kg) " **[1]**
18310	036653-82-4	1-Hexadecanol	
" 18430	000116-15-4	Hexafluoropropylene	SML = ND (DL = 0,01 mg/kg " **[1]**
18460	000124-09-4	Hexamethylenediamine	SML = 2,4 mg/kg
18640	000822-06-0	Hexamethylene diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
18670	000100-97-0	Hexamethylenetetramine	" SML(T) = 15 mg/kg (expressed as formaldehyde " **[1]**
	000123-31-9	Hydroquinone	See "1,4-Dihydroxybenzene"
18880	000099-96-7	P-Hydroxybenzoic acid	
19000	000115-11-7	Isobutene	
" 19210	001459-93-4	Isophthalic acid, dimethyl ester	SML = 0,05 mg/kg " **[2]**
" 19470	000143-07-7	Lauric acid " **[1]**	
19510	011132-73-3	Lignocellulose	
19540	000110-16-7	Maleic acid	SML(T) = 30 mg/kg
19960	000108-31-6	Maleic anhydride	SML(T) = 30 mg/kg (expressed as maleic acid)
	000108-78-1	Melamine	See "2,4,6-Triamino-1,3,5-triazine"
20020	000079-41-4	Methacrylic acid	
" 20080	002495-37-6	Methacrylic acid, benzyl ester " **[2]**	
20110	000097-88-1	Methacrylic acid, butyl ester	
20140	002998-18-7	Methacrylic acid, sec-butyl ester	
20170	000585-07-9	Methacrylic acid, tert-butyl ester	
20890	000097-63-2	Methacrylic acid, ethyl ester	
21010	000097-86-9	Methacrylic acid, isobutyl ester	
21100	004655-34-9	Methacrylic acid, isopropyl ester	
21130	000080-62-6	Methacrylic acid, methyl ester	
" 21190	000868-77-9	Methacrylic acid, monoester with ethyleneglycol " **[1]**	
" 21280	002177-70-0	Methacrylic acid, phenyl ester " **[2]**	
21340	002210-28-8	Methacrylic acid, propyl ester	
21460	000760-93-0	Methacrylic anhydride	

PM/REF. No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
21490	000126-98-7	Methacrylonitrile	SML = not detectable (DL = 0,020 mg/kg, analytical tolerance included)
21550	000067-56-1	Methanol	
" 21940	000924-42-5	N-Methylolacrylamide	SML = ND (DL = 0,01 mg/kg) " **[1]**
22150	000691-37-2	4-Methyl-1-pentene	" SML = 0,02 mg/kg " **[1]**
" 22350	000544-63-8	Myristic acid " **[1]**	
" 22390	000840-65-3	2,6-Naphtalenedicarboxylic acid, dimethyl ester	SML = 0,05 mg/kg " **[2]**
22420	003173-72-6	1,5-Naphthalene diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
22450	009004-70-0	Nitrocellulose	
22480	000143-08-8	1-Nonanol	
22570	000112-96-9	Octadecyl isocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
22600	000111-87-5	1-Octanol	
22660	000111-66-0	1-Octene	SML = 15 mg/kg
" 22763	000112-80-1	Oleic acid " **[1]**	
22780	000057-10-3	Palmitic acid	
22840	000115-77-5	Pentaerythritol	
22870	000071-41-0	1-Pentanol	
22960	000108-95-2	Phenol	
23050	000108-45-2	1,3-Phenylenediamine	QM = 1 mg/kg in FP
	000075-44-5	Phosgene	See "Carbonyl chloride"
23170	007664-38-2	Phosphoric acid	
		Phthalic acid	See "Terephthalic acid"
" 23200	000088-99-3	o-Phthalic acid " **[1]**	
" 23230	000131-17-9	Phthalic acid, diallyl ester	SML = ND (DL = 0,01 mg/kg) " **[1]**
23380	000085-44-9	Phthalic anhydride	
23470	000080-56-8	alpha-Pinene	
23500	000127-91-3	beta-Pinene	
23590	025322-68-3	Polyethyleneglycol	
23650	025322-69-4	Polypropyleneglycol (Molecular weight greater than 400)	
23740	000057-55-6	1,2-Propanediol	
23800	000071-23-8	1-Propanol	
23830	000067-63-0	2-Propanol	
23860	000123-38-6	Propionaldehyde	
23890	000079-09-4	Propionic acid	
23950	000123-62-6	Propionic anhydride	
23980	000115-07-1	Propylene	
24010	000075-56-9	Propylene oxide	QM = 1 mg/kg in FP

PM/REF. No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
	000120-80-9	Pyrocatechol	See "1,2-Dihydroxybenzene"
" 24057	000089-32-7	Pyromellitic anhydride	SML = 0,05 mg/kg (expressed as pyromellitic acid) " **[2]**
24070	073138-82-6	Resin acids and rosin acids	
	000108-46-3	Resorcinol	See "1,3-Dihydroxybenzene"
24100	008050-09-7	Rosin	
24130	008050-09-7	Rosin gum	
24160	008052-10-6	Rosin tall oil	
24190	009014-63-5	Rosin wood	
24250	009006-04-6	Rubber, natural	
" 24270	000069-72-7	Salicylic acid " **[1]**	
24280	000111-20-6	Sebacic acid	
" 24430	002561-88-8	Sebacic anhydride " **[1]**	
" 24475	001313-82-2	Sodium sulphide " **[2]**	
24490	000050-70-4	Sorbitol	
24520	008001-22-7	Soybean oil	
" 24540	009005-25-8	Starch, edible " **[2]**	
24550	000057-11-4	Stearic acid	
24610	000100-42-5	Styrene	
24820	000110-15-6	Succinic acid	
" 24850	000108-30-5	Succinic anhydride " **[1]**	
24880	000057-50-1	Sucrose	
" 24887	006362-79-4	5-Sulphoisophthalic acid, monosodium salt	SML = 0,05 mg/kg " **[1]**
" 24888	003965-55-7	5-Sulphoisophthalic acid, monosodium salt, dimethyl ester	SML = 0,05 mg/kg " **[2]**
24910	000100-21-0	Terephthalic acid	SML = 7,5 mg/kg
" 24940	000100-20-9	Terephthalic acid dichloride	SML(T) = 7,5 mg/kg (expressed as terephthalic acid " **[2]**
24970	000120-61-6	Terephthalic acid, dimethyl ester	
25090	000112-60-7	Tetraethyleneglycol	
" 25120	000116-14-3	Tetrafluoroethylene	SML = 0,05 mg/kg " **[2]**
25150	000109-99-9	Tetrahydrofuran	SML = 0,6 mg/kg
25180	000102-60-3	N,N,N',N'-Tetrakis(2-hydroxypropyl)ethylenediamine	
25210	000584-84-9	2,4-Toluene diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
25240	000091-08-7	2,6-Toluene diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
25270	026747-90-0	2,4-Toluene diisocyanate dimer	QM(T) = 1 mg/kg in FP (expressed as NCO)
25360		Trialkyl(C5-C1)-acetic acid, 2,3-epoxypropyl ester	SML = 6 mg/kg
25420	000108-78-1	2,4,6-Triamino-1,3,5-triazine	SML = 30 mg/kg
25510	000112-27-6	Triethyleneglycol	
25600	000077-99-6	1,1,1-Trimethylolpropane	SML = 6 mg/kg
" 25910	024800-44-0	Tripropyleneglycol " **[1]**	
25960	000057-13-6	Urea	
26050	000075-01-4	Vinyl chloride	See Council Directive 78/142/EEC (6)
26110	000075-35-4	Vinylidene chloride	QM = 5 mg/kg in FP or SML = not detectable (DL = 0,05 mg/kg)

SECTION B

LIST OF MONOMERS AND OTHER STARTING SUBSTANCES WHICH MAY CONTINUE TO BE USED PENDING A DECISION ON INCLUSION IN SECTION A

PM/REF. No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
	000542-02-9	Acetoguanamine	See "2,4-Diamino-6-methyl-1,3,5-triazine"
" 10160	002206-94-2	alpha-Acetoxystyrene " [1]	
" 10162	010521-96-7	beta-Acetoxystyrene " [1]	
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
10480		Acids, aliphatic, monocarboxylic, saturated (C2-C24)	
10510		Acids, aliphatic, monocarboxylic, unsaturated (C3-C24)	
"..." [1]			
"..." [1]			
" 10599/70		Acids fatty, unsaturated (C18) " [1]	
"..." [2]			
" 10599/90A	061788-89-4	Acids, fatty, unsaturated (C18), dimers, distilled " [2]	
" 10599/91	061788-89-4	Acids, fatty, unsaturated (C18), dimers, non-distilled " [2]	
"..." [2]			
" 10599/92A	068783-41-5	Acids, fatty, unsaturated (C18), dimers, hydrogenated, distilled " [2]	
" 10599/93	068783-41-5	Acids, fatty, unsaturated (C18), dimers, hydrogenated, non-distilled " [2]	
"..." [2]			
"..." [1]			
10660	015214-89-8	Acrylamidomethylpropanesulphonic acid	
"..." [2]			
"..." [2]			
"..." [2]			
"..." [1]			
"..." [1]			

PM/REF. No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
10930	003066-71-5	Acrylic acid, cyclohexyl ester	
"..." **[1]**			
"..." **[2]**			
" 11000	050976-02-8	Acrylic acid, dicyclopentadienyl ester " **[1]**	
"..." **[2]**			
"..." **[2]**			
"..." **[2]**			
11050	001070-70-8	Acrylic acid, diester with 1,4-butanediol	
"..." **[2]**			
"..." **[2]**			
"..." **[2]**			
"..." **[2]**			
" 11180	017831-71-9	Acrylic acid, diester with tetraethyleneglycol " **[1]**	
" 11195	068901-05-3	Acrylic acid, diester with tripropyleneglycol " **[1]**	
"..." **[2]**			
"..." **[2]**			
" 11245	002156-97-0	Acrylic acid, dodecyl ester " **[1]**	
"..." **[2]**			
"..." **[1]**			
"..." **[1]**			
"..." **[1]**			
"..." **[1]**			
"..." **[1]**			
"..." **[1]**			
11500	000103-11-7	Acrylic acid, 2-ethylhexyl ester	
" 11520	002918-23-2	Acrylic acid, 2-hydroxyisopropyl ester (= acrylic acid, 2-hydroxy-1-methylethyl ester) " **[1]**	
11530	000999-61-1	Acrylic acid, 2-hydroxypropyl ester	
"..." **[2]**			
11560	005888-33-5	Acrylic acid, isobornyl ester	
11620	001330-61-6	Acrylic acid, isodecyl ester	
11650	029590-42-9	Acrylic acid, isooctyl ester	
" 11695	003121-61-7	Acrylic acid, 2-methoxyethyl ester " **[1]**	
11740	010095-13-3	Acrylic acid, monoester with 1,3-butanediol	
11770	002478-10-6	Acrylic acid, monoester with 1,4-butanediol	
11800	013533-05-6	Acrylic acid, monoester with diethyleneglycol	

PM/REF. No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
"..." [2]			
"..." [2]			
"..." [2]			
"..." [1]			
"..." [1]			
12010	040074-09-7	Acrylic acid, 2-sulphoethyl ester	
12040	039121-78-3	Acrylic acid, sulphopropyl ester	
" 12055	094160-26-6	Acrylic acid, triester with glycerol tris(2-hydroxypropyl) ether " [1]	
" 12062	075577-70-7	Acrylic acid, triester with 1,1,1-trimethylolpropane tris(2-hydroxy-ethyl) ether " [1]	
"..." [1]			
12160	002998-04-1	Adipic acid, diallyl ester	
12190	000105-97-5	Adipic acid, didecyl ester	
12220	027178-16-1	Adipic acid, diisodecyl ester	
12250	000123-79-5	Adipic acid, dioctyl ester	
" 12265	004074-90-2	Adipic acid, divinyl ester " [1]	
"..." [1]			
12370	002035-75-8	Alcohols, aliphatic, monohydric, saturated, linear, secondary or tertiary (C4-C22)	
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
12610	000107-18-6	Allyl alcohol	
"..." [2]			
"..." [1]			
12700	000150-13-0	*p*-Aminobenzoic acid	
"..." [1]			
"..." [1]			
12790	000080-46-6	*p*-tert-Amylphenol	
12850	029602-44-6	Azelaic acid, bis(2-hydroxyethyl) ester	
"..." [1]			
12910	001732-10-1	Azelaic acid, dimethyl ester	
"..." [1]			
"..." [1]			
"..." [1]			

PM/REF. No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
	000528-44-9	1,2,4-Benzenetricarboxylic acid	See "Trimellitic acid"
13060	004422-95-1	1,3,5-Benzenetricarboxylic acid trichloride	
	000091-76-9	Benzoguanamine	See "2,4-Diamino-6-phenyl-1,3,5-triazine"
"..." [1]			
"..." [1]			
"..." [2]			
"..." [1]			
"..." [1]			
" 13328	000104-38-1	Bis(2-hydroxyethyl) ether of hydroquinone " [1]	
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
	000080-09-1	Bisphenol S	See "4,4'-Dihydroxydiphenylsulphone"
13660	000584-03-2	1,2-Butanediol	
13720	000110-63-4	1,4-Butanediol	
13750	000513-85-9	2,3-Butanediol	
13780	002425-79-8	1,4-Butanediol bis(2,3-epoxypropyl) ether	QM(T) = 5 mg/kg in FP (expressed as epoxy)
13810	000505-65-7	1,4-Butanediol formal	
"..." [1]			
" 13932	000598-32-3	3-Buten-2-ol " [1]	
13960	001852-16-0	N-(Butoxymethyl)acrylamide	
"..." [1]			
"..." [2]			
14020	000098-54-4	4-tert-Butylphenol	
"..." [2]			
"..." [1]			
"..." [1]			
14260	000502-44-3	Caprolactone	
"..." [1]			
"..." [1]			
"..." [1]			
	000115-28-6	Chlorendic acid	See "Hexachloroendomethylenetetrahydrophthalic acid"
"..." [2]			
"..." [1]			
"..." [1]			

PM/REF. No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
"..." **[2]**			
14800	003724-65-0	Crotonic acid	
"..." **[1]**			
"..." **[2]**			
"..." **[1]**			
"..." **[1]**			
"..." **[2]**			
"..." **[1]**			
" 15020	002182-05-0	Cyclohexyl vinyl ether " **[1]**	
"..." **[2]**			
"..." **[1]**			
"..." **[2]**			
15070	001647-16-1	1,9-Decadiene	
"..." **[2]**			
15130	000872-05-9	1-Decene	
"..." **[1]**			
"..." **[1]**			
"..." **[1]**			
"..." **[2]**			
"..." **[2]**			
15280	000542-02-9	2,4-Diamino-6-methyl-1,3,5-triazine	
"..." **[2]**			
15310	000091-76-9	2,4-Diamino-6-phenyl-1,3,5-triazine	
15340	000109-76-2	1,3-Diaminopropane	
15370	003236-53-1	1,6-Diamino-2,2,4-trimethylhexane	
15400	003236-54-2	1,6-Diamino-2,4,4-trimethylhexane	
"..." **[1]**			
"..." **[1]**			
15490	002215-89-6	4,4'-Dicarboxydiphenyl ether	
"..." **[1]**			
"..." **[1]**			
15580	001653-19-6	2,3-Dichloro-1,3-butadiene	
15610	000080-07-9	4,4'-Dichlorodiphenyl sulphone	
"..." **[1]**			
"..." **[1]**			
15730	000077-73-6	Dicyclopentadiene	
"..." **[2]**			
"..." **[1]**			
"..." **[1]**			
16090	000080-09-1	4,4'-Dihydroxydiphenyl sulphone	

PM/REF. No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
"..." [2]			
"..." [2]			
16210	006864-37-5	3,3'-Dimethyl-4,4'-diaminodicyclo-hexylmethane	
"..." [2]			
16270	000526-75-0	2,3-Dimethylphenol	
16300	000105-67-9	2,4-Dimethylphenol	
16330	000095-87-4	2,5-Dimethylphenol	
16360	000576-26-1	2,6-Dimethylphenol	
16390	000126-30-7	2,2-Dimethyl-1,3-propanediol	
"..." [1]			
16450	000646-06-0	1,3-Dioxolane	
"..." [2]			
16540	000102-09-0	Diphenyl carbonate	
16690	001321-74-0	Divinylbenzene	
" 16697	000693-23-2	Dodecanedioic acid " [1]	
"..." [2]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [2]			
"..." [1]			
" 17040	000149-57-5	2-Ethylhexanoic acid " [1]	
17050	000104-76-7	2-Ethyl-1-hexanol	
"..." [1]			
17110	016219-75-3	5-Ethylidenebicyclo(2.2.1)hept-2-ene	
"..." [2]			
"..." [1]			
"..." [2]			
"..." [2]			
"..." [2]			
17350	000105-75-9	Fumaric acid, dibutyl ester	
"..." [2]			
"..." [2]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			

PM/REF. No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [2]			
"..." [2]			
"..." [2]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
18220	068564-88-5	N-Heptylaminoundecanoic acid	
"..." [1]			
"..." [1]			
"..." [1]			
18370	000592-45-0	1,4-Hexadiene	
18400	000592-42-7	1,5-Hexadiene	
"..." [1]			
"..." [2]			
" 18441	000085-42-7	Hexahydrophthalic anhydride " [1]	
"..." [2]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [2]			
18700	000629-11-8	1,6-Hexanediol	
"..." [1]			
"..." [1]			
"..." [1]			
18820	000592-41-6	1-Hexene	
"..." [2]			
"..." [2]			
" 18905	002628-17-3	4-Hydroxystyrene " [1]	

PM/REF. No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
"..." **[1]**			
"..." **[1]**			
18970	000078-83-1	Isobutanol	
19030	016669-59-3	N-(Isobutoxymethyl)acrylamide	
19060	000109-53-5	Isobutyl vinyl ether	
19090	000078-84-2	Isobutyraldehyde	
19120	025339-17-7	Isodecanol	
" 19130	026896-18-4	Isononanoic acid " **[1]**	
"..." **[2]**			
19150	000121-91-5	Isophthalic acid	
19180	000099-63-8	Isophthalic acid dichloride	
"..." **[2]**			
"..." **[1]**			
	000078-79-5	Isoprene	See "2-Methyl-1,3-butadiene"
19270	000097-65-4	Itaconic acid	
"..." **[1]**			
"..." **[1]**			
"... ' **[1]**			
"..." **[1]**			
"..." **[1]**			
"..." **[1]**			
"..." **[2]**			
" 19490	000947-04-6	Laurolactam" **[1]**	
19570	000999-21-3	Maleic acid, diallyl ester	
19600	000105-76-0	Maleic acid, dibutyl ester	
"..." **[1]**			
"..." **[2]**			
"..." **[2]**			
"..." **[2]**			
"..." **[2]**			
"..." **[1]**			
"..." **[1]**			
"..." **[1]**			
"..." **[1]**			
"..." **[1]**			
"..." **[2]**			
"..." **[1]**			
" 19936	007423-42-9	Maleic acid, mono(2-ethylhexyl) ester" **[1]**	
19990	000079-39-0	Methacrylamide	
20050	000096-05-9	Methacrylic acid, allyl ester	

PM/REF. No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
"..." [2]			
"..." [2]			
"..." [2]			
"..." [1]			
20260	000101-43-9	Methacrylic acid, cyclohexyl ester	
"..." [1]			
"..." [2]			
"..." [1]			
20380	001189-08-8	Methacrylic acid, diester with 1,3-butanediol	
20410	002082-81-7	Methacrylic acid, diester with 1,4-butanediol	
20440	000097-90-5	Methacrylic acid, diester with ethyleneglycol	
"..." [2]			
20470	025852-47-5	Methacrylic acid, diester with polyethylenglycol	
"..." [1]			
20530	002867-47-2	Methacrylic acid, 2-(dimethylamino)ethyl ester	
"..." [2]			
20590	000106-91-2	Methacrylic acid, 2,3-epoxypropyl ester	QM(T) = 5 mg/kg in FP (expressed as epoxy)
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
20740	039670-09-2	Methacrylic acid, ester with ethoxytriethyleneglycol	
"..." [1]			
"..." [1]			
"..." [2]			
"..." [1]			
"..." [2]			
"..." [2]			
20950	000923-26-2	Methacrylic acid, 2-hydroxypropyl ester	
"..." [2]			
"..." [2]			
"..." [2]			
"..." [2]			
" 21115	000816-74-0	Methacrylic acid, methallyl ester " [1]	
"..." [1]			

PM/REF. No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
"..." [2]			
"..." [1]			
21220	032360-05-7	Methacrylic acid, octadecyl ester	
"..." [2]			
"..." [2]			
"..." [1]			
21370	010595-80-9	Methacrylic acid, 2-sulphoethyl ester	
21400	054276-35-6	Methacrylic acid, sulphopropyl ester	
"..." [2]			
21520	001561-92-8	Methallylsulphonic acid, sodium salt	QM = 5 mg/kg in FP
"..." [1]			
"..." [1]			
21640	000078-79-5	2-Methyl-1,3-butadiene	
"..." [2]			
"..." [1]			
21730	000563-45-1	3-Methyl-1-butene	
"..." [2]			
"..." [2]			
"..." [2]			
"..." [2]			
"..." [2]			
"..." [2]			
21760	000694-91-7	5-Methylenebicyclo(2.2.1)hept-2-ene	
"..." [1]			
"..." [1]			
	000505-65-7	1,4-(Methylenedioxy)butane	See "1,4-Butanediol formal"
" 21837	001116-90-1	4-Methyl-1,4-hexadiene	SML = ND (DL = 0,05 mg/kg) " [1]
"..." [2]			
"..." [2]			
"..." [1]			
"..." [1]			
21970	000923-02-4	N-Methylolmethacrylamide	
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
22210	000098-83-9	alpha-Methylstyrene	
22240	000622-97-9	p-Methylstyrene	

PM/REF. No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
22270	000107-25-5	Methyl vinyl ether	
"..." [1]			
"..." [1]			
22360	001141-38-4	2,6-Naphthalenedicarboxylic acid	
	000126-30-7	Neopentylglycol	See "2,2-Dimethyl-1,3-propanediol"
" 22428	051000-52-3	Neodecanoic acid, vinyl ester " [1]	
"..." [2]			
"..." [1]			
22540	000104-40-5	4-Nonylphenol	
	000498-66-8	Norbornene	See "Bicyclo(2.2.1)hept-2-ene"
"..." [1]			
" 22585	003710-30-3	1,7-Octadiene" [1]	
"..." [1]			
"..." [2]			
22720	000140-66-9	4-tert-Octylphenol	
"..." [1]			
"..." [1]			
"..." [2]			
"..." [2]			
"..." [2]			
"..." [2]			
22900	000109-67-1	1-Pentene	
"..." [2]			
"..." [1]			
" 22932	001187-93-5	Perfluoromethyl perfluorovinyl ether " [1]	
"..." [2]			
" 22937	001623-05-8	Perfluoropropyl perfluorovinyl ether " [1]	
"..." [2]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [2]			
		Phthalic acids	See "Iso- or o-Phthalic acid"
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			

PM/REF. No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
"..." [1]			
"..." [1]			
"..." [1]			
23530	025190-06-1	Poly(1,4-butyleneglycol) (molecular weight greater than 1 000)	
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
23770	000504-63-2	1,3-Propanediol	
23920	000105-38-4	Propionic acid, vinyl ester	
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
24370	000106-79-6	Sebacic acid, dimethyl ester	
"..." [1]			
"..." [1]			
" 24560	000111-63-7	Stearic acid, vinyl ester " [1]	
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
24760	026914-43-2	Styrenesulphonic acid	
"..." [1]			
"..." [1]			
"..." [2]			
"..." [1]			
25030	016646-44-9	Tetra(allyloxy)ethane	
"..." [1]			
"..." [2]			
"..." [2]			
" 25161	000085-43-8	1,2,3,6-Tetrahydrophthalic anhydride " [1]	
25300	000088-19-7	*o*-Toluenesulphonamide	
"..." [1]			
" 25380		Trialkyl (C5-C15) acetic acid, vinyl ester (= vinyl versatate) " [1]	
25390	000101-37-1	Triallyl cyanurate	
25450	026896-48-0	Tricyclodecanedimethanol	
25480	000102-71-6	Triethanolamine	
25540	000528-44-9	Trimellitic acid	QM(T) = 5 mg/kg in FP

PM/REF. No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
25550	000552-30-7	Trimellitic anhydride	QM(T) = 5 mg/kg in FP (expressed as trimellitic acid)
"..." [1]			
"..." [2]			
"..." [2]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [1]			
"..." [2]			
25810	015625-89-5	1,1,1-Trimethylolpropane triacrylate	
25840	003290-92-4	1,1,1-Trimethylolpropane trimethacrylate	
"..." [1]			
25900	000110-88-3	Trioxane	
	000102-71-6	Tris(2-hydroxyethyl)amine	See "Triethanolamine"
"..." [2]			
"..." [1]			
"..." [1]			
"..." [1]			
26140	000075-38-7	Vinylidene fluoride	" SML = ND(DL = 0,05 mg/kg) " [1]
26170	003195-78-6	N-Vinyl-N-methylacetamide	QM = 5 mg/kg in FP
"..." [2]			
26230	000088-12-0	Vinylpyrrolidone	
"..." [2]			
26290	025013-15-4	Vinyltoluene	
	000622-97-9	*p*-Vinyltoluene	See "*p*-Methylstyrene"
26320	002768-02-7	Vinyltrimethoxysilane	QM = 5 mg/kg in FP
	000105-67-9	*m*-Xylenol	See "2,4-Dimethylphenol"
	000526-75-0	*o*-Xylenol	see "2,3-Dimethylphenol"
	000095-87-4	*p*-Xylenol	See "2,5-Dimethylphenol" " (R1)

(R1) Corrigenda, OJ No L 349, 13/12/1990, p. 26. The entirety of the text of Commission Directive 90/128/EEC is replaced by the Corrigendum.

(1) OJ No L 40, 11/02/1989, p. 38.

(2) OJ No L 123, 11/05/1983, p. 31.

(3) OJ No L 228, 14/08/1986, p. 32.

(4) OJ No L 297, 23/10/1982, p. 26.

(5) OJ No L 372, 31/12/1985, p. 14.

(6) OJ No L 44, 15/02/1978, p. 15.

393L0010

93/10/EEC: COMMISSION DIRECTIVE OF 15 MARCH 1993 RELATING TO MATERIALS AND ARTICLES MADE OF REGENERATED CELLULOSE FILM INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

OFFICIAL JOURNAL NO L 93, 17/04/1993, P. 27
DATE OF TRANSPOSITION: 01/01/1994; SEE ART. 5

[This Directive is a consolidated and amended version of Council Directive 83/229/EEC (OJ No L 123, 11/05/1983, p. 31) as last amended by Directive 92/15/EEC (OJ No L 102, 16/04/1992, p. 44)]

AMENDED BY

393L0111
93/111/EEC: COMMISSION DIRECTIVE OF 10 DECEMBER 1993 [1]
OFFICIAL JOURNAL NO L 310, 14/12/1993, P. 41

ARTICLE 1

1. This Directive is a specific directive within the meaning of Article 3 of Directive 89/109/EEC (1).

2. This Directive shall apply to regenerated cellulose film within the meaning of the description given in Annex I which either:

(a) constitutes a finished product in itself; or

(b) forms part of a finished product containing other materials,

and which is intended to come into contact with foodstuffs or which, by virtue of its purpose, does come into such contact.

3. This Directive does not apply to:

(a) regenerated cellulose film which, on the side intended to come into contact with foodstuffs or which, by virtue of its purpose does come into such contact, has a coating exceeding 50 mg/dm^2;

(b) synthetic casings of regenerated cellulose.

ARTICLE 2

1. Only those substances or groups of substances listed in Annex II may be used for the manufacture of regenerated cellulose film and only under the conditions laid down therein.

2. By way of derogation from paragraph 1, substances other than those listed in Annex II may be used when these substances are employed as colouring matter (dyes and pigments) or as adhesives, provided that there is no trace of migration of the substances into or onto foodstuffs, detectable by a validated method.

ARTICLE 3

Printed surfaces of regenerated cellulose film shall not come into contact with the foodstuffs.

ARTICLE 4

1. At the marketing stages other than the retail stages, materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs shall be accompanied by a written declaration in accordance with Article 6 (5) of Directive 89/109/EEC.

2. Paragraph 1 does not apply to materials and articles made of regenerated cellulose film which by their nature are clearly intended to come into contact with foodstuffs.

3. Where special conditions of use are indicated, the material or article made of regenerated cellulose film shall be labelled accordingly.

ARTICLE 5

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive as from 1 January 1994. They shall immediately inform the Commission thereof.

Member States shall:

- permit, as from 1 January 1994, the trade in and use of regenerated cellulose film which is intended to come into contact with foodstuffs complying with this Directive,
- " prohibit, as from 1 January 1994, the trade in and use of regenerated cellulose film which is intended to come into contact with foodstuffs and which complies with neither this Directive nor Directive 83/229/EEC (2), other than film which Directive 92/15/EEC (3) prohibits as from 1 July 1994. " **[1]**
- prohibit, as from 1 January 1995, the trade in and use of regenerated cellulose film which is intended to come into contact with foodstuffs and which does not comply with this Directive but did comply with Directive 83/229/EEC.

2. When Member States adopt the measures referred to in paragraph 1, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

ARTICLE 6

1. Directive 83/229/EEC is hereby repealed as from 1 January 1994.

2. References to Directive 83/229/EEC shall be construed as references to this Directive and should be read in accordance with the correlation table appearing in Annex III.

ARTICLE 7

This Directive is addressed to the Member States.

ANNEX I

DESCRIPTION OF REGENERATED CELLULOSE FILM

Regenerated cellulose film is a thin sheet material obtained from a refined cellulose derived from unrecycled wood or cotton. To meet technical requirements, suitable substances may be added either in the mass or on the surface. Regenerated cellulose film may be coated on one or both sides.

ANNEX II

LIST OF SUBSTANCES AUTHORIZED IN THE MANUFACTURE OF REGENERATED CELLULOSE FILM

NB

— The percentages in this Annex, first and second parts, are expressed in weight/weight (w/w) and are calculated in relation to the quantity of anhydrous uncoated regenerated cellulose film.

— The usual technical denominations are given in square brackets.

— The substances used shall be of good technical quality as regards the purity criteria.

FIRST PART

UNCOATED REGENERATED CELLULOSE FILM

Denominations	Restrictions
A. Regenerated cellulose	Not less than 72 % (w/w)
B. Additives	
1. *Softeners*	Not more than 27 % (w/w) in total
— Bis (2-hydroxyethyl) ether [= diethyleneglycol]	Only for films intended to be coated and then used for foodstuffs which are not moist, i.e. which do not contain water which is physically free at the surface. The total amount of bis(2 hydroxyethyl)ether and ethanediol present in foodstuffs that have been in contact with film of this type may not exceed 30 mg/kg of the foodstuff.
— Ethanediol [= monoethyleneglycol]	
— 1,3-butanediol	
— Glycerol	
— 1,2-propanediol [= 1,2 propyleneglycol]	
— Polyethylene oxide [= polyethyleneglycol]	Average molecular weight between 250 and 1 200
— 1,2-polypropylene oxide [= 1,2 polypropyleneglycol]	Average molecular weight not greater than 400 and free 1,3-propanediol content not greater than 1 % (w/w) in substance
— Sorbitol	
— Tetraethyleneglycol	
— Triethyleneglycol	
— Urea	
2. *Other additives*	Not more than 1 % (w/w) in total
First class	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm² of the uncoated film
— Acetic acid and its NH_4, Ca, Mg, K and Na salts	
— Ascorbic acid and its NH_4, Ca, Mg, K and Na salts	
— Benzoic acid and sodium benzoate	
— Formic acid and its NH_4, Ca, Mg, K and Na salts	
— Linear fatty acids, saturated or unsaturated, with an even number of carbo atoms from 8 to 20 inclusive and also behenic and ricinoleic acids and the NH_4, Ca, Mg, K, Na, Al, Zn salts of these acids	
— Citric, d and l lactic, maleic, l-tartaric acids and their Na and K salts	
— Sorbic acid and its NH_4, Ca, Mg, K and Na salts	

Denominations	Restrictions
— Amides of linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also the amides of behenic and ricinoleic acids	
— Natural edible starches and flours	
— Edible starches and flours modified by chemical treatment	
— Amylose	
— Calcium and magnesium carbonates and chlorides	
— Esters of glycrol with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and/or with adipic, citric, 12-hydroxystearic (oxystearin), ricinoleic acids	
— Esters of polyoxyethylene (8 to 14 oxyethylene groups) with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive	
— Esters of sorbitol with linear fatty acids, saturated or unsaturated, with an even number of carton atoms from 8 to 20 inclusive	
— Mono-and/or di-esters of stearic acid with ethanediol and/or bis (2-hydroxyethyl) ether and/or triethylene glycol	
— Oxides and hydroxides of aluminium, calcium, magnesium and silicon and silicates and hydrated silicates of aluminium, calcium, magnesium and potassium	
— Polyethylene oxide [= polyethyleneglycol]	Average molecular weight between 1 200 and 4 000
— Sodium propionate	
Second class	The total quantity of the substances may not exceed 1 mg/dm² of the uncoated film and the quantity of the substance or group of substances in each indent may not exceed 0,2 mg/dm² (or a lower limit where one is specified) of the uncoated film
— Sodium alkyl (C_8 to C_{18}) benzene sulphonate	
— Sodium isopropyl naphthalene sulphonate	
— Sodium alkyl (C_8-C_{18}) sulphate	
— Sodium alkyl (C_8-C_{18}) sulphonate	
— Sodium dioctylsulphosuccinate	
— Distearate of dihydroxyethyl diethylene triamine monoacetate	Not more than 0,05 mg/dm² of the uncoated film
— Ammonium, magnesium and potassium lauryl sulphates	
— N,N′-distearoyl diaminoethane, N,N′-dipalmitoyl diaminoethane and N,N′-dioleoyl diaminoethane	
— 2-heptadecyl—4,4-bis(methylene-stearate) oxazoline	
— Polyethylene-aminostearamide ethylsulphate	Not more than 0,1 mg/dm² of the uncoated film

Denominations	Restrictions
Third class — Anchoring agent	The total quantity of substances may not exceed 1 mg/dm² of the uncoated film
— Condensation product of melamine-formaldehyde unmodified, or which may be modified with one or more of the following products : butanol, diethylenetriamine, ethanol, triethylenetetramine, tetraethylenepentamine, tri-(2-hydroxyethyl) amine, 3,3'-diaminodipropylamine, 4,4'-diaminodibutylamine	Free formaldehyde content not greater than 0,5 mg/dm² of the uncoated film Free melamine content not greater than 0,3 mg/dm² of the uncoated film
— Condensation product of melamine-urea-formaldehyde modified with tris-(2-hydroxyethyl)amine	Free formaldehyde content not greater than 0,5 mg/dm² of the uncoated film. Free melamine content not greater than 0,3 mg/dm² of the uncoated film
— Cross-linked cationic polyalkyleneamines : (a) polyamide-epichlorhydrin resin based on diaminopropylmethylamine and epichlorhydrin (b) polyamide-epichlorhydrin resin based on epichlorhydrin, adipic acid, caprolactam, diethylenetriamine and/or ethylenediamine (c) polyamide-epichlorhydrin resin based on adipic acid, diethylenetriamine and epichlorhydrin, or a mixture of epichlorhydrin and ammonia (d) polyamide-polyamine-epichlorhydrin resin based on epichlorhydrin, dimethyl adipate and diethylenetriamine (e) polyamide-polyamine-epichlorhydrin resin based on epichlorhydrin, adipamide and diaminopropylmethylamine	In accordance with Community directives and in their absence, with national legislation, pending the adoption of Community directives
— Polyethyleneamines and polyethyleneimines	Not more than 0,75 mg/dm² of the uncoated film
— Condensation product of urea-formaldehyde unmodified, or which may be modified with one or of the following products : aminomethylsulphonic acid, sulphanilic acid, butanol, diaminobutane, diaminodiethylamine, diaminodipropylamine, diaminopropane, diethylenetriamine, ethanol, guanidine, methanol, tetraethylenepentamine, triethylenetetramine, sodium sulphite	Free formaldehyde content not greater than 0,5 mg/dm² of the uncoated film
Fourth class	The total quantity of substances may not exceed 0,01 mg/dm² of the uncoated film
— Products resulting from the reaction of the amines of edible oils with polyethylene oxide	
— Monoethanolamine lauryl sulphate	

SECOND PART

COATED REGENERATED CELLULOSE FILM

Denominations	Restrictions
A. **Regenerated cellulose**	See first part
B. **Additives**	See first part
C. **Coating**	Not more than 50 mg of coating/dm² of film on the side in contact with foodstuffs
1. *Polymers*	The total quantity of substances may not exceed 50 mg/dm² of the coating on the side in contact with foodstuffs
— Ethyl, hydroxyethyl, hydroxypropyl and methyl ethers of cellulose	
— Cellulose nitrate	Not more than 20 mg/dm² of the coating on the side in contact with foodstuffs ; nitrogen content between 10,8 % (w/w) and 12,2 % (w/w) in the cellulose nitrate
— Polymers, copolymers and their mixtures made with the following monomers :	In accordance with Community directives, and, in their absence, with national legislation pending the adoption of Community directives
vinyl acetals derived from saturated aldehydes (C_1 to C_6)	
vinyl acetate	
alkyl (C_1 to C_4) vinyl ethers	
acrylic, crotonic, itaconic, maleic, methacrylic acids and their esters	
butadiene	
styrene	
methylstyrene	
vinylidene chloride	
acrylonitrile	
methacrylonitrile	
ethylene, propylene, 1- and 2-butylene	
vinyl chloride	According to Directive 78/142/EEC (OJ No L 44, 15. 2. 1978, p. 15)
2. *Resins*	The total quantity of substances may not exceed 12,5 mg/dm² of the coating on the side in contact with foodstuffs and solely for the preparation of regenerated cellulose films with cellulose nitrate or vinyl chloride and vinyl acetate copolymer based coatings
— Casein	
— Colophony and/or its products of polymerization, hydrogenation, or disproportionation and their esters of methyl, ethyl or C_2 to C_6 polyvalent alcohols, or mixtures of these alcohols	
— Colophony and/or its products of polymerization, hydrogenation, or disproportionation condensed with acrylic, maleic, citric, fumaric and/or phthalic acids and/or 2,2 bis (4-hydroxyphenyl) propane formaldehyde and esterified with methyl ethyl or C_2 to C_{4} polyvalent alcohols or mixtures of these alcohols	

Denominations	Restrictions
— Esters derived from bis(2-hydroxyethyl) ether with addition products of betapinene and/or dipentene and/or diterpene and maleic anhydride	
— Edible gelatine	
— Castor oil and its products of dehydration or hydrogenation and its condensation products with polyglycerol, adipic, citric, maleic, phthalic and sebacic acids	
— Natural gum [= damar]	
— Poly-beta-pinene [= terpenic resins]	
— Urea-formaldehyde resins (see anchoring agents)	
3. *Plasticizers*	The total quantity of substances may not exceed 6 mg/dm² of the coating on the side in contact with foodstuffs
— Acetyl tributyl citrate	
— Acetyl tri(2-ethylhexyl) citrate	
— Di-isobutyl adipate	
— Di-n-butyl adipate	
— Di-n-hexyl azelate	
— Butylbenzylphthalate	Not more than 2,0 mg/dm² of the coating on the side in contact with foodstuffs
— Di-n-butyl phthalate	Not more than 3,0 mg/dm² of the coating on the side in contact with foodstuffs
— Dicyclohexyl phthalate	Not more than 4,0 mg/dm² of the coating on the side in contact with foodstuffs
— 2-ethylhexyl diphenyl phosphate	Not more than 2,5 mg/dm² of the coating on the side in contact with foodstuffs
— Glycerol monoacetate [= monoacetin]	
— Glycerol diacetate [= diacetin]	
— Glycerol triacetate [= triacetin]	
— Di-butyl sebacate	
— Di(2-ethylhexal) sebacate [= dioctylsebacate]	
— Di-n-butyl tartrate	
— Di-isobutyl tartrate	
4. *Other additives*	The total quantity of substances may not exceed 6 mg/dm² in the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with foodstuffs
4.1. *Additives listed in the first part*	Same restrictions as in the first part (however the quantities in mg/dm² refer to the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with foodstuffs)
4.2. *Specific coating additives:*	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm² (or a lower limit where one is specified) of the coating on the side in contact with foodstuffs
— 1-hexadecanol and 1-octadecanol	
— Esters of linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and of ricinoleic acid with ethyl, butyl, amyl and oleyl linear alcohols	
— Montan waxes, comprising purified montanic (C_{26} to C_{32}) acids and/or their esters with ethanediol and/or 1,3 butanediol and/or their calcium and potassium salts	

Denominations	Restrictions
— Carnauba wax	
— Beeswax	
— Esparto wax	
— Candelilla wax	
— Dimethylpolysiloxane	Not more than 1 mg/dm² of the coating on the side in contact with foodstuffs
— Epoxidized soya-bean oil (oxirane content 6 to 8 %)	
— Refined paraffin and microcrystalline waxes	
— Pentaerythritol tetrastearate	
— Mono and bis(octadecyldiethyleneoxide)-phosphates	Not more than 0,2 mg/dm² of the coating on the side in contact with foodstuffs
— Aliphatic acids (C_8 to C_{20}) esterified with mono- or di-(2-hydroxyethyl)amine	
— 2- and 3-tert.butyl-4-hydroxyanisole [= butylated hydroxyanisole — BHA]	Not more than 0,06 mg/dm² of the coating on the side in contact with foodstuffs
— 2,6-di-tert.butyl-4-methylphenol [= butylated hydroxytoluene — BHT]	Not more than 0,06 mg/dm² of the coating on the side in contact with foodstuffs
— Di-n-octyltin-bis(2-ethylhexyl) maleate	Not more than 0,06 mg/dm² of the coating on the side in contact with foodstuffs
5. *Solvents*	The total quantity of substances may not exceed 0,6 mg/dm² of the coating on the side in contact with foodstuffs
— Butyl acetate	
— Ethyl acetate	
— Isobutyl acetate	
— Isopropyl acetate	
— Propyl acetate	
— Acetone	
— 1-butanol	
— Ethanol	
— 2-butanol	
— 2-propanol	
— 1-propanol	
— Cyclohexane	
— Ethyleneglycol monobutyl ether	
— Ethyleneglycol monobutyl ether acetate	
— Ethyleneglycol monoethyl ether	
— Ethyleneglycol monoethyl ether acetate	
— Ethyleneglycol monomethyl ether	
— Ethyleneglycol monomethyl ether acetate	
— Methyl ethyl ketone	
— Methyl isobutyl ketone	
— Tetrahydrofuran	
— Toluene	Not more than 0,06 mg/dm² of the coating on the side in contact with foodstuffs.

ANNEX III

CORRELATION TABLE

Directive 83/229/EEC	Present Directive
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3
Article —	Article 4
Article 4 (1)	Article 5
Article 4 (2)	Article —
Article —	Article 6
Article 5	Article 7

(1) OJ No L 40, 11/02/1989, p. 38.
(2) OJ No L 123, 11/05/1983, p. 31.
(3) OJ No L 102, 16/04/1992, p. 44.

COMMISSION DIRECTIVE 93/11/EEC

of 15 March 1993

concerning the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs (1), and in particular Article 3 thereof,

Whereas the Community measures envisaged by this Directive are not only necessary but also indispensable for the attainment of the objectives of the internal market; whereas these objectives cannot be achieved by Member States individually; whereas furthermore their attainment at Community level is already provided for by Directive 89/109/EEC;

Whereas it has been shown that teats and soothers, made of elastomer or rubber, may release N-nitrosamines and substances capable of being converted into N-nitrosamines (N-nitrosatable substances);

Whereas the Scientific Committee for Food has given the opinion that N-nitrosamines and N-nitrosatable substances may endanger human health owing to their toxicity and has therefore recommended that migration of these substances from the abovementioned articles be kept below the detection limit of an appropriate sensitive method;

Whereas Article 2 of Directive 89/109/EEC lays down that materials and articles, in their finished state, must not transfer their constituents to foodstuffs in quantities which could endanger human health;

Whereas, in order to achieve this objective, the suitable instrument for teats is a specific directive within the meaning of Article 3 of Directive 89/109/EEC;

Whereas the use of soothers may produce the same type of risk and therefore it is convenient to adopt the same provisions for these articles too;

Whereas it is necessary to act immediately and therefore this Directive is limited to establishing specific rules regarding the release of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers, postponing to a more general directive regarding elastomers and rubber the solution of other problems concerning teats and soothers;

Whereas this Directive establishes the basic rules and general criteria for determining the release of N-nitrosamines and N-nitrosatable substances and postpones the definition of a detailed method of analysis;

Whereas the outline method of analysis given in the Annexes is adopted as a temporary measure until more results are available on the performance of this method and possible alternative methods;

Whereas the Commission has undertaken to promote further research on methods of analysis, to review the proposed methodology and to consider establishing analytical tolerances in the light of that research;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive is a specific directive within the meaning of Article 3 of Directive 89/109/EEC.

It concerns the release of N-nitrosamines and of substances capable of being converted into N-nitrosamines, hereinafter called 'N-nitrosatable substances', from teats and soothers, made of elastomer or rubber.

Article 2

The teats and soothers referred to in Article 1 must not pass on to release-test liquid (saliva test solution) under the conditions specified in Annex I any N-nitrosamine and N-nitrosatable substance detectable by a validated method which complies with the criteria laid down in Annex II and which can detect the following quantities:

— 0,01 mg in total of N-nitrosamines released/kg (of the parts of teat or soother made of elastomer or rubber),

— 0,1 mg in total of N-nitrosatable substances/kg (of the parts of teat or soother made of elastomer or rubber).

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive as from 1 April 1994. They shall immediately inform the Commission thereof.

(1) OJ No L 40, 11. 2. 1989, p. 38.

Member States shall :

— permit, as from 1 April 1994, the trade in and use of teats and soothers complying with this Directive,

— prohibit, as from 1 April 1995, the trade in and use of teats and soothers which do not comply with this Directive.

2. When Member States adopt the measures referred to in paragraph 1, these shall contain a reference to this Directive or shall be accompanied by such reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 15 March 1993.

For the Commission
Martin BANGEMANN
Member of the Commission

ANNEX I

BASIC RULES FOR DETERMINING THE RELEASE OF N-NITROSAMINES AND N-NITROSATABLE SUBSTANCES

1. **Release-test liquid (saliva test solution)**

To obtain the release-test liquid, dissolve 4,2 g of sodium bicarbonate ($NaHCO_3$), 0,5 g of sodium chloride (NaCl), 0,2 g of potassium carbonate (K_2CO_3) and 30,0 mg of sodium nitrite ($NaNO_2$) in one litre of distilled water or water of equivalent quality. The solution must have a pH value of 9.

2. **Test conditions**

Samples of material obtained from an appropriate number of teats or soothers are immersed in the test-release liquid for 24 hours at a temperature of 40 ± 2 °C.

ANNEX II

CRITERIA APPLICABLE TO THE METHOD FOR DETERMINING THE RELEASE OF N-NITROSAMINES AND N-NITROSATABLE SUBSTANCES

1. The release of N-nitrosamines is determined in one aliquot of each solution obtained according to Annex I. The N-nitrosamines are extracted from the aliquot with nitrosamine-free dichloromethane (DCM) and determined by gas chromatography.

2. The release of N-nitrosatable substances is determined in another aliquot of each solution obtained according to Annex I. The nitrosatable substances are converted into nitrosamines by acidification of the aliquot with hydrochloric acid. Subsequently the nitrosamines are extracted from the solution with DCM and determined by gas chromatography.

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 15 October 1984

on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs

(84/500/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 76/893/EEC of 23 November 1976 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs (1), and in particular Article 3 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas Article 2 of Directive 76/893/EEC provides that materials and articles must not transfer their constituents to foodstuffs in quantities which could endanger human health;

Whereas Article 3 of the same Directive provides that the Council, under the procedure provided for in Article 100 of the Treaty, shall adopt by means of Directives special provisions applicable to certain groups of materials and articles (specific Directives);

Whereas in most of the Member States ceramic articles intended to come into contact with foodstuffs are subject to mandatory provisions for protecting human health which lay down limits for the extractable quantities of lead and cadmium;

Whereas these provisions vary from one Member State to another, thus creating obstacles to the establishment and functioning of the common market;

Whereas these obstacles may be eliminated if the placing of ceramic articles on the Community market is made subject to uniform rules; whereas it is therefore necessary to harmonize the limit values and the test and analysis methods for such articles;

Whereas the appropriate instrument for attaining this objective is a specific Directive within the meaning of Article 3 of Directive 76/893/EEC the general provisions of which also become applicable in this particular case;

Whereas the adaptation to technical progress of certain checking and analysis measures provided for in the Directive is an implementing measure the adoption of which should be entrusted to the Commission in order to simplify and expedite the procedure;

Whereas, in all cases where the Council grants the Commission powers to implement provisions concerning materials and articles intended to come into

(1) OJ No L 340, 9. 12. 1976, p. 19.
(2) OJ No C 95, 28. 4. 1975, p. 41.
(3) OJ No C 263, 17. 11. 1975, p. 66.

contact with foodstuffs, a procedure should be established to ensure close cooperation between the Member States and the Commission in the Standing Committee for Foodstuffs set up by the Council Decision of 13 November 1969,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific Directive within the meaning of Article 3 of Directive 76/893/EEC.

2. This Directive concerns the possible migration of lead and cadmium from ceramic articles which, in their finished state, are intended to come into contact with foodstuffs, or which are in contact with foodstuffs, and are intended for that purpose.

3. 'Ceramic articles' means articles manufactured from a mixture of inorganic materials with a generally high argillaceous or silicate content to which small quantities of organic materials may have been added. These articles are first shaped and the shape thus obtained is permanently fixed by firing. They may be glazed, enamelled and/or decorated.

Article 2

1. The quantities of lead and cadmium transferred from ceramic articles shall not exceed the limits laid down below.

2. The quantities of lead and cadmium transferred from ceramic articles shall be determined by means of a test, the conditions of which are specified in Annex I, using the method of analysis described in Annex II.

3. Where a ceramic article consists of a vessel fitted with a ceramic lid, the lead and/or cadmium limit which may not be exceeded (mg/dm² or mg/litre) shall be that which applies to the vessel alone.

The vessel alone and the inner surface of the lid shall be tested separately and under the same conditions.

The sum of the two lead and/or cadmium extraction levels thus obtained shall be related as appropriate to the surface area or the volume of the vessel alone.

4. A ceramic article shall be recognized as satisfying the requirements of this Directive if the quantities of lead and/or cadmium extracted during the test carried out under the conditions laid down in Annexes I and II do not exceed the following limits:

	Pb	*Cd*
— Category 1: Articles which cannot be filled and articles which can be filled, the internal depth of which, measured from the lowest point to the horizontal plane passing through the upper rim, does not exceed 25 mm	0,8 mg/dm²	0,07 mg/dm²
— Category 2: All other articles which can be filled	4,0 mg/l	0,3 mg/l
— Category 3: Cooking ware; packaging and storage vessels having a capacity of more than three litres	1,5 mg/l	0,1 mg/l

5. However, where a ceramic article does not exceed the above quantities by more than 50 %, that article shall nevertheless be recognized as satisfying the requirements of this Directive if at least three other articles with the same shape, dimensions, decoration and glaze are subjected to a test carried out under the conditions laid down in Annexes I and II and the average quantities of lead and/or cadmium extracted from those articles do not exceed the limits set, with none of those articles exceeding those limits by more than 50 %.

Article 3

The amendments to be made to the Annexes in the light of developments in scientific and technical knowledge, with the exception of sections 1 and 2 of Annex I, shall be adopted in accordance with the procedure laid down in Article 10 of Directive 76/893/EEC.

Article 4

1. Within three years of notification (1) of this Directive, the Council shall determine in accordance with the procedure laid down in Article 100 of the Treaty:

(a) the limitations to be imposed on those areas of ceramic articles with which the mouth is intended to come into contact;

(b) the methods for checking that the limitations provided for in (a) are complied with.

2. Within the same period, the Commission shall, on the basis of toxicological and technological data, re-examine the limits laid down in Article 2, with a view to reducing them, and the lighting conditions for the test specified in Annex I, and shall, if appropriate, submit to the Council proposals for amendments to the Directive.

(1) This Directive was notified to the Member States on 17 October 1984.

Article 5

1. The Member States shall, if necessary, amend their national laws to comply with this Directive so that :

— three years after the notification of this Directive, trade in ceramic articles which comply with its provisions is permitted,

— five years after the notification of this Directive, the placing on the market of ceramic articles which do not comply with its provisions is prohibited.

They shall forthwith inform the Commission of any such amendment.

2. Without prejudice to paragraph 1, Member States may prohibit or continue to prohibit the manufacture of ceramic articles which do not comply with this Directive.

Article 6

This Directive is addressed to the Member States.

Done at Luxembourg, 15 October 1984.

For the Council

The President

J. BRUTON

ANNEX I

BASIC RULES FOR DETERMINING THE MIGRATION OF LEAD AND CADMIUM

1. **Test liquid ('simulant')**

   4 % (v/v) acetic acid, in a freshly prepared aqueous solution.

2. **Test conditions**

2.1. Carry out the test at a temperature of 22 ± 2 °C for a duration of 24 ± 0,5 hours.

2.2. When the migration of lead is to be determined, cover the sample by an appropriate means of protection and expose it to the usual lighting conditions in a laboratory.

When the migration of cadmium or of lead and cadmium is to be determined, cover the sample so as to ensure that the surface to be tested is kept in total darkness.

3. **Filling**

3.1. *Samples which can be filled*

Fill the article with a 4 % (v/v) acetic acid solution to a level no more than 1 mm from the overflow point; the distance is measured from the upper rim of the sample.

Samples with a flat or slightly sloping rim should be filled so that the distance between the surface of the liquid and the overflow point is no more than 6 mm measured along the sloping rim.

3.2. *Samples which cannot be filled*

The surface of the sample which is not intended to come into contact with foodstuffs is first covered with a suitable protective layer able to resist the action of the 4 % (v/v) acetic acid solution. The sample is then immersed in a recipient containing a known volume of acetic acid solution in such a way that the surface intended to come into contact with foodstuffs is completely covered by the test liquid.

4. **Determination of the surface area**

The surface area of the articles in category 1 is equal to the surface area of the meniscus formed by the free liquid surface obtained by complying with the filling requirements set out in section 3 above.

ANNEX II

METHODS OF ANALYSIS FOR DETERMINING THE MIGRATION OF LEAD AND CADMIUM

1. Object and field of application

The method allows the specific migration of lead and/or cadmium to be determined.

2. Principle

The determination of the specific migration of lead and/or cadmium is carried out by atomic absorption spectrophotometry.

3. Reagents

— All reagents must be of analytical quality, unless otherwise specified.

— Where reference is made to water, this always means distilled water or water of equivalent quality.

3.1. *4 % (v/v) acetic acid, in aqueous solution*

Add 40 ml of glacial acetic acid to water and make up to 1 000 ml.

3.2. *Stock solutions*

Prepare stock solutions containing 1 000 mg/litre of lead and at least 500 mg/litre of cadmium respectively in a 4 % acetic acid solution (3.1).

4. Instruments

4.1. *Atomic absorption spectrophotometer*

The instrument's detection limit for lead and cadmium must be equal to or lower than :

— 0,1 mg/litre for lead,

— 0,01 mg/litre for cadmium.

The detection limit is defined as the concentration of the element in 4 % acetic acid (3.1) which gives a signal equal to twice the background noise of the instrument.

5. Method

5.1. *Preparation of the sample*

The sample must be clean and free from grease or other matter likely to affect the test.

Wash the sample in a solution containing a household liquid detergent at a temperature of approximately 40 °C. Rinse the sample first in tapwater and then in distilled water or water of equivalent quality. Drain and dry so as to avoid any stain. The surface to be tested should not be handled after it has been cleaned.

5.2. *Determination of lead and/or cadmium*

— The sample thus prepared is tested under the conditions laid down in Annex I.

— Before taking the test solution for determining lead and/or cadmium, homogenize the content of the sample by an appropriate method which avoids any loss of solution or abrasion of the surface being tested.

— Carry out a blank test on the reagent used for each series of determinations.

— Carry out determinations for lead and/or cadmium under appropriate conditions by atomic absorption spectrophotometry.

FOODSTUFFS FOR PARTICULAR NUTRITIONAL USES

COUNCIL DIRECTIVE

of 3 May 1989

on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses

(89/398/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas Council Directive 77/94/EEC of 21 December 1976 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses (4), as last amended by Directive 85/7/EEC (5), has been amended on a number of occasions; whereas, on the occasion of new amendments, the said Directive should, for reasons of clarity, be redrafted;

Whereas the adoption of Directive 77/94/EEC was justified by the fact that the differences between national laws relating to foodstuffs for particular nutritional uses impeded their free movement, may have created unequal conditions of competion, and thus had a direct impact on the establishment and functioning of the common market;

Whereas the approximation of national laws presupposed, in an initial stage, the drawing-up of a common definition, the determination of measures enabling the consumer to be protected against fraud concerning the nature of these products and the adoption of rules to be complied with in labelling the products in question;

Whereas the products covered by this Directive are foodstuffs the composition and preparation of which must be specially designed to meet the particular nutritional requirements of the persons for whom they are mainly intended; whereas it may be necessary, therefore, to provide for derogations to the general or specific provisions applicable to foodstuffs in order to achieve the specific nutritional objective;

Whereas, although foodstuffs intended for particular nutritional uses which are the subject of specific provisions can be efficiently monitored on the basis of the general rules for monitoring all types of foodstuffs, this is not always the case for those foodstuffs in respect of which no such specific provisions exist;

Whereas for the latter the usual means available to the monitoring bodies might not in certain cases enable them to check whether a foodstuff actually has the particular nutritional properties attributed to it; whereas it is necessary therefore to provide that, where necessary, the person responsible for placing that foodstuff on the market should assist the monitoring body in carrying out its activities;

Whereas the current state of development of Community rules on additives means that it is not possible, in the framework of this Directive, to adopt provisions on the use of additives in foodstuffs intended for particular nutritional uses if they do not belong to one of the groups mentioned in Annex I; whereas this question should therefore be re-examined in due course;

Whereas the drawing-up of specific Directives implementing the basic principles of Community rules and amendments thereto are implementing measures of a technical nature; whereas their adoption should be entrusted to the Commission in order to simplify and expedite the procedure;

Whereas in all cases where the Council empowers the Commission to implement rules relating to foodstuffs intended for human consumption, provision should be made for a procedure establishing close cooperation between the Member States and the Commission within the Standing Committee for Foodstuffs, set up by Decision 69/414/EEC (6);

Whereas this Directive does not affect the time limits within which the Member States must comply with Directive 77/94/EEC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive concerns foodstuffs for particular nutritional uses.

(1) OJ No C 124, 23. 5. 1986, p. 7, and OJ No C 161, 19. 6. 1987, p. 12.
(2) OJ No C 99, 13. 4. 1987, p. 54, and OJ No C 120, 16. 5. 1989.
(3) OJ No C 328, 22. 12. 1986, p. 9.
(4) OJ No L 26, 31. 1. 1977, p. 55.
(5) OJ No L 2, 3. 1. 1985, p. 22.
(6) OJ No L 291, 19. 11. 1969, p. 9.

2. (a) Foodstuffs for particular nutritional uses are foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability.

(b) A particular nutritional use must fulfil the particular nutritional requirements:

(i) of certain categories of persons whose digestive processes or metabolism are disturbed; or

(ii) of certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs; or

(iii) of infants or young children in good health.

Article 2

1. The products referred to in Article 1 (2) (b) (i) and (ii) may be characterized as 'dietetic' or 'dietary'.

2. In the labelling, presentation and advertising of foodstuffs for normal consumption the following shall be prohibited:

(a) the use of the adjectives 'dietetic' or 'dietary' either alone or in conjunction with other words, to designate these foodstuffs;

(b) all other markings or any presentation likely to give the impression that one of the products referred to in Article 1 is involved.

3. However, in accordance with provisions to be adopted according to the procedure provided for in Article 13, it shall be possible for foodstuffs for normal consumption which are suitable for a particular nutritional use to indicate such suitability.

The aforesaid provisions may lay down the arrangements for indicating this suitability.

Article 3

1. The nature or composition of the products referred to in Article 1 must be such that the products are appropriate for the particular nutritional use intended.

2. The products referred to in Article 1 must also comply with any mandatory provisions applicable to foodstuffs for normal consumption, save as regards changes made to them to ensure their conformity with the definitions given in Article 1.

Article 4

1. The specific provisions applicable to the groups of foods for particular nutritional uses appearing in Annex I shall be laid down by means of specific Directives.

Such specific Directives may cover in particular:

(a) essential requirements as to the nature or composition of the products;

(b) provisions regarding the quality of raw materials;

(c) hygiene requirements;

(d) permitted changes within the meaning of Article 3 (2);

(e) a list of additives;

(f) provisions regarding labelling, presentation and advertising;

(g) sampling procedures and methods of analysis necessary for checking compliance with the requirements of the specific Directives.

Such specific Directives shall be adopted:

— in the case of point (e), by the Council acting in accordance with the procedure laid down in Article 100a,

— in the case of the other points, in accordance with the procedure laid down in Article 13.

Provisions likely to have an effect on public health shall be adopted after consultation of the Scientific Committee for Food, set up by Decision 74/234/EEC (1).

2. A list of substances with specific nutritional purposes such as vitamins, mineral salts, amino acids and other substances intended to be added to foodstuffs intended for particular nutritional uses, together with the purity criteria applicable to them, and, where appropriate, the conditions under which they should be used, shall be adopted in accordance with the procedure laid down in Article 13.

Article 5

Conditions under which reference may be made in labelling, presentation and advertising to a diet or to a category of persons for which a product referred to in Article 1 is intended may be adopted in accordance with the procedure laid down in Article 13.

(1) OJ No L 136, 20. 5. 1974, p. 1.

Article 6

1. The labelling and the labelling methods used, the presentation and the advertising of the products referred to in Article 1 must not attribute properties for the prevention, treatment or cure of human disease to such products or imply such properties.

Derogations from the first subparagraph may be provided for in accordance with the procedure laid down in Article 13 in exceptional and clearly defined cases. Derogations may be continued until that procedure has been completed.

2. Paragraph 1 shall not prevent the dissemination of any useful information or recommendations exclusively intended for persons having qualifications in medicine, nutrition or pharmacy.

Article 7

1. Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs [1], as last amended by Directive 89/395/EEC [2], shall apply to the products referred to in Article 1, under the conditions set out below.

2. The designation under which a product is sold shall be accompanied by an indication of its particular nutritional characteristics; however, in the case of the products referred to in Article 1 (2) (b) (iii), this reference shall be replaced by a reference to the purpose for which they are intended.

3. The labelling of products for which no specific Directive has been adopted in accordance with Article 4 must also include:

(a) the particular elements of the qualitative and quantitative composition or the special manufacturing process which gives the product its particular nutritional characteristics;

(b) the available energy value expressed in kilojoules and kilocalories and the carbohydrate, protein and fat content per 100 grams or 100 millilitres of the product as marketed and, where appropriate, per specified quantity of the product as proposed for consumption.

If, however, the energy value is less than 50 kilojoules (12 kilocalories) per 100 grams or 100 millilitres of the product as marketed, these particulars may be replaced either by the words 'energy value less than 50 kilojoules (12 kilocalories) per 100 grams' or by the words 'energy value less than 50 kilojoules (12 kilocalories) per 100 millilitres'.

4. The particular labelling requirements for those products for which a specific Directive has been adopted shall be laid down in that Directive.

Article 8

1. The products referred to in Article 1 shall only be allowed on the retail market in pre-packaged form, and the packaging shall completely cover the products.

2. Member States may, however, permit derogations from these provisions for purposes of the retail trade provided that the product is accompanied by the particulars provided for in Article 7 at the time when it is put on sale.

Article 9

To permit efficient official monitoring of foodstuffs intended for a particular nutritional use which do not belong to one of the groups listed in Annex I the following specific provisions shall apply:

1. When a product as referred to above is placed on the market for the first time the manufacturer or, where a product is manufactured in a third State, the importer, shall notify the competent authority of the Member State where the product is being marketed by forwarding it a model of the label used for the product.

2. Where the same product is subsequently placed on the market in another Member State the manufacturer or, where appropriate, the importer, shall provide the competent authority of that Member State with the same information, together with an indication of the recipient of the first notification.

3. Where necessary, the competent authority shall be empowered to require the manufacturer or, where appropriate, the importer, to produce the scientific work and the data establishing the product's compliance with Article 1 (2) together with the information provided for in Article 7 (3) (a). If such work is contained in a readily available publication, a mere reference to this publication shall suffice.

4. Member States shall communicate to the Commission the identity of the competent authorities within the meaning of this Article and any other useful information on them.

   The Commission shall publish this information in the *Official Journal of the European Communities*.

   Detailed rules for implementing this paragraph may be adopted in accordance with the procedure laid down in Article 13.

5. Four years after notification of this Directive, the Commission shall send the Council a report on the implementation of this Article, if necessary, together with appropriate proposals.

[1] OJ No L 33, 8. 2. 1979, p. 1.
[2] See page 17 of this Official Journal.

Article 10

1. Member States shall not, for reasons related to their composition, manufacturing specifications, presentation or labelling, prohibit or restrict trade in products referred to in Article 1 which comply with this Directive and where appropriate, with Directives adopted in implementation of this Directive.

2. Paragraph 1 shall not affect national provisions which are applicable in the absence of Directives adopted in implementation of this Directive.

Article 11

1. Where a Member State has detailed grounds for establishing that a foodstuff intended for a particular nutritional use which does not belong to one of the groups listed in Annex I does not comply with Article 1 (2) or endangers human health, albeit freely circulating in one or more Member States, that Member State may temporarily suspend or restrict trade in that product within its territory. It shall immediately inform the Commission and the other Member States thereof and give reasons for its decision.

2. The Commission shall examine as soon as possible the grounds adduced by the Member State concerned, consult the Member States within the Standing Committee for Foodstuffs, and shall then deliver its opinion without delay and take appropriate measures.

3. If the Commission considers that the national measure must be dispensed with or modified, it shall initiate the procedure laid down in Article 13 for the adoption of appropriate measures.

Article 12

1. Where a Member State, as a result of new information or of a reassessment of existing information made since one of the specific Directives was adopted, has detailed grounds for establishing that a foodstuff intended for particular nutritional uses endangers human health although it complies with the relevant specific Directive, that Member State may temporarily suspend or restrict application of the provisions in question within its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its Decision.

2. The Commission shall examine as soon as possible the grounds adduced by the Member State concerned and shall consult the Member States within the Standing Committee for Foodstuffs, and shall then deliver its opinion without delay and take appropriate measures.

3. If the Commission considers that amendments to this Directive or to the specific Directives are necessary in order to remedy the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure laid down in Article 13 with a view to adopting those amendments. The Member State which has adopted safeguard measures may in that event retain them until the amendments have been adopted.

Article 13

Where the procedure laid down in this Article is to be followed, the chairman shall refer the matter to the Standing Committee for Foodstuffs, hereinafter referred to as 'the Committee', either on his own initiative or at the request of the representative of a Member State.

The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date on which the matter was referred to it, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 14

Directive 77/94/EEC is hereby repealed.

References to the repealed Directive shall be construed as references to this Directive and are to be read in accordance with the correlation table set out in Annex II.

Article 15

1. Member States shall amend their laws, regulations and administrative provisions in such a way as:

— to permit trade in products complying with this Directive not later than 16 May 1990,

— to prohibit trade in products not complying with this Directive with effect from 16 May 1991.

They shall forthwith inform the Commission thereof.

2. Paragraph 1 shall not affect those national provisions which in the absence of the Directives referred to in Article 4 apply to certain groups of foodstuffs intended for particular nutritional uses.

Article 16

This Directive is addressed to the Member States.

Done at Brussels, 3 May 1989.

For the Council

The President

P. SOLBES

ANNEX I

Groups of foods for particular nutritional uses for which specific provisions will be laid down by specific Directives (1)

1. Infant formulae
2. Follow-up milk and other follow-up foods
3. Baby foods
4. Low-energy and energy-reduced foods intended for weight control
5. Dietary foods for special medical purposes
6. Low-sodium foods, including low-sodium or sodium-free dietary salts
7. Gluten-free foods
8. Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen
9. Foods for persons suffering from carbohydrate-metabolism disorders (diabetes)

(1) It is understood that products already on the market when the Directive is adopted will not be affected by it.

ANNEX II

CORRELATION TABLE

Directive 77/94/EEC	This Directive
Article 1 (1)	Article 1 (1)
Article 1 (2)	Article 2 (2)
Article 1 (3)	—
Article 2 (1)	Article 3 (1)
Article 2 (2) first subparagraph	Article 2 (1)
Article 2 (2) second subparagraph	—
Article 2 (3)	Article 2 (2)
Article 2 (4)	Article 2 (3)
Article 3	Article 3 (2)
—	Article 4
Article 4 (1)	Article 6 (1)
Article 4 (2)	Article 5
Article 4 (3)	Article 6 (2)
Article 5 (1)	Article 7 (1)
Article 5 (2) point (a)	Article 7 (2)
Article 5 (2) points (b) and (c)	Article 7 (3) points (a) and (b)
Article 5 (2) point (d)	—
Article 5 (2) point (e)	Article 7 (4)
Article 5 (3)	—
Article 6	Article 8
—	Article 9
Article 7 (1)	Article 10 (1)
—	Article 10 (2)
Article 7 (2)	—
Article 8	—
—	Article 11
—	Article 12
Article 9	Article 13
Article 10	—
Article 11	—
—	Article 14
Article 12	Article 15
Article 13	Article 16
—	Annex I

COMMISSION

COMMISSION DIRECTIVE
of 14 May 1991
on infant formulae and follow-on formulae

(91/321/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses [1], and in particular Article 4 thereof,

Whereas the essential composition of the products in question must satisfy the nutritional requirements of infants in good health as established by generally accepted scientific data;

Whereas on the basis of these data the essential composition of infant formulae and follow-on formulae manufactured from cows' milk proteins and soya proteins alone or in a mixture can already be defined; whereas the same is not true for preparations based wholly or partly on other sources of protein; whereas for this reason specific rules for such products, if necessary, will therefore have to be adopted at a later date;

Whereas this Directive reflects current knowledge about these products; whereas any modification, to allow innovation based on scientific and technical progress, will be decided by the procedure laid down in Article 13 of Directive 89/398/EEC;

Whereas because of the persons for which these products are intended it will be necessary to lay down microbiological criteria and maximum levels for contaminants; whereas given the complexity of the subject these will have to be adopted at a later stage;

Whereas infant formula is the only processed foodstuff which wholly satisfies the nutritional requirements of infants during the first four to six months of life; whereas in order to safeguard the health of such infants it is necessary to ensure that the only products marketed as suitable for such use during the period would be infant formulae;

Whereas pursuant to Article 7 (1) of Directive 89/398/EEC the products covered by this Directive are subject to the general rules laid down by Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer [2], as last amended by Directive 89/395/EEC [3]; whereas this Directive adopts and expands upon the additions and exceptions to those general rules, where it is appropriate, in order to promote and protect breast-feeding;

Whereas, in particular, the nature and destination of the products covered by this Directive require nutritional labelling for the energy value and principal nutrients they contain; whereas, on the other hand, the method of use must be specified in conformity with Article 3 (1) (8) and Article 10 (2) of Directive 79/112/EEC, in order to prevent inappropriate uses likely to be detrimental to the health of infants;

Whereas, pursuant to Article 2 (2) of Directive 79/112/EEC, and in order to supply objective and scientifically verified information, it is necessary to define the conditions under which claims about the particular composition of an infant formula are authorized;

Whereas, in an effort to provide better protection for the health of infants, the rules of composition, labelling and advertising laid down in this Directive should be in conformity with the principles and the aims of the International Code of Marketing of Breast-Milk Substitutes adopted by the 34th World Health Assembly, bearing in mind the particular legal and factual situations existing in the Community;

[1] OJ No L 186, 30. 6. 1989, p. 27.

[2] OJ No L 33, 8. 2. 1979, p. 1.
[3] OJ No L 186, 30. 6. 1989, p. 17.

Whereas given the important role which information on infant feeding plays in choosing, by pregnant women and mothers of infants, the type of nourishment provided to their children, it is necessary for Member States to take appropriate measures in order that this information ensures an adequate use of the products in question and is not counter to the promotion of breast-feeding;

Whereas this Directive does not concern the conditions of sale of publications specializing in baby care and of scientific publications;

Whereas the Scientific Committee for Food, in accordance with Article 4 of Directive 89/398/EEC, has been consulted on the provisions liable to affect public health;

Whereas issues relating to products intended for export to third countries should be dealt with in a coherent and homogeneous manner in a separate measure;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific Directive within the meaning of Article 4 of Directive 89/398/EEC and lays down compositional and labelling requirements for infant formulae and follow-on formulae intended for use by infants in good health in the Community. It also provides for Member States to give effect to principles and aims of the International Code of Marketing of Breast-Milk Substitutes dealing with marketing, information and responsibilities of health authorities.

2. For the purposes of this Directive,

(a) 'infants' means children under the age of 12 months;

(b) 'young children' means children aged between one and three years;

(c) 'infant formulae' means foodstuffs intended for particular nutritional use by infants during the first four to six months of life and satisfying by themselves the nutritional requirements of this category of persons;

(d) 'follow-on formulae' means foodstuffs intended for particular nutritional use by infants aged over four months and constituting the principal liquid element in a progressively diversified diet of this category of persons.

Article 2

Member States shall ensure that the products referred to in Article 1 (2) (c) and (d) may be marketed within the Community only if they conform to the definitions and rules laid down in this Directive. No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life.

Article 3

1. Infant formulae shall be manufactured from protein sources defined in the Annexes and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants from birth has been established by generally accepted scientific data.

2. Follow-on formulae shall be manufactured from protein sources defined in the Annexes and other food ingredients as the case may be whose suitability for particular nutritional use by infants aged over four months has been established by generally accepted scientific data.

3. The prohibitions and limitations on the use of food ingredients laid down in Annexes I and II shall be observed.

Article 4

1. Infant formulae must comply with the compositional criteria specified in Annex I.

2. Follow-on formulae must comply with the compositional criteria specified in Annex II.

3. In order to make infant formulae and follow-on formulae ready for use, nothing more shall be required, as the case may be, than the addition of water.

Article 5

1. Only the substances listed in Annex III may be used in the manufacture of infant formulae and follow-on formulae in order to satisfy the requirements on:

— mineral substances,

— vitamins,

— amino acids and other nitrogen compounds,

— other substances having a particular nutritional purpose.

The purity criteria for these substances shall be stipulated at a later stage.

2. The provisions relating to the use of additives in the manufacture of infant formulae and follow-on formulae shall be laid down in a Council directive.

Article 6

1. Infant formulae and follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants. Where necessary the maximum levels of any such substance shall be stipulated at a later date.

2. Microbiological criteria shall be established at a later date.

Article 7

1. The name under which the products covered by Article 1 (2) are sold shall be, respectively :

— in English :

'infant formula' and 'follow-on formula',

— in Danish :

'Modermælkserstatning' and 'Tilskudsblanding',

— in German :

'Säuglingsanfangsnahrung' and 'Folgenahrung',

— in Greek :

'Παρασκεύασμα για βρέφη' and 'Παρασκεύασμα δεύτερης βρεφικής ηλικίας',

— in Spanish :

'Preparado para lactentes' and 'Preparado de continuación',

— in French :

'Préparation pour nourrissons' and 'Préparation de suite',

— in Italian :

'Alimento per lattanti' and 'Alimento di proseguimento',

— in Dutch :

'Volledige zuigelingenvoeding' and 'Opvolgzuigelingenvoeding',

— in Portuguese :

'Fórmula para lactentes' and 'Fórmula de transição'.

However, the name of products manufactured entirely from cows' milk proteins, shall be respectively :

— in English :

'Infant milk' and 'follow-on milk',

— in Danish :

'Modermælkserstatning udelukkende baseret på mælk' and 'Tilskudsblanding udelukkende baseret på mælk',

— in German :

'Säuglingsmilchnahrung' and 'Folgemilch',

— in Greek :

'Γάλα για βρέφη' and 'Γάλα δεύτερης βρεφικής ηλικίας',

— in Spanish :

'Leche para lactentes' and 'Leche de continuación',

— in French :

'Lait pour nourrissons' and 'Lait de suite',

— in Italian :

'Latte per lattanti' and 'Latte di proseguimento',

— in Dutch :

'Volledige zuigelingenvoeding op basis van melk' or 'Zuigelingenmelk' and 'Opvolgmelk',

— in Portuguese :

'Leite para lactentes' and 'Leite de transição'.

2. The labelling shall bear, in addition to those provided for in Article 3 of Directive 79/112/EEC, the following mandatory particulars :

(a) in the case of infant formulae, a statement to the effect that the product is suitable for particular nutritional use by infants from birth when they are not breast-fed ;

(b) in the case of infant formulae that do not contain added iron, a statement to the effect that, when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources ;

(c) in the case of follow-on formulae, a statement to the effect that the product is suitable only for particular nutritional use by infants over the age of four months, that it should form only part of a diversified diet and that it is not to be used as a substitute for breast milk during the first four months of life ;

(d) in the case of infant formulae and follow-on formulae, the available energy value, expressed in kJ and kcal, and the content of proteins, lipids and carbohydrates per 100 ml of the product ready for use ;

(e) in the case of infant formulae and follow-on formulae, the average quantity of each mineral substance and of each vitamin mentioned in Annexes I and II respectively, and where applicable of choline, inositol and carnitine, per 100 ml of the product ready for use ;

(f) in the case of infant formulae and follow-on formulae, instructions for appropriate preparation of the product and a warning against the health hazards of inappropriate preparation.

3. The labelling of infant formulae and follow-on formulae shall be designed to provide the necessary information about the appropriate use of the products so as not to discourage breast-feeding. The use of the terms 'humanized', 'maternalized', or similar terms shall be prohibited. The term 'adapted' may only be used in conformity with paragraph 6 and Annex IV, point 1.

4. The labelling of infant formulae shall in addition bear the following mandatory particulars, preceded by the words 'Important Notice' or their equivalent:

(a) a statement concerning the superiority of breast-feeding;

(b) a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care;

5. The labelling of infant formulae shall not include pictures of infants, nor shall it include other pictures or text which may idealize the use of the product. It may, however, have graphic representations for easy identification of the product and for illustrating methods of preparation.

6. The labelling may bear claims concerning the special composition of an infant formula only in the cases listed in Annex IV and in accordance with the conditions laid down therein.

7. The requirements, prohibitions and restrictions referred to in paragraphs 3 to 6 shall also apply to:

(a) the presentation of the products concerned, in particular their shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed;

(b) advertising.

Article 8

1. Advertising of infant formulae shall be restricted to publications specializing in baby care and scientific publications. Member States may further restrict or prohibit such advertising. Such advertisements for infant formulae shall be subject to the conditions laid down in Article 7 (3), (4), (5), (6) and (7) (b) and contain only information of a scientific and factual nature. Such information shall not imply or create a belief that bottle-feeding is equivalent or superior to breast-feeding.

2. There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of infant formula directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.

3. Manufacturers and distributors of infant formulae shall not provide, to the general public or to pregnant women, mothers or members of their families, free or low-priced products, samples or any other promotional gifts, either directly or indirectly via the health care system or health workers.

Article 9

1. Member States shall ensure that objective and consistent information is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition covering the planning, provision, design and dissemination of information and their control.

2. Member States shall ensure that informational and educational materials, whether written or audiovisual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, shall include clear information on all the following points:

(a) the benefits and superiority of breast-feeding;

(b) maternal nutrition and the preparation for and maintenance of breast-feeding;

(c) the possible negative effect on breast-feeding of introducing partial bottle-feeding;

(d) the difficulty of reversing the decision not to breast-feed;

(e) where needed, the proper use of infant formulae, whether manufactured industrially or home-prepared.

When such materials contain information about the use of infant formulae, they shall include the social and financial implications of its use; the health hazards of inappropriate foods or feeding methods, and, in particular, the health hazards of improper use of infant formulae. Such material shall not use any pictures which may idealize the use of infant formulae.

3. Member States shall ensure that donations of informational or educational equipment or materials by manufacturers or distributors shall be made only on request and with the written approval of the appropriate national authority or within guidelines given by that authority for this purpose. Such equipment or materials may bear the donating company's name or logo, but shall not refer to a proprietary brand of infant formulae and shall be distributed only through the health care system.

4. Member States shall ensure that donations or low-price sales of supplies of infant formulae to institutions or organizations, whether for use in the institutions or for distribution outside them, shall only be used by or distributed for infants who have to be fed on infant formulae and only for as long as required by such infants.

Article 10

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive. They shall immediately inform the Commission thereof. Those provisions shall be applied in such a way as to :

— permit trade in products complying with this Directive, by 1 December 1992,

— prohibit trade in products which do not comply with this Directive, with effect from 1 June 1994.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 11

This Directive is addressed to the Member States.

Done at Brussels, 14 May 1991.

For the Commission

Martin BANGEMANN

Vice-President

ANNEX I

ESSENTIAL COMPOSITION OF INFANT FORMULAE WHEN RECONSTITUTED AS INSTRUCTED BY THE MANUFACTURER

NB: The values refer to the product ready for use

1. **Energy**

Minimum	Maximum
250 kJ	315 kJ
(60 kcal/100 ml)	(75 kcal/100 ml)

2. **Proteins**

(Protein content = nitrogen content × 6,38) for cows' milk proteins.

(Protein content = nitrogen content × 6,25) for soya protein isolates.

2.1. *Formulae manufactured from unmodified cows' milk proteins*

Minimum	Maximum
0,56 g/100 kJ	0,7 g/100 kJ
(2,25 g/100 kcal)	(3 g/100 kcal)

The chemical index of the proteins present shall be equal to at least 80 % of that of the reference protein (breast milk, as defined in Annex VI); nevertheless, for calculation purposes, the concentrations of methionine and cystine may be added together.

The 'chemical index' shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein.

2.2 *Formulae manufactured from modified cows' milk proteins (alteration of the casein/whey protein ratio)*

Minimum	Maximum
0,45 g/100 kJ	0,7 g/100 kJ
(1,8 g/100 kcal)	(3 g/100 kcal)

For an equal energy value, the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V).

2.3. *Formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins*

Minimum	Maximum
0,56 g/100 kJ	0,7 g/100 kJ
(2,56 g/100 kcal)	(3 g/100 kcal)

Only soya protein isolates must be used in manufacturing these formulae.

The chemical index shall be equal to at least 80 % of that of the reference protein (breast milk, as defined in Annex VI).

For an equal energy value the formula must contain an available quantity of methionine at least equal to that contained in the reference protein (breast milk, as defined in Annex V).

The L-carnitine content shall be at least equal to 1,8 µmolcs/100 kJ (7,5 µmolcs/100 kcal).

2.4. *In all cases,* the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

3. **Lipids**

Minimum	Maximum
0,8 g/100 kJ	1,5 g/100 kJ
(3,3 g/100 kcal)	(6,5 g/100 kcal)

3.1. The use of the following substances is prohibited:

— sesame seed oil,

— cotton seed oil,

— fats containing more than 8 % trans isomers of fatty acids.

3.2. *Lauric acid*

Minimum	Maximum
—	15 % of the total fat content

3.3. *Myristic acid*

Minimum	Maximum
—	15 % of the total fat content

3.4. *Linoleic acid (in the form of glycerides = linoleates)*

Minimum	Maximum
70 mg/100 kJ (300 mg/100 kcal)	285 mg/100 kJ (1 200 mg/100 kcal)

4. **Carbohydrates**

Minimum	Maximum
1,7 g/100 kJ (7 g/100 kcal)	3,4 g/100 kJ (14 g/100 kcal)

4.1. Only the following carbohydrates may be used :

— lactose,
— maltose,
— sucrose,
— malto-dextrins,
— glucose syrup or dried glucose syrup,
— pre-cooked starch, — gelatinized starch } naturally free of gluten

4.2. *Lactose*

Minimum	Maximum
0,85 g/100 kJ (3,5 g/100 kcal)	— —

This provision does not apply to formulae in which soya proteins represent more than 50 % of the total protein content.

4.3. *Sucrose*

Minimum	Maximum
—	20 % of the total carbohydrate content

4.4 *Pre-cooked starch and/or gelatinied starch*

Minimum	Maximum
—	2 g/100 ml, and 30 % of the total carbohydrate content

5. **Mineral substances**

5.1. *Formulae manufactured from cows' milk proteins*

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Sodium (mg)	5	14	20	60
Potassium (mg)	15	35	60	145
Chloride (mg)	12	29	50	125
Calcium (mg)	12	—	50	—
Phosphorus (mg)	6	22	25	90
Magnesium (mg)	1,2	3,6	5	15
Iron (mg) (1)	0,12	0,36	0,5	1,5
Zinc (mg)	0,12	0,36	0,5	1,5
Copper (µg)	4,8	19	20	80
Iodine (µg)	1,2	—	5	—

(1) Limit applicable to formulae with added iron.

The calcium/phosphorus ratio shall not be less than 1,2 nor greater than 2,0.

5.2. *Formulae manufactured from soya proteins, alone or in a mixture with cows' milk proteins*

All requirements of paragraph 5.1 are applicables except those concerning iron and zinc, which are as follows :

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Iron (mg)	0,25	0,5	1	2
Zinc (mg)	0,18	0,6	0,75	2,4

6. **Vitamins**

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (µg-RE) (1)	14	43	60	180
Vitamin D (µg) (2)	0,25	0,65	1	2,5
Thiamin (µg)	10	—	40	—
Riboflavin (µg)	14	—	60	—
Nicotinamide (µg-EN) (3)	60	—	250	—
Pantothenic acid (µg)	70	—	300	—
Vitamin B_6 (µg)	9	—	35	—
Biotin (µg)	0,4	—	1,5	—
Folic acid (µg)	1	—	4	—
Vitamin B_{12} (µg)	0,025	—	0,1	—
Vitamin C (µg)	1,9	—	8	—
Vitamin K (µg)	1	—	4	—
Vitamin E (mg α-TE) (4)	0,5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,1 mg per 100 available kJ	—	0,5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,5 mg per 100 available kcal	—

(1) RE = all trans retinol equivalent.
(2) In the form of cholecalciferol, of which 10 µg = 400 i.u. of vitamin D.
(3) NE = Niacin equivalent = mg nicotinic acid + mg tryptophan/60.
(4) α-TE = d-α-tocopherol equivalent.

ANNEX II

ESSENTIAL COMPOSITION OF FOLLOW-ON FORMULAE WHEN RECONSTITUTED AS INSTRUCTED BY THE MANUFACTURER

NB: The values refer to the product ready for use

1. **Energy**

Minimum	Maximum
250 kJ/100 ml (60 kcal/100 ml)	335 KJ/100 ml (80 kcal/100 ml)

2. **Proteins**

(Protein content = nitrogen content × 6,38) for cows' milk proteins.

(Protein content = nitrogen content × 6,25) for soya protein isolates.

Minimum	Maximum
0,5 g/100 kJ (2,25 g/100 kcal)	1 g/100 kJ (4,5 g/100 kcal)

The chemical index of the proteins present shall be at least equal to 80 % of that of the reference protein (casein as defined in Annex VI).

The 'chemical index' shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein.

For follow-on forumulae manufactured from soya proteins, alone or in a mixture with cows' milk proteins, only protein isolates from soya may be used.

Amino acids may be added to follow-on formulae for the purpose of improving the nutritional value of the proteins, in the proportions necessary for that purpose.

3. **Lipids**

Minimum	Maximum
0,8 g/100 kJ (3,3 g/100 kcal)	1,5 g/100 kJ (6,5 g/100 kcal)

3.1. The use of the following substances is prohibited:

— sesame seed oil,
— cotton seed oil,
— fats containing more than 8 % trans isomers of fatty acids.

3.2. *Lauric acid*

Minimum	Maximum
—	15 % of the total fat content

3.3. *Myristic acid*

Minimum	Maximum
—	15 % of the total fat content

3.4. Linoleic acid (in the form of glycerides = linoleates)

Minimum	Maximum
70 mg/100 kJ (300 mg/100 kcal): this limit applies only to follow-on formulae containing vegetable oils	—

4. **Carbohydrates**

Minimum	Maximum
1,7 g/100 kJ (7 g/100 kcal)	3,4 g/100 kJ (14 g/100 kcal)

4.1. The use of ingredients containing gluten is prohibited.

4.2. *Lactose*

Minimum	Maximum
0,45 g/100 kJ (1,8 g/100 kcal)	—

This provision does not apply to follow-on formulae in which soya protein isolates represent more than 50 % of the total protein content.

4.3. *Sucrose, fructose, honey*

Minimum	Maximum
—	separately or as a whole : 20 % of the total carbohydrate content

5. **Mineral substances**

5.1.

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Iron (mg)	0,25	0,5	1	2
Iodine (µg)	1,2	—	5	—

5.2. **Zinc**

5.2.1. Follow-on formulae manufactured entirely from cows' milk

Minimum	Maximum
0,12 mg/100 kJ (0,5 mg/100 kcal)	—

5.2.2. Follow-on formulae containing soya protein isolates, or mixed with cows' milk

Minimum	Maximum
0,18 mg/100 kJ (0,75 mg/100 kcal)	—

5.3. **Other mineral substances :**

The concentrations are at least equal to those normally found in cows' milk, reduced, where appropriate, in the same ratio as the protein concentration of the follow-on formulae to that of cows' milk. The typical composition of cows' milk is given, for guidance, in Annex VIII.

5.4. The calcium/phosphorus ratio shall not exceed 2,0.

6. **Vitamins**

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (µg-ER) (1)	14	43	60	180
Vitamin D (µg) (2)	0,25	0,75	1	3
Vitamin C (µg)	1,9	—	8	—
Vitamin E (mg α-TE) (3)	0,5/g polyunsaturated fatty acids expressed al linoleic acid but in no case less than 0,1 mg per 100 available kJ	—	0,5/g polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,5 mg per 100 available kcal	—

(1) RE = all trans retinol equivalent.

(2) In the form of cholecalciferol, of which 10 µg = 400 u.i. of vitamin D.

(3) α-TE = d-α-tocopherol equivalent.

ANNEX III

NUTRITIONAL SUBSTANCES

1. Vitamins

Vitamin	Vitamin formulation
Vitamin A	Retinyl acetate Retinyl palmitate Beta-carotene Retinol
Vitamin D	Vitamin D_2 (ergocalciferol) Vitamin D_3 (cholecalciferol)
Vitamin B_1	Thalmin hydrochloride Thalmin mononitrate
Vitamin B_2	Riboflavin Riboflavin-5'-phosphate, sodium
Niacin	Nictotinamide Nicotinic acid
Vitamin B_6	Pyridoxine hydrochloride Pyridoxine-5'-phosphate
Folate	Folic acid
Pantothenic acid	D-pantothenate, calcium D-pantothenate, sodium Dexpanthenol
Vitamin B_{12}	Cyanocobalamin Hydroxocobalamin
Biotin	D-biotin
Vitamin C	L-ascorbic acid Sodium L-ascorbate Calcium L-ascorbate 6-palmityl-L-ascorbic acid (ascorbyl palmitate) Potassium ascorbate
Vitamin E	D-alpha tocopherol DL-alpha tocopherol D-alpha tocopherol acetate DL-alpha tocopherol acetate
Vitamin K	Phylloquinone (Phytomenadione)

2. Mineral substances

Mineral substances	Permitted salts
Calcium (Ca)	Calcium carbonate Calcium chloride Calcium salts of citric acid Calcium gluconate Calcium glycerophosphate Calcium lactate Calcium salts of orthophosphoric acid Calcium hydroxide

Mineral substances	Permitted salts
Magnesium (Mg)	Magnesium carbonate Magnesium chloride Magnesium oxide Magnesium salts of orthophosphoric acid Magnesium sulphate Magnesium gluconate Magnesium hydroxide Magnesium salts of citric acid
Iron (Fe)	Ferrous citrate Ferrous gluconate Ferrous lactate Ferrous sulphate Ferric ammonium citrate Ferrous fumarate Ferric diphosphate (Ferric pyrophosphate)
Copper (Cu)	Cupric citrate Cupric gluconate Cupric sulphate Copper-lysine complex Cupric carbonate
Iodine (I)	Potassium iodide Sodium iodide Potassium iodate
Zinc (Zn)	Zinc acetate Zinc chloride Zinc lactate Zinc sulphate Zinc citrate Zinc gluconate Zinc oxide
Manganese (Mn)	Manganese carbonate Manganese chloride Manganese citrate Manganese sulphate Manganese gluconate
Sodium (Na)	Sodium bicarbonate Sodium chloride Sodium citrate Sodium gluconate Sodium carbonate Sodium lactate Sodium salts of orthophosphoric acid Sodium hydroxide
Potassium (K)	Potassium bicarbonate Potassium carbonate Potassium chloride Potassium salts of citric acid Potassium gluconate Potassium lactate Potassium salts of orthophosphoric acid Potassium hydroxide

3. Amino acids and other nitrogen compounds

L-arginine and its hydrochloride
L-cystine and its hydrochloride
L-histidine and its hydrochloride
L-isoleucine and its hydrochloride
L-leucine and its hydrochloride
L-cysteine and its hydrochloride
L-cysteine and its hydrochloride
L-methionine
L-phenylalanine
L-threonine
L-tryptophan
L-tyrosine
L-valine
L-carnitine and its hydrochloride
Taurine

4. Others

Choline
Choline chloride
Choline citrate
Choline bitartrate
Inositol

ANNEX IV

COMPOSITIONAL CRITERIA FOR INFANT FORMULAE, WARRANTING A CORRESPONDING CLAIM

Claim related to	Conditions warranting the claim
1. Adapted protein	The protein content is lower than 0,6 g/100 kJ (2,5 g/100 kcal) and the whey protein/casein ratio is not less than 1,0.
2. Low sodium	The sodium content is lower than 9 mg/100 kJ (39 mg/100 kcal).
3. Sucrose free	No sucrose is present.
4. Lactose only	Lactose is the only carbohydrate present.
5. Lactose free	No lactose is present (1).
6. Iron enriched	Iron is added.

(1) When determined by a method the detection limits of which will be established at a later stage.

ANNEX V

ESSENTIAL AND SEMI-ESSENTIAL AMINO ACIDS IN BREAST MILK

For the purpose of this report, the essential and semi-essential amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

	Per 100 kJ (1)	Per 100 kcal
Arginine	16	69
Cystine	6	24
Histidine	11	45
Isoleucine	17	72
Leucine	37	156
Lysine	29	122
Methionine	7	29
Phenylalanine	15	62
Threonine	19	80
Tryptophan	7	30
Tyrosine	14	59
Valine	19	80

(1) 1 kJ = 0,239 kcal.

ANNEX VI

Amino acid composition of casein and breast milk protein

The amino acid composition of casein and breast milk protein :

(g/100 g of protein)

	Casein (1)	Breast milk (1)
Arginine	3,7	3,8
Cystine	0,3	1,3
Histidine	2,9	2,5
Isoleucine	5,4	4,0
Leucine	9,5	8,5
Lysine	8,1	6,7
Methionine	2,8	1,6
Phenylalanine	5,2	3,4
Threonine	4,7	4,4
Tryptophan	1,6	1,7
Tyrosine	5,8	3,2
Valine	6,7	4,5

(1) Amino acid content of foods and biological data on protein. FAO Nutritional Studies, No 24, Rome 1970, items 375 and 383.

ANNEX VII

The mineral elements in cows' milk

As a reference, the contents of mineral elements in cows' milk expressed per 100 g of solids-non-fat and per g of proteins are the following :

	Per 100 g SNF (1)	Per g of proteins
Sodium (mg)	550	15
Potassium (mg)	1 680	43
Chloride (mg)	1 050	28
Calcium (mg)	1 350	35
Phosphorus (mg)	1 070	28
Magnesium (mg)	135	3,5
Copper (µg)	225	6
Iodine	NS (2)	NS

(1) SNF : 'solids-no fats'.

(2) NS : non-specified, varies widely according to season and stock farming conditions.

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE 92/52/EEC

of 18 June 1992

on infant formulae and follow-on formulae intended for export to third countries

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 113 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas Community rules concerning infant formulae and follow-on formulae are laid down by Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses (4) in Commission Directive 91/321/EEC (5);

Whereas given the nature of the products in question it is desirable that Community rules or international standards relating to their composition are made applicable to such products intended for export to third countries;

Whereas in order to prevent inappropriate use of these products which could prejudice the health of infants it is also desirable to extend the application of the Community rules on labelling of infant formulae and follow-on formuale to those products intended for export to third countries;

Whereas the products complying with Directive 91/321/EEC may be marketed in the Community as from 1 December 1992; whereas no legislation prohibits the export of such products to third countries,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive concerns infant formuale and follow-on formulae, as defined by Article 1 (2) (c) and (d) of Directive 91/321/EEC, intended for export to third countries.

Article 2

Member States shall ensure that the products referred to in Article 1 may be exported from the Community only if they comply with this Directive.

Article 3

1. No product other than infant formulae may be represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life.

2. In addition the products referred to in Article 1 must comply:

(a) with Articles 3, 4, 5 and 6 of Directive 91/321/EEC or with relevant applicable world standards established by Codex Alimentarius;

(b) with Article 7 (2) to (6) of Directive 91/321/EEC;

(1) OJ No C 124, 16. 5. 1992, p. 14 and OJ No C 155, 20. 6. 1992, p. 18.
(2) OJ No C 125, 18. 5. 1992.
(3) OJ No C 106, 27. 4. 1992, p. 4.
(4) OJ No L 186, 30. 6. 1989, p. 27.
(5) OJ No L 175, 4. 7. 1991, p. 35.

(c) with the provisions of Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs (1),

unless otherwise requested or stipulated by provisions established by the importing country.

3. These products shall be labelled in an appropriate language and in such a way as to avoid any risk of confusion between infant formulae and follow-on formulae.

4. The stipulations, prohibitions and restrictions laid down in Article 7 (2) to (6) of Directive 91/321/EEC shall also apply to the presentation of the products concerned and in particular their form, aspect or packaging and the packaging materials used.

Article 4

Member States shall take the necessary measures to comply with this Directive. They shall forthwith inform the Commission thereof. Those measures shall be applied in such a way as to prohibit exports of products which do not comply with this Directive, with effect from 1 June 1994.

When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 5

This Directive is addressed to the Member States.

Done at Luxembourg, 18 June 1992.

For the Council

The President

Vitor MARTINS

(1) OJ No L 186, 30. 6. 1989, p. 21. As last amended by Directive 91/238/EEC (OJ No L 107, 27. 4. 1991, p. 50).

SPECIFIC FOODSTUFFS

I

(Acts whose publication is obligatory)

COUNCIL REGULATION (EEC) No 2081/92

of 14 July 1992

on the protection of geographical indications and designations of origin for agricultural products and foodstuffs

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas the production, manufacture and distribution of agricultural products and foodstuffs play an important role in the Community economy;

Whereas, as part of the adjustment of the common agricultural policy the diversification of agricultural production should be encouraged so as to achieve a better balance between supply and demand on the markets; whereas the promotion of products having certain characteristics could be of considerable benefit to the rural economy, in particular to less-favoured or remote areas, by improving the incomes of farmers and by retaining the rural population in these areas;

Whereas, moreover, it has been observed in recent years that consumers are tending to attach greater importance to the quality of foodstuffs rather than to quantity; whereas this quest for specific products generates a growing demand for agricultural products or foodstuffs with an identifiable geographical origin;

Whereas in view of the wide variety of products marketed and of the abundance of information concerning them provided, consumers must, in order to be able to make the best choice, be given clear and succinct information regarding the origin of the product;

Whereas the labelling of agricultural products and foodstuffs is subject to the general rules laid down in Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (4); whereas, in view of their specific nature, additional special provisions should be adopted for agricultural products and foodstuffs from a specified geographical area;

Whereas the desire to protect agricultural products or foodstuffs which have an identifiable geographical origin has led certain Member States to introduce 'registered designations of origin'; whereas these have proved successful with producers, who have secured higher incomes in return for a genuine effort to improve quality, and with consumers, who can purchase high quality products with guarantees as to the method of production and origin;

Whereas, however, there is diversity in the national practices for implementing registered designations or origin and geographical indications; whereas a Community approach should be envisaged; whereas a framework of Community rules on protection will permit the development of geographical indications and designations of origin since, by providing a more uniform approach, such a framework will ensure fair competition between the producers of products bearing such indications and enchance the credibility of the products in the consumers' eyes;

Whereas the planned rules should take account of existing Community legislation on wines and spirit drinks, which provide for a higher level of protection;

(1) OJ No C 30, 6. 2. 1991, p. 9 and OJ No C 69, 18. 3. 1992, p. 15.
(2) OJ No C 326, 16. 12. 1991, p. 35.
(3) OJ No C 269, 14. 10. 1991, p. 62.
(4) OJ No L 33, 8. 2. 1979, p. 1. Last amended by Directive 91/72/EEC (OJ No L 42, 15. 2. 1991, p. 27).

Whereas the scope of this Regulation is limited to certain agricultural products and foodstuffs for which a link between product or foodstuff characteristics and geographical origin exists; whereas, however, this scope could be enlarged to encompass other products or foodstuffs;

Whereas existing practices make it appropriate to define two different types of geographical description, namely protected geographical indications and protected designations of origin;

Whereas an agricultural product or foodstuff bearing such an indication must meet certain conditions set out in a specification;

Whereas to enjoy protection in every Member State geographical indications and designations of origin must be registered at Community level; whereas entry in a register should also provide information to those involved in trade and to consumers;

Whereas the registration procedure should enable any person individually and directly concerned in a Member State to exercise his rights by notifying the Commission of his opposition;

Whereas there should be procedures to permit amendment of the specification, after registration, in the light of technological progress or withdrawal from the register of the geographical indication or designation of origin of an agricultural product or foodstuff if that product or foodstuff ceases to conform to the specification on the basis of which the geographical indication or designation of origin was granted;

Whereas provision should be made for trade with third countries offering equivalent guarantees for the issue and inspection of geographical indications or designations of origin granted on their territory;

Whereas provision should be made for a procedure establishing close cooperation between the Member States and the Commission through a Regulatory Committee set up for that purpose,

HAS ADOPTED THIS REGULATION:

Article 1

1. This Regulation lays down rules on the protection of designations of origin and geographical indications of agricultural products intended for human consumption referred to in Annex II to the Treaty and of the foodstuffs referred to in Annex I to this Regulation and agricultural products listed in Annex II to this Regulation.

However, this Regulation shall not apply to wine products or to spirit drinks.

Annex I may be amended in accordance with the procedure set out in Article 15.

2. This Regulation shall apply without prejudice to other specific Community provisions.

3. Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations (1) shall not apply to the designations of origin and geographical indications covered by this Regulation.

Article 2

1. Community protection of designations of origin and of geographical indications of agricultural products and foodstuffs shall be obtained in accordance with this Regulation.

2. For the purposes of this Regulation:

(a) *designation of origin:* means the name of a region, a specific place or, in exceptional cases, a country, used to describe an agricultural product or a foodstuff:

— originating in that region, specific place or country, and

— the quality or characteristics of which are essentially or exclusively due to a particular geographical environment with its inherent natural and human factors, and the production, processing and preparation of which take place in the defined geographical area;

(b) *geographical indication:* means the name of a region, a specific place or, in exceptional cases, a country, used to describe an agricultural product or a foodstuff:

— originating in that region, specific place or country, and

— which possesses a specific quality, reputation or other characteristics attributable to that geographical origin and the production and/or processing and/or preparation of which take place in the defined geographical area.

3. Certain traditional geographical or non-geographical names designating an agricultural product or a foodstuff originating in a region or a specific place, which fulfil the conditions referred to in the second indent of paragraph 2 (a) shall also be considered as designations of origin.

(1) OJ No L 109, 26. 4. 1983, p. 8. Last amended by Decision 90/230/EEC (OJ No L 128, 18. 5. 1990, p. 15).

4. By way of derogation from Article 2 (a), certain geographical designations shall be treated as designations of origin where the raw materials of the products concerned come from a geographical area larger than or different from the processing area, provided that:

— the production area of the raw materials is limited,

— special conditions for the production of the raw materials exist, and

— there are inspection arrangements to ensure that those conditions are adhered to.

5. For the purposes of paragraph 4, only live animals, meat and milk may be considered as raw materials. Use of other raw materials may be authorized in accordance with the procedure laid down in Article 15.

6. In order to be eligible for the derogation provided for in paragraph 4, the designations in question may be or have already been recognized as designations of origin with national protection by the Member State concerned, or, if no such scheme exists, have a proven, traditional character and an exceptional reputation and renown.

7. In order to be eligible for the derogation provided for in paragraph 4, applications for registration must be lodged within two years of the entry into force of this Regulation.

Article 3

1. Names that have become generic may not be registered.

For the purposes of this Regulation, a 'name that has become generic' means the name of an agricultural product or a foodstuff which, although it relates to the place or the region where this product or foodstuff was originally produced or marketed, has become the common name of an agricultural product or a foodstuff.

To establish whether or not a name has become generic, account shall be taken of all factors, in particular:

— the existing situation in the Member State in which the name originates and in areas of consumption,

— the existing situation in other Member States,

— the relevant national or Community laws.

Where, following the procedure laid down in Articles 6 and 7, an application of registration is rejected because a name has become generic, the Commission shall publish that decision in the *Official Journal of the European Communities.*

2. A name may not be registered as a designation of origin or a geographical indication where it conflicts with the name of a plant variety or an animal breed and as a result is likely to mislead the public as to the true origin of the product.

3. Before the entry into force of this Regulation, the Council, acting by a qualified majority on a proposal from the Commission, shall draw up and publish in the *Official Journal of the European Communities* a non-exhaustive, indicative list of the names of agricultural products or foodstuffs which are within the scope of this Regulation and are regarded under the terms of paragraph 1 as being generic and thus not able to be registered under this Regulation.

Article 4

1. To be eligible to use a protected designation of origin (PDO) or a protected geographical indication (PGI) an agricultural product or foodstuff must comply with a specification.

2. The product specification shall include at least:

(a) the name of the agricultural product or foodstuffs, including the designation of origin or the geographical indication;

(b) a description of the agricultural product or foodstuff including the raw materials, if appropriate, and principal physical, chemical, microbiological and/or organoleptic characteristics of the product or the foodstuff;

(c) the definition of the geographical area and, if appropriate, details indicating compliance with the requirements in Article 2 (4);

(d) evidence that the agricultural product or the foodstuff originates in the geographical area, within the meaning of Article 2 (2) (a) or (b), whichever is applicable;

(e) a description of the method of obtaining the agricultural product or foodstuff and, if appropriate, the authentic and unvarying local methods;

(f) the details bearing out the link with the geographical environment or the geographical origin within the meaning of Article 2 (2) (a) or (b), whichever is applicable;

(g) details of the inspection structures provided for in Article 10;

(h) the specific labelling details relating to the indication PDO or PGI, whichever is applicable, or the equivalent traditional national indications;

(i) any requirements laid down by Community and/or national provisions.

Article 5

1. Only a group or, subject to certain conditions to be laid down in accordance with the procedure provided for in Article 15, a natural or legal person, shall be entitled to apply for registration.

For the purposes of this Article, 'Group' means any association, irrespective of its legal form or composition, of producers and/or processors working with the same agricultural product or foodstuff. Other interested parties may participate in the group.

2. A group or a natural or legal person may apply for registration only in respect of agricultural products or foodstuffs which it produces or obtains within the meaning of Article 2 (2) (a) or (b).

3. The application for registration shall include the product specification referred to in Article 4.

4. The application shall be sent to the Member State in which the geographical area is located.

5. The Member State shall check that the application is justified and shall forward the application, including the product specification referred to in Article 4 and other documents on which it has based its decision, to the Commission, if it considers that it satisfies the requirements of this Regulation.

If the application concerns a name indicating a geographical area situated in another Member State also, that Member State shall be consulted before any decision is taken.

6. Member States shall introduce the laws, regulations and administrative provisions necessary to comply with this Article.

Article 6

1. Within a period of six months the Commission shall verify, by means of a formal investigation, whether the registration application includes all the particulars provided for in Article 4.

The Commission shall inform the Member State concerned of its findings.

2. If, after taking account of paragraph 1, the Commission concludes that the name qualifies for protection, it shall publish in the *Official Journal of the European Communities* the name and address of the applicant, the name of the product, the main points of the application, the references to national provisions governing the preparation, production or manufacture of the product and, if necessary, the grounds for its conclusions.

3. If no statement of objections is notified to the Commission in accordance with Article 7, the name shall be entered in a register kept by the Commission entitled 'Register of protected designations of origin and protected geographical indications', which shall contain the names of the groups and the inspection bodies concerned.

4. The Commission shall publish in the *Official Journal of the European Communities*:

— the names entered in the Register,

— amendments to the Register made in accordance with Article 9 and 11.

5. If, in the light of the investigation provided for in paragraph 1, the Commission concludes that the name does not qualify for protection, it shall decide, in accordance with the procedure provided for in Article 15, not to proceed with the publication provided for in paragraph 2 of this Article.

Before publication as provided for in paragraphs 2 and 4 and registration as provided for in paragraph 3, the Commission may request the opinion of the Committee provided for in Article 15.

Article 7

1. Within six months of the date of publication in the *Official Journal of the European Communities* referred to in Article 6 (2), any Member State may object to the registration.

2. The competent authorities of the Member States shall ensure that all persons who can demonstrate a legitimate economic interest are authorized to consult the application. In addition and in accordance with the existing situation in the Member States, the Member States may provide access to other parties with a legitimate interest.

3. Any legitimately concerned natural or legal person may object to the proposed registration by sending a duly substantiated statement to the competent authority of the Member State in which he resides or is established. The competent authority shall take the necessary measures to consider these comments or objection within the deadlines laid down.

4. A statement of objection shall be admissible only if it:

— either shows non-compliance with the conditions referred to in Article 2,

— or shows that the proposed registration of a name would jeopardize the existence of an entirely or partly identical name or trade mark or the existence of products which are legally on the market at the time of publication of this regulation in the *Official Journal of the European Communities*,

— or indicates the features which demonstrate that the name whose registration is applied for is generic in nature.

5. Where an objection is admissible within the meaning of paragraph 4, the Commission shall ask the Member States concerned to seek agreement among themselves in accordance with their internal procedures within three months. If:

(a) agreement is reached, the Member States in question shall communicate to the Commission all the factors which made agreement possible together with the applicant's opinion and that of the objector. Where there has been no change to the information received under Article 5, the Commission shall proceed in accordance with Article 6 (4). If there has been a change, it shall again initiate the procedure laid down in Article 7;

(b) no agreement is reached, the Commission shall take a decision in accordance with the procedure laid down in Article 15, having regard to traditional fair practice and of the actual likelihood of confusion. Should it decide to proceed with registration, the Commission shall carry out publication in accordance with Article 6 (4).

Article 8

The indications PDO, PGI or equivalent traditional national indications may appear only on agricultural products and foodstuffs that comply with this Regulation.

Article 9

The Member State concerned may request the amendment of a specification, in particular to take account of developments in scientific and technical knowledge or to redefine the geographical area.

The Article 6 procedure shall apply *mutatis mutandis.*

The Commission may, however, decide, under the procedure laid down in Article 15, not to apply the Article 6 procedure in the case of a minor amendment.

Article 10

1. Member States shall ensure that not later than six months after the entry into force of this Regulation inspection structures are in place, the function of which shall be to ensure that agricultural products and foodstuffs bearing a protected name meet the requirements laid down in the specifications.

2. An inspection structure may comprise one or more designated inspection authorities and/or private bodies approved for that purpose by the Member State. Member States shall send the Commission lists of the authorities and/or bodies approved and their respective powers. The Commission shall publish those particulars in the *Official Journal of the European Communities.*

3. Designated inspection authorities and/or approved private bodies must offer adequate guarantees of objectivity and impartiality with regard to all producers or processors subject to their control and have permanently at their disposal the qualified staff and resources necessary to carry out inspection of agricultural products and foodstuffs bearing a protected name.

If an inspection structure uses the services of another body for some inspections, that body must offer the same guarantees. In that event the designated inspection authorities and/or approved private bodies shall, however, continue to be responsible *vis-à-vis* the Member State for all inspections.

As from 1 January 1998, in order to be approved by the Member States for the purpose of this Regulation, private bodies must fulfil the requirements laid down in standard EN 45011 of 26 June 1989.

4. If a designated inspection authority and/or private body in a Member State establishes that an agricultural product or a foodstuff bearing a protected name of origin in that Member State does not meet the criteria of the specification, they shall take the steps necessary to ensure that this Regulation is complied with. They shall inform the Member State of the measures taken in carrying out their inspections. The parties concerned must be notified of all decisions taken.

5. A Member State must withdraw approval from an inspection body where the criteria referred to in paragraphs 2 and 3 are no longer fulfilled. It shall inform the Commission, which shall publish in the *Official Journal of the European Communities* a revised list of approved bodies.

6. The Member States shall adopt the measures necessary to ensure that a producer who complies with this Regulation has access to the inspection system.

7. The costs of inspections provided for under this Regulation shall be borne by the producers using the protected name.

Article 11

1. Any Member State may submit that a condition laid down in the product specification of an agricultural product or foodstuff covered by a protected name has not been met.

2. The Member State referred to in paragraph 1 shall make its submission to the Member State concerned. The Member State concerned shall examine the complaint and inform the other Member State of its findings and of any measures taken.

3. In the event of repeated irregularities and the failure of the Member States concerned to come to an agreement, a duly substantiated application must be sent to the Commission.

4. The Commission shall examine the application by consulting the Member States concerned. Where appropriate, having consulted the committee referred to in Article 15, the Commission shall take the necessary steps. These may include cancellation of the registration.

Article 12

1. Without prejudice to international agreements, this Regulation may apply to an agricultural product or foodstuff from a third country provided that:

— the third country is able to give guarantees identical or equivalent to those referred to in Article 4,

— the third country concerned has inspection arrangements equivalent to those laid down in Article 10,

— the third country concerned is prepared to provide protection equivalent to that available in the Community to corresponding agricultural products for foodstuffs coming from the Community.

2. If a protected name of a third country is identical to a Community protected name, registration shall be granted with due regard for local and traditional usage and the practical risks of confusion.

Use of such names shall be authorized only if the country of origin of the product is clearly and visibly indicated on the label.

Article 13

1. Registered names shall be protected against:

(a) any direct or indirect commercial use of a name registered in respect of products not covered by the registration in so far as those products are comparable to the products registered under that name or insofar as using the name exploits the reputation of the protected name;

(b) any misuse, imitation or evocation, even if the true origin of the product is indicated or if the protected name is translated or accompanied by an expression such as 'style', 'type', 'method', 'as produced in', 'imitation' or similar;

(c) any other false or misleading indication as to the provenance, origin, nature or essential qualities of the product, on the inner or outer packaging, advertising material or documents relating to the product concerned, and the packing of the product in a container liable to convey a false impression as to its origin;

(d) any other practice liable to mislead the public as to the true origin of the product.

Where a registered name contains within it the name of an agricultural product or foodstuff which is considered generic, the use of that generic name on the appropriate agricultural product or foodstuff shall not be considered to be contrary to (a) or (b) in the first subparagraph.

2. However, Member States may maintain national measures authorizing the use of the expressions referred to in paragraph 1 (b) for a period of not more than five years after the date of publication of this Regulation, provided that:

— the products have been marketed legally using such expressions for at least five years before the date of publication of this Regulation,

— the labelling clearly indicates the true origin of the product.

However, this exception may not lead to the marketing of products freely on the territory of a Member State where such expressions are prohibited.

3. Protected names may not become generic.

Article 14

1. Where a designation of origin or geographical indication is registered in accordance with this Regulation, the application for registration of a trade mark corresponding to one of the situations referred to in Article 13 and relating to the same type of product shall be refused, provided that the application for registration of the trade mark was submitted after the date of the publication provided for in Article 6 (2).

Trade marks registered in breach of the first subparagraph shall be declared invalid.

This paragraph shall also apply where the application for registration of a trade mark was lodged before the date of publication of the application for registration provided for in Article 6 (2), provided that that publication occured before the trade mark was registered.

2. With due regard for Community law, use of a trade mark corresponding to one of the situations referred to in Article 13 which was registered in good faith before the date on which application for registration of a designation of origin or geographical indication was lodged may continue notwithstanding the registration of a designation of origin or geographical indication, where there are no grounds for invalidity or revocation of the trade mark as provided respectively by Article 3 (1) (c) and (g) and Article 12 (2) (b) of First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks (1).

3. A designation of origin or geographical indication shall not be registered where, in the light of a trade mark's reputation and renown and the length of time it has been used, registration is liable to mislead the consumer as to the true identity of the product.

Article 15

The Commission shall be assisted by a committee composed of the representatives of the Member States and chaired by the representative of the Commission.

(1) OJ No L 40, 11. 2. 1989, p. 1. Amended by Decision 92/10/EEC (OJ No L 6, 11. 1. 1992, p. 35).

The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 16

Detailed rules for applying this Regulation shall be adopted in accordance with the procedure laid down in Article 15.

Article 17

1. Within six months of the entry into force of the Regulation, Member States shall inform the Commission which of their legally protected names or, in those Member States where there is no protection system, which of their names established by usage they wish to register pursuant to this Regulation.

2. In accordance with the procedure laid down in Article 15, the Commission shall register the names referred to in paragraph 1 which comply with Articles 2 and 4. Article 7 shall not apply. However, generic names shall not be added.

3. Member States may maintain national protection of the names communicated in accordance with paragraph 1 until such time as a decision on registration has been taken.

Article 18

This Regulation shall enter into force twelve months after the date of its publication in the *Official Journal of the European Communities.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 July 1992.

For the Council

The President

J. GUMMER

ANNEX I

Foodstuffs referred to in Article 1 (1)

— Beer,
— Natural mineral waters and spring waters,
— Beverages made from plant extracts,
— Bread, pastry, cakes, confectionery, biscuits and other baker's wares,
— Natural gums and resins.

ANNEX II

Agricultural products referred to in Article 1 (1)

— Hay
— Essential oils.

COMMISSION DECISION

of 21 December 1992

setting up a scientific committee for designations of origin, geographical indications and certificates of specific character

(93/53/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Whereas within the framework of Community protection of designations of origin and geographical indications, registration thereof may involve examining problems concerning the generic nature of a name and the factors to be taken into account when defining the designation of origin and geographical indication for agricultural products and foodstuffs, on the one hand, and the application of criteria regarding fair competition in commercial transactions and the danger of confusing consumers within the meaning of Articles 13 and 14 of Council Regulation (EEC) No 2081/92 [1] in cases where there is a conflict between the designation of origin or geographical indication and the trademark, homonyms or existing products which are legally marketed, on the other hand;

Whereas within the framework of Community protection of certificates of specific character, registration thereof may involve examining problems concerning assessment of the traditional nature of agricultural products and foodstuffs;

Whereas the search for solutions to such problems requires the assistance of highly qualified experts with legal or agricultural backgrounds, and particularly with knowledge of intellectual property rights;

Whereas it is therefore appropriate to set up a scientific committee to assist the Commission,

HAS DECIDED AS FOLLOWS:

Article 1

A scientific committee, hereinafter called 'the Committee', is hereby established to assist the Commission.

Article 2

The task of the Committee shall be to examine, at the request of the Commission, all technical problems relating to the application of Regulation (EEC) No 2081/92 and Council Regulation (EEC) No 2082/92 [2] with regard to the registration of names of agricultural products and foodstuffs and cases of conflict between Member States, in particular:

1. the factors to be taken into account when defining geographical indications and designations of origin and exceptions thereto, particularly exceptional reputation and renown;
2. generic nature;
3. the assessment of traditional nature;
4. the assessment of criteria regarding fair competition in commercial transactions and the risk of confusing consumers in cases of conflict between the designation of origin or geographical indication and the trademark, homonyms or existing products which are legally marketed.

Article 3

1. The members of the Committee shall be appointed by the Commission from among highly-qualified experts with competence in the fields referred to in Article 2.

2. The Committee shall consist of seven members and seven alternate members authorized to participate in the meetings.

Article 4

1. The Committee shall elect a Chairman and a Vice-Chairman from among its members.

They shall be elected on the basis of a simple majority.

2. The Commission shall provide the secretariat of the Committee.

Article 5

The Committee's proceedings shall be valid only when all its members are present. The Committee shall give a favourable opinion when votes in favour exceed votes against. Where votes in favour and against are equal, abstention shall be considered as a vote in favour.

[1] OJ No L 208, 24. 7. 1992, p. 1.

[2] OJ No L 208, 24. 7. 1992, p. 9.

Article 6

1. Members shall be appointed for a term of five years, which term shall be renewable. However, the terms of office of the Chairman and Vice-Chairman shall be of two years. They may not be re-elected immediately after having performed their duties for two consecutive two-year periods. Members shall not be remunerated for their services.

2. Upon the expiry of the period of five years or two years, as the case may be, the members, Chairman and Vice-chairman shall remain in office until they are replaced or their appointments are renewed.

3. Where a member, Chairman or Vice-Chairman is unable to carry out his duties or in the event of his resignation, he shall be replaced for the remaining period of his term of office, in accordance with the procedure provided for in Articles 3 and 4, as the case may be.

Article 7

1. The Committee shall meet at the request of a representative of the Commission.

2. The Commission's representative and officials and other servants of the Commission concerned shall attend the meetings of the Committee.

3. The Commission's representative may invite leading figures with special qualifications in the subjects under study to attend these meetings.

Article 8

1. The proceedings of the Committee shall relate to matters on which the Commission has requested an opinion.

The Commission may specify a period within which such opinion must be delivered.

2. Where the opinion requested is the subject of unanimous agreement by the members of the Committee, they shall establish their joint conclusions. Failing unanimity, the various positions adopted during the proceedings shall be entered in a report drawn up under the responsibility of the Committee's secretariat.

Article 9

Where the Commission's representative informs members of the Committee that the opinion requested relates to a subject of a confidential nature, such members shall be under an obligation not to disclose information which has come to their knowledge through the work of the Committee.

Done at Brussels, 21 December 1992.

For the Commission

Ray MAC SHARRY

Member of the Commission

COUNCIL REGULATION (EEC) No 2082/92

of 14 July 1992

on certificates of specific character for agricultural products and foodstuffs

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas the production, manufacture and distribution of agricultural products and foodstuffs play an important role in the Community economy;

Whereas, in the context of the reorientation of the common agricultural policy, the diversification of agricultural production should be encouraged; whereas the promotion of specific products could be of considerable benefit to the rural economy, particularly in less-favoured or remote areas, both by improving the income of farmers and by retaining the rural population in these areas;

Whereas, in the context of the completion of the internal market in foodstuffs, economic operators should be provided with instruments which enable them to enhance the market value of their products while protecting consumers against improper practices and guaranteeing at the same time fair trade;

Whereas, in accordance with the Council resolution of 9 November 1989 on future priorities for relaunching consumer protection policy (4), account should be taken of increasing consumer demand for greater emphasis on quality and information as regards the nature, method of production and processing of foodstuffs and their special characteristics; whereas, given the diversity of products on the market and the abundance of information concerning them, consumers must, in order to be able to make a better choice, be provided with clear and succinct information regarding the specific characteristics of foodstuffs;

Whereas a voluntary system based on regulatory criteria will help attain these aims; whereas such a system enabling producers to make known the quality of a foodstuff throughout the Community must offer every guarantee so that any references which may be made to it in the trade are substantiated;

Whereas certain producers would like to derive market value from the specific character of agricultural products or foodstuffs because their inherent characteristics distinguish them clearly from similar products or foodstuffs; whereas, in order to protect the consumer, the certified specific character should be subject to inspection;

Whereas, given the specific character of such products or foodstuffs, special provisions should be adopted to supplement the labelling rules laid down in Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (5) and whereas, in particular, an expression and, as appropriate, a Community symbol should be devised to accompany the trade description of such products or foodstuffs informing the consumer that it is a product or foodstuff presenting inspected specific characteristics;

Whereas, to guarantee that agricultural products and foodstuffs consistently possess the certified specific characteristics, groups of producers must themselves define the said characteristics in a product specification but whereas the rules for approving inspection bodies responsible for checking that the product specification is complied with must be uniform throughout the Community;

Whereas, in order not to create unfair conditions of competition, any producer must be able to use either a registered trade description together with details and, where appropriate, a Community symbol or a trade description registered as such, as long as the agricultural product or foodstuff he produces or processes complies with the requirements of the relevant specification and the inspection body he has selected is approved;

Whereas provision should be made for allowing trade with third countries offering equivalent guarantees for the issue and inspection of certificates of specific character in their territory;

Whereas, if they are to be attractive to producers and reliable for consumers, expressions relating to the specific character of an agricultural product or a foodstuff must be granted legal protection and be subject to official inspection;

(1) OJ No C 30, 6. 2. 1991, p. 4 and OJ No C 71, 20. 3. 1992, p. 14.
(2) OJ No C 326, 16. 12. 1991, p. 40.
(3) OJ No C 40, 17. 2. 1992, p. 3.
(4) OJ No C 294, 22. 11. 1989, p. 1.
(5) OJ No L 33, 8. 2. 1979, p. 1. Last amended by Directive 91/72/EEC (OJ N L 42, 15. 2. 1991, p. 27).

Whereas a procedure should be provided for to establish close cooperation between the Member States and the Commission in a regulatory committee set up for the purpose,

HAS ADOPTED THIS REGULATION :

Article 1

1. This Regulation lays down rules under which a Community certificate of specific character may be obtained for :

— agricultural products listed in Annex II to the Treaty and intended for human consumption,

— foodstuffs listed in the Annex to this Regulation.

The Annex may be amended in accordance with the procedure set out in Article 19.

2. This Regulation shall apply without prejudice to other specific Community provisions.

3. Council Directive 83/189/EEC of 28 March 1989 laying down a procedure for the provision of information in the field of technical standards and regulations (1) shall not apply to certificates of specific character which are the subject of this Regulation.

Article 2

For the purposes of this Regulation :

1. 'specific character' shall mean the feature or set of features which distinguishes an agricultural product or a foodstuff clearly from other similar products or foodstuffs belonging to the same category.

   The presentation of an agricultural product or a foodstuff is not regarded as a feature within the meaning of the first subparagraph.

   Specific character may not be restricted to qualitative or quantitative composition or to a mode of production laid down in Community or national legislation, in standards set by standardization bodies or in voluntary standards ; however, this rule shall not apply where the said legislation or standard has been established in order to define the specific character of a product ;

2. 'group' shall mean any association, irrespective of its legal form or composition, of producers and/or processors working with the same agricultural product or foodstuff. Other interested parties may participate in the group ;

3. 'certificate of specific character' shall mean recognition by the Community of the specific character of a product by means of its registration in accordance with this Regulation.

(1) OJ No L 109, 26. 4. 1983, p. 8. Last amended by Decision 90/230/EEC (OJ No L 128, 18. 5. 1990, p. 15).

Article 3

The Commission shall set up and administer a register of certificates of specific character which will list the names of agricultural products and foodstuffs of which the specific character has been recognized at Community level in accordance with this Regulation.

The register shall distinguish between the names referred to in Article 13 (1) and those referred to in Article 13 (2).

Article 4

1. In order to appear in the register referred to in Article 3, an agricultural product or foodstuff must either be produced using traditional raw materials or be characterized by a traditional composition or a mode of production and/or processing reflecting a traditional type of production and/or processing.

2. Registration shall not be permitted in the case of an agricultural product or foodstuff the specific character of which is due :

(a) to its provenance or geographical origin ;

(b) solely to application of a technological innovation.

Article 5

1. To be registered, the name must :

— be specific in itself, or

— express the specific character of the agricultural product or the foodstuff.

2. A name expressing specific character, as referred to in the second indent of paragraph 1, may not be registered if :

— it refers only to claims of a general nature used for a set of agricultural products or foodstuffs, or to those provided for by specific Community legislation,

— it is misleading, such as that, in particular, which refers to an obvious characteristic of the product or does not correspond to the specification or to the consumer's expectations in view of the characteristics of the product.

3. In order to be registered, a specific name as referred to in the first indent of paragraph 1 must be traditional and comply with national provisions or be established by custom.

4. The use of geographical terms shall be authorized in a name not covered by Council Regulation (EEC) No 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs (2).

(2) See p. 1 of this Official Journal.

Article 6

1. In order to qualify for a certificate of specific character, an agricultural product or foodstuff must comply with a product specification.

2. The product specification shall include at least:

— the name within the meaning of Article 5, in one or more languages,

— a description of the method of production, including the nature and characteristics of the raw material and/or ingredients used and/or the method of preparation of the agricultural product or the foodstuff, referring to its specific character,

— aspects allowing appraisal of traditional character, within the meaning of Article 4 (1),

— a description of the characteristics of the agricultural product or the foodstuff giving its main physical, chemical, microbiological and/or organoleptic characteristics which relate to the specific character,

— the minimum requirements and inspection procedures to which specific character is subject.

Article 7

1. Only a group shall be entitled to apply for registration of the specific character of an agricultural product or a foodstuff.

2. The application for registration comprising the product specification shall be submitted to the competent authority of the Member State in which the group is established.

3. The competent authority shall forward the application to the Commission if it considers that the requirements of Articles 4, 5 and 6 are fulfilled.

4. No later than the date of entry into force of this Regulation, Member States shall publish the particulars of the competent authorities which they have designated and shall inform the Commission accordingly.

Article 8

1. The Commission shall forward the translated application for registration to the other Member States within a period of six months from the date of receipt of the application referred to in Article 7 (3).

As soon as the forwarding referred to in the first subparagraph has been carried out, the Commission shall publish in the *Official Journal of the European Communities* the main points of the application forwarded by the competent authority referred to in Article 7 and, in particular, the name of the agricultural product or the foodstuff, as prescribed by the first indent of Article 6 (2), and the applicant's references.

2. The competent authorities of the Member States shall ensure that all persons who can demonstrate a legitimate economic interest are authorized to consult the application referred to in paragraph 1. In addition, and in accordance with the rules in force in the Member States, the said competent authorities may provide access to other parties with a legitimate interest.

3. Within five months of the date of publication referred to in paragraph 1, any natural or legal person legitimately concerned by the registration may object to the intended registration by sending a duly substantiated statement to the competent authorities of the Member State in which that person resides or is established.

4. The competent authorities of the Member States shall adopt the necessary measures to take account of the statement referred to in paragraph 3 within the period laid down. Member States may also submit objections on their own initiative.

Article 9

1. If no objections are notified to the Commission within six months, the Commission shall enter in the register provided for in Article 3 the main points referred to in Article 8 (1) and publish them in the *Official Journal of the European Communities.*

2. If objections are notified, the Commission shall, within three months, ask the Member States concerned to seek agreement between themselves in accordance with their internal procedures within a further period of three months. If:

(a) such agreement is reached, the Member States in question shall notify the Commission of all the factors which enabled that agreement to be reached and the opinions of the applicant and the objector. If the information received pursuant to Article 6 (2) is unchanged, the Commission shall proceed in accordance with paragraph 1 above. Otherwise, it shall again initiate the procedure laid down in Article 8;

(b) no agreement is reached, the Commission shall decide on the registration in accordance with the procedure laid down in Article 19. If a decision is taken to register the specific character, the Commission shall proceed in accordance with paragraph 1 above.

Article 10

1. Any Member State may submit that a criterion laid down in the product specification of an agricultural product or a foodstuff covered by a Community certificate of specific character has ceased to be met.

2. The Member State referred to in paragraph 1 shall make its submission to the Member State concerned. The Member State concerned shall examine the complaint and inform the other Member State of its findings and of any measures taken.

3. In the event of repeated irregularities and the failure of the Member States to come to an agreement, a duly substantiated application must be sent to the Commission.

4. The Commission shall examine the application by consulting the Member States concerned. Where appropriate, the Commission shall take the necessary steps in accordance with the procedure laid down in Article 19. These may include cancellation of the registration.

Article 11

1. A Member State may, at the request of a group established in its territory, apply for an amendment to the product specification.

2. The Commission shall ensure that the request for amendment and the applicant's references are published in the *Official Journal of the European Communities*. Article 8 (2), (3) and (4) shall apply.

The competent authorities of the Member State shall ensure that any producer and/or processor applying the product specification for which an amendment has been requested is informed of the publication.

3. Within three months of the date of the publication provided for in paragraph 2, any producer and/or processor applying the product specification for which an amendment has been requested may exercise his right to preserve the initial product specification by forwarding a statement to the competent authority of the Member State in which he is established, which must forward it to the Commission together with its comments, if appropriate.

4. If no objection or statement as referred to in paragraph 3 is notified to the Commission within four months of the date of publication laid down in paragraph 2, the Commission shall enter the requested amendment in the register provided for in Article 3 and publish it in the *Official Journal of the European Communities*.

5. If an objection or a statement as referred to in paragraph 3 is notified to the Commission, the amendment shall not be registered. In such case the requesting group, referred to in paragraph 1, may apply for a new certificate of specific character in accordance with the procedure laid down in Articles 7 to 9.

Article 12

In accordance with the procedure laid down in Article 19, the Commission may define a Community symbol which may be used in the labelling, presentation and advertising of agricultural products or foodstuffs carrying a Community certificate of specific character in accordance with this Regulation.

Article 13

1. From the date of publication provided for in Article 9 (1), the name referred to in Article 5, together with the indication referred to in Article 15 (1), and, where appropriate, the Community symbol referred to in Article 12, shall be reserved for the agricultural product or the foodstuff corresponding to the published product specification.

2. By way of derogation from paragraph 1, the name alone shall be reserved for the agricultural product or the foodstuff corresponding to the published product specification where :

(a) the group so requested in its application for registration ;

(b) the procedure referred to in Article 9 (2) (b) does not show that use of the name is lawful, recognized and economically significant for similar agricultural products or foodstuffs.

Article 14

1. Member States shall ensure that at the latest six months following the date of entry into force of this Regulation inspection structures are in place, the function of which shall be to ensure that agricultural products and foodstuffs carrying a certificate of specific character meet the criteria laid down in the specifications.

2. An inspection structure may comprise one or more designated inspection authorities and/or private bodies approved for that purpose by the Member State. Member States shall forward to the Commission lists of the authorities and/or bodies approved and their respective powers. The Commission shall publish these particulars in the *Official Journal of the European Communities*.

3. Designated inspection authorities and/or private bodies must offer adequate guarantees of objectivity and impartiality with regard to all producers or processors subject to their control and have permanently at their disposal the qualified staff and resources necessary to carry out inspections of agricultural products and foodstuffs covered by a Community certificate of specific character.

If an inspection structure uses the services of another body for some inspections, that body must offer the same guarantees. However, the designated inspection authorities and/or approved private bodies shall continue to be responsible *vis-à-vis* the Member State for all inspections.

As from 1 January 1998, in order to be approved by a Member State for the purpose of this Regulation, bodies must fulfil the requirements laid down in standard EN 45011 of 26 June 1989.

4. If a Member State's designated inspection authority and/or private body establishes that an agricultural product or a foodstuff carrying a certificate of specific character issued by that Member State does not meet the criteria of the specification, it shall take the steps necessary to ensure that this Regulation is complied with. It shall inform the Member State of the measures taken in carrying out its inspections. The parties concerned must be notified of all decisions taken.

5. A Member State must withdraw approval from an inspection body where the criteria referred to in paragraphs 2 and 3 are no longer fulfilled. It shall inform the Commission, which shall publish in the *Official Journal of the European Communities* a revised list of approved bodies.

6. Member States shall adopt the measures necessary to ensure that a producer who complies with this Regulation has access to the inspection system.

7. The costs of the inspections provided for by this Regulation shall be borne by the users of the certificate of specific character.

Article 15

1. The following may be used only by producers complying with the registered product specification :

— an indication to be determined in accordance with the procedure laid down in Article 19,

— where appropriate, the Community symbol, and,

— subject to Article 13 (2), the registered name.

2. A producer using, for the first time after registration, a name reserved pursuant to Article 13 (1) or (2), even if he belongs to the group making the original application, shall in due course notify a designated inspection authority or body of the Member State in which he is established thereof.

3. The designated inspection authority or body shall ensure that the producer complies with the published information before the product is placed on the market.

Article 16

Without prejudice to international agreements, this Regulation shall apply to agricultural products and foodstuffs coming from a third country, on condition that the third country :

— is able to provide guarantees identical or equivalent to those referred to in Articles 4 and 6,

— has inspection arrangements equivalent to those defined in Article 14,

— is prepared to give protection equivalent to that available in the Community to corresponding agricultural products or foodstuffs coming from the Community and covered by a Community certificate of specific character.

Article 17

1. Member States shall take the necessary measures to ensure legal protection against any misuse or misleading use of the term referred to in Article 15 (1) and, where applicable, of the Community symbol referred to in Article 12 and against any imitation of names registered and reserved pursuant to Article 13.

2. Registered names shall be protected against any practice liable to mislead the public including, *inter alia*, practices suggesting that the agricultural product or foodstuff is covered by a certificate of specific character issued by the Community.

3. Member States shall inform the Commission and the other Member States of the measures taken.

Article 18

Member States shall take all appropriate measures to ensure that sales descriptions used at national level do not give rise to confusion with names registered and reserved pursuant to Article 13 (2).

Article 19

The Commission shall be assisted by a committee composed of the representatives of the Member States and chaired by the representative of the Commission.

The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 20

Detailed rules for applying this Regulation shall be adopted in accordance with the procedure laid down in Article 19.

Article 21

Within five years of the date on which this Regulation enters into force, the Commission shall submit to the Council a report on the application of the Regulation, together with any appropriate proposals.

The report shall cover, in particular, the consequences of applying Articles 9 and 13.

Article 22

This Regulation shall enter into force twelve months after its publication in the *Official Journal of the European Communities.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 July 1992.

For the Council

The President

J. GUMMER

ANNEX

Foodstuffs referred to in Article 1 (1)

— Beer,
— Chocolate and other food preparations containing cocoa,
— Confectionery, bread, pastry, cakes, biscuits and other baker's wares,
— Pasta, whether or not cooked or stuffed,
— Pre-cooked meals,
— Prepared condiment sauces,
— Soups or broths,
— Beverages made from plant extracts,
— Ice-cream and sorbets.

CONTROL AND HYGIENE OF FOODSTUFFS

COUNCIL DIRECTIVE

of 14 June 1989

on the official control of foodstuffs

(89/397/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas trade in foodstuffs is one of the most important aspects of the common market; whereas all the Member States must endeavour to protect the health and economic interests of their citizens; whereas the protection of health must be given unconditional priority and whereas, therefore, official control of foodstuffs must be harmonized and made more effective;

Whereas, however, the differences between national legislations with respect to this type of control are such as to represent barriers to the free movement of goods;

Whereas it is therefore necessary to approximate these legislations;

Whereas, first of all, the general principles governing the carrying-out of such control must be harmonized;

Whereas specific provisions, in addition to the general principles, may, if necessary, be adopted subsequently;

Whereas the subject of this Directive is verification of the compliance of foodstuffs with legislation on foodstuffs; whereas such legislation contains provisions on health, rules on composition and rules on quality designed to protect consumers' economic interests as well as provisions on consumer information and fair commercial transactions;

Whereas, at the same time as foodstuffs, materials and articles intended to come into contact with such foodstuffs should be controlled;

Whereas for the purposes of the completion of the internal market, foodstuffs intended to cross intra-Community frontiers must be inspected with the same care as those intended for marketing in the Member State of production;

Whereas inspection must therefore be based in principle on the provisions in force in the Member State of production; whereas, however, such a principle should not apply where it has been established to the the satisfaction of the inspecting authority by appropriate means, including the submission of commercial documents, that the product in question is intended for consignment to another Member State and that it complies with the provisions in force in that Member State;

Whereas, to be effective, inspections must be carried out regularly; whereas they must not be limited as to the subject, stage or moment at which it is convenient to carry them out, and whereas they must take the most suitable forms to guarantee their effectiveness;

Whereas in order to ensure that inspection procedures are not evaded, it is necessary to provide that Member States shall not exclude a product from appropriate inspection on the grounds that it is intended for export outside the Community;

Whereas the inspectors must be granted adequate powers;

Whereas although, on the one hand, undertakings should not have the right to oppose the inspections, on the other hand their legitimate rights must be preserved, in particular the right to manufacturing secrecy and the right of appeal;

Whereas the authorities made responsible for the control of foodstuffs may differ from one Member State to another; whereas it is, therefore, desirable to publish a list of the competent authorities in the field in each Member State, with an indication of the territories for which they are competent, and approved laboratories for the analyses to be carried out in connection with such control;

Whereas official controls should contribute effectively to the prevention of food law infringements; whereas to that end programmes should be drawn up on the basis of appropriate criteria;

Whereas, although it is primarily for Member States to lay down their inspection programmes, it is necessary, with a view to the completion and operation of the internal market, to arrange also for coordinated programmes at Community level;

Whereas simultaneous implementation of national programmes and coordinated programmes will provide

(1) OJ No C 20, 27. 1. 1987, p. 6, OJ No C 88, 5. 4. 1987, p. 14, and OJ No C 131, 27. 5. 1989, p. 6.
(2) OJ No C 345, 21. 12. 1987, p. 80, and OJ No C 120, 16. 5. 1989.
(3) OJ No C 347, 22. 12. 1987, p. 1.

experience which is still widely lacking at present; whereas, in the light of that experience, it may prove necessary to revise this Directive to improve the arrangements which it introduces;

Whereas Member States should be allowed a certain degree of freedom as to the practical means of carrying out inspections so as not to interfere with systems of proven worth which are best suited to the particular situation in each Member State,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive lays down the general principles for the performance of official control of foodstuffs.

2. For the purposes of this Directive 'official control of foodstuffs' — hereinafter called 'control' — means an inspection by the competent authorities of the compliance:

— of foodstuffs,

— of food additives, vitamins, mineral salts, trace elements and other additives intended to be sold as such,

— of materials and articles intended to come into contact with foodstuffs,

with provisions aimed at preventing risks to public health, guaranteeing fair commercial transactions or protecting consumer interests, including provisions on consumer information.

3. This Directive shall apply without prejudice to the provisions adopted in the context of more specific Community rules.

4. This Directive shall not apply to metrological control.

Article 2

1. Member States shall take all necessary measures to ensure that control is carried out in accordance with this Directive.

2. Member States shall ensure that products intended for consignment to another Member State are inspected with the same care as those intended for marketing on their own territory.

Article 3

Member States shall not exclude a product from appropriate control on the grounds that it is intended for export outside the Community.

Article 4

1. Inspections shall be carried out:

(a) regularly;

(b) where non-compliance is suspected.

2. Inspections shall be carried out using means proportionate to the end to be observed.

3. Inspection shall cover all stages of production, manufacture, import into the Community, processing, storage, transport, distribution and trade.

4. As a general rule, inspections shall be carried out without prior warning.

5. As a general rule, inspections shall, in each case, select the stage or stages which it considers the most appropriate for its examination from those listed in paragraph 3.

Article 5

Control shall comprise one or more of the following operations in accordance with the conditions laid down in Articles 6 to 9 and in the light of the examination to be carried out:

1. inspection;

2. sampling and analysis;

3. inspection of staff hygiene;

4. examination of written and documentary material;

5. examination of any verification systems set up by the undertaking and of the results obtained.

Article 6

1. The following shall be subject to inspection:

(a) the state and use which is made at the different stages enumerated in Article 4 (3) of the site, premises, offices, plant surroundings, means of transport, machinery and equipment;

(b) raw materials, ingredients, technological aids and other products used for the preparation and production of foodstuffs;

(c) semi-finished products;

(d) finished products;

(e) materials and articles intended to come into contact with foodstuffs;

(f) cleaning and maintenance products and processes and pesticides;

(g) processes used for the manufacture or processing of foodstuffs;

(h) labelling and presentation of foodstuffs;

(i) preserving methods.

2. The operations enumerated in paragraph 1 may, where necessary, be supplemented by:

— interviews with the head of the inspected undertaking and with persons working for that undertaking,

— the reading of values recorded by measuring instruments installed by the undertaking,

— inspections carried out by the competent authority, with its own instruments, of measurements taken with the instruments installed by the undertaking.

Article 7

1. Samples of the products enumerated in Article 6 (1) (b) to (f) may be taken for the purposes of analysis.

Member States shall take the necessary steps to ensure that those subject to inspection may apply for a second opinion.

2. The analyses shall be carried out by official laboratories.

Member States may also empower other laboratories to carry out these analyses.

Article 8

Persons who, in the exercise of their activity, come into contact, whether directly or indirectly, with the materials and products referred to in Article 6 (1) (b) to (f) shall be subject to the hygiene inspection referred to in Article 5 (3).

The purpose of this inspection shall be to check that the health standards concerning personal cleanliness and clothing are respected. It shall be carried out without prejudice to medical examinations.

Article 9

1. Inspectors may take note of written and documentary material held by the natural and legal persons at the various stages enumerated in Article 4 (3).

2. Inspectors may also make copies or take extracts of written and documentary material submitted to them for examination.

Article 10

Where inspectors discover or suspect an irregularity, they shall take the requisite measures.

Article 11

1. Member States shall ensure that inspectors have the right to carry out the operations provided for in Articles 6 to 10.

2. Member States shall prescribe that the natural and legal persons concerned shall be obliged to undergo any inspection carried out in accordance with this Directive and to assist inspectors in the accomplishment of their tasks.

Article 12

1. Member States shall take the measures necessary to ensure that natural and legal persons concerned by the inspection have a right of appeal against measures taken by the competent authority for the purpose of inspection.

2. They shall prescribe that inspectors shall be bound by professional secrecy.

Article 13

In order to ensure that the application of this Directive is uniform throughout the Member States, the Commission shall, within one year of its adoption, make a report to the European Parliament and to the Council on:

(a) the current standard of training provision for food inspectors in the Member States;

(b) the possibility of establishing Community provisions on what should constitute the basic and further training of inspectors;

(c) the possibility of establishing Community quality standards for all laboratories involved in inspection and sampling under this Directive;

(d) the possibility of establishing a Community inspection service, including opportunities for all institutions and persons involved in the inspections to exchange information.

Article 14

1. The competent authority or authorities of the Member States shall draw up forward programmes laying down the nature and frequency of the inspections to be carried out regularly in accordance with Article 4 (1) (a) over a specific period.

2. By 1 May of each year the Member States shall send to the Commission all the necessary information on implementation during the previous year of the programmes referred to in paragraph 1, specifying:

— the criteria applied in drawing up these programmes,

— the number and type of inspections carried out,

— the number and type of infringements established.

3. By 16 October of each year, and for the first time in 1991, the Commission shall transmit to the Member States, after having consulted them within the framework of the Standing Committee for Foodstuffs, a recommendation concerning a coordinated programme of inspections for the following year. This recommendation may be subsequently adjusted as required during implementation of the coordinated programme.

The coordinated programme shall set out in particular the priority criteria to be applied in its implementation.

The information provided for in paragraph 2 shall contain a special, separate section on implementation of the coordinated programme.

4. Five years after notification of this Directive the Commission shall transmit to the Council a report on the application of this Article, accompanied, if necessary, by any appropriate proposals.

Article 15

Each Member State shall communicate to the Commission the names of:

— the competent authority or authorities and the extent of their territorial responsibility and functions,

— the official laboratories or laboratories authorized by the competent authorities, which are responsible for carrying out analyses in connection with the control.

These lists shall be published in the 'C' series of the *Official Journal of the European Communities*.

Article 16

Member States shall adopt and publish, not later than 12 months after notification of this Directive, the laws, regulations and administrative provisions necessary to comply with this Directive not later than 24 months after its notification (1). They shall forthwith inform the Commission thereof.

Article 17

This Directive is addressed to the Member States.

Done at Luxembourg, 4 June 1989.

For the Council
The President
P. SOLBES

(1) This Directive was notified to the Member States on 20 June 1989.

COUNCIL DIRECTIVE 93/99/EEC

of 29 October 1993

on the subject of additional measures concerning the official control of foodstuffs

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having reagard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas it is necessary to adopt measures in the context of the internal market; whereas the internal market comprises an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

Whereas trade in foodstuffs occupies a very important place in the internal market;

Whereas it is therefore essential that the application of Council directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs (4) is uniform throughout the Member States; whereas this Directive lays down general rules on the official control of foodstuffs;

Whereas there is a need for additional rules designed to improve the control procedures in force in the Community;

Whereas Member States should take the necessary action to ensure that the staff of the competent authorities have sufficient technical and administrative competence;

Whereas, in order to guarentee the quality of the test data, a system of quality standards should be introduced for laboratories entrusted by the Member States with the official control of foodstuffs; whereas such a system should comply with generally accepted and standardized norms; whereas, in addition, it is essential that these laboratories use validated methods of analysis, whenever possible;

Whereas the development of trade in foodstuffs between the various Member States necessitates closer cooperation between the authorities involved in the control of foodstuffs;

Whereas general rules are required for the Commission officials specialized in the control of foodstuffs who cooperate with specific officials of the Member States in order to ensure the uniform application of legislation on foodstuffs;

Whereas provisions should be laid down under which the national authorities and the Commission must provide mutual administrative assistance with a view to ensuring proper application of the legislation on foodstuffs, in particular through preventive action and the detection of infringements or behaviour suspected of infringing the rules;

Whereas, in view of the nature of the information exchanged pursuant to this Directive, it should be covered by the requirements of commercial or professional secrecy;

Whereas a procedure should be provided for to establish close cooperation between the Member States and the Commission,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive supplements Directive 89/397/EEC.

2. For the purposes of this Directive, the provisions of Article 1 (2), (3) and (4) of Directive 89/397/EEC apply.

Article 2

Member States shall ensure that the competent authorities have, or have access to, a sufficient number of suitably qualified and experienced staff, in particular in areas such as chemistry, food chemistry, veterinary medicine, medicine, food microbiology, food hygiene, food technology and law so that the controls referred to in Article 5 of Directive 89/397/EEC can be carried out adequately.

Article 3

1. Member States shall take all measures necessary to ensure that the laboratories referred to in Article 7 of

(1) OJ No C 51, 26. 2. 1992, p. 20.
(2) OJ No C 337, 21. 12. 1992, p. 143 and Decision of 27. October 1993 (not yet published in the Official Journal).
(3) OJ No C 332, 16. 12. 1992, p. 5.
(4) OJ No L 186, 30. 6. 1989, p. 23.

Directive 89/397/EEC comply with the general criteria for the operation of testing laboratories laid down in European Standard EN 45001 supplemented by standard operating procedures and the random audit of their compliance by quality assurance personnel, in accordance with the OECD principles No 2 and 7 of good laboratory practice as set out in Section II of Annex 2 to the Decision of the Council of the OECD of 12 May 1981 concerning the mutual acceptance of data in the assessment of chemicals.

2. In assessing the laboratories referred to in Article 7 of Directive 89/397/EEC, Member States shall:

(a) apply the criteria laid down in European Standard EN 45002; and

(b) require the use of proficiency testing schemes as far as appropriate.

Laboratories meeting the assessment criteria shall be presumed to fulfil the criteria referred to in paragraph 1.

Laboratories which do not meet the assessment criteria shall not be considered as laboratories referred to in Article 7 of the said Directive.

3. Member States shall designate bodies responsible for the assessment of laboratories as referred to in Article 7 of Directive 89/397/EEC. These bodies shall comply with the general criteria for laboratory accreditation bodies laid down in European Standard EN 45003.

4. The accreditation and assessment of testing laboratories referred to in this Article may relate to individual tests or groups of tests. Any appropriate deviation in the way in which the standards referred to in paragraphs 1, 2 and 3 are applied shall be adopted in accordance with the procedure laid down in Article 8.

Article 4

Member States shall ensure that the validation of methods of analysis used within the context of official control of foodstuffs by the laboratories referred to in Article 7 of Directive 89/397/EEC comply whenever possible with the provisions of paragraphs 1 and 2 of the Annex to Council Directive 85/591/EEC of 23 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption (1).

Article 5

1. The Commission shall appoint and designate specific officials to cooperate with the competent authorities of the Member States to monitor and evaluate the equivalence and effectiveness of official food control systems operated by the competent authorities of the Member States. The Commission shall send regular reports to the Member States concerned on the work of its specific officials.

The Commission shall ensure that such officials are suitably qualified and possess the appropriate knowledge and experience to carry out this task; detailed rules of application may be adopted in accordance with the procedure laid down in Article 8.

The competent authorities of the Member States shall cooperate with the Commission's designated officials and give all the necessary assistance to enable them to accomplish their tasks.

2. In pursuante of the duties set out in paragraph 1, Member States shall permit the Commission's designated officials to accompany the officials of their competent authorities carrying out the operations provided for in Article 5 of Directive 89/397/EEC. In any event, the officials of the competent authorities of the Member States shall remain responsible for the carrying out of the control operations.

The Commission shall give Member States at least five working days' notice before the start of these operations. After the execution of each operation referred to in this paragraph the Commission shall forward a report on the work of its specific officials to the Member States concerned.

For the purpose of the operations referred to in this paragraph, the Commission's designated officials shall produce written authorization specifying their identity and status.

The Commission's designated officials shall comply with the rules and practices which officials of the competent authorities of the Member States must follow.

3. The Commission shall present an annual report to the Member States and to the European Parliament on the implementation of this Article.

Article 6

1. The competent authorities of the Member States shall afford each other administrative assistance in all supervisory procedures in connection with legal provisions and quality standards applicable to foodstuffs and in all proceedings for infringements of the law applicable to foodstuffs.

2. To facilitate this administrative assistance each Member State shall designate a single liaison body. It shall be for the body designated by the Member State to liaise as appropriate with the liaison bodies of other Member States. The role of the bodies shall be to assist

(1) OJ No L 372, 31. 12. 1985, p. 50.

and coordinate communication and, in particular, the transmission and reception of requests for assistance.

3. Member States shall inform the Commission of all the relevant details of their designated liaison body. The list of designated liaison bodies and the relevant details shall be published in the 'C' series of the *Official Journal of the European Communities.*

4. Upon receiving a reasoned request, the body concerned shall be responsible for ensuring that the requesting body is provided with all necessary information, except that which cannot be released because it is the subject of legal proceedings, enabling that body to guarantee compliance with legal provisions and quality standards applicable to foodstuffs within its jurisdiction.

5. The information and documents provided pursuant to paragraph 4 shall be forwarded without undue delay either through the liaison body or directly, as appropriate. When original documents cannot be sent, copies of the documents may be transmitted.

6. When, during the exchange of information, it becomes clear that there may have been a case of non-compliance of Community laws or rules or national law of either the receiving Member State or the sending Member State, the competent authority in the Member State in whose territory the alleged non-compliance has taken place shall in due time report back to the competent authority in the other Member State

— on any action that may have been undertaken to deal with the alleged non-compliance, and also

— on any action which has taken, including any action to try to prevent a reoccurrence of the alleged non-compliance.

Such a report may also be copied to the Commission on the initiative of either the transmitting or the receiving Member State.

7. This Article shall apply without prejudice to Council Decision 89/45/EEC of 21 December 1988 on dangers arising from the use of consumer products (1) and Council Directive 92/59/EEC on general product safety (2).

Article 7

1. Information forwarded pursuant to Article 6 of this Directive, in whatever form, is covered by professional secrecy. In criminal proceedings, the information can be used only with the prior consent of the sending Member State in accordance with, for those Member States who are parties to them, the international conventions and agreements in force on mutual assistance in criminal affairs.

2. Where a Member State has rules permitting free access by persons to information held by competent authorities, this fact must be revealed at the time of the request to another Member State or during the exchange of information if no such request occurs. If the sending Member State indicates that the information involves matters of professional or commercial secrecy, the receiving Member State shall ensure that the information is not divulged more widely than is provided under paragraph 1. If it is not possible for the receiving Member State to restrict the giving out of the information in this way, it shall not be contrary to the terms of this Directive for the sending Member State to withhold the information.

3. Any refusal to provide information according to the provisions of this Article must be justified.

Article 8

1. Where the procedure laid down in this Article is to be followed, the Commission shall be assisted by the Standing Committee for Foodstuffs, set up under Decision 69/414/EEC (3), hereinafter referred to as the Committee.

2. The Chairman shall refer the matter to the Committee either on his own initiative or at the request of the representative of a Member State.

3. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representative of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

(1) OJ No L 17, 21. 1. 1989, p. 51. Decision as amended by Decision 90/352/EEC (OJ No L 173, 6. 7. 1990, p. 49).

(2) OJ No L 228, 11. 8. 1992, p. 24.

(3) OJ No L 291, 19. 11. 1969, p. 9.

4. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

(b) If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 9

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply

— with this Directive, except for Article 3, before 1 May 1995,

— with Article 3 before 1 November 1998.

They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field governed by this Directive.

Article 10

This Directive is addressed to the Member States.

Done at Brussels, 29 October 1993.

For the Council

The President

R. URBAIN

COMMISSION RECOMMENDATION

of 11 March 1994

concerning a coordinated programme for the official control of foodstuffs for 1994

(94/175/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular the second indent of Article 155 thereof,

Having regard to Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs (1), and in particular Article 14 (3) thereof,

After consultation with the Standing Committee for Foodstuffs,

Whereas it is necessary, with a view to the sound operation of the internal market, to arrange for coordinated food inspection programmes at Community level;

Whereas such programmes should not only establish compliance with the Community legislation but also serve for checking that the food is fit for consumption;

Whereas simultaneous implementation of national programmes and coordinated programmes can provide experience which is still widely lacking at present,

HEREBY RECOMMENDS THAT THE MEMBER STATES TAKE SAMPLES OF THE FOLLOWING PRODUCTS AND ANALYSE THE SPECIFIED PARAMETERS IN 1994:

1. Aflatoxine B 1 in products liable to contain aflatoxin B 1, especially those intended for children.
2. *Lysteria monocytogenes* in meat-based patés, sold in the retail sector.
3. Adulteration of frozen, fish-based products.
4. Adulteration of goat's and sheep's cheese.

Explanatory memorandum of the coordinated programme of inspections for 1994

In 1994 the coordinated programme of inspections provided for by Article 14 (3) of Directive 89/397/EEC will be carried out for the second time. At the request of the Member States, the Commission has spent ample time discussing the 1994 programme with the technical experts of the Member States.

Like last year, the subjects chosen cover existing Community problems relating to the protection of public health and consumer interests, as well as fair trade.

In order not to overburden the budget for laboratory costs in certain Member States, the Commission decided to limit the number of subjects this year to four.

Each subject is accompanied by a suggested method of anlaysis. As far as sampling is concerned, no uniform rates have been set. The number of samples taken should be extensive enough to provide an overview of the market in the foodstuffs concerned in each Member State.

The number of samples and the methods of analysis used should be mentioned or described briefly on the answer sheets annexed hereto.

I. Aflatoxine B 1 in products liable to contain aflatoxin B 1, especially those intended for children

Aflatoxine B 1 is a carcinogenic toxin, formed by the fungi *Aspergillus flavus* and *Aspergillus parasiticus*. The objective of this analysis is to determine the content of this toxin in products liable to contain aflatoxin B 1, especially those intended for children.

II. *Lysteria monocytogenes* in meat-based patés, sold in the retail sector

Lysteria monocytogenes has become established as a foodborne pathogen and may be transmitted to human beings through a variety of foodstuffs. Surveys suggest that the incidence of listeriosi is increasing. This involves a risk of infection, particularly with infants, elderly people, pregnant women and immuno-compromised individuals.

III. Adulteration of frozen, fish-based products

Most frozen fish-based products such as fish fingers, nuggets, bites, fish fillets and seafood specialities such as prawns, scampis and crab are made from frozen fish-blocks. Now that popular types of fish such as cod and haddock have become expensive, there are indications that block producers are replacing more expensive fish

(1) OJ No L 186, 30. 6. 1989, p. 23.

with cheaper varieties. The survey should examine specification in a wide range of frozen fish products for which label declarations of named fish species are made. In order to limit this survey, it should specifically target cod, haddock and scampi products.

IV. Adulteration of goat's and sheep's cheese

This analysis is specifically aimed at detecting the illicit use of cow's milk in the production of sheep's and goat's cheese. Those products should be examined for which label declarations are made. In addition to sampling and analysis, inspections of food businesses may be useful.

Done at Brussels, 11 March 1994.

For the Commission

Martin BANGEMANN

Member of the Commission

ANNEX

Coordinated programme of inspections, as provided for by Article 14 (3) of Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs

Member State :

I. Aflatoxine B1 in product liable to contain aflatoxine B1, especially those intended for children

	No of samples analysed	Not detectable - < 10	10-$<10^2$	10^2-2×10^2	2×10^2-4×10^2	4×10^2-$<10^3$	Limit or guide value for rejection	Legal basis
Products								
Method of analysis used (if different from the suggested one)								

Coordinated programme of inspections, as provided for by Article 14 (3) of Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs

Member State :

II. Listerya monocytogenes in meat based pâtés, sold in the retail sector

	No of samples analysed	Not detectable - < 10	10-$<10^2$	10^2-10^3	10^3-$<10^4$	10^4-$<10^5$	10^5-$<10^6$	10^6-10^7	Limit or guide value for rejection	Legal basis
Listeria monocytogenes in 25 g										
Method of analysis used (if different from the suggested one)										

Coordinated programme of inspections, as provided for by Article 14 (3) of Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs

Member State :

III. Adulteration of frozen fish based products in 1994

	Number of samples analysed	Number of samples rejected	Legal basis for rejecction
I.1. Analysis for cod products, labelled as such			
I.2. Analysis for haddock products, labelled as such			
I.3. Analysis for scampi products, labelled as such			
Method of analysis used (if different from the suggested one)			

Coordinated programme of inspections, as provided for by Article 14 (3) of Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs

Member State :

IV A. Adulteration of goat's and sheep's cheese in 1994

	Number of samples analysed	Number of samples rejected	Legal basis for rejection
I. Sheep's cheese analysed for adulteration			
I.1. Analysis for cow's milk protein			
II. Goat's cheese analysed for adulteration			
II.1. Analysis for cow's milk protein			
I.2. Method of analysis used (if different from the suggested one)			

Coordinated programme of inspections, as provided for by Article 14 (3) of Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs

Member State :

IV B. Adulteration of goat's and sheep's cheese in 1994

On-the-spot inspection

	Number of undertakings inspected	Number of cases of of adulteration detected	Legal basis for rejection
I. On-the-spot inspection — sheep's cheese producers			
I.1. Inspection on the use of cow's milk			
II. On-the-spot inspection — goat's cheese producers			
II.1. Inspection on the use of cow's milk			
III. Statutory stock accounts available (delete as appropriate)	Yes / No		

COUNCIL DIRECTIVE

of 20 December 1985

concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption

(85/591/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas the production, manufacture, marketing and use of foodstuffs intended for human consumption are of considerable importance in the European Economic Community;

Whereas the methods of sampling and analysis used for this purpose can have direct repercussions on the establishment and functioning of the common market; whereas they should, therefore, be harmonized;

Whereas the laying down of these methods of sampling and analysis constitutes a measure of a purely scientific and technical nature; whereas a rapid procedure for developing, improving and supplementing such methods is necessary; whereas, in order to facilitate the adoption of such measures, a procedure should be introduced for close cooperation between the Member States and the Commission within the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. Where it is necessary to introduce Community methods of sampling or analysis for the purpose of determining the composition, conditions of manufacture, packaging or labelling of a foodstuff, such methods shall be adopted by the Commission or by the Council as appropriate in accordance with the procedure laid down in Article 4.

2. Paragraph 1 shall be without prejudice to any specific provisions currently in force or hereafter adopted in the context of special Community rules.

3. For the purposes of determining whether it is necessary to introduce the measures provided for in paragraph 1, the following criteria in particular will be taken into consideration:

(a) the need to ensure that Community law is uniformly applied;

(b) the existence of barriers to intra-Community trade;

(c) the permanent or recurrent nature of the criteria referred to in (a) or (b).

Article 2

1. The Directives provided for in Article 1 shall take account of the state of scientific and technical knowledge, in particular of proven methods of sampling and analysis.

2. Such Directives shall specify appropriate time limits for Member States to implement them.

3. The introduction of the measures provided for in Article 1 (1) shall not preclude Member States from using other tested and scientifically valid methods provided that this does not hinder the free movement of products recognized as complying with the rules by virtue of Community methods. However, in the event of differences in the interpretation of results, those obtained by the use of Community methods shall be determinant.

4. The methods of analysis introduced shall comply with the criteria set out in the Annex.

5. Without prejudice to Article 3, the necesaary amendments to existing Directives in so far as appropriate in view of the advanced state of scientific and technological knowledge may, at the request of a Member State, be adopted by means of the procedure provided for in Article 4.

Article 3

1. Where a Member State has detailed evidence that a measure adopted in accordance with Article 1 is inappropriate in a particular case for technical reasons or because it is insufficiently conclusive for the examination of an important health question, that Member State may

(1) OJ No C 53, 24. 2. 1984, p. 9.
(2) OJ No C 46, 18. 2. 1985, p. 95.
(3) OJ No C 44, 15. 2. 1985, p. 1.

temporarily suspend the measure in question in its territory but only for that particular case. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

2. The Commission shall examine as soon as possible the evidence given by the Member State and then consult the Member States within the Standing Committee for Foodstuffs referred to in Article 4, after which it shall deliver its opinion forthwith and take the appropriate measures.

3. If the Commission considers that amendments to the measure adopted in accordance with Article 1 are necessary in order to resolve the difficulties mentioned in paragraph 1, it shall initiate the procedure laid down in Article 4. The member State which has suspended the Community measure may, in that event, continue to do so until the amendments enter into force.

Article 4

1. Where the procedure defined in this Article is invoked, the matter shall be referred to the Standing Committee for Foodstuffs set up by Decision 69/414/EEC (1) (hereinafter called 'the Committee') by its chairman, either on his own initiative or at the request of a representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its own opinion on that draft within a time limit set by the chairman having regard to the urgency of the matter. Opinions shall be delivered by a majority of 45 votes, the votes of the Member States being weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) Where the measures envisaged are in accordance with the opinion of the Committee, the Commission shall adopt them;

(b) Where the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay submit to the Council a proposal on the measures to be taken. The Council shall act by a qualified majority;

(c) If the Council has not acted within three months after submission of the proposal, the proposed measures shall be adopted by the Commission.

Article 5

Member States shall, within a period of two years following notification thereof (2), bring into force by law, regulation or administrative action any provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 20 December 1985.

For the Council

The President

R. STEICHEN

(1) OJ No L 291, 19. 11. 1969, p. 9.

(2) This Directive was notified to the Member States on 23 December 1985.

ANNEX

1. Methods of analysis which are to be considered for adoption under the provisions of the Directive shall be examined with respect to the following criteria:

   (i) specificity,

   (ii) accuracy,

   (iii) precision; repeatability intra-laboratory (within laboratory) and reproducibility inter-laboratory (within and between laboratories) variabilities,

   (iv) limit of detection,

   (v) sensitivity,

   (vi) practicability and applicability,

   (vii) other criteria which may be selected as required.

2. The precision values referred to in 1 (iii) shall be obtained from a collaborative trial which has been conducted in accordance with an internationally recognized protocol on collaborative trials (e.g. International Organization of Standarization 'Precision of Test Methods' (ISO 5725/1981)). The repeatability and reproducibility values shall be expressed in an internationally recognized form (e.g. the 95 % confidence intervals as defined by ISO 5725/1981). The results from the collaborative trial shall be published or freely available.

3. Methods of analysis which are applicable uniformly to various groups of commodities should be given preference over methods which apply only to individual commodities.

4. Methods of analysis adopted under this Directive should be edited in the standard layout for methods of analysis recommended by the International Organization for Standardization.

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE 93/43/EEC

of 14 June 1993

on the hygiene of foodstuffs

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community and in particular Article 100a thereof,

Having regard to the proposal from the Commission,

In cooperation with the European Parliament (1),

Having regard to the opinion of the Economic and Social Committee (2)

Whereas the free movement of foodstuffs is an essential pre-condition for the completion of the internal market; whereas this principle implies confidence in the standard of safety of foodstuffs for human consumption in free circulation, and in particular their standard of hygiene, throughout all stages of preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the consumer;

Whereas the protection of human health is of paramount concern;

Whereas this protection has already been the subject of Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs (3) as well as of more specific rules in this field; whereas an important objective of such controls is food hygiene; whereas Directive 89/397/EEC concentrates on inspection, sampling and analysis and should be supplemented by provisions aimed at improving the level of food hygiene and increasing confidence in the standard of hygiene of foodstuffs in free circulation;

Whereas the general rules of hygiene for foodstuffs to be observed at the time of preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the consumer must be harmonized in order to protect human health;

Whereas the use of hazard analysis, risk assessment and other management techniques to identify, control and monitor critical points is recognized;

Whereas microbiological criteria and temperature control criteria may be adopted for certain classes of foodstuffs; whereas, if adopted, they should be in accordance with scientifically accepted general principles;

Whereas Member States shall encourage and participate in the development of guides to good hygiene practice to which food businesses may refer, based, where appropriate, on the Recommended International Code of Practice, General Principles of Food Hygiene of the *Codex Alimentarius* (4);

Whereas the Commission, assisted by Member States and other interested parties, is to encourage the development

(1) OJ No C 174, 23. 11. 1992; and OJ No C 150, 31. 5. 1993.
(2) OJ No C 223, 31. 8. 1992, p. 16.
(3) OJ No L 186, 30. 6. 1989, p. 23.

(4) *Codex Alimentarius* Volume A. Recommended International Code of Practice. General Principles of Food Hygiene. Second Revision (1985). Food and Agricultural Organization of the United Nations World Health Organization, Rome, 1988.

of guides to good hygiene practice to which food businesses may refer where necessary throughout the Community;

Whereas, however, a food business operator is responsible for the hygiene conditions in his food business; whereas this Directive does not therefore impose observance of guides to good hygiene practice, which have no legal force;

Whereas, in order to have the general rules of hygiene for foodstuffs and the guides to good hygiene practices implemented, the application of standards of the EN 29000 series should be recommended;

Whereas observance of the general rules of hygiene for foodstuffs should be controlled in accordance with Directive 89/397/EEC by the competent authorities of the Member States, with the aim of preventing the consumer from being harmed by foodstuffs unfit for human consumption or potentially dangerous to human health;

Whereas food business operators must ensure that only foodstuffs not harmful to health are placed on the market and appropriate powers should be granted to the competent authorities to protect public health; whereas, however, the legitimate rights of food businesses should be guaranteed;

Whereas the Commission should be made aware of the identity of the competent authorities in the Member States responsible for the official control of food hygiene,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive lays down the general rules of hygiene for foodstuffs and the procedures for verification of compliance with these rules.

2. This Directive shall apply without prejudice to the provisions adopted in the context of more specific Community food hygiene rules. Within three years of the adoption of this Directive, the Commission shall examine the relationship between the specific Community food hygiene rules and those of this Directive and, if necessary, make proposals.

Article 2

For the purposes of this Directive:

— *food hygiene*, hereinafter called 'hygiene' shall mean all measures necessary to ensure the safety and wholesomeness of foodstuffs. The measures shall cover all stages after primary production (the latter including, for example, harvesting, slaughter and milking), during preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the consumer,

— *food business* shall mean any undertaking, whether for profit or not and whether public or private, carrying out any or all of the following: preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling or offering for sale or supply of foodstuffs,

— *wholesome food* shall mean food which is fit for human consumption as far as hygiene is concerned.

Article 3

1. The preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply of foodstuffs shall be carried out in a hygienic way.

2. Food business operators shall identify any step in their activities which is critical to ensuring food safety and ensure that adequate safety procedures are identified, implemented, maintained and reviewed on the basis of the following principles, used to develop the system of HACCP (Hazard analysis and critical control points):

— analysing the potential food hazards in a food business operation,

— identifying the points in those operations where food hazards may occur,

— deciding which of the points identified are critical to food safety — the 'critical points',

— identifying and implementing effective control and monitoring procedures at those critical points, and

— reviewing the analysis of food hazards, the critical control points and the control and monitoring procedures periodically and whenever the food business operations change.

3. Food business operators shall comply with the rules of hygiene as listed in the Annex. Derogations from certain provisions of the Annex may be granted according to the procedure laid down in Article 14.

Article 4

Without prejudice to more specific Community rules, microbiological criteria and temperature control criteria for certain classes of foodstuffs may be adopted in

accordance with the procedure laid down in Article 14 and after consulting the Scientific Committee for Food set up by Decision 74/234/EEC (1).

Article 5

1. Member States shall encourage the development of guides to good hygiene practice which may be used voluntarily by food businesses as a guide to compliance with the provisions of Article 3.

2. Where the guides to good hygiene practice referred to in paragraph 1 are developed, they shall be developed as follows:

— by food business sectors and representatives of other interested parties, such as appropriate authorities and consumer groups,

— in consultation with interests substantially affected, including the competent authorities,

— where appropriate, having regard to the Recommended International Code of Practice, General Principles of Food Hygiene of the *Codex Alimentarius*.

3. The guides referred to in paragraphs 1 and 2 may be developed under the aegis of a national standards institute referred to in list 2 of the Annex to Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations (2)

4. Member States shall assess the guides to good hygiene practice referred to in paragraphs 1 and 2 with a view to determining the extent to which they may be presumed to comply with Article 3.

5. Member States shall forward to the Commission those guides to good hygiene practice which they presume to comply with Article 3.

The Commission shall make these guides available to the Member States.

6. Where one or more Member States, or the Commission, consider that, for the purposes of harmonization, there may be a need for guides to good hygiene practice to be developed on a European basis (hereafter referred to as 'European guides to good hygiene practice'), the Commission shall consult Member States in the framework of the Standing Committee on Foodstuffs in accordance with Article 14. The object of this consultation shall be to consider the case for such voluntary guides in the sectors or activities concerned, and, where such guides are considered necessary:

— to indicate the intended scope, subject matter and timetable for development of such voluntary guides, taking into account the time needed for consultation with interests substantially affected by them, and

— to refer such voluntary guides for development and/or assessment under the aegis of a European standards institute.

7. In developing the European guides to good hygiene practice referred to in paragraph 6, all necessary measures shall be taken in order to:

— ensure that such guides are developed by representatives of food business sectors and representatives of other interests substantially affected, such as, for example, the competent authorities and consumer groups,

— ensure that the contents of such guides comply with the provisions of Article 3 and, where appropriate, have regard to the Recommended International Code of Practice, General Principles of Food Hygiene of the *Codex Alimentarius*,

— ensure that the contents of such guides are practicable for the food industry sectors to which they refer throughout the Community,

— ensure that the relevant guides to good hygiene practice drawn up in accordance with paragraphs 1 to 3 are taken into account,

— ensure that all interests substantially affected by such guides, including Member States, are consulted and their comments taken into account.

8. The titles and references of European guides to good hygiene practice developed in accordance with the procedure in paragraphs 6 and 7 shall be published in the C series of the *Official Journal of the European Communities*. Member States shall ensure that such published guides are drawn to the attention of the relevant food business sectors and the appropriate authorities in their territories.

Article 6

Member States shall, if they consider it appropriate, recommend food business operators to apply the European Standards of the EN 29000 series in order to implement the general rules of hygiene and the guides to good hygiene practice.

(1) OJ No L 136, 20. 5. 1974, p. 1.
(2) OJ No L 109, 26. 4. 1983, p. 8. Directive as last amended by Decision 92/400/EEC (OJ No L 221, 6. 8. 1992, p. 55).

Article 7

1. Subject to the Treaty, Member States may maintain, amend or introduce national hygiene provisions that are more specific than those laid down by this Directive, provided that such provisions:

— are not less stringent than those given in the Annex,

— do not constitute a restriction, hindrance or barrier to trade in foodstuffs produced in accordance with this Directive.

2. Until detailed provisions have been laid down in accordance with Article 4, Member States may maintain, amend or introduce the relevant national provisions, subject to the Treaty.

3. Should a Member State deem it necessary, in the cases provided for in paragraphs 1 and 2, to adopt new legislation or amend existing legislation, it shall communicate to the Commission and the other Member States the measures envisaged and give the reasons justifying them. The Commission shall consult the Member States within the Standing Committee on Foodstuffs set up by Decision 69/414/EEC (1) if it considers such consultation to be useful or if a Member State so requests.

The Member State may take the envisaged measures only three months after such communication and provided that it has not received an opinion to the contrary from the Commission.

In the latter event, before the expiry of the period referred to in the second subparagraph, the Commission shall initiate the procedure provided for in Article 14 in order to determine whether the envisaged measures may be implemented subject, if necessary, to the appropriate amendments.

Article 8

1. The competent authorities shall carry out controls in accordance with Directive 89/397/EEC in order to ensure that the provisions of Article 3 of this Directive and, where appropriate, any provisions laid down pursuant to Article 4 of this Directive are being complied with by food businesses. In doing so, due consideration shall be given to the guides to good hygiene practice referred to in Article 5 of this Directive, where they exist.

2. Inspections by competent authorities shall include a general assessment of the potential food safety hazards associated with the business. Competent authorities shall pay particular attention to critical control points identified by food businesses to assess whether the necessary monitoring and verification controls are being operated.

Member States shall provide that all food premises are inspected at a frequency which has regard to the risk associated with the premises.

3. The competent authorities shall ensure that controls on foodstuffs imported into the Community are carried out in accordance with Directive 89/397/EEC for the purpose of ensuring that the relevant provisions of Article 3 and, where appropriate, any provisions laid down pursuant to Article 4, are being observed.

Article 9

1. If while carrying out the controls referred to in Article 8, the competent authorities ascertain that failure to comply with the provisions of Article 3 or, where appropriate, any provisions laid down pursuant to Article 4 might result in risks to the safety or wholesomeness of foodstuffs they shall take appropriate measures, which may extend to the withdrawal and/or the destruction of the foodstuff or to the closure of all or part of the undertaking for an appropriate period of time.

In determining the risk to food safety or wholesomeness regard shall be had to the nature of the food, the manner in which it is handled and packed and any process to which the food is subjected before supply to the consumer and the conditions under which it is displayed and/or stored.

2. Member States shall take the necessary measures to ensure that any natural or legal person affected by the control has a right of appeal against the measures taken by the competent authority following the control.

Article 10

1. If a hygiene problem likely to pose a serious risk to human health arises or spreads in the territory of a third country, the Commission, either on its own initiative or at the request of a Member State, shall take the following measures without delay, depending on the seriousness of the situation:

— suspend imports from all or part of the third country concerned and, where necessary, from the transit third country, and/or

— lay down special conditions for foodstuffs from all or part of the third country concerned.

2. The Commission may, in the case provided for in paragraph 1, take interim protective measures regarding the foodstuffs concerned.

(1) OJ No L 291, 19. 11. 1969, p. 9.

3. Except in an emergency, the Commission shall consult the Member States before taking the measures referred to in paragraphs 1 and 2.

4. The Commission shall notify the Council and the Member States without delay of any decision taken pursuant to paragraphs 1 and 2.

Any Member State may refer the Commission's decision to the Council within 30 days of the notification referred to in the first subparagraph. The Council, acting by a qualified majority, may confirm, amend or revoke the decision adopted by the Commission. If the Council has not taken a decision within 30 days, the decision of the Commission is deemed to be revoked.

5. Where a Member State officially informs the Commission of the need to take safeguard measures and the Commission has not had recourse to the provisions of paragraphs 1 and 2, that Member State may take interim protective measures with regard to imports of the foodstuffs in question.

When a Member State takes interim protective measures, it shall inform the other Member States and the Commission.

Within 10 working days, the Commission shall put the matter before the Standing Committee on Foodstuffs in accordance with the procedure laid down in Article 14 with a view to the extension, amendment or abrogation of the national interim protective measures.

Article 11

1. Where a Member State, as a result of new information or of a reassessment of existing information, has good reason to suspect that application of the detailed provisions laid down pursuant to Article 4 constitutes a health risk, it may temporarily suspend or restrict application of the provisions in question in its territory. It shall inform the other Member States and the Commission thereof without delay and give reasons for its decision.

2. The Commission shall examine the reasons given by the Member State referred to in paragraph 1 as soon as possible in the Standing Committee on Foodstuffs and shall deliver its opinion and take any necessary measures in accordance with the procedure laid down in Article 14.

Article 12

Member States shall designate the competent authorities responsible for the control of hygiene and shall notify the Commission of them.

Article 13

Amendments to references to international standards, such as those of the *Codex Alimentarius*, contained in this Directive, may be adopted in accordance with the procedure laid down in Article 14.

Article 14

The Commission shall be assisted by the Standing Committee on Foodstuffs (hereinafter referred to as 'the Committee').

The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission.

The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

Article 15

The Commission shall submit a report to the European Parliament and the Council, by 31 December 1998, together with any appropriate proposals, on the experience gleaned from the implementation of this Directive.

Article 16

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 months after adoption. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, the provisions shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Member States shall communicate to the Commission the provisions of national law which they adopted in the field governed by this Directive. The Commission shall inform the other Member States thereof.

Article 17

This Directive is addressed to the Member States.

Done at Luxembourg, 14 June 1993.

For the Council
The President
J. TRØJBORG

ANNEX

Preface

1. Chapters V to X of this Annex apply throughout all stages after primary production during preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the consumer.

   The remaining chapters of the Annex apply as follows:

   — Chapter I to all food premises except those covered by Chapter III,

   — Chapter II to all rooms where food is prepared, treated or processed except those covered by Chapter III and excluding dining areas,

   — Chapter III to those premises listed in the heading to the Chapter,

   — Chapter IV to all transportation.

2. The terms 'where appropriate' and 'where necessary' used in this Annex mean for the purposes of ensuring the safety and wholesomeness of foodstuffs.

I

General requirements for food premises (other than those specified in Chapter III)

1. Food premises must be kept clean and maintained in good repair and condition.

2. The layout, design, construction and size of food premises shall:

   (a) permit adequate cleaning and/or disinfection;

   (b) be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces;

   (c) permit good food hygiene practices, including protection against cross contamination between and during operations by foodstoffs, equipment, materials, water, air supply or personnel and external sources of contamination such as pests;

   (d) provide, where necessary, suitable temperature conditions for the hygienic processing and storage of products.

3. An adequate number of washbasins must be available, suitably located and designated for cleaning hands. An adequate number of flush lavatories must be available and connected to an effective drainage system. Lavatories must not lead directly into rooms in which food is handled.

4. Washbasins for cleaning hands must be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. When necessary, the provisions for washing food must be separate from the hand-washing facility.

5. There must be suitable and sufficient means of natural or mechanical ventilation. Mechanical air flow from a contaminated area to a clean area must be avoided. Ventilation systems must be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.

6. All sanitary conveniences within food premises shall be provided with adequate natural or mechanical ventilation.

7. Food premises must have adequate natural and/or artificial lighting.

8. Drainage facilities must be adequate for the purpose intended; they must be designed and constructed to avoid the risk of contamination of foodstuffs.

9. Adequate changing facilities for personnel must be provided where necessary.

II

Specific requirements in rooms where foodstuffs are prepared, treated or processed (excluding dining areas and those premises specified in Chapter III)

1. In rooms where food is prepared, treated or processed (excluding dining areas):

   (a) floor surfaces must be maintained in a sound condition and they must be easy to clean and, where necessary, disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate. Where appropriate, floors must allow adequate surface drainage;

   (b) wall surfaces must be maintained in a sound condition and they must be easy to clean and, where necessary, disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials and require a smooth surface up to a height appropriate for the operations unless food business operators can satisfy the competent authority that other materials used are appropriate;

   (c) ceilings and overhead fixtures must be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable moulds and the shedding of particles;

   (d) windows and other openings must be constructed to prevent the accumulation of dirt. Those which can be opened to the outside environment must where necessary be fitted with insect-proof screens which can be easily removed for cleaning. Where open windows would result in contamination of foodstuffs, windows must remain closed and fixed during production;

   (e) doors must be easy to clean and, where necessary, disinfect. This will require the use of smooth and non-absorbent surfaces unless food business operators can satisfy the competent authority that other materials used are appropriate;

   (f) surfaces (including surfaces of equipment) in contact with food must be maintained in a sound condition and be easy to clean and, where necessary, disinfect. This will require the use of smooth, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate.

2. Where necessary, adequate facilities must be provided for the cleaning and disinfecting of work tools and equipment. These facilities must be constructed of materials resistant to corrosion and must be easy to clean and have an adequate supply of hot and cold water.

3. When appropriate, adequate provision must be made for any necessary washing of the food. Every sink or other such facility provided for the washing of food must have an adequate supply of hot and/or cold potable water as required and be kept clean.

III

Requirements for movable and/or temporary premises (such as Marquees, market stalls, mobile sales vehicles) premises used primarily as a private dwelling house, premises used occasionally for catering purposes, and vending machines

1. Premises and vending machines shall be so sited, designed, constructed and kept clean and maintained in good repair and condition as to avoid the risk of contaminating foodstuffs and harbouring pests, so far as is reasonably practicable.

2. In particular and where necessary:

   (a) appropriate facilities must be available to maintain adequate personal hygiene (including facilities for the hygienic washing and drying of hands, hygienic sanitary arrangements and changing facilities);

(b) surfaces in contact with food must be in a sound condition and be easy to clean and, where necessary, disinfect. This will require the use of smooth, washable, non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate;

(c) adequate provision must be made for the cleaning and, where necessary, disinfecting of work utensils and equipment;

(d) adequate provision must be made for the cleaning of foodstuffs;

(e) an adequate supply of hot and/or cold potable water must be available;

(f) adequate arrangements and/or facilities for the hygienic storage and disposal of hazardous and/or inedible substances and waste (whether liquid or solid) must be available;

(g) adequate facilities and/or arrangements for maintaining and monitoring suitable food temperature conditions must be available;

(h) foodstuffs must be so placed as to avoid, so far as is reasonably practicable, the risk of contamination.

IV

Transport

1. Conveyances and/or containers used for transporting foodstuffs must be kept clean and maintained in good repair and condition in order to protect foodstuffs from contamination and must, where necessary, be designed and constructed to permit adequate cleaning and/or disinfection.

2. Receptacles in vehicles and/or containers must not be used for transporting anything other than foodstuffs where this may result in contamination of foodstuffs.

   Bulk foodstuffs in liquid, granular or powder form must be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. Such containers must be marked in a clearly visible and indelible fashion, in one or more Community languages, to show that they are used for the transport of foodstuffs, or must be marked 'for foodstuffs only'.

3. Where conveyances and/or containers are used for transporting anything in addition to foodstoffs or for transporting different foodstuffs at the same time, there must be effective separation of products, where necessary, to protect against the risk of contamination.

4. Where conveyances and/or containers have been used for transporting anything other than foodstuffs or for transporting different foodstuffs, there must be effective cleaning between loads to avoid the risk of contamination.

5. Foodstuffs in conveyances and/or containers must be so placed and protected as to minimize the risk of contamination.

6. Where necessary, conveyances and/or containers used for transporting foodstuffs, must be capable of maintaining foodstuffs at appropriate temperatures and, where necessary, designed to allow those temperatures to be monitored.

V

Equipment requirements

All articles, fittings and equipment with which food comes into contact shall be kept clean and:

(a) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimize any risk of contamination of the food;

(b) with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept thoroughly cleaned and, where necessary, disinfected, sufficient for the purposes intended;

(c) be installed in such a manner as to allow adequate cleaning of the surrounding area.

VI

Food waste

1. Food waste and other refuse must not be allowed to accumulate in food rooms except so far as is unavoidable for the proper functioning of the business.

2. Food waste and other refuse must be deposited in closable containers unless food business operators can satisfy the competent authority that other types of containers used are appropriate. These containers must be of an appropriate construction, kept in sound condition and where necessary be easy to clean and disinfect.

3. Adequate provision must be made for the removal and storage of food waste and other refuse. Refuse stores must be designed and managed in such a way as to enable them to be kept clean and to protect against access by pests and against contamination of food, drinking water, equipment or premises.

VII

Water supply

1. There must be an adequate supply of potable water as specified in Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption [1]. This potable water must be used whenever necessary to ensure foodstuffs are not contamined.

2. When appropriate, ice must be made from water which meets the specifications referred to in Directive 80/778/EEC. This ice must be used whenever necessary to ensure foodstuffs are not contamined. It must be made, handled and stored under conditions which protect it from all contamination.

3. Steam used directly in contact with food must not contain any substance which presents a hazard to health or is likely to contaminate the product.

4. Water unfit for drinking used for the generation of steam, refrigeration, fire control and other similar purposes not relating to food, must be conducted in separate systems, readily identifiable and having no connection with, nor any possibility of reflux into, the potable water systems.

VIII

Personal hygiene

1. Every person working in a food handling area shall maintain a high degree of personal cleanliness and shall wear suitable, clean and, where appropriate, protective clothing.

2. No person, known or suspected to be suffering from, or to be a carrier of, a disease likely to be transmitted through food or while afflicted, for example with infected wounds, skin infections, sores or with diarrhoea, shall be permitted to work in any food handling area in any capacity in which there is any likelihood of directly or indirectly contaminating food with pathogenic micro-organisms.

IX

Provisions applicable to foodstuffs

1. No raw materials or ingredients shall be accepted by a food business if they are known to be, or might reasonably be expected to be, so contaminated with parasites, pathogenic micro-organisms or toxic, decomposed or foreign substances that, after normal sorting and/or preparatory or processing procedures hygienically applied by food businesses, they would still be unfit for human consumption.

[1] OJ No L 229, 30. 8. 1980, p. 11. Directive as last amended by Directive 91/692/EEC (OJ No L 377, 31. 12. 1991, p. 48).

2. Raw materials and ingredients stored in the establishment shall be kept in appropriate conditions designed to prevent harmful deterioration and to protect them from contamination.

3. All food which is handled, stored, packaged, displayed and transported shall be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state. In particular, food must be so placed and/or protected as to minimize any risk of contamination. Adequate procedures must be in place to ensure pests are controlled.

4. Raw materials, ingredients, intermediate products and finished products likely to support the growth of pathogenic micro-organisms or the formation of toxins must be kept at temperatures which would not result in a risk to health. Consistent with food safety, limited periods outside temperature control are permitted where necessary to accommodate the practicalities of handling during preparation, transport, storage, display and service of food.

5. When foodstuffs are to be held or served at chilled temperatures they must be cooled as quickly as possible following the final heat processing stage, or final preparation stage if no heat process is applied, to a temperature which would not result in a risk to health.

6. Hazardous and/or inedible substances, including animal feedstuffs, shall be adequately labelled and stored in separate and secure containers.

X

Training

Food business operators shall ensure that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity.

CONTAMINATION

387R3954

3954/87/EURATOM: COUNCIL REGULATION OF 22 DECEMBER 1987 LAYING DOWN MAXIMUM PERMITTED LEVELS OF RADIOACTIVE CONTAMINATION OF FOODSTUFFS AND OF FEEDINGSTUFFS FOLLOWING A NUCLEAR ACCIDENT OR ANY OTHER CASE OF RADIOLOGICAL EMERGENCY

OFFICIAL JOURNAL NO L 371, 30/12/1987, P. 11

AMENDED BY

389R2218
2218/89/EURATOM: COUNCIL REGULATION OF 18 JULY 1989 [1]
OFFICIAL JOURNAL NO L 211, 22/07/1989, P. 1

ARTICLE 1

1. THIS REGULATION LAYS DOWN THE PROCEDURE FOR DETERMINING THE MAXIMUM PERMITTED LEVELS OF RADIOACTIVE CONTAMINATION OF FOODSTUFFS AND OF FEEDINGSTUFFS WHICH MAY BE PLACED ON THE MARKET FOLLOWING A NUCLEAR ACCIDENT OR ANY OTHER CASE OF RADIOLOGICAL EMERGENCY WHICH IS LIKELY TO LEAD TO OR HAS LED TO SIGNIFICANT RADIOACTIVE CONTAMINATION OF FOODSTUFFS AND FEEDINGSTUFFS.

2. FOR THE PURPOSES OF THIS REGULATION, "FOODSTUFFS" MEANS PRODUCTS WHICH ARE INTENDED FOR HUMAN CONSUMPTION EITHER IMMEDIATELY OR AFTER PROCESSING AND "FEEDINGSTUFFS" MEANS PRODUCTS WHICH ARE INTENDED ONLY FOR ANIMAL NUTRITION.

ARTICLE 2

1. IN THE EVENT OF THE COMMISSION RECEIVING - IN PARTICULAR ACCORDING TO EITHER THE COMMUNITY ARRANGEMENTS FOR THE EARLY EXCHANGE OF INFORMATION IN CASE OF A RADIOLOGICAL EMERGENCY OR UNDER THE IEA CONVENTION OF 26 SEPTEMBER 1986 ON EARLY NOTIFICATION OF A NUCLEAR ACCIDENT - OFFICIAL INFORMATION ON ACCIDENTS OR ON ANY OTHER CASE OF RADIOLOGICAL EMERGENCY, SUBSTANTIATING THAT THE MAXIMUM PERMISSIBLE LEVELS IN THE ANNEX ARE LIKELY TO BE REACHED OR HAVE BEEN REACHED, IT WILL IMMEDIATELY ADOPT, IF THE CIRCUMSTANCES SO REQUIRE, A REGULATION RENDERING APPLICABLE THOSE MAXIMUM PERMISSIBLE LEVELS.

2. THE PERIOD OF VALIDITY OF ANY REGULATION WITHIN THE MEANING OF PARAGRAPH 1 SHALL BE AS SHORT AS POSSIBLE AND SHALL NOT EXCEED THREE MONTHS SUBJECT TO THE PROVISIONS OF ARTICLE 3 (4).

ARTICLE 3

1. AFTER CONSULTATION WITH EXPERTS, WHICH SHALL INCLUDE THE ARTICLE 31 GROUP OF EXPERTS, THE COMMISSION SHALL SUBMIT TO THE COUNCIL A PROPOSAL FOR A REGULATION TO ADAPT OR CONFIRM THE PROVISIONS OF THE REGULATION REFERRED TO IN ARTICLE 2 (1) WITHIN ONE MONTH OF ITS ADOPTION.

2. THE COMMISSION SHALL WHEN SUBMITTING THE PROPOSAL FOR A REGULATION REFERRED TO IN PARAGRAPH 1 TAKE INTO ACCOUNT THE BASIC STANDARDS LAID DOWN IN ACCORDANCE WITH ARTICLES 30 TO 31 OF THE TREATY INCLUDING THE PRINCIPLE THAT ALL EXPOSURES SHALL BE KEPT AS LOW AS REASONABLY ACHIEVABLE, TAKING THE ASPECT OF THE PROTECTION OF THE HEALTH OF THE GENERAL PUBLIC AND ECONOMIC AND SOCIAL FACTORS INTO ACCOUNT.

3. THE COUNCIL SHALL, ACTING BY A QUALIFIED MAJORITY, TAKE A DECISION ON THE PROPOSAL FOR A REGULATION REFERRED TO IN PARAGRAPHS 1 AND 2 WITHIN THE TIME LIMIT SET OUT IN ARTICLE 2 (2).

4. IN THE EVENT THAT THE COUNCIL DOES NOT DECIDE WITHIN THIS TIME LIMIT, THE LEVELS SET OUT IN THE ANNEX SHALL CONTINUE TO APPLY UNTIL THE COUNCIL DOES DECIDE OR UNTIL THE COMMISSION WITHDRAWS ITS PROPOSAL BECAUSE THE CONDITIONS SET OUT IN ARTICLE 2 (1) NO LONGER APPLY.

ARTICLE 4

THE PERIOD OF VALIDITY OF ANY REGULATION WITHIN THE MEANING OF ARTICLE 3 SHALL BE LIMITED. THIS PERIOD MAY BE REVISED AT THE REQUEST OF A MEMBER STATE OR ON THE INITIATIVE OF THE COMMISSION IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 3.

ARTICLE 5

1. IN ORDER TO ENSURE THAT THE MAXIMUM PERMITTED LEVELS LAID DOWN IN THE ANNEX TAKE ACCOUNT OF ANY NEW SCIENTIFIC DATA BECOMING AVAILABLE, THE COMMISSION SHALL, FROM TIME TO TIME, SEEK THE OPINION OF EXPERTS, WHICH SHALL INCLUDE THE ARTICLE 31 GROUP OF EXPERTS.

2. AT THE REQUEST OF A MEMBER STATE OR THE COMMISSION, THE MAXIMUM PERMITTED LEVELS LAID DOWN IN THE ANNEX MAY BE REVISED OR SUPPLEMENTED, UPON THE SUBMISSION OF A PROPOSAL FROM THE COMMISSION TO THE COUNCIL IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 31 OF THE TREATY.

ARTICLE 6

1. FOODSTUFFS OR FEEDINGSTUFFS NOT IN COMPLIANCE WITH THE MAXIMUM PERMITTED LEVELS LAID DOWN IN A REGULATION ADOPTED IN ACCORDANCE WITH ARTICLES 2 OR 3 SHALL NOT BE PLACED ON THE MARKET. FOR THE PURPOSES OF APPLYING THIS REGULATION, FOODSTUFFS OR FEEDINGSTUFFS IMPORTED FROM THIRD COUNTRIES SHALL BE CONSIDERED TO BE PLACED ON THE MARKET IF, ON THE CUSTOMS TERRITORY OF THE COMMUNITY, THEY UNDERGO A CUSTOMS PROCEDURE OTHER THAN A TRANSIT PROCEDURE.

2. EACH MEMBER STATE SHALL PROVIDE THE COMMISSION WITH ALL INFORMATION CONCERNING THE APPLICATION OF THIS REGULATION, IN PARTICULAR CONCERNING CASES OF NON-COMPLIANCE WITH THE MAXIMUM PERMITTED LEVELS. THE COMMISSION SHALL COMMUNICATE SUCH INFORMATION TO THE OTHER MEMBER STATES.

ARTICLE 7

" Rules for applying this Regulation, a list of minor foodstuffs together with the maximum levels to be applied thereto, and the maximum levels for feedingstuffs shall be adopted in accordance with the procedure laid down in Article 30 of Regulation (EEC) No 804/68 (1), which shall apply by analogy. To this end an ad hoc Committee shall be set up. " **[1]**

ARTICLE 8

THIS REGULATION SHALL ENTER INTO FORCE ON THE THIRD DAY FOLLOWING THAT OF ITS PUBLICATION IN THE OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITIES. THIS REGULATION SHALL BE BINDING IN ITS ENTIRETY AND DIRECTLY APPLICABLE IN ALL MEMBER STATES.

"*ANNEX*

MAXIMUM PERMITTED LEVELS FOR FOODSTUFFS AND FEEDINGSTUFFS (Bq/kg)

	Foodstuffs (2)				Feedingstuffs (3)
	Baby foods (4)	Dairy produce (5)	Other foodstuffs except minor foodstuffs (6)	Liquid foodstuffs (7)	
Isotopes of strontium, notably Sr-90	75	125	750	125	
Isotopes of iodine, notably I-131	150	500	2 000	500	
Alpha-emitting isotopes of plutonium and transpluto-nium elements, notably Pu-239, Am-241	1	20	80	20	
All other nuclides of half-life greater than 10 days, notably Cs-134, Cs-137 (8)	400	1 000	1 250	1 000	" **[1]**

(1) OJ No L 148, 28/06/1968, p. 13.
(2) The level applicable to concentrated or dried products is calculated on the basis of the reconstituted product as ready for consumption. Member States may make recommendations concerning the diluting conditions in order to ensure that the maximum permitted levels laid down in this Regulation are observed.
(3) Maximum permitted levels for feedingstuffs will be defined in accordance with Article 7, since such levels are intended to contribute to the observance of the permitted maximum levels for foodstuffs, do not alone guarantee such observance in all circumstances and do not lessen the requirement for monitoring levels in animal products destined for human consumption.
(4) Baby foods are defined as those foodstuffs intended for the feeding of infants during the first four to six months of life, which meet, in themselves, the nutritional requirements of this category of person and are put up for retail sale in packages which are clearly identified and labelled "food preparation for infants".
(5) Dairy produce is defined as those products falling within the following CN codes including, where appropriate, any adjustments which might be made to them later: 0401, 0402 (except 0402 29 11).
(6) Minor foodstuffs and the corresponding levels to be applied to them will be defined in accordance with Article 7.
(7) Liquid foodstuffs as defined in the heading 2009 and in chapter 22 of the combined nomenclature. Values are calculated taking into account consumption of tap-water and the same values should be applied to drinking water supplies at the discretion of competent authorities in Member States.
(8) Carbon 14, tritium and potassium 40 are not included in this group.

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 14 December 1987

on Community arrangements for the early exchange of information in the event of a radiological emergency

(87/600/Euratom)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 31 thereof,

Having regard to the proposal from the Commission, submitted after obtaining the opinion of the group of persons appointed by the Scientific and Technical Committee,

Having regard to the opinion of the European Parliament (1),

Having regard to the opinion of the Economic and Social Committee (2),

Whereas Article 2 (b) of the Treaty requires the Community to establish uniform safety standards to protect the health of workers and of the general public;

Whereas, on 2 February 1959, the Council adopted Directives laying down basic standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiations (3), which were last amended by Directive 80/836/Euratom (4) and Directive 84/467/Euratom (5);

Whereas Article 45 (5) of Directive 80/836/Euratom already requires that any accident involving exposure of the population be notified as a matter of urgency, when the circumstances so require, to neighbouring Member States and to the Commission;

Whereas Articles 35 and 36 of the Treaty already provide that Member States are to establish the facilities necessary to carry out continuous monitoring of the level of radioactivity in the air, water and soil and to communicate such information to the Commission so that it is kept informed of the levels of radioactivity to which the public is exposed;

Whereas Article 13 of Directive 80/836/Euratom requires Member States regularly to transmit to the Commission results of reviews and estimates referred to in that Article;

Whereas the accident at the nuclear power station at Chernobyl in the Soviet Union demonstrated that, in the event of a radiological emergency and in order to fulfil its tasks, the Commission needs to receive promptly all relevant information in an agreed format;

Whereas some bilateral arrangements have been agreed upon by Member States and whereas all Member States have signed the IAEA Convention on Early Notification of a Nuclear Accident;

Whereas these Community arrangements will ensure that all Member States are promptly informed in the event of a radiological emergency in order to provide that the uniform standards for protection of the population as is laid down in the Directives made pursuant to Title Two, Chapter III, of the Treaty are applied throughout the Community;

Whereas the establishment of Community arrangements for the early exchange of information does not affect the rights and obligations of Member States under bilateral and multilateral treaties or conventions;

(1) OJ No C 318, 30. 11. 1987.
(2) OJ No C 105, 21. 4. 1987, p. 9.
(3) OJ No 11, 20. 2. 1959, p. 221/59.
(4) OJ No L 246, 17. 9. 1980, p. 1.
(5) OJ No L 265, 5. 10. 1984, p. 4.

Whereas, in furtherance of international cooperation, the Community will participate in the IAEA Convention on Early Notification of a Nuclear Accident,

HAS ADOPTED THIS DECISION:

Article 1

1. These arrangements shall apply to the notification and provision of information whenever a Member State decides to take measures of a wide-spread nature in order to protect the general public in case of a radiological emergency following:

(a) an accident in its territory involving facilities or activities referred to in paragraph 2 from which a significant release of radioactive material occurs or is likely to occur; or

(b) the detection, within or outside its own territory, of abnormal levels of radioactivity which are likely to be detrimental to public health in that Member State; or

(c) accidents other than those specified in (a) involving facilities or activities referred to in paragraph 2 from which a significant release of radioactive material occurs or is likely to occur; or

(d) other accidents from which a significant release of radioactive materials occurs or is likely to occur.

2. The facilities or activities referred to in paragraph 1 (a) and 1 (c) are the following:

(a) any nuclear reactor, wherever located;

(b) any other nuclear fuel cycle facility;

(c) any radioactive waste management facility;

(d) the transport and storage of nuclear fuels or radioactive wastes;

(e) the manufacture, use, storage, disposal and transport of radioisotopes for agricultural, industrial, medical and related scientific and research purposes; and

(f) the use of radioisotopes for power generation in space objects.

Article 2

1. When a Member State decides to take measures as referred to in Article 1, that Member State shall:

(a) forthwith notify the Commission and those Member States which are, or are likely to be, affected of such measures and the reasons for taking them;

(b) promptly provide the Commission and those Member States which are, or are likely to be, affected with available information relevant to minimizing the foreseen radiological consequences, if any, in those States.

2. A Member State should whenever possible provide the Commission and those Member States which are likely to be affected with notification of its intention to take without delay measures as referred to in Article 1.

Article 3

1. The information to be provided pursuant to Article 2 (1) (b) shall, without jeopardy to matters of national security, include, as far as practicable and appropriate, the following:

(a) the nature and time of the event, its exact location and the facility or the activity involved;

(b) the assumed or established cause and the foreseeable development of the accident relevant to the release of the radioactive materials;

(c) the general characteristics of the radioactive release, including the nature, probable physical and chemical form and the quantity, composition and effective height of the radioactive release;

(d) information on current and forecast meteorological and hydrological conditions, necessary for forecasting the dispersion of the radioactive release;

(e) the results of environmental monitoring;

(f) the results of measurements of foodstuffs, feedingstuffs and drinking water;

(g) the protective measures taken or planned;

(h) the measures taken, or planned, to inform the public;

(i) the predicted behaviour over time of the radioactive release.

2. The information shall be supplemented at appropriate intervals by further relevant information, including the development of the emergency situation and its foreseeable or actual termination.

3. The Member State referred to in Article 1 shall, in accordance with Article 36 of the Treaty, continue to inform the Commission at appropriate intervals of the levels of radioactivity as laid down in paragraph 1 (e) and (f).

Article 4

Any Member State, upon receipt of the information set out in Articles 2 and 3, shall:

(a) promptly inform the Commission of the measures taken and recommendations issued following the receipt of such information;

(b) inform the Commission, at appropriate intervals, of the levels of radioactivity measured by their monitoring facilities in foodstuffs, feedingstuffs, drinking water and the environment.

Article 5

1. Upon receipt of the information referred to in Articles 2, 3 and 4, the Commission shall, subject to Article 6, immediately forward it to the competent authorities of all other Member States. Likewise the Commission shall forward to all Member States any information it receives about significant increases in the level of radioactivity or about nuclear accidents in non-Community countries and especially those adjacent to the Community.

2. Detailed procedures for the transmission of the information referred to in Articles 1 to 4 shall be agreed by the Commission and the competent authorities of the Member States and tested at regular intervals.

3. Each Member State shall indicate to the Commission the competent national authorities and points of contact designated to forward or receive the information set out in Articles 2 to 5. The Commission shall in turn communicate this and details of the designated Commission service to the competent authorities of the other Member States.

4. Points of contact and the designated Commission service shall be available on a 24 hour basis.

Article 6

1. Information received pursuant to Articles 2, 3 and 4 may be used without restrictions except when such information is provided in confidence by the notifying Member State.

2. Information received by the Commission relating to an establishment of the Joint Research Centre will not be circulated or released without the agreement of the host Member State.

Article 7

This Decision does not affect the reciprocal rights and obligations of the Member States resulting from bilateral or multilateral agreements or Conventions existing or to be concluded in the field covered by this Decision and in accordance with its object and purpose.

Article 8

Member States shall take the measures necessary to comply with this Decision within three months of the date of its notification.

Article 9

This Decision is addressed to the Member States.

Done at Brussels, 14 December 1987.

For the Council

The President

U. ELLEMANN-JENSEN

COUNCIL REGULATION (EEC) No 2219/89

of 18 July 1989

on the special conditions for exporting foodstuffs and feedingstuffs following a nuclear accident or any other case of radiological emergency

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 113 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament,

Whereas the Commission must be informed of any nuclear accident or unusually high levels of radioactivity, in accordance with Council Decision 87/600/Euratom of 14 December 1987 on Community arrangements for the early exchange of information in the event of a radiological emergency (2) or pursuant to the Convention of the International Atomic Energy Agency (IAEA) of 26 September 1986 on the Early Notification of a Nuclear Accident;

Whereas the Council adopted Regulation (Euratom) No 3954/87 of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency (3), as last amended by Regulation (Euratom) No 2218/89 (4);

Whereas the maximum permitted levels fixed by the abovementioned Regulation take due account of the most recent international scientific opinion and reflect the need to avoid any discrepancies in international regulations;

Whereas the resolution of the Council and the representatives of the Governments of the Member States meeting within the Council of 22 December 1987, adopted at the same time as Regulation (Euratom) No 3954/87, provides for the adoption of specific rules governing the export of foodstuffs;

Whereas after a nuclear accident or in any other case of radiological emergency it is not acceptable to allow products with contamination levels in excess of the maximum permitted levels relating to products for consumption in the Community to be exported to third countries; whereas in such special circumstances it is difficult in practical terms to treat products differently depending on their final destination;

Whereas the provisions concerning exports should also relate to feedingstuffs since these products are covered by Regulation (Euratom) No 3954/87 for reasons of public health;

Whereas it is therefore appropriate to define specific conditions for exporting foodstuffs and feedingstuffs after a nuclear accident or any other case of radiological emergency and to apply to such products the maximum permitted levels of radioactive contamination laid down in Regulation (Euratom) No 3954/87,

HAS ADOPTED THIS REGULATION:

Article 1

1. This Regulation lays down the conditions for exporting foodstuffs and feedingstuffs after a nuclear accident or any other radiological situation likely to lead to significant radioactive contamination of foodstuffs and feedingstuffs.

2. For the purposes of this Regulation 'foodstuffs' means products which are intended for human consumption either immediately or after processing, and 'feedingstuffs' means products which are intended only for animal nutrition.

Article 2

Foodstuffs and feedingstuffs in which the level of radioactive contamination exceeds the relevant maximum permitted levels laid down in Articles 2 and 3 of Regulation (Euratom) No 3954/87 may not be exported.

Article 3

The Member States shall carry out checks to ensure that the maximum permitted levels referred to in Article 2 are observed.

Article 4

Each Member State shall communicate to the Commission the fullest information on the application of this Regulation, and in particular on any cases where the maximum permitted levels have been exceeded. The Commission shall forward this information to the other Member States.

Article 5

The rules of application for this Regulation shall be laid down by the Commission in accordance with the procedure defined in Article 7 of Regulation (Euratom) No 3954/87. To this end an *ad hoc* Committee shall be set up.

Article 6

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Communities.*

(1) OJ No C 214, 16. 8. 1988, p. 31.
(2) OJ No L 371, 30. 12. 1987, p. 76.
(3) OJ No L 371, 30. 12. 1987, p. 11.
(4) See page 1 of this Official Journal.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 July 1989.

For the Council

The President

R. DUMAS

COMMISSION REGULATION (Euratom) No 944/89

of 12 April 1989

laying down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Atomic Energy Community,

Having regard to Council Regulation (Euratom) No 3954/87 of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency (1), and in particular Article 7 thereof,

Whereas, in accordance with Regulation (Euratom) No 3954/87, the Commission shall adopt a list of minor foodstuffs, together with the maximum levels of radioactive contamination to be applied thereto;

Whereas, the group of experts appointed by the Scientific and Technical Committee pursuant to Article 31 of the Euratom Treaty has been consulted;

Whereas the foodstuffs to be considered are those of minor dietary importance which make only a marginal contribution to food consumption by the population;

Whereas foodstuffs for inclusion in the list of minor foodstuffs must be identified by means of their combined nomenclature code number and description set out in Commission Regulation (EEC) No 3174/88 of 21 September 1988 amending Annex 1 to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff (2);

Whereas the *ad hoc* Committee, instituted by Council Regulation (Euratom) No 3954/87 has not delivered an opinion within the time limit set by its chairman,

HAS ADOPTED THIS REGULATION:

Article 1

The list of minor foodstuffs established pursuant to Article 7 of Regulation (Euratom) No 3954/87 is set out in the Annex.

Article 2

For the minor foodstuffs given in the Annex, the maximum permitted levels to be applied are 10 times those applicable to 'other foodstuffs except minor foodstuffs' fixed in the Annex of Regulation (Euratom) No 3954/87 or pursuant to Regulations adopted on the basis of Article 3 of that Regulation.

Article 3

This Regulation shall enter into force on the third day following its publication in the *Official Journal of the European Communities.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 12 April 1989.

For the Commission

Carlo RIPA DI MEANA

Member of the Commission

(1) OJ No L 371, 30. 12. 1987, p. 11.
(2) OJ No L 298, 31. 10. 1988, p. 1.

ANNEX

List of minor foodstuffs

CN code	Description
0703 20 00	Garlic (fresh or chilled))
0709 52 00	Truffles (fresh or chilled)
0709 90 40	Capers (fresh or chilled)
0711 30 00	Capers (provisionally preserved, but unsuitable in that state for immediate consumption)
0712 30 00	Truffles (dried, whole, cut, sliced, broken or in powder, but not further prepared)
0714	Manioc, arrowroot, salep, Jerusalem artichokes, sweet potatoes and similar roots and tubers with high starch or inulin content, fresh or dried, whether or not sliced or in the form of pellets; sago pith
0814 00 00	Peel of citrus fruit or melons (including watermelons), fresh, frozen, dried or provisionally preserved in brine, in sulphur water or in other preservative solutions
0903 00 00	Maté
0904	Pepper of the genus *Piper*; dried or crushed of ground fruits of the genus *Capsicum* or of the genus *Pimenta*
0905 00 00	Vanilla
0906	Cinnamon and cinnamon-tree flowers
0907 00 00	Cloves (whole fruit, cloves and stems)
0908	Nutmeg, mace and cardamons
0909	Seeds of anise, badian, fennel, coriander, cumin or caraway; juniper berries
0910	Ginger, saffron, turmeric (curcuma), thyme, bay leaves, curry and other spices
1106 20	Flour and meal of sago, roots or tubers of heading No 0714
1108 14 00	Manioc (cassava) starch
1210	Hop cones, fresh or dried, whether or not ground, powdered or in the form of pellets; lupulin
1211	Plants and parts of plants (including seeds and fruits), of a kind used primarily in perfumery, in pharmacy or for insecticidal, fungicidal or similar purposes, fresh or dried, whether or not cut, crushed or powdered
1301	Lac; natural gums, resins, gum-resins and balsams
1302	Vegetable saps and extracts; pectic substances, pectinates and pectates; agar-agar and other mucilages and thickeners, whether or not modified, derived from vegetable products
1504	Fats and oils and their fractions, of fish or marine mammals, whether or not refined, but not chemically modified
1604 30	Caviar and caviar substitutes
1801 00 00	Cocoa beans, whole or broken, raw or roasted
1802 00 00	Cocoa shells, husks, skins and other cocoa waste
1803	Cocoa paste, whether or not defatted
2003 20 00	Truffles (prepared or preserved otherwise than by vinegar or acetic acid)
2006 00	Fruit, nuts, fruit-peel and other parts of plants, preserved by sugar (drained, glacé or crystallized)
2102	Yeasts (active or inactive); other single-cell micro-organisms, dead (but not including vaccines of heading No 3002); prepared baking powders
2936	Provitamins and vitamins, natural or reproduced by synthesis (including natural concentrates), derivatives thereof used primarily as vitamins, and intermixtures of the foregoing, whether or not in any solvent
3301	Essential oils (terpeneless or not), including concretes and absolutes; resinoids; concentrates of essential oils in fats, in fixed oils, in waxes or the like, obtained by enfleurage or maceration; terpenic by-products of the deterpenation of essential oils; aqueous distillates and aqueous solutions of essential oils

I

(Acts whose publication is obligatory)

COUNCIL REGULATION (EEC) No 737/90

of 22 March 1990

on the conditions governing impots of agricultural products originating in third countries following the accident at the Chernobyl nuclear power-station

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 113 thereof,

Having regard to the proposal from the Commission,

Whereas, following the accident at the Chernobyl nuclear power-station on 26 April 1986, considerable quantities of radioactive elements were released into the atmosphere ;

Whereas 3955/87 (1), as amended by 4003/89 (2), fixed maximum permitted levels of radioactivity for agricultural products originating in third countries and intended for human consumption with which imports of the products concerned must comply and in connection with which checks are carried out by the Member States ; whereas that Regulation applies only until 31 March 1990 ;

Whereas, without prejudice to the possibility of resorting, where necessary, in the future to the provisions of Council Regulation (Euratom) No 3954/87 of 22 December 1987 laying down maximum permitted radioactivity levels for foodstuffs and feedingstuffs following a nuclear accident or any other case of radiological emergency (3), as amended by Regulation (Euratom) No 2218/89 (4), the Community must continue to ensure, with regard to the specific effects of the accident at Chernobyl, that agricultural products and processed agricultural products intended for human consumption and likely to be contaminated are introduced into the Community only according to common arrangements ;

Whereas these common arrangements should safeguard the health of consumers, maintain, without having unduly adverse effects on trade between the Community and third countries, the unified nature of the market and prevent deflections of trade ;

Whereas the reasons prevailing when Regulation (EEC) No 3955/87 was adopted are still valid, particularly on account of the fact that radioactive contamination in certain agricultural products originating in the third countries affected by the accident still exceed the maximum permitted levels of radioactivity laid down in that Regulation ;

Whereas compliance with the maximum permitted levels must be the subject of appropriate checks, which may lead to prohibiting imports in cases of non-compliance ;

Whereas radioactive contamination in many agricultural products has decreased and will continue to decrease to the levels existing before the Chernobyl accident ; whereas a procedure should therefore be established enabling such products to be excluded from the scope of the abovementioned Regulation ;

Whereas, since this Regulation covers all agricultural products and processed agricultural products intended for human consumption, there is no need, in the present case, to apply the procedure provided for in Article 29 of Directive 72/462/EEC (5) ;

Whereas, in order to clarify or adjust, as necessary, the measures provided for by this Regulation, a simplified procedure should be established,

HAS ADOPTED THIS REGULATION :

Article 1

With the exception of the products unfit for human consumption listed in Annex I and those products which may come to be excluded from the scope of this Regulation pursuant to the procedure laid down in Article 7, this Regulation shall apply to the products originating in third countries covered by :

— Annex II to the Treaty,

— Council Regulation (EEC) No 2730/75 of 29 October 1975 on glucose and lactose (6), as amended by Commission Regulation (EEC) No 222/88 (7),

(1) OJ No L 371, 30. 12. 1987, p. 14.
(2) OJ No L 382, 30. 12. 1989, p. 4.
(3) OJ No L 371, 30. 12. 1987, p. 11.
(4) OJ No L 211, 27. 7. 1989, p. 1.
(5) OJ No L 302, 31. 12. 1972, p. 28.
(6) OJ No L 281, 1. 11. 1975, p. 20.
(7) OJ No L 28, 1. 2. 1988, p. 1.

— Council Regulation (EEC) No 2783/75 of 29 October 1975 on the common system of trade for ovalbumin and lactalbumin (1), as amended by Commission Regulation (EEC) No 4001/87 (2),

— Council Regulation (EEC) No 3033/80 of 11 November 1980 laying down the trade arrangements applicable to certain goods resulting from the processing of agricultural products (3), as amended by Commission Regulation (EEC) No 3743/87 (4),

— Council Regulation (EEC) No 3035/80 of 11 November 1980 laying down general rules for granting export refunds on certain on certain agricultural products exported in the form of goods not covered by Annex II to the Teaty, and the criteria for fixing the amount of such refunds (5), as last amended by Regulation (EEC) No 3209/88 (6).

Article 2

Without prejudice to other provisions in force, the release for free circulation of the products referred to in 'Article 1 shall be subject to compliance with the maximum permitted levels laid down in Article 3.

Article 3

The maximum permitted levels referred to in Article 2 shall be as follows :

the accumulated maximum radioactive level in terms of caesium-134 and -137 shall be :

— 370 Bq/kg for milk and milk products listed in Annex II and for foodstuffs intended for the special feeding of infants during the first four to six months of life, which meet, in themselves, the nutritional requirements of this category of person and are put up for retail sale in packages which are clearly indentified and labelled 'food preparation for infants' (7),

— 600Bq/kg for all other products concerned.

Article 4

1. Member States shall check compliance with the maximum permitted levels set in Article 3 in respect of the products referred to in Article 1, taking into account contamination levels in the country of origin. Checking may also include the presentation of export certificates. Depending on the results of the checks carried out, Member States shall take the measures required for Article 2 to apply, including the prohibition of release for free circulation, taking each case individually or generally for a given product.

2. Each Member State shall provide the Commission with all information concerning the application of this Regulation, notably cases of non-compliance with the maximum permitted levels. The Commission shall circulate such information to the other Member States.

Article 5

Where cases of repeated non-compliance with the macimum permitted levels have been recorded, the necessary measures may be taken in accordance with the procedure laid down in Article 7. Such measures may even include the prohibition of the import of products originating in the third country concerned.

Article 6

The arrangements for applying this Regulation, any amendments to be made to the products in Annex I, and the list of products excluded from this Regulation shall be adopted in accordance with the procedure laid down in Article 7.

Article 7

1. The Commission shall be assisted by an *ad hoc* committee composed of the representatives of the Member States and chaired by the representative of the Commission.

2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committe shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. The Commission shall adopt measures which shall apply immediately.

(1) OJ No L 282, 1. 11. 1975, p. 104.
(2) OJ No L 377, 31. 12. 1987, p. 44.
(3) OJ No L 323, 29. 11. 1980, p. 1.
(4) OJ No L 352, 15. 12. 1987, p. 29.
(5) OJ No L 323, 29. 11. 1980, p. 27.
(6) OJ No L 286, 20. 10. 1988, p. 6.
(7) The level applicable to concentrated or dried products shall be calculated on the basis of the reconstituted product as ready for consumption.

However, if these measures are not in accordance with the opinion of the committee, they shall be communicated by the Commission to the Council fortwith. In that event :

— the Commission may defer application of the measures which it has decided for a period of not more than one month from the date of such communication,

— the Council, acting by a qulified majority, may take a different decision within the time limit referred to in the first indent.

Article 8

This Regulation shall enter into force on 1 April 1990.

It shall expire on 31 March 1995, unless the Council decides otherwise at an earlier date, particularly should the list of excluded products referred to in Article 6 cover all the products fit for human consumption to which this Regulation applies.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 22 March 1990.

For the Council

The President

P. FLYNN

ANNEX I

Products unfit for human consumption

CN code	Description
ex 0101 19 90	Racehorses
ex 0106 00 99	Other (live animals, excluding domestic rabbits and pigeons : not for human consumption)
ex 03 01	Live ornamental fish
0408 11 90 0408 19 90 0408 91 90 0408 99 90	Eggs, not in shell, and egg yolks, unfit for human consumption (a)
ex 0504	Non-edible guts, bladders and stomachs of animals (other than fish), whole and pieces thereof
0511 10 00 ex 0511 91 90 0511 99 10 0511 99 90	Animal products not elsewhere specified or included, excluding edible animal blood; dead animals of Chapter 1 or Chapter 3, unfit for human consumption
0713 20 10 0713 31 10 0713 32 10 0713 33 10 0713 39 10 0713 40 10 0713 50 10 0713 90 10	Dried leguminous vegetables, shelled, whether or not skinned or split, for sowing
1001 90 10	Spelt for sowing (a)
1005 10 11 1005 10 13 1005 10 15 1005 10 19	Hybrid maize for sowing (a)
1006 10 10	Rice for sowing (a)
ex 1007 00 00	Hybrid sorghum for sowing (a)
1201 00 10 1202 10 10 1204 00 10 1205 00 10 1206 00 10 1207 10 10 1207 20 10 1207 30 10 1207 40 10 1207 50 10 1207 60 10 1207 91 10 1207 92 10 1207 99 10	Oil seeds and oleaginous fruit, whole or broken, for sowing (a)
1209 11 00 1209 19 00 1209 21 00 1209 23 10 1209 24 00 1209 26 00 1209 30 00 1209 91 1209 99	Seeds, fruit and spores, of a kind used for sowing
1501 00 11	Lard and other pig fat for industrial uses other than the manufacture of foodstuffs for human consumption (a)
1502 00 10	Fats of bovine animals, sheep or goats, raw or rendered, whether or not pressed or solvent-extracted, for industrial uses other than the manufacture of foodstuffs for human consumption (a)

CN code	Description
1503 00 11	Lard stearin and oleostearin for industrial uses (a)
1503 00 30	Tallow oil for industrial uses other than the manufacture of foodstuffs for human consumption (a)
1505 10	Wool grease and fatty substances derived therefrom (including lanolin)
1507 10 10 1507 90 10	Soya bean oil and its fractions, whether or not refined ; but not chemically modified, for technical uses other than the manufacture of foodstuffs for human consumption (a)
1508 10 10 1508 90 10	Ground-nut oil and its fractions, whether or not refined but not chemically modified, for technical or industrial uses other than the manufacture of foodstuffs for human consumption (a)
1511 10 10	Crude palm oil and its fractions, whether or not refined, but not chemically modified, for technical or industrial uses other than the manufacture of foodstuffs for human consumption (a)
1515 30 10	Castor oil and its fractions for the production for the production of aminoundecanoic acid for use in the manufacture of synthetic textile fibres or of artificial plastic materials (a)
1515 40 00	Tung oil and its fractions
1515 90 10	Oiticica oils, myrtle wax and Japan wax ; their fractions
1511 90 91 1512 11 90 1512 19 10 1512 19 90 1512 21 10 1512 29 10 1513 11 10 1513 19 30 1513 21 11 1513 21 19 1513 29 30 1514 10 10 1514 90 10 1515 11 00 1515 19 10 1515 21 10 1515 29 10 1515 50 11 1515 50 91 1515 90 21 1515 90 31 1515 90 40 1515 90 60 1516 20 91 1516 20 99	Other oils for technical or industrial uses other than the manufacture of foodstuffs for human consumption (a)
1518 00 31 1518 00 39	Fixed vegetables oils, fluid, mixed, for technical or industrial uses other than the manufacture of foodstuffs for human consumption (a)
2207 20 00	Ethyl alcohol and other spirits ; denatured, of any strength
3823 10 00	Prepared binders for foundry moulds or cores
4501	Natural cork, raw or simply prepared ; waste cork ; crushed granulated or ground cork
5301 10 00 5301 21 00 5301 29 00	Flax, raw or processed but not spun
5302	True hemp *(Cannabis sativa* L.), raw or processed but not spun ; tow and waste of true hemp (including yarn waste and garnetted stock)
ex Chapter 6	Live trees and other plants ; bulbs, roots and the like, cut flowers and ornamental foliage, excluding plants and roots of chicory of subheading 0601 20 10

(a) Entry under this subheading is subject to conditions laid down in the relevant Community provisions.

ANNEX II

Milk and milk products to which a maximum permitted level of 370 Bq/kg applies

CN codes 0401
0402
0403 10 11 to 39
0403 90 11 to 69
0404

COMMISSION REGULATION (EEC) No 1518/93

of 21 June 1993

establishing a list of products excluded from the application of Council Regulation (EEC) No 737/90 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Regulation (EEC) No 737/90 of 22 March 1990 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station (1), and in particular Article 6 thereof,

Whereas, in accordance with Regulation (EEC) No 737/90 the Commission shall adopt a list of products excluded from its application;

Whereas most agricultural products currently imported from third countries are free of radioactive contamination from the Chernobyl accident or so slightly contaminated as to present a negligible risk to health;

Whereas the list of products excluded from the application of Regulation (EEC) No 737/90, established by Commission Regulation (EEC) No 598/92 (2), has to be extended to take this into account;

Whereas the measures provided in this Regulation are in accordance with the opinion of the *ad hoc* Committee instituted by Regulation (EEC) No 737/90,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EEC) No 598/92 is hereby repealed.

Article 2

All products other than those listed in the Annex are excluded from the scope of Regulation (EEC) No 737/90.

Article 3

This Regulation shall enter into force on the third day following its publication in the *Official Journal of the European Communities.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 21 June 1993.

For the Commission

Yannis PALEOKRASSAS

Member of the Commission

(1) OJ No L 82, 29. 3. 1990, p. 1.
(2) OJ No L 64, 10. 3. 1992, p. 15.

ANNEX

List of products to which Council Regulation (EEC) No 737/90 of 22 March 1990 is applicable

CN code	Description
0101 19 10	(Live horses, asses, mules and hinnies): (Horses): For slaughter
0102 90	(Live bovine animals): (other): Domestic species
0103 91	(Live swine): (Other): Weighing less than 50 kg
0103 92	(—"—): (—"—): Weighing 50 kg or more
0104 10	(Live sheep and goats): (Sheep) (except pure-bred breeding animals 0410 10 10)
0104 20 90	(—"—): (Goats): Other
0105	Live poultry, that is to say, fowls of the species *Gallus domesticus*, ducks, geese, turkeys and guinea fowls
0106 00	Other live animals
02	Meat and edible meat offal
04	Dairy produce ; birds' eggs ; natural honey ; edible products of animal origin, not elsewhere specified or included (except 0408 11 90, 0408 19 90, 0408 91 90, 0408 99 90)
0701 90	(Potatoes, fresh or chilled): Other
0703	Onions, shallots, garlic, leeks and other alliaceous vegetables, fresh or chilled (except 0703 20 00 garlic)
0706	Carrots, turnips, salad beetroot, salsify, celeriac, radishes and similar edible roots, fresh or chilled
0709 51	(Other vegetables, fresh or chilled): Mushrooms (except cultivated mushrooms 0709 51 10)
0710 10 00	(Vegetables (uncooked or cooked by steaming or boiling in water), frozen): Potatoes
0710 80 60	(—"—): Mushrooms
0711 90 40	(Vegetables provisionally preserved (for example, by sulphur dioxide gas, in brine, in sulphur water or in other preservative solutions) but unsuitable in that state for immediate consumption): (other vegetables ; mixtures of vegetables): (Mushrooms): of the species *Agaricus*
0711 90 60	(—"—): (—"—): (—"—): Other
0712 10 00	(Dried vegetables, whole, cut, sliced, broken or in powder, but not further prepared): Potatoes whether or not cut or sliced but not further prepared
0712 20 00	(—"—): Onions
0712 30 00	(—"—): Mushrooms and truffles
0712 90 50	(—"—): (Other vegetables ; mixtures of vegetables): Carrots
0810 40	(Other fruit, fresh): Cranberries, bilberries and other fruits of the genus *Vaccinium*
0811 90 50	(Fruit and nuts, uncooked or cooked by steaming or boiling in water, frozen, whether or not containing added sugar or other sweetening matter): (Other): Fruit of the species *Vaccinium myrtillus*
0811 90 70	(—"—): (Other): Fruit of the species *Vaccinium myrtilloides* and *Vaccinium angustifolium*
0812 90 40	(Fruit and nuts provisionally preserved (for example) by sulphur dioxide gas, in brine, in sulphur water or in other preservative solutions), but unsuitable in that state for immediate consumption): (Other): Fruit of the species *Vaccinium myrtillus*

CN code	Description
0813	Fruit, dried, other than that of heading Nos 0801 to 0806 ; mixtures of nuts or dried fruits of this chapter : (except 0813 40 50 papaws and 0813 40 60, tamarinds)
0902	Tea, whether or not flavoured
0909	Seeds of anise, badian, fennel, coriander, cumin or caraway ; juniper berries (except 0909 30 11, 0909 40 11, 0909 50 11)
0910	Ginger, saffron, turmeric (curcuma), thyme, bay leaves, curry and other spices
1601 00	Sausages and similar products, of meat, offal or blood ; food preparations based on these products
1602	Other prepared or preserved meat, meat offal or blood
1603 00	Extracts and juices of meat, fish or crustaceans, molluscs or other aquatic invertebrates
2001 90 50	(Vegetables, fruit, nuts and other edible parts of plants, prepared or preserved by vinegar or acetic acid) : (Other) : Mushrooms
2001 90 75	(—"—) : (—"—) : Salad beetroot *(Beta vulgaris var. conditiva)*
2003 10	(Mushrooms and truffles, prepared or preserved otherwise than by vinegar or acetic acid) : Mushrooms
2004 10	(Other vegetables prepared or preserved otherwise than by vinegar or acetic acid, frozen) : Potatoes
2005 20	(Other vegetables prepared or preserved otherwise than by vinegar or acetic acid, not frozen) : Potatoes
2101 20	(Extracts, essences and concentrates, of coffee, tea or maté and preparations with a basis of these products or with a basis of coffee, tea or maté ; roasted chicory and other roasted coffee substitutes, and extracts, essences and concentrates thereof) : Extracts, essences and concentrates, of tea or maté, and preparations with a basis of these extracts, essences or concentrates, jor with a basis of tea or maté
2101 30	(—"—) : Roasted chicory and other roasted coffee substitutes, and extracts, essences and concentrates thereof

388L0344

88/344/EEC: COUNCIL DIRECTIVE OF 13 JUNE 1988 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES ON EXTRACTION SOLVENTS USED IN THE PRODUCTION OF FOODSTUFFS AND FOOD INGREDIENTS

OFFICIAL JOURNAL NO L 157, 24/06/1988, P. 28
DATE OF NOTIFICATION: 22/06/1988
DATE OF TRANSPOSITION: 13/06/1991; SEE ART. 9

AMENDED BY

392L0115
92/115/EEC: COUNCIL DIRECTIVE OF 17 DECEMBER 1992 **[1]**
OFFICIAL JOURNAL NO L 409, 31/12/1992, P. 31
DATE OF TRANSPOSITION: 01/07/1993; SEE ART. 2

ARTICLE 1

1. This Directive applies to extraction solvents used or intended for use in the production of foodstuffs or food ingredients.
This Directive shall not apply to extraction solvents used in the production of food additives, vitamins and other nutritional additives, unless such food additives, vitamins or nutritional additives are listed in the Annex.
However, the Member States shall ensure that the use of food additives, vitamins and other nutritional additives does not result in foodstuffs containing extraction solvent residue levels dangerous to human health.
" This Directive shall apply without prejudice to the provisions adopted under more specific Community rules. " **[1]**

2. "..." **[1]**

3. For the purposes of this Directive:

(a) "solvent" means any substance for dissolving a foodstuff or any component thereof, including any contaminant present in or on that foodstuff;

(b) "extraction solvent" means a solvent which is used in an extraction procedure during the processing of raw materials, of foodstuffs, or of components or ingredients of these products and which is removed but which may result in the unintentional, but technically unavoidable, presence of residues or derivatives in the foodstuff or food ingredient.

ARTICLE 2

1. Member States shall authorize the use as extraction solvents in the manufacture of foodstuffs or food ingredients of those substances and materials listed in the Annex, under the conditions of use and where appropriate within the maximum residue limits therein specified.
Member States may not prohibit, restrict or obstruct the marketing of foodstuffs or food ingredients on grounds relating to the extraction solvents used or their residues if these comply with the provisions of this Directive.

2. Member States shall not authorize the use of other substances and materials as extraction solvents, nor extend the conditions or use or permitted residues of the extraction solvents listed in the Annex beyond those specified therein.

3. Until the adoption of Community provisions on substances used for diluting and dissolving flavourings Member States may, on their territory, allow the use, as solvents for the extraction of flavourings from natural flavouring materials, of substances used for diluting or dissolving flavourings.

4. Water, to which substances regulating acidity or alkalinity may have been added, other food substances which possess solvent properties and ethanol are authorized as extraction solvents in the manufacture of foodstuffs or food ingredients.

5. "..." **[1]**

6. "..." **[1]**

ARTICLE 3

Member States shall take all measures to ensure that the substances and materials listed as extraction solvents in the Annex satisfy the following purity criteria:

(a) they shall not contain a toxicologically dangerous amount of any element or substance;

(b) subject to any exceptions deriving from the specific purity criteria referred to in (c), they shall not contain more than 1 mg/kg of arsenic or more than 1 mg/kg of lead;

(c) they shall satisfy the specific purity criteria determined in accordance with Article 4.

ARTICLE 4

The following shall be determined in accordance with the procedure laid down in Article 6:

(a) the methods of analysis necessary to verify compliance with the general and specific purity criteria referred to in Article 3;

(b) the procedure for taking samples and the methods for qualitative and quantitative analysis of the extraction solvents cited in the Annex used in foodstuffs or food ingredients;

(c) if necessary, the specific purity criteria for the extraction solvents listed in the Annex, and in particular maximum permitted limits of mercury and cadmium in the extraction solvents; these criteria are to be adopted within three years from the date of adoption of this Directive.

ARTICLE 5

1. Where a Member State, as a result of new information or of a reassessment of existing information made since the Directive was adopted, has detailed grounds for establishing that the use in foodstuffs of any substance listed in the Annex or the level of one or more of the components referred to in Article 3 contained in such substances might endanger human health although it complies with the conditions laid down in this Directive, that Member State may temporarily suspend or restrict application of the provisions in question in its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

2. The Commission shall examine as soon as possible the evidence given by the Member State concerned and consult the Standing Committee for Foodstuffs, and shall then deliver its opinion forthwith and take the appropriate measures, which may replace the measures referred to in paragraph 1.

3. If the Commission considers that amendments to the Directive are necessary in order to resolve the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall initiate the

procedure laid down in Article 6 with a view to adopting these amendments. Any Member State which has adopted safeguard measures may in that event retain them until the amendments enter into force in its territory.

ARTICLE 6

1. Where the procedure laid down in this Article is to be followed, the chairman shall refer the matter to the Standing Committee for Foodstuffs.

2. The Commission representative shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a period fixed by the chairman according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. (a) The Commission shall adopt the intended measures when they are in accordance with the Committee's opinion.

(b) Where the intended measures are not in accordance with the opinion of the Committee, or in the absence of any opinion, the Commission shall forthwith submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

(c) If, on the expiry of three months from the date on which the matter was referred to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures.

ARTICLE 7

1. Member States shall take all the necessary measures to ensure that the substances listed in the Annex and intended for use as extraction solvents in foodstuffs may not be marketed unless their packaging, containers or labels carry the following information in such a way as to be easily visible, clearly legible and indelible:

(a) the commercial name as given in the Annex;

(b) a clear indication that the material is of a quality suitable for use for the extraction of food or food ingredients;

(c) a reference by which the batch or lot may be identified;

(d) the name or business name and address of the manufacturer or packer or of a seller established within the Community;

(e) the net quantity given as units of volume;

(f) if necessary, the special storage conditions or conditions of use.

2. By way of derogation from paragraph 1, the information specified in points (c), (d), (e) and (f) of that paragraph may appear merely on the trade documents relating to the batch or lot which are to be supplied with or prior to the delivery.

3. This Article is without prejudice to more precise or more extensive Community provisions regarding weights and measures or provisions applying to the classification, packaging and labelling of dangerous substances and preparations.

4. Member States shall refrain from laying down requirements more detailed than those already contained in this Article concerning the manner in which the particulars provided are to be shown.
Member States shall, however, ensure that the sale of extraction solvents within their own territories is prohibited if the particulars provided for in this Article do not appear in a language easily understood by

purchasers, unless other measures have been taken to ensure that the purchaser is informed. This provision shall not prevent such particulars from being indicated in various languages.

ARTICLE 8

1. This Directive shall apply equally to extraction solvents used or intended for use in the production of foodstuffs or ingredients imported into the Community.

2. This Directive shall not apply to extraction solvents, or foodstuffs intended for export outside the Community.

ARTICLE 9

Member States shall take the measures necessary to comply with this Directive within three years of its adoption, so as to authorize from that date trade in and use of extraction solvents complying with the provisions of this Directive and to prohibit trade in and use of extraction solvents which do not comply therewith. They shall immediately inform the Commission thereof.

ARTICLE 10

This Directive is addressed to the Member States.

ANNEX

EXTRACTION SOLVENTS WHICH MAY BE USED DURING THE PROCESSING OF RAW MATERIALS, OF FOODSTUFFS, OF FOOD COMPONENTS OR OF FOOD INGREDIENTS

PART I

Extraction solvents to be used in compliance with good manufacturing practice for all uses (1)

Name
Propane
Butane
Butyl acetate
Ethyl acetate
Ethanol
Carbon dioxide
Acetone " (2) " **[1]**
Nitrous oxide

(1) An extraction solvent is considered as being used in compliance with good manufacturing practice if its use results only in the presence of residues or derivatives in technically unavoidable quantities presenting no danger to human health.

" (2) The use of acetone in the refining of olive-pomace oil is forbidden. " **[1]**

PART II

Extraction solvents for which conditions of use are specified

Name	Conditions of use (summary description of extraction)	Maximum residue limits in the extracted foodstuff or food ingredient
Hexane (1)	Production or fractionation of fats and oils and production of cocoa butter	5 mg/kg in the fat or oil or cocoa butter
	Preparation of protein products and defatted flours	10 mg/kg in the food containing the protein products and defatted flours
	Preparation of defatted cereal germs	5 mg/kg in the defatted cereal germ
	Defatted soya products	30 mg/kg in the soya product as sold to the final consumer
Methyl acetate	Decaffeination of, or removal of irritants and bitterings from coffee and tea	20 mg/kg in the coffee or tea
	Production of sugar from molasses	1 mg/kg in the sugar
Ethylmethylketone " (2) " **[1]**	Fractionation of fats and oils	5 mg/kg in the fat or oil
	Decaffeination of, or removal of irritants and bitterings from coffee and tea	20 mg/kg in the coffee or tea
Dichloromethane	Decaffeination of, or removal of irritants and bitterings from coffee and tea	" 2 mg/kg " **[1]** in the roasted coffee and 5 mg/kg in the tea
" Methanol		10 mg/kg " **[1]**
" Propan-2-ol		10 mg/kg " **[1]**

(1) Hexamine means a commercial product consisting essentially of acyclic saturated hydrocarbons containing six carbon atoms and distilling between 64 °C and 70 °C. " The combined use of hexane and ethylmethylketone is forbidden. " **[1]**
(2) " The presence of n-Hexane in this solvent should not exceed 50 mg/kg. This solvent may not be used in combination with Hexane. " **[1]**

PART III

Extraction solvents for which conditions of use are specified

Name	Maximum residue limits in the foodstuff due to the use of extraction solvents in the preparation of flavourings from natural flavouring materials
Diethyl ether	2 mg/kg
"..." **[1]**	
Hexane " (1) "**[1]**	1 mg/kg
"..." **[1]**	
Methyl acetate	1 mg/kg
Butan-1-ol	1 mg/kg
Butan-2-ol	1 mg/kg
Ethylmethylketone " (1) " **[1]**	1 mg/kg
Dichloromethane	" 0,02 mg/kg " **[1]**
Methyl-propan-1-ol	1 mg/kg
" Propan-1-ol	1 mg/kg " **[1]**

(1) " The combined use of these two solvents is forbidden. " **[1]**

I

(Acts whose publication is obligatory)

COUNCIL REGULATION (EEC) No 315/93
of 8 February 1993
laying down Community procedures for contaminants in food

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas it is important to adopt measures with the aim of progressively establishing the internal market over a period expiring on 31 December 1992; whereas the internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

Whereas the differences in rules adopted by the Member States may hinder the functioning of the common market and whereas it is necessary to lay down a procedure for the adoption of harmonized Community rules;

Whereas contaminants may enter into food at any stage from production to consumption;

Whereas it is essential, in the interest of public health protection, to keep these contaminants at levels which are toxicologically acceptable;

Whereas further elimination must be carried out whenever it is achievable through good working practices; whereas compliance with such good practices can be efficiently monitored by public authorities, given the vocational traiing and experience of their agents;

Whereas this Regulation must apply without prejudice to the provisions adopted in the context of more specific Community rules;

Whereas it is appropriate in terms of health protection to encourage the search for a comprehensive approach to the question of contaminants in food;

Whereas the Scientific Committee for Food set up by Decision 74/234/EEC (4) must be consulted on all questions which may have an effect on public health,

HAS ADOPTED THIS REGULATION:

Article 1

1. This Regulation concerns contaminants contained in food.

'Contaminant' means any substance not intentionally added to food which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination. Extraneous matter, such as, for example, insect fragments, animal hair, etc, is not covered by this definition.

2. This Regulation shall not apply to contaminants which are the subject of more specific Community rules.

Upon the entry into force of this Regulation, the Commission shall publish in the C series of the *Official Journal of the European Communities*, for the purposes of information, a list of the rules referred to in the first subparagraph. That list shall be updated, as appropriate, by the Commission.

3. Provisions relating to contaminants shall be adopted in accordance with this Regulation, except those laid down by the rules referred to in paragraph 2.

(1) OJ No C 57, 4. 3. 1992, p. 11.
(2) OJ No C 129, 20. 5. 1991, p. 104 and Decision of 20 January 1993 (not yet published in the Official Journal).
(3) OJ No C 223, 31. 8. 1992, p. 24.
(4) OJ No L 136, 20. 5. 1974, p. 1.

Article 2

1. Food containing a contaminant in an amount which is unacceptable from the public health viewpoint and in particular at a toxicological level shall not be placed on the market.

2. Furthermore, contaminant levels shall be kept as low as can reasonably be achieved by following good practices at all the stages referred to in Article 1.

3. In order to protect public health and pursuant to paragraph 1, where necessary, maximum tolerances for specific contaminants shall be established in accordance with the procedure laid down in Article 8.

These tolerances shall be adopted in the form of a non-exhaustive Community list and may include:

— limits for the same contaminant in different foods;

— analytical detection limits;

— a reference to the sampling and analysis methods to be used.

Article 3

Provisions which may have an effect upon public health shall be adopted after consultation of the Scientific Committee for Food.

Article 4

1. Where a Member State, as a result of new information or of a reassessment of existing information, has reason to suspect that a contaminant in food, although complying with this Regulation or specific Regulations adopted pursuant to this Regulation, constitutes a health risk, it may temporarily suspend or restrict application of the provisions in question in its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

2. The Commission shall examine the reasons given by the Member State referred to in paragraph 1 as soon as possible in the Standing Committee for Foodstuffs, set up by Decision 69/314/EEC (1) and shall deliver its opinion immediately and take any necessary measures in accordance with the procedure laid down in Article 8.

Article 5

1. Member States may not prohibit, restrict, or impede the placing on the market of foods which comply with this Regulation or specific provisions adopted pursuant to this Regulation for reasons relating to their contaminant levels.

2. Where Community provisions concerning the maximum tolerances referred to in Article 2 (3) have not been adopted, the relevant national provisions shall be applicable subject to compliance with the provisions of the Treaty.

3. (a) When a Member State maintains the provisions of its domestic laws, it shall inform the Commission and the other Member States thereof within a period of six months after the adoption of this Regulation.

(b) Should a Member State deem it necessary to adopt new legislation, it shall communicate to the Commission and the other Member States the measures envisaged and give the reasons justifying them. The Commission shall consult the Member States within the Standing Committee on Foodstuffs if it considers such consultation to be useful or if a Member State so requests.

Member States may take such envisaged measures only three months after such communication and provided that the Commission's opinion is not negative.

In the latter event, before the expiry of the period referred to in the second paragraph, the Commission shall initiate the procedure provided for in Article 8 in order to determine whether the envisaged measures may be implemented subject, if necessary, to the appropriate amendments.

Article 6

Each year the Commission shall submit to the Standing Committee on Foodstuffs a report on the overall development of Community legislation on contaminants.

Article 7

Four years after this Regulation comes into force, the Commission shall forward to the Council a report on the experience gained accompanied, should the need arise, by any appropriate proposal.

Article 8

The Commission shall be assisted by the Standing Committee for Foodstuffs, hereinafter referred to as 'the Committee'.

The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

(1) OJ No L 291, 19. 11. 1969, p. 9.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referred to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

Article 9

This Regulation shall enter into force on 1 March 1993.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 February 1993.

For the Council

The President

J. TRØJBORG

MANUFACTURING AND PROCESSING PROCEDURES

COUNCIL DIRECTIVE

of 21 December 1988

on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption

(89/108/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission,

In cooperation with the European Parliament (1),

Having regard to the opinion of the Economic and Social Committee (2),

Whereas the manufacture of and trade in quick-frozen foodstuffs intended for human consumption (hereinafter referred to as 'quick-frozen foodstuffs') are assuming increasing importance in the Community;

Whereas the differences between national laws relating to quick-frozen foodstuffs hamper the free movement thereof; whereas they may create unequal conditions of competition and therefore have a direct effect on the establishment and functioning of the common market;

Whereas it is therefore necessary to approximate these laws;

Whereas to that end the Community rules must be given the widest possible scope, extending to all quick-frozen foodstuffs intended for human consumption and including not only products intended for supply without further processing to the ultimate consumer and to restaurants, hospitals, canteens and to other similar mass caterers, but also products having to be further processed or prepared;

Whereas, however, these rules need not apply to products not offered for sale as quick-frozen foodstuffs;

Whereas it is in any case appropriate to lay down the general principles which any quick-frozen foodstuffs must satisfy;

Whereas at a later stage special provisions over and above the general principles may, where necessary, be adopted for certain categories of quick-frozen foodstuffs, in accordance with the procedure applicable to each of these categories;

Whereas the purpose of quick-freezing is to preserve the intrinsic characteristics of foodstuffs by a process of rapid freezing; whereas it is necessary to attain a temperature of − 18 °C or lower at all points in the product;

Whereas at − 18 °C all microbiological activity likely to impair the quality of a foodstuff is suspended; whereas it is therefore necessary to maintain at least that temperature, subject to a certain technically inevitable tolerance, during the storage and distribution of quick-frozen foodstuffs before their sale to the ultimate consumer;

Whereas for technical reasons certain temperature increases are inevitable and may therefore be tolerated provided they do not harm the quality of the products, which may be ensured by complying with good storage and distribution practice, taking account in particular of the proper level of stock rotation;

Whereas the performance of certain technical equipment at present in use for the local distribution of quick-frozen foodstuffs is not capable of ensuring in every case full compliance with the temperature limits imposed in this Directive, and it is therefore necessary to provide for a transitional system allowing for existing material to be used for its normal lifetime;

Whereas this Directive need merely state the objectives to be attained as regards both the equipment used for the quick-freezing process and the temperatures to be observed in the storage, handling, transport and distribution installations and equipment;

Whereas it is incumbent upon Member States to ensure by means of official checks that the equipment used is capable of meeting these objectives;

Whereas such checks render superfluous any system of official certification for trade purposes;

Whereas it is desirable to provide for the possibility of using cryogenic fluids in direct contact with quick-frozen foodstuffs; whereas therefore these fluids must be sufficiently inert not to impart to the foodstuffs any constituents in quantities liable to constitute a hazard to human health, or to

(1) OJ No C 175, 15. 7. 1985, p. 296 and OJ No C 12, 16. 1. 1989.
(2) OJ No C 104, 25. 4. 1985, p. 17.

give rise to an unacceptable change in the composition of foodstuffs, or to impair their organoleptic characteristics;

Whereas in order to attain this objective it is necessary to adopt a list of these substances and to lay down criteria for their purity and conditions for their use;

Whereas quick-frozen foodstuffs intended for the ultimate consumer and for restaurants, hospitals, canteens and other similar mass caterers are subject, as far as their labelling is concerned, to the rules laid down by Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (1), as last amended by Directive 86/197/EEC (2); whereas the present Directive need therefore merely lay down the particulars which are specific to quick-frozen foodstuffs;

Whereas, to facilitate trade, rules should also be adopted for the labelling of quick-frozen foodstuffs not intended for supply in the frozen state to the ultimate consumer or to restaurants, hospitals, canteens and other similar mass caterers;

Whereas, in order to simplify and speed up the procedure, the Commission should be assigned the task of adopting implementing measures of a technical nature;

Whereas, in all cases in which the Council empowers the Commission to implement the rules laid down for foodstuffs, a procedure establishing close cooperation between the Member States and the Commission within the Standing Committee on Foodstuffs set up by Council Decision 69/414/EEC (3) should be laid down,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to quick-frozen foods intended for human consumption, hereinafter referred to as 'quick-frozen foodstuffs'.

2. For the purposes of this Directive 'quick-frozen foodstuffs' means foodstuffs

— which have undergone a suitable freezing process known as 'quick-freezing' whereby the zone of maximum crystallization is crossed as rapidly as possible, depending on the type of product, and the resulting temperature of the product (after thermal stabilization) is continuously maintained at a level of − 18 °C or lower at all points, and

— which are marketed in such a way as to indicate that they possess this characteristic.

For the purposes of this Directive, ice-cream and other edible ices shall not be regarded as quick-frozen foodstuffs.

3. This Directive shall apply without prejudice to Community provisions relating to:

(a) the common organization of markets in the agricultural and fisheries sectors;

(b) veterinary hygiene.

Article 2

Only the products defined in Article 1 (2) may bear the names provided for in Articles 8 and 9.

Article 3

1. Raw materials used in the manufacture of quick-frozen foodstuffs must be of sound, genuine and merchantable quality and be of the required degree of freshness.

2. Preparation and quick-freezing of products must be carried out promptly, using appropriate technical equipment, in order to limit chemical, biochemical and microbiological changes to a minimum.

Article 4

The cryogenic media authorized, to the exclusion of all others, for use in direct contact with quick-frozen foodstuffs shall be the following:

— air,

— nitrogen,

— carbon dioxide.

By way of derogation from the first paragraph, Member States may retain until 31 December 1992 national laws authorizing the use of dichlorodifluoromethane (R 12) as a cryogenic medium.

The purity criteria to be satisfied by these cryogenic media shall be determined, as far as necessary, in accordance with the procedure laid down in Article 12.

Article 5

1. The temperature of quick-frozen foodstuffs must be stable and maintained, at all points in the product, at − 18 °C or lower, with possibly brief upward fluctuations of no more than 3 °C during transport.

(1) OJ No L 33, 8. 2. 1979, p. 1.
(2) OJ No L 144, 29. 5. 1986, p. 38.
(3) OJ No L 291, 19. 11. 1969, p. 9.

2. However, tolerances in the temperature of the product in accordance with good storage and distribution practice shall be permitted during local distribution and in retail display cabinets subject to the following conditions:

(a) these tolerances shall not exceed 3 °C;

(b) they may, however reach 6 °C in retail display cabinets, if and to the extent that the Member States so decide. In that case, the Member States shall select the temperature in the light of stock or product rotation in the retail trade. They shall inform the Commission of the measures taken and of the grounds for those measures.

The Commission shall review the tolerance provided for in the previous subparagraph in the light of technical developments and shall make proposals to the Council if appropriate before 1 January 1993.

3. For a period of eight years from the notification of this Directive, the Member States may, for local distribution, authorize tolerances of up to 6 °C.

Article 6

1. The Member States shall:

(a) ensure that the equipment used for quick-freezing, storage, transport, local distribution and retail display cabinets is such that compliance with the requirements of this Directive can be guaranteed;

(b) conduct random official checks on the temperature of quick-frozen foodstuffs.

2. Member States shall not require that, as a preliminary to or during the marketing of quick-frozen foodstuffs, compliance with the provisions of paragraph 1 be attested by means of an official certificate.

Article 7

Quick-frozen foodstuffs intended for supply to the ultimate consumer must be packed by the manufacturer or packer in suitable pre-packaging which protects them from microbial or other forms of external contamination and against drying.

Article 8

1. Directive 79/112/EEC shall apply to products covered by this Directive and intended for supply without further processing to the ultimate consumer and to restaurants, hospitals, canteens and other similar mass caterers on the following conditions:

(a) one or more of the following shall be added to the sales name:

in Danish: 'dybfrossen',

in German: 'tiefgefroren' or 'Tiefkühlkost' or 'tiefgekühlt' or 'gefrostet',

in Spanish: 'ultracongelado' or 'congelado rapidamente',

in Greek: 'βαθείας κατάψυξης' or 'ταχείας κατάψυξης' or 'υπερ-κατεψυγμένα',

in English: 'quick-frozen',

in French: 'surgelé',

in Italian: 'surgelato',

in Dutch: 'diepvries',

in Portuguese: 'ultracongelado';

(b) in addition to the date of minimum durability, the period during which quick-frozen products may be stored by the purchaser and the storage temperature and/or type of storage equipment required must be indicated;

(c) the labelling of any quick-frozen foodstuff must include a reference from which the batch may be identified;

(d) the label of any quick-frozen foodstuff must bear a clear message of the type 'do not refreeze after defrosting'.

Article 9

1. The labelling of the products defined in Article 1 (2) which are not intended for sale to the ultimate consumer or to restaurants, hospitals, canteens and other similar mass caterers shall contain only the following mandatory particulars:

(a) the sales name supplemented in accordance with Article 8 (1) (a) of this Directive;

(b) the net quantity expressed in units of mass;

(c) a reference enabling the batch to be identified;

(d) the name or business name and address of the manufacturer or packer, or of a seller established within the Community.

2. The particulars provided for in paragraph 1 shall appear on the packaging, container or wrapping, or on a label attached thereto.

3. This Article shall not affect any Community metrological provisions which are more detailed or more comprehensive.

Article 10

Member States may not, for reasons related to their manufacturing specifications, presentation or labelling,

prohibit or restrict the marketing of any of the products defined in Article 1 (2) which comply with this Directive and, with measures taken for its application.

Article 11

The sampling procedures for quick-frozen foodstuffs, the procedures for monitoring their temperature and for monitoring temperatures in the means of transport and warehousing and storage shall be determined in accordance with the procedure laid down in Article 12, before the end of a 24-month period following notification of this Directive.

Article 12

1. Where the procedure provided for in this Article is invoked, the matter shall be referred to the Standing Committee on Foodstuffs, hereinafter referred to as the 'committee', by its chairman, acting either on his own initiative or at the request of the representative of a Member State.

2. The Commission representative shall submit to the committee a draft of the measures to be adopted. The committee shall deliver its opinion on the draft within a period to be determined by the chairman having regard to the urgency of the matter. It shall decide by a qualified majority, as laid down in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the measures proposed where these are in conformity with the opinion of the committee;

(b) where the measures proposed are not in conformity with the opinion of the committee or where no opinion is delivered, the Commission shall forthwith submit to the Council a proposal concerning the measures to be taken. The Council shall act by a qualified majority;

(c) if, upon the expiry of a period of three months from the date on which the matter is brought before the Council, the latter has failed to take any measures, the Commission shall adopt the proposed measures.

Article 13

1. The Member States shall take the measures necessary to comply with this Directive. They shall forthwith inform the Commission thereof. The measures taken shall:

— permit no later than 18 months after notification (1) of the Directive trade in products which comply with this Directive,

— prohibit no later than 24 months after notification of the Directive trade in products which do not comply with this Directive.

2. As regards retail display cabinets, for a period of eight years following notification of this Directive, Member States may retain the laws applying on the date when this Directive enters into force.

In this case, the Member States shall inform the Commission, stating the reasons for their decision.

Article 14

This Directive is addressed to the Member States.

Done at Brussels, 21 December 1988.

For the Council
The President
V. PAPANDREOU

(1) This Directive was notified to the Member States on 10 January 1989.

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DIRECTIVE 92/1/EEC

of 13 January 1992

on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 89/108/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to quick-frozen foods intended for human consumption (1), and in particular Article 11 thereof,

Whereas the legal provisions must, in this case, be restricted solely to the requirements that are necessary in order to meet essential and imperative needs regarding the monitoring of temperatures in means of transport, warehousing and storage in such a way as to ensure that the temperatures required by Article 5 of Directive 89/108/EEC are fully maintained;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive concerns the monitoring of temperatures in the means of transport, warehousing and storage for quick-frozen foods.

Article 2

1. The means of transport, warehousing and storage must be fitted with suitable recording instruments to monitor, at frequent and regular intervals, the air temperatures to which quick-frozen foods intended for human consumption are subjected.

In the case of transport, the measuring instruments must be approved by the competent authorities of the country in which means of transport is registered.

Temperature recordings obtained in this manner must be dated and stored by the operator for at least one year or longer according to the nature of food.

2. The air temperature during storage in retail display cabinets, and in the course of local distribution, shall be measured by at least one easily visible thermometer which, in the case of open retail display cabinets, shall indicate the temperature at the air return side at the level of the clearly marked maximum load line.

3. Member States may permit a derogation from paragraph 1 in the case of cold chambers of less than 10 cubic metres for storing stock in retail outlets, so as to permit the air temperature to be measured by an easily visible thermometer.

Article 3

Member States shall bring into force the laws, regulations and administrative provisions needed in order to comply with this Directive by 31 July 1993, except for railways for which the date of implementation will be decided later.

They shall immediately inform the Commission thereof.

When Member States adopt these measures, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

(1) OJ No L 40, 11. 2. 1989, p. 34.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 13 January 1992.

For the Commission
Martin BANGEMANN
Vice-President

COMMISSION DIRECTIVE 92/2/EEC

of 13 January 1992

laying down the sampling procedure and the Community method of analysis for the official control of the temperatures of quick-frozen foods intended for human consumption

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 89/108/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to quick-frozen foods intended for human consumption (1), and in particular Article 11 thereof,

Whereas the temperature of quick-frozen foods should be controlled;

Whereas the Member States may use other methods scientifically valid provided that this does not hinder the free movement of quick-frozen foods and that the rules of competition are not altered;

Whereas after checking air temperature records according to procedures laid down in Commission Directive 92/1/EEC of 13 January 1992 on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption (2) and taking into account temperatures required in Article 5 of Directive 89/108/EEC, and where this leaves reasonable doubt, Member States may proceed to a destructive test;

Whereas the inspection conforms to Council Directive 89/397/EEC of 14 June 1989, concerning the official control of foodstuffs (3) and principally to its Articles 4 and 14;

Whereas the provisions provided for in this Directive are in line with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. Member States shall ensure that the sampling procedure and the method of analysis needed for the official inspection of the temperatures of quick-frozen foods is carried out in accordance with the provisions described in Annexes I and II of this Directive.

2. However, the method of analysis described in Annex II of this Directive may be used only in the case where the inspection leaves reasonable doubts on the threshold of temperatures provided for in Directive 89/108/EEC on the approximation of the laws of the Member States relating to quick-frozen foods intended for human consumption.

Article 2

The introduction of requirements provided for in Article 1 (1) and Annexes I and II shall not preclude Member States from using other scientifically valid methods provided that this does not hinder the free movement of quick-frozen foods recognized as complying with the rules by virtue of the method described in Annex II of this Directive.

However, in the event of differences in the results, those obtained by the use of Community methods shall take precedence.

Article 3

1. Member States shall put into effect the laws, regulations and administrative provisions needed in order to comply with this Directive by, at the latest by 31 July 1993.

They shall forthwith inform the Commission thereof.

2. When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 13 January 1992.

For the Commission

Martin BANGEMANN

Vice-President

(1) OJ No L 40, 11. 2. 1989, p. 34.
(2) See page 28 of this Official Journal.
(3) OJ No L 186, 30. 6. 1989, p. 23.

ANNEX I

PROCEDURE FOR THE SAMPLING OF QUICK-FROZEN FOODS INTENDED FOR HUMAN CONSUMPTION

1. **Selection of packages for inspection**

The type and quantity of packages selected shall be such that their temperature is representative of the warmest points of the consignment inspected.

1.1. *Cold-storage*

Samples should be selected from several critical points in the cold store, for example : near the doors (upper and lower levels), near the centre of the cold store (upper and lower levels), and near to the air return of the cooling unit. The duration of storage of any products should be taken into account (for the stabilization of the temperature).

1.2. *Transport*

(a) Where it is necessary to select samples during transport :

Select from the top and the bottom of the consignment adjacent to the opening edge of each door or pair of doors.

(b) Sampling during unloading :

Choose four samples from amongst the following critical points :

— top and bottom of the consignment adjacent to the opening edge of doors,
— top rear corners of the consignment (at a point as far away from the refrigeration unit as possible),
— centre of the consignment,
— centre of the front surface of the consignment (as close as possible to the refrigeration unit),
— top and bottom corners of the front surface of the consignment (as close as possible to the return air to the refrigeration unit).

1.3. *Retail display cabinets*

A sample must be selected for testing from each of three locations representative of the warmest points within the retail display cabinet used.

ANNEX II

METHOD OF MEASURING THE TEMPERATURE OF QUICK-FROZEN FOODSTUFFS INTENDED FOR HUMAN CONSUMPTION

1. Scope

Under Article 1 (2) (1) of Directive 89/108/EEC the temperature throughout the product, following thermal stabilization, must be maintained at all times at a temperature of − 18° C or colder with possible brief upward fluctuations as specified in Article 5 of the Directive.

2. Principle

Measurement of the temperature of quick-frozen foodstuffs consists of accurately recording the temperature of a sample selected in accordance with Annex 1 by means of appropriate equipment.

3. Definition of temperature

'Temperature' means the temperature measured at the specified location by the temperature sensitive part of the measuring instrument or device.

4. Apparatus

4.1. *Thermometric measuring device.*

4.2. *Product-penetration instruments.*

A pointed metallic instrument shall be used such as an ice punch, a hand drill or an auger that is easy to clean.

5. General specification for the temperature measuring instruments

The measuring instruments shall meet the following specifications :

(a) the response time should achieve 90 % of the difference between the initial and final reading within three minutes ;

(b) the instrument must have an accuracy of ± 0,5° C within the measurement range − 20° C to + 30° C ;

(c) the measuring accuracy must not be changed by more than 0,3° C during operation in the ambient temperature range − 20° C to + 30° C ;

(d) the display resolution of the instruments should be 0,1° C ;

(e) the accuracy of the instrument should be checked at regular intervals ;

(f) the instrument should have a current certificate of calibration ;

(g) the temperature probe should be capable of being easily cleaned ;

(h) the temperature-sensitive part of the measuring device must be so designed as to ensure good thermal contact with the product ;

(i) the electrical equipment must be protected against undesirable effects due to the condensation of moisture.

6. Procedure for measurement

6.1. *Pre-cooling of instruments*

The temperature measuring probe and the product penetration instrument should be pre-cooled before measuring the temperature of the product.

The pre-cooling method used should ensure that both instruments equilibrate as close to the product temperature as possible.

6.2. *Preparation af samples for temperature measurement*

Temperature measuring probes are not generally designed to penetrate a quick-frozen product. Therefore it is necessary to make a hole in the product in which to insert the probe by using the pre-cooled product penetration instrument. The diameter of the holde should provide a close fit to that of the probe, and its depth will depend on the type of product (as described in 6.3).

6.3. *Measurement of product temperature*

The sample preparation and its temperature measurement should be undertaken whilst the sample remains in the selected refrigerated environment. Measurement is as follows :

(a) Where the product dimensions allow, insert the pre-cooled probe to a depth of 2,5 mm from the surface of the product ;

(b) Where (a) is not possible the probe should be inserted to a minimum depth from the surface of 3 to 4 times the diameter of the probe.

(c) Certain foods, because of their size or composition (e.g. green peas) cannot be drilled to determine their internal temperature. In these cases, the internal temperature of the food package should be determined by insertion of a suitable pre-cooled sharp-stemmed probe to the centre of the pack to measure the temperature in contact with the food.

(d) Read the temperature indicated when it has reached a steady value.

391R2092

2092/91/EEC: COUNCIL REGULATION OF 24 JUNE 1991 ON ORGANIC PRODUCTION OF AGRICULTURAL PRODUCTS AND INDICATIONS REFERRING THERETO ON AGRICULTURAL PRODUCTS AND FOODSTUFFS

OFFICIAL JOURNAL NO L 198, 22/07/1991, P. 1

AMENDED BY

392R1535
1535/92/EEC: COMMISSION REGULATION OF 15 JUNE 1992 **[1]**
OFFICIAL JOURNAL NO L 162, 16/06/1992, P. 15

392R2083
2083/92/EEC: COUNCIL REGULATION OF 14 JULY 1992 **[2]**
OFFICIAL JOURNAL NO L 208, 24/07/1992, P. 15

393R0207
207/93/EEC: COMMISSION REGULATION OF 29 JANUARY 1993 **[3]**
OFFICIAL JOURNAL NO L 25, 02/02/1993, P. 5

394R0468
468/94/EC: COMMISSION REGULATION OF 2 MARCH 1994 **[4]**
OFFICIAL JOURNAL NO L 59, 03/03/1994, P. 1

Scope

ARTICLE 1

1. This Regulation shall apply to the following products, where such products bear, or are intended to bear, indications referring to organic production methods:

(a) unprocessed agricultural crop products; also animals and unprocessed animal products, to the extent that principles of production and specific inspection rules for them are introduced into Annexes I and III;

(b) products intended for human consumption composed essentially of one or more ingredients of plant origin; in addition, upon adoption of the provisions concerning livestock production referred to in (a), products intended for human consumption containing ingredients of animal origin.

2. A proposal concerning the principles and specific measures of control governing organic animal production, non-processed animal products and products intended for human consumption containing ingredients of animal origin shall be submitted by the Commission as soon as possible and before 1 July 1992.

ARTICLE 2

For the purposes of this Regulation a product shall be regarded as bearing indications referring to organic production methods where, in the labelling, advertising material or commercial documents, such a product or

its ingredients is described by the indications in use in each Member State suggesting to the purchaser that the product or its ingredients have been obtained in accordance with the rules of production laid down in Articles 6 and 7 and in particular the following terms, unless such terms are not applied to agricultural products in foodstuffs or clearly have no connection with the method of production:

- in Spanish: ecológico,
- in Danish: økologisk,
- in German: ökologisch,
- in Greek: [see OJ for reference to the Greek characters],
- in English: organic,
- in French: biologique,
- in Italian: biologico,
- in Dutch: biologisch,
- in Portuguese: biológico.

ARTICLE 3

This Regulation shall apply without prejudice to other Community provisions governing the production, preparation, marketing, labelling and inspection of the products specified in Article 1.

Definitions

ARTICLE 4

For the purpose of this Regulation:

1. "labelling" shall mean any words, particulars, trade marks, brand names, pictorial matter or symbols on any packaging, document, notice, label, board or collar accompanying or referring to a product specified in Article 1;

2. "production" shall mean the operations involved in producing agricultural products in the state in which they are normally produced on the farm;

3. "preparation" shall mean the operations of processing, preserving and packaging of agricultural products;

4. "marketing" shall mean holding or displaying for sale, offering for sale, selling, delivering or placing on the market in any other form;

5. "operator" shall mean any natural or legal person who produces, prepares or imports from a third country, with a view to the subsequent marketing thereof, products as referred to in Article 1, or who markets such products;

6. "ingredients" shall mean the substances, including additives, used in the preparation of the products specified in Article 1 (1) (b) that are still present, albeit in modified form, in the final product;

7. "plant protection products" shall mean products as defined in Article 2 (1) of Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances (1), as last amended by Directive 89/365/EEC (2);

8. "detergents" shall mean substances and preparations, within the meaning of Council Directive 73/404/EEC of 22 November 1973 on the approximation of the laws of the Member States relating to detergents (3), as last amended by Directive 86/94/EEC (4), which are intended to be used for cleaning certain products as referred to in Article 1 (1) (a).

Labelling

ARTICLE 5

1. The labelling and advertising of a product specified in Article 1 (1) (a) may refer to organic production methods only where:

(a) such indications show clearly that they relate to a method of agricultural production;

(b) the product was produced in accordance with the rules laid down in Articles 6 and 7 or imported from a third country under the arrangements laid down in Article 11;

(c) the product was produced or imported by an operator who is subject to the inspection measures laid down in Articles 8 and 9.

2. The labelling and advertising of a product specified in Article 1 (1) (b) may refer to organic production methods only where such indications show clearly that they relate to a method of agricultural production and are accompanied by a reference to the agricultural product in question, as obtained on the farm.

3. The labelling and advertising of a product specified in Article 1 (1) (b) may refer, in the sales description of the product, to organic production methods only where:

(a) all the ingredients of agricultural origin of the product are, or are derived from, products obtained in accordance with the rules laid down in Articles 6 and 7 or imported from third countries under the agreements laid down in Article 11;

(b) the product contains only substances listed in Annex VI, Section A, as ingredients of non-agricultural origin;

(c) the product or its ingredients have not been subjected, during preparation, to treatments involving the use of ionizing radiation or substances not listed in Annex VI, Section B;

(d) the product was prepared by an operator who is subject to the inspection measures laid down in Articles 8 and 9.

4. By way of derogation from paragraph 3 (a), certain ingredients of agricultural origin not satisfying the requirement in that paragraph may be used, within the limit of a maximum level of 5 % of the ingredients of agricultural origin in the final product, in the preparation of products as referred to in Article 1 (1) (b), providing that such ingredients:

- are of agricultural origin and are not produced in the Community in accordance with the rules laid down in Articles 6 and 7, or
- are of agricultural origin and are not produced in sufficient quantity in the Community in accordance with the rules laid down in Articles 6 and 7.

5. During a transitional period expiring on 1 July 1994, indications referring to conversion to organic production methods may be given on the labelling and in the advertising of a product referred to in Article 1 (1) (a) or (b) where it is composed of a single ingredient of agricultural origin, provided that:

(a) the requirements referred to in paragraph 1 or paragraph 3 respectively are fully complied with, with the exception of that concerning the length of the conversion period referred to in paragraph 1 of Annex I;

(b) a conversion period of at least 12 months before the harvest has been complied with;

(c) the indications concerned do not mislead the purchaser of the product regarding its difference from products which satisfy all the requirements of this Regulation;

(d) compliance with the condition laid down in (a) and (b) has been duly checked by the inspection body.

6. The labelling and advertising of a product as referred to in Article 1 (1) (b) prepared partly from ingredients not satisfying the requirements in paragraph 3 (a) may refer to organic production methods provided that:

(a) at least 50 % of the ingredients of agricultural origin satisfy the requirements in paragraph 3 (a);

(b) the product satisfies the requirements in paragraph 3 (b), (c) and (d);

(c) the indications referring to organic production methods:

- appear only in the list of ingredients as provided for in Directive 79/112/EEC (5), as last amended by Directive 89/395/EEC (6),
- clearly refer to only those ingredients obtained according to the rules as referred to in Articles 6 and 7;

(d) the ingredients and their relative levels appear in descending order by weight in the list of ingredients;

(e) indications in the list of ingredients appear in the same colour and with an identical size and style of lettering.

7. Detailed rules concerning the implementation of this Article may be established according to the procedure laid down in Article 14.

8. Limitative lists of the substances and products referred to in paragraph 3 (b) and (c) and in the first and second indents of paragraph 4 shall be established in Annex VI according to the procedure laid down in Article 14.

Conditions of use and compositional requirements of these ingredients and substances may be specified.

Where a Member State considers that a product should be added to the abovementioned lists or that amendments should be made thereto, it shall ensure that a dossier giving the reasons for the inclusion or the amendments is sent officially to the other Member States and the Commission, which shall present it to the Committee referred to in Article 14.

9. Before " 31 July 1994 " **[2]**, the Commission shall review the provisions of this Article, in particular paragraphs 5 and 6, and submit any appropriate proposal with a view to revision, if any.

Rules of production

ARTICLE 6

1. The organic production method implies that for the production of products referred to in Article 1 (1) (a):

(a) at least the requirements of Annex I and, where appropriate, the detailed rules relating thereto, must be satisfied;

(b) only products composed of substances listed in Annexes I and II may be used as plant-protection products, detergents, fertilizers, or soil conditioners; they may be used only under the specific conditions laid down in Annexes I and II and in so far as the corresponding use is authorized in general agriculture in the Member States concerned in accordance with the relevant Community provisions or national provisions in conformity with Community law.

2. By way of derogation from paragraph 1 (b), seeds treated with products not included in Annex II and authorized in general agriculture in the Member State concerned may be used in so far as users of such seed can show to the satisfaction of the inspection body, that they were unable to obtain on the market non-treated seed of an appropriate variety of the species in question.

ARTICLE 7

1. Products not authorized at the date of adoption of this Regulation for a purpose indicated in Article 6 (1) (b) may be included in Annex II, provided that the following conditions are satisfied:

(a) if they are used for the purpose of plant pest or disease control:

- they are essential for the control of a harmful organism or a particular disease for which other biological, cultural, physical or plant breeding alternatives are not available, and
- the conditions for their use preclude any direct contact with the seed, the crop or crop products; however, in the case of perennial crops, direct contact may take place, but only outside the growing season of the edible parts (fruits) provided that such application does not indirectly result in the presence of residues of the product in the edible parts, and
- their use does not result in, or contribute to, unacceptable effects on, or contamination of, the environment;

(b) if they are used for fertilization or soil-conditioning purposes:

- they are essential for specific nutrition requirements of crops or specific soil-conditioning purposes which cannot be satisfied by the practices mentioned in Annex I, and
- their use does not result in unacceptable effects on the environment or contribute to the contamination thereof.

2. If need be, the following may be specified for any product included in Annex II:

- the detailed description of the product,
- the conditions of its use and compositional and/or solubility requirements, with regard in particular to the need to insure for these products a minimal presence of residues on edible parts of the crop and on edible crop products as well as a minimum effect on the environment,
- particular labelling requirements for products referred to in Article 1 where such products are obtained with the aid of certain products referred to in Annex II.

3. Amendments to Annex II, concerning either inclusion or cancelling of products as referred to in paragraph 1 or inclusion or amendments of specifications as referred to in paragraph 2, shall be adopted by the Commission in accordance with the procedure laid down in Article 14.

4. Where a Member State considers that a product should be added to Annex II or that amendments should be made thereto, it shall ensure that a dossier giving the reasons for the inclusion or the amendments is sent officially to the other Member States and the Commission, which shall introduce it to the committee referred to in Article 14.

Inspection system

ARTICLE 8

1. Any operator who produces, prepares or imports from a third country products as specified in Article 1 for the purpose of marketing them shall:

(a) notify this activity to the competent authority of the Member State in which the activity is carried out; such notification shall include the information specified in Annex IV;

(b) submit his undertaking to the inspection system referred to in Article 9.

2. Member States shall designate an authority or body for the reception of notifications.
Member States may provide for the communication of any additional information which they consider to be necessary for effective supervision of the operators concerned.

3. The competent authority shall ensure that an updated list containing the names and addresses of operators subject to the inspection system is made available to interested parties.

ARTICLE 9

1. Member States shall set up an inspection system operated by one or more designated inspection authorities and/or by approved private bodies to which the operators producing or preparing products as referred to in Article 1 shall be subject.

2. Member States shall adopt the measures necessary to ensure that an operator who complies with the provisions of this Regulation and pays his contribution to inspection expenses has access to the inspection system.

3. The inspection system shall comprise at least the application of the precautionary and inspection measures specified in Annex III.

4. For the application of the inspection system operated by private bodies, Member States shall designate an authority responsible for the approval and supervision of such bodies.

5. For the approval of a private inspection body, the following shall be taken into account:

(a) the standard inspection procedure to be followed, containing a detailed description of the inspection measures and precautions which the body undertakes to impose on operators subject to its inspection;

(b) the penalties which the body intends to apply where irregularities are found;

(c) the availability of appropriate resources in the form of qualified staff, administrative and technical facilities, inspection experience and reliability;

(d) the objectivity of the inspection body vis-à-vis the operators subject to its inspection.

6. After an inspection body has been approved, the competent authority shall:

(a) ensure that the inspections carried out by the inspection body are objective;

(b) verify the effectiveness of its inspections;

(c) take cognizance of any infringements found and penalties applied;

(d) withdraw approval of the inspection body where it fails to satisfy the requirements referred to in (a) and (b) or no longer fulfils the criteria indicated in paragraph 5 or fails to satisfy the requirements laid down in paragraphs 7, 8 and 9.

7. The inspection authority and the approved inspection bodies referred to in paragraph 1 shall:

(a) ensure that at least the inspection measures and precautions specified in Annex III are applied to undertakings subject to their inspection;

(b) not disclose information and data they obtain in their inspection activity to persons other than the person responsible for the undertaking concerned and the competent public authorities.

8. Approved inspection bodies shall:

(a) give the competent authority, for inspection purposes, access to their offices and facilities, together with any information and assistance deemed necessary by the competent authority for the fulfilment of its obligations pursuant to this Regulation;

(b) send to the competent authority of the Member State by 31 January each year a list of operators subject to their inspection on 31 December of the previous year and present to the said authority a concise annual report.

9. The inspection authority and inspection bodies referred to in paragraph 1 shall:

(a) ensure that, where an irregularity is found regarding the implementation of Articles 5, 6 and 7 or of the measures referred to in Annex III, the indications provided for in Article 2 referring to the organic production method are removed from the entire lot or production run affected by the irregularity concerned;

(b) where a manifest infringement, or an infringement with prolonged effects is found, prohibit the operator concerned from marketing products with indications referring to the organic production method for a period to be agreed with the competent authority of the Member State.

10. The following may be adopted in accordance with the procedure laid down in Article 14:

(a) detailed rules concerning the requirements indicated in paragraph 5 and the measures listed in paragraph 6;

(b) implementation measures concerning the provisions of paragraph 9.

Indication that products are covered by the inspection scheme

ARTICLE 10

1. The indication that products are covered by the specific inspection scheme, shown in Annex V, may appear on the labelling of products as referred to in Article 1 only where such products:

(a) satisfy the requirements of Article 5 (1), (2), (3) and (4) and Articles 6 and 7, as well as any provisions adopted pursuant to those Articles;

(b) have been subject to the inspection arrangements referred to in Article 9 (3) throughout the production and preparation stages;

(c) have been produced or prepared by operators whose undertakings are subject to inspection by the inspection authority or an inspection body as referred to in Article 9 (1) and have been awarded the right by that authority or body to use the indication shown in Annex V;

(d) are packed and transported to the point of retail sale in closed packaging;

(e) show on the labelling the name and any registered mark of the inspection body, the name and address of the producer or processor and, where Directive 79/112/EEC applies, the indications required thereby.

2. No claim may be made on the label or advertising material that suggests to the purchaser that the indication shown in Annex V constitutes a guarantee of superior organoleptic, nutritional or salubrious quality.

3. The inspection authority and inspection bodies referred to in Article 9 (1) must:

(a) ensure that, where an irregularity is found under Articles 5, 6 and 7 or the measures referred to in Annex III, the indication shown in Annex V is removed from the entire lot or production run affected by the irregularity concerned;

(b) where a manifest infringement, or an infringement with prolonged effects, is found, withdraw from the operator concerned the right to use the indication shown in Annex V for a period to be agreed with the competent authority of the Member State.

4. Rules on withdrawal of the indication shown in Annex V where certain infringements of Articles 5, 6 and 7 or of the requirements and measures in Annex III are detected may be adopted in accordance with the procedure laid down in Article 14.

5. Where a Member State finds, in a product coming from another Member State and bearing the indication shown in Article 2 and/or Annex V, irregularities in the application of this Regulation, it shall inform the Member State which approved the inspection body and the Commission thereof.

6. Member States shall take whatever action is required to prevent fraudulent use of the indication shown in Article 2 and/or Annex V.

7. The Commission shall, before " 31 July 1994 " **[2]**, review Article 10, in particular as regards the possibility of making the indication referred to in Annex V mandatory and shall submit appropriate proposals for a revision thereof, if any.

Imports from third countries

ARTICLE 11

1. Without prejudice to Article 5, products as specified in Article 1 which are imported from a third country may be marketed only where:

(a) they originate in a third country appearing in a list to be drawn up by Commission decision in accordance with the procedure laid down in Article 14 and were produced in a region or a production unit and under the inspection of an inspection body specified, where appropriate, in the decision concerning the third country in question;

(b) the competent authority or body in the third country has issued a certificate of inspection stating that the lot designated in the certificate:

- was obtained within a system of production applying rules equivalent to those laid down in Articles 6 and 7, and
- was subject to a system of inspection recognized as equivalent in accordance with paragraph 2 (b).

2. For the purpose of deciding whether, for certain products as specified in Article 1, a third country may at its request be included in the list referred to in paragraph 1 (a), the following shall be taken into account in particular:

(a) the guarantees which the third country can offer, at least in respect of production for export to the Community, as regards the application of rules equivalent to those laid down in Articles 6 and 7;

(b) the effectiveness of the inspection measures applied, which, at least in respect of production for export to the Community, must be equivalent to the inspection measures referred to in Articles 8 and 9 to ensure compliance with the rules referred to in (a).

On the basis of this information, the regions or production units of origin, or the bodies whose inspections are deemed to be equivalent, may be specified in the Commission decision.

3. The certificate referred to in paragraph 1 (b) must:

(a) accompany the goods, in the original copy, to the premises of the first consignee; thereafter the importer must keep the certificate at the disposal of the inspection authorities for not less than two years;

(b) be drawn up in accordance with procedures and a model to be adopted in accordance with the procedure laid down in Article 14.

4. Detailed rules for the implementation of this Article may be determined according to the procedure referred to in Article 14.

5. When examining a request from a third country, the Commission shall require it to supply all the necessary information; it may also entrust experts with the task of carrying out, under its authority, an on-the-spot examination of the rules of production and inspection measures actually applied in the third country in question.

" 6. (a) By way of derogation from paragraph 1, the importer(s) in a Member State shall be authorized by the competent authority of the Member State to market until 31 July 1995, products imported from a third country

not included in the list referred to in paragraph 1 (a) provided the importer(s) furnish(es) the competent authority of the importing Member State with sufficient evidence that the imported products were manufactured according to production rules equivalent to those laid down in Articles 6 and 7 and were subject to inspection measures of equivalent effectiveness to those referred to in Articles 8 and 9, and that such inspection measures will be permanently and effectively applied.
Such authorization shall be valid only as long as the abovementioned conditions are shown to be satisfied. It shall expire from the time of inclusion of a third country in the list referred to in paragraph 1 (a).

(b) Where a Member State has received sufficient evidence from an importer, it shall forthwith notify to the Commission and the other Member States the third country from which products are imported and supply detailed information on the production and inspection arrangements and the guarantees that they will be permanently and effectively applied.

(c) At the request of a Member State or at the Commission's initiative, the matter shall be submitted to the Committee referred to in Article 14 for examination. Should it emerge from this examination that the imported products were not manufactured according to equivalent production rules and/or inspection measures of equivalent effectiveness, the Commission shall request the Member State which granted the authorization to withdraw it.
It may be decided, in accordance with the procedure laid down in Article 14, that the imports in question shall be prohibited or that their continuation shall be subject to certain of the import conditions being amended within a given period.

(d) The notification referred to in (b) shall not be required where it concerns production and inspection arrangements already notified by another Member State, pursuant to (b), unless significant new evidence is submitted justifying a review of the examination and decision referred to in (c).
Before 31 July 1994, the Commission shall re-examine the provisions of paragraph 1 and submit any appropriate proposal for its review. " **[2]**

Free movement within the Community

ARTICLE 12

Member States may not, on grounds relating to the method of production, to labelling or to the presentation of that method, prohibit or restrict the marketing of products as specified in Article 1 that meet the requirements of this Regulation.

Administrative provisions and implementation

ARTICLE 13

The following may be adopted in accordance with the procedure laid down in Article 14:

- amendments to Annexes I, II, III, IV and VI,
- detailed rules for the implementation of Annexes I and III.

ARTICLE 14

The Commission shall be assisted by a committee composed of representatives of the Member States and chaired by the representative of the Commission.
Where the procedure laid down in this Article is to be followed, the representative of the Commission shall submit to the committee a draft of the measures to be taken.
The committee shall deliver its opinion on the draft, within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.
The Commission shall adopt the measure envisaged if they are in accordance with the opinion of the committee.
If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.
If, on the expiry of a period of three months from the date of referral to it the Council has not acted, the proposed measures shall be adopted by the Commission.

ARTICLE 15

Before 1 July each year, Member States shall inform the Commission of measures taken in the preceding year for the implementation of this Regulation and shall communicate in particular:

- a list of the operators who, on 31 December of the previous year, had given notification under Article 8 (1) (a) and are subject to the inspection system referred to in Article 9,
- a report on supervision pursuant to Article 9 (6).

In addition, by 31 March each year, Member States shall inform the Commission of the list of inspection bodies approved on 31 December of the previous year, their legal and operational structure, their standard inspection procedure, their penalty arrangements and, where appropriate, their mark.
The Commission shall each year publish, in the "C" series of the Official Journal of the European Communities, the lists of approved bodies notified to it within the deadlines laid down in the foregoing subparagraph.

ARTICLE 16

1. This Regulation shall enter into force on the day of its publication in the Official Journal of the European Communities.

2. Within nine months of the entry into force of this Regulation, Member States shall implement Articles 8 and 9.

3. " Article 5, Article 8 (1) and Article 11 (1) shall apply from 1 January 1993. " **[2]**
In accordance with the procedure laid down in Article 14, the date of application of Article 11 (1) may be deferred for a specified period for imports from a third country where, following a request by the third country, the stage reached in examining the matter does not permit a decision regarding the inclusion of the country concerned in the list provided for in Article 11 (1) (a) before expiry of the period referred to in the first subparagraph.
For the purposes of complying with the conversion period referred to in paragraph 1 of Annex I, the period which has elapsed before the entry into force of this Regulation shall be taken into account where the operator can demonstrate to the satisfaction of the inspection body that during that period he was producing in accordance with the national provisions in force or, failing that, with the recognized international standards for organic production.

4. For 12 months following the entry into force of this Regulation, Member States may, by way of derogation from Article 6 (1), authorize the use in their territory of products containing substances not listed in Annex II, where they consider that the requirements of Article 7 (1) are satisfied.

5. For a period expiring 12 months after the establishment of Annex VI in accordance with Article 5 (7), Member States may continue to authorize, in accordance with their national provisions, the use of substances not listed in the said Annex VI.

6. Each Member State shall inform the other Member States and the Commission of substances authorized pursuant to paragraph 4 and 5.

ANNEX I

PRINCIPLES OF ORGANIC PRODUCTION AT FARM LEVEL

Plants and plant products

1. The principles set out in this Annex must normally have been applied on the parcels during a conversion period of at least two years before sowing or, in the case of perennial crops other than grassland, at least three years before the first harvest of products as referred to in Article 1 (1) (a). The inspection body may, with the approval of the competent authority, decide, in certain cases, to extend or reduce that period, having regard to previous parcel use.

2. The fertility and the biological activity of the soil must be maintained or increased, where appropriate, by:

(a) cultivation of legumes, green manures or deep-rooting plants in an appropriate multiannual rotation programme;

(b) incorporation in the soil of organic material, composted or not, from holdings producing according to the rules of this Regulation. Pending the adoption of common technical rules concerning organic livestock production, by-products from livestock farming, such as farmyard manure, may be used if they come from livestock holdings respecting existing national rules or, in the absence thereof, internationally recognized practices concerning organic livestock production.

Other organic or mineral fertilizers, mentioned in Annex II, may be applied only to the extent that adequate nutrition of the crop being rotated or soil conditioning are not possible by the methods set out under (a) and (b) of the preceding subparagraph.
For compost activation, appropriate micro-organism or plant-based preparations (biodynamic preparations) may be used.

3. Pests, diseases and weeds shall be controlled by a combination of the following measures:

- choice of appropriate species and varieties,
- appropriate rotation programme,
- mechanical cultivation procedures,
- protection of natural enemies of pests through provisions favourable to them (e.g. hedges, nesting sites, release of predators),
- flame weeding.

Only in cases of immediate threat to the crop may recourse be had to products referred to in Annex II.

" Animals and animal products

Pending the adoption of the proposal referred to in Article 1 (2), and for the purpose of preparation of ingredients referred to in Article 5 (3) (a), animals shall be raised in accordance with the existing national rules, or in the absence thereof, internationally recognized practices concerning organic livestock production. " **[1]**

ANNEX II

A. PRODUCTS FOR USE IN FERTILIZATION AND SOIL-CONDITIONING

Name / Description; compositional requirements; conditions for use

Farmyard and poultry manure / (...)
Slurry or urine / (...)
Straw / (...)
Peat / (...)
Composts from spent mushroom and vermiculture substrates / (...)
Composts from organic household refuse / (...)
Composts from plant residues / (...)
Processed animal products from slaughterhouses and fish industries / (...)
Organic by-products of foodstuffs and textile industries / (...)
Seaweeds and seaweed products / (...)
Sawdust, bark and wood waste / (...)
Wood ash / (...)
Natural phosphate rock / (...)
Calcinated aluminium phosphate rock / (...)
Basic slag / (...)
Rock potash / (...)
Sulphate of potash / Need recognized by control body
Limestone / (...)
Chalk / (...)
Magnesium rock / (...)
Calcareous magnesium rock / (...)
Epsom salt (magnesium-sulphate) / (...)
Gypsum (calcium sulphate) / (...)
Trace elements (boron, copper, iron, manganese, molybdenum, zinc) / Need recognized by control body
Sulphur / Need recognized by control body
Stone meal / (...)
Clay (bentonite, perlite) / (...)

B. PRODUCTS FOR PLANT PEST AND DISEASE CONTROL

Name / Description; compositional requirements; conditions for use

Preparations on basis of pyrethrins extracted from Chrysanthemum cinerariaefolium, containing possibly a synergist / (...)
Preparations from Derris elliptica, / (...)
Preparations from Quassia amara / (...)
Preparations from Ryania speciosa / (...)
Propolis / (...)
Diatomaceous earth / (...)
Stone meal / (...)
Preparations on basis of metaldehyde containing a repellent to higher animal species and as far as applied within traps / (...)
Sulphur / (...)
Bordeaux mixture / (...)
Burgundy mixture / (...)
Sodium silicate / (...)
Sodium bicarbonate / (...)
Potassium soap (soft soap) / (...)
Pheromone preparations / (...)
Bacillus thuringiensis preparations / (...)
Granulose virus preparations / (...)
Plant and animal oils / (...)
Paraffin oil / (...)

C. OTHER PRODUCTS

ANNEX III

MINIMUM INSPECTION REQUIREMENTS AND PRECAUTIONARY MEASURES UNDER THE INSPECTION SCHEME REFERRED TO IN ARTICLE 8 AND 9

A. Farms producing plants and plant products

1. Production must take place in a unit the land parcels and production and storage locations of which are clearly separate from those of any other unit not producing in accordance with the rules laid down in this Regulation; processing and/or packaging workshops may form part of the unit, where its activity is limited to processing and packaging of its own agricultural produce.

2. When the inspection arrangements are first implemented, the producer and inspection body must draw up:

-a full description of the unit, showing the storage and production premises and land parcels and, where applicable, premises where certain processing and/or packaging operations take place,
-all the practical measures to be taken at the level of the unit to ensure compliance with this Regulation.

This description and the measures concerned must be contained in an inspection report countersigned by the responsible person of the unit.
In addition, the report must specify:

-the date of the last application on the parcels concerned of products the use of which is not compatible with Articles 6 (1) (b) and 7,
-an undertaking by the producer to carry out operations in accordance with Articles 5, 6 and 7 and to accept, in event of infringements, implementation of the measures as referred to in Article 9 (9).

3. Each year, before the date indicated by the inspection body, the producer must notify the body of its schedule of production of crop products, giving a breakdown by parcel.

4. Written and/or documentary accounts must be kept which enable the inspection body to trace the origin, nature and quantities of all raw materials bought, and the use of such materials; in addition, written or documentary accounts must be kept of the nature, quantities and consignees of all agricultural products sold. Quantities sold directly to the final consumer shall be accounted on a daily basis.
" Where the unit itself processes its own agricultural produce, the accounts must contain the information as referred to in point B, 2, third hyphen of this Annex. " **[1]**

5. Storage, in the unit, of input products other than those the use of which is compatible with Articles 6 (1) (b) and 7 is prohibited.

6. Apart from unannounced inspection visits, the inspection body must make a full physical inspection, at least once a year, of the unit. Samples for testing of products not authorized under this Regulation may be taken. However, such samples must be taken where the use of unauthorized products is suspected. An inspection report must be drawn up after each visit, countersigned by the responsible person of the unit.

7. The producer must give the inspection body, for inspection purposes, access to the storage and production premises and to the parcels of land, as well as to the accounts and relevant supporting documents. He must provide the inspection body with any information deemed necessary for the purposes of the inspection.

8. Products as referred to in Article 1 which are not in their packaging for the end consumer may be transported to other units only in appropriate packaging or containers closed in a manner which would prevent substitution of the content and provided with a label stating, without prejudice to any other indications required by law:

- the name and address of the person responsible for the production or preparation of the product,
- the name of the product,

- that the product is covered by the inspection arrangements laid down in this Regulation.

9. Where an operator runs several production units in the same area, units in the area producing crops or crop products not covered by Article 1 must also be subject to the inspection arrangements as regards the first subparagraph of point 2 and points 3, 4 and 5. Plants of the same variety as those produced at the unit referred to in point 1 may not be produced at these units.

B. Processing and packaging units for plant products and foodstuffs composed essentially of plant products

1. When the inspection arrangements are first implemented, the producer and inspection body must draw up:

- a full description of the unit, showing the facilities used for the processing, packaging and storage of agricultural products before and after the operations concerning them,
- all the practical measures to be taken at the level of the unit to ensure compliance with this Regulation.

This description and the measures concerned must be contained in an inspection report, countersigned by the responsible person of the unit.
In addition, the report must include an undertaking by the operator to perform the operations in such a way as to comply with Article 5 and to accept, in the event of infringements, the implementation of measures as referred to in Article 9 (9).

2. Written accounts must be kept enabling the inspection body to trace:

- the origin, nature and quantities of agricultural products as referred to in Article 1 which have been delivered to the unit,
- the nature, quantities and consignees of products as referred to in Article 1 which have left the unit,
- any other information, such as the origin, nature and quantities of ingredients, additives and manufacturing aids delivered to the unit and the composition of processed products, that is required by the inspection body for the purposes of proper inspection of the operations.

3. Where products not referred to in Article 1 are also processed, packaged or stored in the unit concerned:

- the unit must have separate areas within the premises for the storage of products as referred to in Article 1, before and after the operations,
- operations must be carried out continuously until the complete run has been dealt with, separated by place or time from similar operations performed on products not covered by Article 1,
- if such operations are not carried out frequently, they must be announced in advance, with a deadline agreed on with the inspection body,
- every measure must be taken to ensure identification of lots and to avoid mixtures with products not obtained in accordance with the rules laid down in this Regulation.

4. Apart from unannounced inspection visits, the inspection body must make a full physical inspection, at least once a year, of the unit. Samples for testing of products not authorized under this Regulation may be taken. However, they must be taken where the use of unauthorized products is suspected. An inspection report must be drawn up after each visit countersigned by the person responsible for the unit inspected.

5. The operator must give the inspection body, for inspection purposes, access to the unit and to the written accounts and relevant supporting documents. He must provide the inspection body with any information necessary for the purposes of the inspection.

6. The requirements in respect of transport laid down in point 8 of Part A are applicable.
" On reception of a product as referred to in Article 1, the operator shall check the closing of the packaging or container and the presence of the indications referred to in point A, 8 of this Annex. The result of this verification shall be explicitly mentioned in the accounts referred to in point B, 2. Where the check leaves any doubt that the product concerned came from an operator subject to the inspection system provided for in Article 9, it may only be put into processing or packaging after elimination of that doubt. " **[1]**

ANNEX IV

INFORMATION TO BE NOTIFIED AS PROVIDED IN ARTICLE 8 (1) (a)

(a) Name and address of operator

(b) Location of premises and, where appropriate, parcels (land register data) where operations are carried out

(c) Nature of operations and products

(d) Undertaking by the operator to carry out the operations in accordance with Articles 5, 6, 7 and/or 11

(e) In the case of an agricultural holding, the date on which the producer ceased to apply products the use of which is not compatible with Articles 6 (1) (6) and 7 on the parcels concerned

(f) The name of the approved body to which the operator entrusted inspection of his undertaking, where the Member State has implemented the inspection system by approving such bodies

ANNEX V

INDICATION THAT PRODUCTS ARE COVERED BY THE INSPECTION SCHEME

The indication that a product is covered by the inspection scheme must be shown in the same language or languages as used for the labelling.

ES: Agricultura Biológica - Sistema de control CEE
DK: Økologisk Landbrug - EF Kontrolordning
D: Biologische Agrarwirtschaft - EWG-Kontrollsystem
GR: [see OJ for reference to the Greek characters]
EN: Organic Farming - EEC Control System
F: Agriculture biologique - Système de contrôle CEE
I: Agricoltura Biologica - Regime di controllo CEE
NL: Biologische landbouw - EEG-controlesysteem
P: Agricultura Biológica - Systema de Controlo CEE

ANNEX VI

" INTRODUCTION

For the purposes of this Annex, the following definitions will apply:

1. Ingredients: substances as defined in Article 4 of this Regulation under the restrictions as referred to in Article 6 (4) of Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer.

2. Ingredients of agricultural origin:

(a) single agricultural products and products derived therefrom by appropriate washing, cleaning, thermic and/or mechanical processes and/or by physical processes having the effect of reducing the moisture content of the product;

(b) also, products derived from the products mentioned under (a) by other processes used in food processing, unless these products are considered food additives or flavourings as defined under points 5 or 7 hereunder.

3. Ingredients of non-agricultural origin: ingredients other than ingredients of agricultural origin and belonging to at least one of the following categories:

3.1. food additives, including carriers for food additives, as defined under points 5 and 6 hereunder;

3.2. flavourings, as defined under point 7 hereunder;

3.3. water and salt;

3.4. micro-organism preparations;

3.5. minerals (including trace elements) and vitamins.

4. Processing aids: substances as defined in Article 1 (3) (a) of Council Directive 89/107/EEC (7) on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption.

5. Food additives: substances as defined in Article 1 (1) and (2) of Directive 89/107/EEC and covered by that Directive or by a comprehensive Directive as referred to in Article 3 (1) of Directive 89/107/EEC.

6. Carriers, including carrier solvents: food additives used to dissolve, dilute, disperse or otherwise physically modify a food additive without altering its technological function in order to facilitate its handling, application or use.

7. Flavouring: substances and products as defined in Article 1 (2) of Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production (8), and covered by that Directive.

GENERAL PRINCIPLES

Sections A, B and C cover the ingredients and processing aids which may be used in the preparation of foodstuffs composed essentially of one or more ingredients of plant origin, referred to in Article 1 (1) (b) of this Regulation, with the exception of wines.

Notwithstanding reference to any ingredient in Sections A and C or any processing aid in Section B, any ingredient or such processing aid shall be used only in accordance with relevant Community legislation and/or national legislation compatible with the Treaty and, in the absence thereof, in accordance with the principles of good manufacturing practice for foodstuffs. In particular additives shall be used according to the provisions of Directive 89/107/EEC and, where relevant, those of any comprehensive Directive as referred to in Article 3 (1) of Directive 89/107/EEC; flavourings shall be used according to the provisions of Directive 88/388/EEC and solvents according to the provisions of Council Directive 88/344/EEC of 13 June 1988 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (9).

SECTION A - INGREDIENTS OF NON-AGRICULTURAL ORIGIN (REFERRED TO IN ARTICLE 5 (3) (b) OF REGULATION (EEC) No 2092/91):

A.1. Food additives, including carriers

Name / Specific conditions (10)

E 170 Calciumcarbonates / (...)
E 270 Lactic aid / (...)

E 290 Carbondioxyde / (...)
E 296 Malic acid / (...)
E 300 Ascorbic acid / (...)
" E 306 Tocopherol-rich extract / Anti-oxidant in fats and oils " **[4]**
E 322 Lecithins / (...)
E 330 Citric acid / (...)
" E 333 Calcium citrates / (...) " **[4]**
E 334 Tartaric acid (L (+) -) / (...)
E 335 Sodium tartrate / (...)
E 336 Potassium tartrate / (...)
" E 341 (i) Monocalciumphosphate / Raising agent for self raising flour " **[4]**
E 400 Alginic acid / (...)
E 401 Sodium alginate / (...)
E 402 Potassium alginate / (...)
E 406 Agar / (...)
" E 407 Carrageenan / (...) " **[4]**
E 410 Locust bean gum / (...)
E 412 Guar gum / (...)
E 413 Tragacanth gum / (...)
E 414 Arabic gum / (...)
E 415 Xanthan gum / (...)
E 416 Karaga gum / (...)
E 440 (i) Pectin / (...)
E 500 Sodiumcarbonates / (...)
E 501 Potassiumcarbonates / (...)
E 503 Ammoniumcarbonates / (...)
E 504 Magnesiumcarbonates / (...)
E 516 Calcium sulphate / CR
" E 524 Sodiumhydroxide / Surface treatment of Laugengebäck " **[4]**
E 938 Argon / (...)
E 941 Nitrogen / (...)
E 948 Oxygen / (...)

A.2. Flavourings within the meaning of Directive 88/388/EEC

Substances and products as defined in Article 1 (2) (b) (i) and 1 (2) (c) of Directive 88/388/EEC labelled as natural flavouring substances or natural flavouring preparations, according to Article 9 (1) (d) and (2) of that Directive.

A.3. Water and salt

Drinking water
Salt (with sodium chloride or potassium chloride as basic components), generally used in food processing.

A.4. Micro-organism preparations

(i) Any preparations of micro-organisms normally used in food processing, with the exception of micro-organisms genetically modified within the meaning of Article 2 (2) of Directive 90/220/EEC (11);

(ii) Micro-organisms genetically modified within the meaning of Article 2 (2) of Directive 90/220/EEC: if they have been included according to the decision procedure of Article 14.

A.5. Minerals (including trace elements) and vitamins

Only authorized as far as their use is legally required in the foodstuffs in which they are incorporated.

SECTION B - PROCESSING AIDS AND OTHER PRODUCTS WHICH MAY BE USED FOR PROCESSING OF ORGANICALLY PRODUCED INGREDIENTS OF AGRICULTURAL ORIGIN, REFERRED TO IN ARTICLE 5 (3) (c) OF REGULATION (EEC) No 2092/91.

Name / Specific conditions

Water / (...)
Calcium chloride / Coagulation agent
Calcium carbonate / (...)
Calcium hydroxide / (...)
Calcium sulphate / Coagulation agent
Magnesium chloride (or nigari) / Coagulation agent
Potassium carbonate / Drying of grapes
" Sodium carbonate / Sugar production
Sodium hydroxyde / Sugar production, olive treatment
Sulphuric acid / Sugar production " **[4]**
Carbon dioxide / (...)
Nitrogen / (...)
Ethanol / Solvent
Tannic acid / Filtration aid
Egg white albumen / (...)
Casein / (...)
Gelatin / (...)
Isinglass / (...)
Vegetable oils / " Greasing, releasing or anti-foaming agent " **[4]**
Silicon dioxide gel or colloidal solution / (...)
Activated carbon / (...)
Talc / (...)
Bentonite / (...)
Kaolin / (...)
Diatomaceous earth / (...)
Perlite / (...)
Hazelnut shells / (...)
" Rice meal / (...) " **[4]**
Beeswax / Releasing agent
Carnauba wax / Releasing agent

Preparations of micro-organisms and enzymes:

(i) Any preparations of micro-organisms and enzymes normally used as processing aids in food processing, with the exception of micro-organisms genetically modified within the meaning of Article 2 (2) of Directive 90/220/EEC;

(ii) Micro-organisms genetically modified within the meaning of Article 2 (2) of Directive 90/220/EEC: If they have been included hereunder according to the decision procedure of Article 14.

SECTION C - INGREDIENTS OF AGRICULTURAL ORIGIN WHICH HAVE NOT BEEN PRODUCED ORGANICALLY, REFERRED TO IN ARTICLE 5 (4) OF REGULATION (EEC) No 2092/91

C.1. Unprocessed vegetable products, as well as products derived therefrom by processes referred to under definition 2 (a):

C.1.1. Edible fruits, nuts and seeds

Coconuts
Brazil nuts
Cashew nuts
Dates

Pineapples
Mangoes
Papayas
Sloes
Cocoa
Maracujas (Passion fruit)
Colanuts
Peanuts
Rosehips
Sallowthorns
Blueberries
Maple syrup
Quinoa
Amaranth
Horseradish seeds
"..." **[4]**
Radish seeds
" Acorns
Fenugreek
Acerola
Chicory " **[4]**

C.1.2. Edible spices and herbs

All products with the exception of thyme

C.1.3. Cereals

"..." **[4]**
Wild rice (Zizania plauspra)

C.1.4. Oil seeds and oleaginous fruits

Sesamum seeds

C.1.5. Miscellaneous

Algae, including seaweed

C.2. Vegetable products, processed by processes as referred to under definition 2 (b):

C.2.1. Fats and oils, whether or not refined, but not chemically modified, derived from plants other than:

olive
sunflower

C.2.2. Sugars; starch; other products from cereals and tubers

Cane and beet sugar
Starches produced from cereals and tubers, not chemically modified
Rice paper
Gluten
" Fructose " **[4]**

C.2.3. Miscellaneous

Lemon juice
" Vinegar other than vinegar from wine and applecider " **[4]**

C.3. Animal products

Honey
Gelatin
" Buttermilk powder " **[4]**
Edible aquatic organisms, not originating from aquaculture. " **[3]**
" Lactose " **[4]**

[NB: Regulation No 207/93 carries also the following details:

ARTICLE 2

No amendments to Sections A and B of Annex VI shall be adopted unless at least the following requirements are satisfied:

(a) for food additives covered by Section A, point 1 of Annex VI: without prejudice to the requirements for acceptance of additives provided for in Council Directive 89/107/EEC only substances shall be included for which it has been shown that, without having recourse to such substances, it is impossible to produce or preserve such foodstuffs;

(b) for processing aids covered by Part B of Annex VI: only substances are included which are accepted in general food processing and for which it has been shown that, without having recourse to such substances, it is impossible to produce such foodstuffs.

ARTICLE 3

1. As long as an ingredient of agricultural origin has not been included in Section C of Annex VI to the Regulation, that ingredient may be used according to the derogation provided for in Article 5 (4) of that Regulation on the following conditions:

(a) that the operator has notified to the competent authority of the Member State all the requisite evidence showing that the ingredient concerned satisfies Article 5 (4); and

(b) that the competent authority of the Member State has authorized the use for a maximum period of three months, which may be reduced if it appears that supplies of the ingredient concerned are available in the Community.

2. Where an authorization as referred to in paragraph 1 has been granted, the Member State shall immediately notify to the other Member States and to the Commission the following information:

(a) the date of the authorization;

(b) the name of the ingredient of agricultural origin concerned;

(c) the quantities that are required and the justification for those quantities;

(d) the reasons for, and expected period of, the shortage.

3. If the information submitted by any Member State to the Commission and to the Member State which granted the authorization shows that supplies are available during the period of the shortage, the Member State shall consider withdrawing the authorization or reducing its period of validity, and shall inform the Commission and the other Member States of the measures it has taken, within 10 days of the date of receipt of the information.

4. At the request of a Member State or at the Commission's initiative, the matter shall be submitted for examination to the Committee referred to in Article 14 of the Regulation. It may be decided, in accordance with

the procedure laid down in Article 14, that the authorization shall be withdrawn or its period of validity amended, or, where appropriate, that the ingredient concerned be included in Section C of Annex VI.]

(1) OJ No L 33, 08/02/1979, p. 36.
(2) OJ No L 159, 10/06/1989, p. 58.
(3) OJ No L 347, 17/12/1973, p. 51.
(4) OJ No L 80, 25/03/1986, p. 51.
(5) OJ No L 33, 08/02/1979, p. 1.
(6) OJ No L 186, 30/06/1989, p. 17.
(7) OJ No L 40, 11/02/1989, p. 27.
(8) OJ No L 184, 15/07/1988, p. 61.
(9) OJ No L 157, 24/06/1988, p. 28.
(10) CR-carrier.
(11) OJ No L 117, 08/05/1990, p. 15.

VERTICAL LEGISLATION
(by foodstuff category)

ERUCIC ACID IN OILS

376L0621

76/621/EEC: COUNCIL DIRECTIVE OF 20 JULY 1976 RELATING TO THE FIXING OF THE MAXIMUM LEVEL OF ERUCIC ACID IN OILS AND FATS INTENDED AS SUCH FOR HUMAN CONSUMPTION AND IN FOODSTUFFS CONTAINING ADDED OILS OR FATS

OFFICIAL JOURNAL NO L 202, 28/07/1976, P. 35
DATE OF NOTIFICATION: 28/07/1976
DATE OF TRANSPOSITION: 01/01/1977; SEE ART. 7

AMENDED BY

179H
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE HELLENIC REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES [1]
OFFICIAL JOURNAL NO L 291, 19/11/1979, P. 110

185I
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE KINGDOM OF SPAIN AND THE PORTUGUESE REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES [2]
OFFICIAL JOURNAL NO L 302, 15/11/1985, P. 216

ARTICLE 1

THIS DIRECTIVE SHALL APPLY:

(a) TO OILS, FATS AND MIXTURES THEREOF WHICH ARE INTENDED AS SUCH FOR HUMAN CONSUMPTION,

(b) TO COMPOUND FOODSTUFFS TO WHICH OILS, FATS OR MIXTURES THEREOF HAVE BEEN ADDED AND THE OVERALL FAT CONTENT OF WHICH EXCEEDS 5 %; MEMBER STATES MAY, HOWEVER, ALSO APPLY THE PROVISIONS OF THIS DIRECTIVE TO THESE FOODSTUFFS WHEN THEIR FAT CONTENT IS EQUAL TO OR LESS THAN 5 %.

ARTICLE 2

1. AS FROM 1 JULY 1979 AT THE LATEST, THE LEVEL OF ERUCIC ACID OF THE PRODUCTS REFERRED TO IN ARTICLE 1, CALCULATED ON THE TOTAL LEVEL OF FATTY ACIDS IN THE FAT COMPONENT, MAY NOT BE GREATER THAN 5 %.

2. IN ANY EVENT, AS FROM 1 JULY 1977, MEMBER STATES SHALL FIX A LEVEL OF ERUCIC ACID NOT EXCEEDING 10 %.

ARTICLE 3

THE SAMPLING PROCEDURES AND METHODS OF ANALYSIS NECESSARY TO ESTABLISH THE LEVEL OF ERUCIC ACID OF THE PRODUCTS REFERRED TO IN ARTICLE 1 SHALL BE DETERMINED IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 5.

ARTICLE 4

1. WHERE A MEMBER STATE, AS A RESULT OF NEW INFORMATION OR OF A RE-ASSESSMENT OF EXISTING INFORMATION MADE SINCE THE DIRECTIVE WAS ADOPTED, HAS DETAILED GROUNDS FOR ESTABLISHING THAT THE MAXIMUM LEVELS OF ERUCIC ACID LAID DOWN IN ARTICLE 2 ENDANGER HUMAN HEALTH ALTHOUGH THEY COMPLY WITH THE PROVISIONS OF THIS DIRECTIVE, THAT MEMBER STATE MAY TEMPORARILY SUSPEND OR RESTRICT APPLICATION OF THE PROVISIONS IN QUESTION IN ITS TERRITORY. IT SHALL IMMEDIATELY INFORM THE OTHER MEMBER STATES AND THE COMMISSION THEREOF AND GIVE REASONS FOR ITS DECISION.

2. THE COMMISSION SHALL EXAMINE AS SOON AS POSSIBLE THE GROUNDS GIVEN BY THE MEMBER STATE CONCERNED AND CONSULT THE MEMBER STATES WITHIN THE STANDING COMMITTEE ON FOODSTUFFS, AND SHALL THEN DELIVER ITS OPINION FORTHWITH AND TAKE THE APPROPRIATE MEASURES.

3. IF THE COMMISSION CONSIDERS THAT AMENDMENTS TO THE DIRECTIVE ARE NECESSARY IN ORDER TO RESOLVE THE DIFFICULTIES MENTIONED IN PARAGRAPH 1 AND TO ENSURE THE PROTECTION OF HUMAN HEALTH, IT SHALL INITIATE THE PROCEDURE LAID DOWN IN ARTICLE 5, WITH A VIEW TO ADOPTING THESE AMENDMENTS; THE MEMBER STATE WHICH HAS ADOPTED SAFEGUARD MEASURES MAY IN THAT EVENT RETAIN THEM UNTIL THE AMENDMENTS ENTER INTO FORCE.

ARTICLE 5

1. WHERE THE PROCEDURE LAID DOWN IN THIS ARTICLE IS TO BE FOLLOWED, THE MATTER SHALL BE REFERRED TO THE STANDING COMMITTEE ON FOODSTUFFS, SET UP BY THE COUNCIL DECISION OF 13 NOVEMBER 1969 (HEREINAFTER CALLED "THE COMMITTEE") (1) BY ITS CHAIRMAN, EITHER ON HIS OWN INITIATIVE OR AT THE REQUEST OF A REPRESENTATIVE OF A MEMBER STATE.

2. THE COMMISSION REPRESENTATIVE SHALL SUBMIT A DRAFT OF THE MEASURES TO BE TAKEN TO THE COMMITTEE. THE COMMITTEE SHALL GIVE ITS OPINION ON THAT DRAFT WITHIN THE TIME LIMIT SET BY THE CHAIRMAN HAVING REGARD TO THE URGENCY OF THE MATTER. OPINIONS SHALL BE ADOPTED BY A MAJORITY OF " fifty-four " **[2]** VOTES, THE VOTES OF THE MEMBER STATES BEING WEIGHTED AS PROVIDED IN ARTICLE 148 (2) OF THE TREATY. THE CHAIRMAN SHALL NOT VOTE.

3. (a) WHERE THE MEASURES ENVISAGED ARE IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE, THE COMMISSION SHALL ADOPT THEM.

(b) WHERE THE MEASURES ENVISAGED ARE NOT IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE, OR IF NO OPINION IS DELIVERED, THE COMMISSION SHALL WITHOUT DELAY SUBMIT TO THE COUNCIL A PROPOSAL ON THE MEASURES TO BE TAKEN. THE COUNCIL SHALL ACT BY A QUALIFIED MAJORITY.

(c) IF, WITHIN THREE MONTHS OF THE PROPOSAL BEING SUBMITTED TO IT, THE COUNCIL HAS NOT ACTED, THE PROPOSED MEASURES SHALL BE ADOPTED BY THE COMMISSION.

ARTICLE 6

ARTICLE 5 SHALL APPLY FOR A PERIOD OF 18 MONTHS FROM THE DATE ON WHICH THE MATTER WAS FIRST REFERRED TO THE COMMITTEE UNDER ARTICLE 5 (1).

ARTICLE 7

1. BEFORE 1 JANUARY 1977, MEMBER STATES SHALL IF NECESSARY AMEND THEIR LAWS TO CONFORM WITH THE PROVISIONS OF THIS DIRECTIVE AND SHALL IMMEDIATELY INFORM THE COMMISSION.

2. THE LAWS THUS AMENDED SHALL APPLY TO THOSE PRODUCTS FIRST PUT ON THE MARKET AFTER 1 JULY 1977 AND 1 JULY 1979, RESPECTIVELY.

ARTICLE 8

THIS DIRECTIVE IS ADDRESSED TO THE MEMBER STATES.

(1) OJ No L 291, 19/11/1969, p. 9.

COMMISSION DIRECTIVE

of 25 July 1980

relating to the Community method of analysis for determining the erucic acid content in oils and fats intended to be used as such for human consumption and foodstuffs containing added oils or fats

(80/891/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 76/621/EEC of 20 July 1976 relating to the fixing of the maximum level of erucic acid in oils and fats intended as such for human consumption and in foodstuffs containing added oils or fats (1), and in particular Article 3 thereof,

Whereas Article 2 of Directive 76/621/EEC provides that, as from 1 July 1979, the erucic acid content of the products referred to in Article 1 of that Directive, calculated on the total level of fatty acids in the fat component, may not be greater than 5 % ;

Whereas Article 3 of Directive 76/621/EEC provides that the erucic acid content shall be determined by a Community method of analysis ;

Whereas Regulation (EEC) No 1470/68 of 23 September 1968 on the drawing and reduction of samples and the determination of the oil content, impurities and moisture in oil seeds (2), lays down in Annex VI, as introduced by Regulation (EEC) No 72/77 (3), a method of analysis determining the erucic acid content of colza and rape seeds ; whereas this method should be used as a screening method ;

Whereas it is not possible, when the constituent fatty acids of oils and fats are analyzed by gas-liquid chromatography under normal conditions, to distinguish erucic acid from other isomers of docosenoic acid such as cetoleic acid ;

Whereas it is necessary to determine the level of erucic acid in oils and fats, as well as in foodstuffs to which oils or fats have been added, which may contain cetoleic acid and other isomers of docosenoic acid ;

Whereas the level of erucic acid need not be determined in oils and fats and in foodstuffs to which oils or fats have been added when, after using the screening analysis methods, they have been found not to contain more than 5 % of total docosenoic acids or of cis-docosenoic acids ;

Whereas, pending the introduction of an improved method of analysis for the determination of erucic acid, this method of analysis is considered to be the most suitable at present ;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE :

Article 1

Member States shall require that the analysis necessary for the determination of the erucic acid content of the products referred to in Article 1 of Directive 76/621/EEC be carried out as laid down in Article 2.

Article 2

1. For screening purposes either of the following shall be determined :

(a) the total docosenoic acid content of products referred to in Article 1 using the method set out in Annex VI to Regulation (EEC) No 1470/68 ; or

(b) the total cis-docosenoic acid content of products referred to in Article 1, by the method set out in Annex VI to Regulation (EEC) No 1470/68 using gas-liquid chromatography in conditions whereby the cis- and trans-isomers of docosenoic acids are separated ; stationary phases suitable for this purpose are, for example, the cyanopropylpolysiloxanes or liquid crystals.

2. If the total content of either :

(a) docosenoic acids, determined according to paragraph 1 (a), or

(b) cis-docosenoic acids, determined according to paragraph 1 (b),

(1) OJ No L 202, 28. 7. 1976, p. 35.
(2) OJ No L 239, 28. 9. 1968, p. 2.
(3) OJ No L 12, 15. 1. 1977, p. 11.

of the products referred to in Article 1, calculated on their total fatty acid content in the fat component, does not exceed 5 %, no further determination shall be required. Otherwise, the erucic acid content shall be determined by the method set out in the Annex hereto.

Article 3

Member States shall bring into force the laws, regulations or administrative provisions necessary to comply with this Directive not later than 1 February 1982. They shall forthwith inform the Commission thereof.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 25 July 1980.

For the Commission

Étienne DAVIGNON

Member of the Commission

ANNEX

THE DETERMINATION OF THE ERUCIC ACID CONTENT IN OILS AND FATS INTENDED TO BE USED AS SUCH FOR HUMAN CONSUMPTION AND IN THE FAT OR OIL COMPONENT OF FOODSTUFFS TO WHICH OILS OR FATS HAVE BEEN ADDED

I. INTRODUCTION

1. SAMPLE PREPARATION

1.1. General

The mass of the sample presented to the laboratory for analysis shall normally be 50 g unless a larger quantity is required.

1.2. Preparation of the sample for analysis in the laboratory

The sample must be homogenized before it is analyzed.

1.3. Containers

A sample so prepared shall be stored in an air-tight and moisture-tight container.

2. REAGENTS

2.1. Water

2.1.1. Where water is required as a solvent, diluent or for washing, distilled water or demineralized water of at least equivalent purity shall be used.

2.1.2. Where 'solution' or 'dilution' is mentioned without any other reagent being specified, an aqueous solution or dilution is meant.

2.2. Chemicals

All chemicals used, shall be of recognized analytical quality except where otherwise specified.

3. APPARATUS

3.1. List of apparatus

This list contains only those items with a specialized use and with a specification.

3.2. Analytical balance

'Analytical balance' means a balance with a sensitivity of 0·1 mg or better.

4. EXPRESSION OF THE RESULTS

4.1. Results

The result referred to in the official analysis report shall be the mean value obtained from not less than two determinations, the repeatability of which is satisfactory.

4.2. Calculation of the percentage

Unless otherwise stated the results shall be expressed as percentages (m/m) of the total fatty acids in the sample as received by the laboratory.

4.3. Number of significant figures

The number of significant figures in the result so expressed shall be governed by the precision of the method.

II. DETERMINATION OF ERUCIC ACID

1. SCOPE AND FIELD OF APPLICATION

The method determines the erucic acid content of:

(i) oils and fats containing cetoleic acid (a particular cis-isomer of docosenoic acid which occurs in fish oils), and

(ii) hydrogenated oils and fats containing trans and cis-isomers of docosenoic acid.

2. DEFINITION

Erucic acid content: the content of erucic acid as determined by the method specified.

3. PRINCIPLE

The methyl esters of the component fatty acids of the oil or fat are separated by low temperature argentation thin-layer chromatography and quantitatively determinated by gas-liquid chromatography.

4. REAGENTS

4.1. Diethyl ether peroxide-free freshly distilled.

4.2. n-hexane.

4.3. Silica gel G, for thin-layer chromatography.

4.4. Silica gel, for column chromatography.

4.5. Silver nitrate solution, 200 g/litre. Dissolve 24 g silver nitrate in water and make up to 120 ml with water.

4.6. Methyl erucate solution 5 mg/ml. Dissolve 50 mg methyl erucate in a few ml of n-hexane and dilute to 10 ml with n-hexane.

4.7. Methyl tetracosanoate, internal standard solution, 0·25 mg/ml. Dissolve 25 mg methyl tetracosanoate in a few ml of n-hexane (as 4·6) and dilute to 100 ml with n-hexane.

4.8. Development solvent. Toluene : n-hexane 90 : 10 (v/v).

4.9. 2,7 Dichlorofluorescein solution 0·5 g/litre. Dissolve by warming and stirring 50 mg of 2,7 dichlorofluorescein in 100 ml of 50 % aqueous methanol.

5. APPARATUS

5.1. Apparatus for thin-layer chromatography to include, in particular:

5.1.1. Deep-freeze unit, capable of maintaining developing tank and contents at a temperature of minus 20 to minus 25 °C.

5.1.2. Glass plates, 200 × 200 mm.

5.1.3. Ultra-violet lamp.

5.1.4. Glass columns, length about 200 mm, internal diameter about 10 mm with filter of glass wool or sintered glass. Alternatively, small funnels with sintered glass filters.

5.1.5. Applicator, for depositing solutions in the form of a narrow band or streak on TLC plates.

5.2. Gas-liquid chromatograph, together with an electronic integrator, as described in Section III of Annex VI to Commission Regulation (EEC) No 72/77.

6. PROCEDURE

6.1. Preparation of fatty-acid methyl esters

Take about 400 mg of the oil or fat component of the sample for analysis and prepare a solution containing about 20 to 50 mg/ml of the fatty acid methyl esters in n-hexane by the method described in Section II.3 of Annex VI to Commission Regulation (EEC) No 72/77.

6.2. Thin-layer chromatography

6.2.1. *Preparation of plates*

Place 60 g silica gel (4.3) in a 500 ml round-bottomed flask, add 120 ml of silver nitrate solution (4.5) and shake for one minute to obtain a fully homogeneous slurry. Spread the slurry in the usual manner over the plates; the thickness of the layer should be approximately 0·5 mm. This quantity of slurry is sufficient for the preparation of five 200 × 200 mm plates.

Allow the plates to partially air-dry (preferably by leaving them in the dark for about 30 minutes). Fully dry and activate the plates by placing them in an oven, maintained at 100 °C, for two hours 30 minutes. Use the plates as soon as possible after activation or carefully store in a dark cabinet and then reactivate before use. (Note : activation at 110 °C for one hour may be found satisfactory provided the plates are not darkened as a result). Score lines through the coating 10 mm from the sides and the top of each plate before use to reduce edge effects during the development.

6.2.2. *Application of methyl esters*

Using the applicator (5.1.5) deposit 50 µl of the solution of methyl esters (6.1) prepared from the sample in a narrow streak about 50 mm long, at least 40 mm from the side of the plate and 10 mm from the bottom. Apply in a similar way 100 µl of a solution containing equal volumes of the prepared solution of methyl esters (6.1) and the methyl erucate solution (4.6). Take particular care during the application of solutions because of the fragile nature of the coating. (Note : if desired, 50 µl of the methyl erucate solution (4.6) may be applied to the plate to assist in identifying the methyl erucate band after development : see figure). After the application of the methyl esters stand the bottom edge of the plate in diethyl ether until the ether ascends to about 5 mm above the area of sample application. This concentrates the methyl esters in a narrow band.

6.2.3. *Development of the plates*

Pour the development solvent (4.8) into the tank to a depth of about 5 mm and place the tank, complete with lid, in a deep freeze cabinet (5.1.1) held at minus 25 °C, or as near to this temperature as possible. (In some cases it may be advantageous to line the tank). After two hours, place the plate carefully in the tank and allow the solvent to ascend to about one half to two thirds of the height of the plate. Remove the plate and gently evaporate the solvent from it in a nitrogen stream. Replace the plate in the tank and allow the solvent to ascend to the top of the plate. Remove the plate and as previously dry in a nitrogen stream and then spray carefully with 2,7 dichlorofluorescein solution (4.9).

View the plate under ultra-violet light and locate the band containing methyl erucate in the sample by reference to the intensified band in the sample to which methyl erucate has been added (see figure).

6.2.4. *Separation of the methyl ester fractions*

Scrape off the methyl erucate band derived from the sample into a 50 ml beaker taking care to avoid losses. Similarly transfer the silica gel located above and below the methyl erucate band into another 50 ml beaker. This band will contain all the other fatty-acid methyl ester fractions. Add 1·0 ml of the methyl tetracosanoate standard solution (4.7) and 10 ml of diethyl ether (4.1) to each beaker. Stir, and transfer the contents of the beakers to separate columns or funnels (5.1.4) each containing about 1 g silica gel (4.4); elute the methyl esters using three or four 10 ml portions of diethyl ether. Collect the filtrates in small flasks. Evaporate each filtrate to a small volume using a gentle nitrogen stream and transfer the methyl esters to small pointed-bottom glass tubes. Remove all the solvent by evaporation with a nitrogen stream in such a way that the methyl esters concentrate at the bottom of the tubes. Dissolve the methyl esters in about 25 to 50 µl of n-hexane (4.2).

6.3. **Gas-liquid chromatography**

6.3.1. Carry out the procedure described in Section III of Annex VI to Commission Regulation 72/77/EEC and analyze 1 to 2 µl of the methyl ester solutions obtained from (i) the fraction containing methyl erucate, and (ii) the fractions containing the remainder of the methylated fatty acids.

6.3.2. Obtain from the electronic integrator the following peak areas :

(i) from the chromatogram of the fraction containing the methyl erucate :

(a) methyl erucate [E]

(b) internal standard [L_1]

(c) total methyl ester peak areas excluding the internal standard [EF]

(ii) from the chromatogram of the fractions containing the remainder of te fatty acid methyl esters

(a) total methyl ester peak areas excluding the internal standard [RF]

(b) internal standard [L_2]

7. EXPRESSION OF RESULTS

7.1. **Method of calculation and formula**

7.1.1. The erucic acid content of the sample, expressed in terms of its methyl ester as a percentage of the total fatty acid methyl esters prepared from the sample, is given by :

$$\frac{E}{L_1\left(\frac{EF}{L_1} + \frac{RF}{L_2}\right)} \times 100$$

where

E, EF, RF, L_1 and L_2 are the peak areas referred to in 6.3.2, corrected as necessary by the use of calibration factors.

For practical purposes the value for methyl erucate given by the above formula is equivalent to the level of erucic acid expressed as a percentage of the total level of fatty acids in the sample.

7.1.2. If peak areas are obtained in percentages the values for EF and RF may be calculated as follows :

$EF = 100 - L_1$

$RF = 100 - L_2$

7.1.3. The method of calculation (7.1.1) assumes that the level of tetracosanoic acid in the sample is negligible. If significant amounts of this acid are shown to be present the value for tetracosanoic acid (L_2) obtained from the chromatogram of the fractions containing the remainder of the fatty acid methyl esters must be reduced to :

$L_2 - T_2$

where

$$T_2 = \frac{T_0 P_2}{P_0}$$

and

T_2 = peak area of methyl tetracosanoate derived from the sample and which forms part of the peak area attributed to the internal standard in the chromatogram of the remaining fraction of fatty acid methyl esters

P_2 = peak area of methyl palmitate obtained from the chromatogram of the remaining fraction

T_0 = peak area of methyl tetracosanoate obtained from the chromatogram of the methyl esters of the total fatty acids as determined by the analysis referred to in Article 2 of this Directive

P_0 = peak area of methyl palmitate obtained from the chromatogram of the methyl esters of the total fatty acids as as determined by the analysis referred to in Article 2 of this Directive.

7.1.4. *Derivation of formula*

The proportion of fatty acids in the fraction containing the methyl erucate, expressed as a percentage of the total fatty acids in the sample, is given by:

$$\frac{\frac{EF}{L_1}}{\frac{EF}{L_1} + \frac{RF}{L_2}} \times 100 \quad \text{or} \quad \frac{EF}{L_1\left(\frac{EF}{L_1} + \frac{RF}{L_2}\right)} \times 100$$

The proportion of erucic acid in the fraction containing the methyl erucate, is given by:

$$\frac{E}{EF}$$

Hence the erucic acid content of the sample, expressed as a percentage of the total fatty acids, is given by:

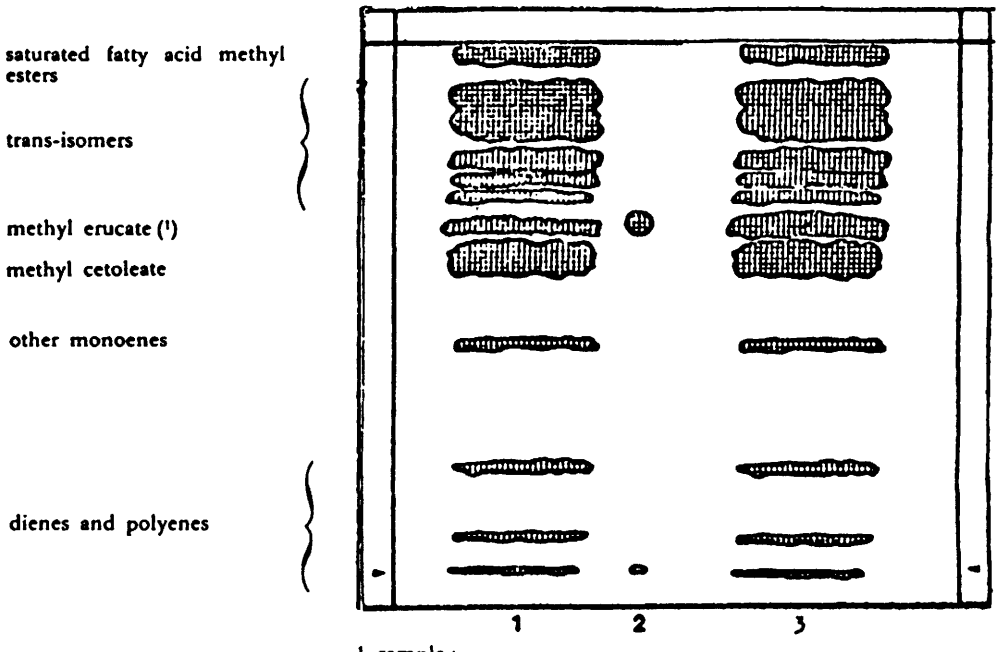
$$\frac{EF}{L_1\left(\frac{EF}{L_1} + \frac{RF}{L_2}\right)} \times \frac{E}{EF} \times 100 \quad \text{or} \quad \frac{E}{L_1\left(\frac{EF}{L_1} + \frac{RF}{L_2}\right)} \times 100$$

7.1.5. *Repeatability*

The difference between the values of two deteriminations when carried out simultaneously or in rapid succession on the same sample, by the same analyst under the same conditions, shall not exceed 10 % of the result or 0·5 g per 100 g of sample, taking the greater value.

FIGURE

Typical thin-layer chromatogram showing the separation of the methyl esters of erucic acid, cetoleic acid and trans-isomers of docosenoic acid



1 sample;
2 methyl erucate;
3 sample + methyl erucate

(1) The fraction designated methyl erucate will usually contain methyl esters of other monoenoic acids but should be free of methyl cetoleate.

COCOA AND CHOCOLATE

373L0241

73/241/EEC: COUNCIL DIRECTIVE OF 24 JULY 1973 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO COCOA AND CHOCOLATE PRODUCTS INTENDED FOR HUMAN CONSUMPTION

OFFICIAL JOURNAL NO L 228, 16/08/1973, P. 23
DATE OF NOTIFICATION: 01/08/1973
DATE OF TRANSPOSITION: 01/08/1974; SEE ART. 15

AMENDED BY

374L0411
74/411/EEC: COUNCIL DIRECTIVE OF 1 AUGUST 1974 **[1]**
OFFICIAL JOURNAL NO L 221, 12/08/1974, P. 17
DATE OF NOTIFICATION: 02/08/1974

374L0644
74/644/EEC: COUNCIL DIRECTIVE OF 19 DECEMBER 1974 **[2]**
OFFICIAL JOURNAL NO L 349, 28/12/1974, P. 63
DATE OF NOTIFICATION: 20/12/1974

375L0155
75/155/EEC: COUNCIL DIRECTIVE OF 4 MARCH 1975 **[3]**
OFFICIAL JOURNAL NO L 64, 11/03/1975, P. 21
DATE OF NOTIFICATION: 07/03/1975
DATE OF TRANSPOSITION: 30/06/1975; SEE ART. 19

376L0628
76/628/EEC: COUNCIL DIRECTIVE OF 20 JULY 1976 **[4]**
OFFICIAL JOURNAL NO L 223, 16/08/1976, P. 1
DATE OF NOTIFICATION: 29/07/1976
DATE OF TRANSPOSITION: 29/07/1977; SEE ART. 2

378L0609
78/609/EEC: COUNCIL DIRECTIVE OF 29 JUNE 1978 **[5]**
OFFICIAL JOURNAL NO L 197, 22/07/1978, P. 10
DATE OF NOTIFICATION: 05/07/1978
DATE OF TRANSPOSITION: 05/07/1979; SEE ART. 2

378L0842
78/842/EEC: COUNCIL DIRECTIVE OF 10 OCTOBER 1978 **[6]**
OFFICIAL JOURNAL NO L 291, 17/10/1978, P. 15
DATE OF NOTIFICATION: 13/10/1978

179H
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE HELLENIC REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES **[7]**
OFFICIAL JOURNAL NO L 291, 19/11/1979, P. 110

380L0608
80/608/EEC: COUNCIL DIRECTIVE OF 30 JUNE 1980 **[8]**
OFFICIAL JOURNAL NO L 170, 03/07/1980, P. 33
DATE OF NOTIFICATION: 08/07/1980

385L0007
85/7/EEC: COUNCIL DIRECTIVE OF 19 DECEMBER 1984 **[9]**
OFFICIAL JOURNAL NO L 2, 03/01/1985, P. 22
DATE OF NOTIFICATION: 27/12/1984

185I
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE KINGDOM OF SPAIN AND THE PORTUGUESE REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES **[10]**
OFFICIAL JOURNAL NO L 302, 15/11/1985, P. 216

389L0344
89/344/EEC: COUNCIL DIRECTIVE OF 3 MAY 1989 **[11]**
OFFICIAL JOURNAL NO L 142, 25/05/1989, P. 19
DATE OF NOTIFICATION: 16/05/1989

ARTICLE 1

FOR THE PURPOSES OF THIS DIRECTIVE COCOA AND CHOCOLATE PRODUCTS SHALL MEAN THE PRODUCTS INTENDED FOR HUMAN CONSUMPTION DEFINED IN ANNEX I.

ARTICLE 2

MEMBER STATES SHALL TAKE ALL MEASURES NECESSARY TO ENSURE THAT THE PRODUCTS REFERRED TO IN ARTICLE 1 MAY BE OFFERED FOR SALE ONLY IF THEY CONFORM TO THE DEFINITIONS AND RULES LAID DOWN IN THIS DIRECTIVE AND IN ANNEX I THERETO.

ARTICLE 3

1. THE NAMES LISTED IN ANNEX I (1) SHALL BE APPLIED ONLY TO THE PRODUCTS DEFINED IN THAT PARAGRAPH AND MUST BE USED IN TRADE TO DESIGNATE THEM. NEVERTHELESS,

- THE NAMES "PRALINA" OR "CIOCCOLATINO" MAY BE USED IN ITALY AND THE NAME "A CHOCOLATE" MAY BE USED IN IRELAND AND THE UNITED KINGDOM TO DESCRIBE CHOCOLATE, PLAIN CHOCOLATE, GIANDUJA NUT CHOCOLATE, MILK CHOCOLATE, MILK CHOCOLATE WITH HIGH MILK CONTENT, GIANDUJA NUT MILK CHOCOLATE OR WHITE CHOCOLATE IN SINGLE-MOUTHFUL SIZES;
- THE SAME NAME "MILK CHOCOLATE" MAY BE REQUIRED IN IRELAND AND THE UNITED KINGDOM TO DESCRIBE THE PRODUCTS DEFINED IN ANNEX I PARAGRAPH (1) UNDER HEADINGS 1.21 AND 1.22, ON CONDITION THAT THE TERM IS ACCOMPANIED IN BOTH CASES BY AN INDICATION OF THE AMOUNT OF MILK SOLIDS OBTAINED BY EVAPORATION, LAID DOWN FOR EACH OF THE TWO PRODUCTS, IN THE FORM "MILK SOLIDS:... % MINIMUM";
" - THE NAME "FILLED CHOCOLATE" MAY BE REPLACED IN ENGLISH BY ONE OF THE FOLLOWING: "CHOCOLATE WITH... FILLING", "CHOCOLATE WITH... CENTRE". " **[3]**

2. THE PROVISIONS OF THE AFOREGOING PARAGRAPH SHALL NOT, HOWEVER, AFFECT ARRANGEMENTS WHEREBY THESE NAMES CAN BE USED ADDITIONALLY, IN ACCORDANCE WITH CUSTOM, TO INDICATE OTHER PRODUCTS WHICH CANNOT BE CONFUSED WITH THOSE DEFINED IN ANNEX I.

ARTICLE 4

COCOA BEANS WHICH ARE NOT SOUND, WHOLESOME AND IN GOOD MARKET CONDITION, SHELLS, GERMS OR ANY OTHER RESIDUAL PRODUCTS FROM THE SOLVENT-EXTRACTION OF COCOA-BUTTER MAY NOT BE USED IN THE MANUFACTURE OF THE PRODUCTS DEFINED IN ANNEX I.

ARTICLE 5

1. THE COUNCIL, ACTING UNANIMOUSLY ON A PROPOSAL FROM THE COMMISSION, SHALL DETERMINE:

(a) THE LIST OF SOLVENTS WHICH MAY BE USED FOR EXTRACTING COCOA-BUTTER;

(b) PURITY CRITERIA FOR COCOA-BUTTER, FOR THE SOLVENTS USED IN ITS EXTRACTION AND, WHERE NECESSARY, FOR THE OTHER PRODUCTS USED AS ADDITIVES OR FOR TREATMENT LISTED IN ANNEX I.

2. UNTIL THE ENTRY INTO FORCE OF THE IMPLEMENTING MEASURES REFERRED TO IN PARAGRAPH 1 (a), MEMBER STATES SHALL PERMIT NO SOLVENT TO BE USED IN THE EXTRACTION OF COCOA-BUTTER OTHER THAN PETROLEUM SPIRIT 60/75 KNOWN AS ESSENCE B, OR ITS PURE PRINCIPAL FRACTION. DURING THIS PERIOD MEMBER STATES MAY, HOWEVER, CONTINUE TO IMPLEMENT NATIONAL PROVISIONS AUTHORIZING OTHER SOLVENTS IN RESPECT OF PRODUCTS MARKETED IN THEIR TERRITORY.

3. WHERE THE USE IN THE PRODUCTS REFERRED TO IN ARTICLE 1 OF ONE OF THE SUBSTANCES REFERRED TO IN PARAGRAPHS 1 AND 2, OR THE LEVEL OF ONE OR MORE OF THE INGREDIENTS DETERMINED BY VIRTUE OF PARAGRAPH 1 (b) CONTAINED IN SUCH A SUBSTANCE, MIGHT ENDANGER HUMAN HEALTH, A MEMBER STATE MAY, FOR A MAXIMUM PERIOD OF ONE YEAR, SUSPEND AUTHORIZATION TO USE THAT SUBSTANCE OR MAY REDUCE THE MAXIMUM AUTHORIZED LEVEL OF ONE OR MORE OF THE INGREDIENTS IN QUESTION. IT SHALL IMMEDIATELY INFORM THE COMMISSION THEREOF AND THE COMMISSION SHALL CONSULT THE MEMBER STATES.
THE COUNCIL ACTING UNANIMOUSLY ON A PROPOSAL FROM THE COMMISSION SHALL DECIDE WITHOUT DELAY WHETHER MEASURES NEED TO BE ADOPTED AND, IF SO, SHALL ADOPT BY DIRECTIVE THE NECESSARY AMENDMENTS. THE COUNCIL ACTING BY A QUALIFIED MAJORITY ON A PROPOSAL FROM THE COMMISSION MAY ALSO, IF NECESSARY, EXTEND FOR A MAXIMUM OF ONE YEAR THE PERIOD SET IN THE AFOREGOING PARAGAPH.

ARTICLE 6

1. " CHOCOLATE, PLAIN CHOCOLATE, GIANDUJA NUT CHOCOLATE, MILK CHOCOLATE, MILK CHOCOLATE WITH HIGH MILK CONTENT, GIANDUJA NUT MILK CHOCOLATE, WHITE CHOCOLATE AND FILLED CHOCOLATE, IN THE FORM OF BARS OR TABLETS EACH WEIGHING NOT LESS THAN 85 g AND NOT MORE THAN 500 g, SHALL BE MARKETED IN THE FOLLOWING INDIVIDUAL WEIGHTS ONLY: 85 g, 100 g, 125 g, 150 g, 200 g, 250 g, 300 g, 400 g AND 500 g. " **[3]**

2. " THE COCOA POWDER PRODUCTS REFERRED TO IN ANNEX I, HEADINGS 1.8 TO 1.13, WHEN PACKAGED IN UNITS HAVING AN INDIVIDUAL NET WEIGHT EQUAL TO OR MORE THAN 50 g AND

NOT EXCEEDING 1 kg, SHALL BE MARKETED IN THE FOLLOWING INDIVIDUAL NET WEIGHTS ONLY: 50 g, 75 g, 125 g, 250 g, 500 g, 750 g AND 1 kg. " **[4]**

ARTICLE 7

1. THE ONLY INFORMATION WHICH IS COMPULSORY ON THE PACKAGES, CONTAINERS OR LABELS OF THE PRODUCTS DEFINED IN ANNEX 1 AND WHICH MUST BE CONSPICUOUS, CLEARLY LEGIBLE AND INDELIBLE SHALL BE THE FOLLOWING:

(a) THE NAME WHICH IS RESERVED FOR THEM; IN THE CASE OF THE PRODUCTS DEFINED IN ANNEX I, PARAGRAPH 1, HEADING 1.27, THIS NAME SHALL BE ACCOMPANIED BY AN INDICATION TO THE CONSUMER OF THE FILLING PRODUCT USED, WITHOUT PREJUDICE TO THE PROVISIONS WHICH MAY APPLY TO THE LATTER;

(b) FOR PRODUCTS SPECIFIED IN ANNEX I (1) UNDER HEADINGS 1.10, 1.11, 1.12, 1.13, 1.16, 1.17, 1.21 AND 1.22, AN INDICATION OF THE TOTAL DRY COCOA CONTENT BY THE DECLARATION "COCOA SOLIDS... % MINIMUM";

(c) FOR FILLED CHOCOLATE AND CHOCOLATES OBTAINED FROM CHOCOLATE PRODUCTS OTHER THAN CHOCOLATE AND COUVERTURE CHOCOLATE, AN ADDITIONAL INDICATION OF THE TYPE OR TYPES OF CHOCOLATE USED. HOWEVER, IN THE CASE OF CHOCOLATES, FOR A PERIOD OF FIVE YEARS FROM THE NOTIFICATION OF THIS DIRECTIVE, IN AS MUCH AS THIS IS NOT COMPULSORY UNDER NATIONAL PROVISIONS, THE ADDITIONAL INDICATION IN QUESTION SHALL BE COMPULSORY ONLY IN CASES WHERE THESE PRODUCTS ARE OBTAINED FROM PLAIN CHOCOLATE, MILK CHOCOLATE WITH HIGH MILK CONTENT OR WHITE CHOCOLATE;

(d) WHERE APPROPRIATE, THE DECLARATIONS REQUIRED BY ANNEX I (4) TO (7);

" (e) THE NET WEIGHT, UNLESS THE PRODUCTS WEIGH LESS THAN 50 g; HOWEVER, IN THE CASE OF PRODUCTS WEIGHING LESS THAN 50 g PER UNIT AND PRESENTED IN PACKAGES CONTAINING TWO OR MORE SUCH PRODUCTS WHOSE TOTAL NET WEIGHT ON THE OUTER WRAPPER OR THE INDIVIDUAL NET WEIGHT ON EACH UNIT WRAPPER IN SO FAR AS THIS IS CLEARLY LEGIBLE FROM THE OUTSIDE; IN THE CASE OF HOLLOW MOULDED PRODUCTS THIS INFORMATION MAY BE REPLACED BY THE MINIMUM NET WEIGHT. " **[3]**

(f) THE NAME OR TRADE NAME AND THE ADDRESS OR REGISTERED OFFICE OF THE MANUFACTURER OR PACKER, OR OF A SELLER ESTABLISHED WITHIN THE COMMUNITY.

2. BY WAY OF DEROGATION FROM PARAGRAPH 1, AND WITHOUT PREJUDICE TO THE PROVISIONS TO BE ADOPTED BY THE COMMUNITY WITH REGARD TO THE LABELLING OF FOODSTUFFS, THE MEMBER STATES MAY RETAIN NATIONAL PROVISIONS WHICH REQUIRE INDICATION OF:

(a) THE FACTORY IN RESPECT OF NATIONAL PRODUCTION;

(b) THE COUNTRY OF ORIGIN, ALTHOUGH THIS INFORMATION MAY NOT BE REQUIRED FOR PRODUCTS MANUFACTURED WITHIN THE COMMUNITY.

" 2a. WHERE THE PRODUCTS DEFINED IN ANNEX I ARE PUT UP IN PACKAGES OR CONTAINERS HOLDING A NET WEIGHT OF NOT LESS THAN 10 KILOGRAMMES AND ARE NOT RETAILED, THE INFORMATION REFERRED TO IN PARAGRAPH 1 (b), (c), (d) AND (e), TOGETHER WITH THE INFORMATION REFERRED TO IN PARAGRAPH 1 (f) FOR PRODUCTS DEFINED IN ANNEX I, HEADINGS 1.1 TO 1.7, MAY APPEAR ONLY IN THE ACCOMPANYING DOCUMENTS. " **[3]**

3. MEMBER STATES SHALL REFRAIN FROM STATING, APART FROM WHAT IS LAID DOWN IN PARAGRAPH 1, HOW THE INFORMATION REFERRED TO IN THAT PARAGRAPH IS TO BE GIVEN. HOWEVER, MEMBER STATES MAY FORBID TRADE ON THEIR TERRITORY:

- IN THE PRODUCTS DEFINED IN ANNEX I, IF THE MARKINGS LAID DOWN IN PARAGRAPHS 1 (a), (c) AND (d) ARE NOT SHOWN ON ONE SIDE OF THE WRAPPING OR CONTAINER IN THE NATIONAL LANGUAGE OR LANGUAGES;

- IN THE PRODUCT DEFINED IN ANNEX I (1) UNDER HEADING 1.22 IF THE DESCRIPTION "MILK CHOCOLATE" APPEARS ON THE WRAPPING.

ARTICLE 8

THE MAIN NAME "CHOCOLATE" AND "MILK CHOCOLATE" MAY BE SUPPLEMENTED BY DECLARATIONS OR ADJECTIVES RELATING TO QUALITY ONLY IF:

(a) THE CHOCOLATE HAS A TOTAL DRY COCOA SOLIDS CONTENT OF AT LEAST 43 %, INCLUDING AT LEAST 26 % COCOA BUTTER;

(b) THE MILK CHOCOLATE CONTAINS NOT MORE THAN 50 % SUCROSE AND AT LEAST 30 % TOTAL DRY COCOA SOLIDS, AND 18 % MILK SOLIDS OBTAINED BY EVAPORATION, INCLUDING AT LEAST 4.5 % BUTTER FAT.

ARTICLE 9

1. NOTWITHSTANDING ARTICLE 7 (1) (a), MEMBER STATES MAY, FOR A PERIOD OF FOUR YEARS AFTER THE NOTIFICATION OF THIS DIRECTIVE, ALLOW THE RESERVED NAME TO BE SHOWN ON PACKAGES, CONTAINERS OR LABELS, TOGETHER WITH THE NAME PREVIOUSLY USED IN ACCORDANCE WITH THE USAGES OR REGULATIONS OF THE COUNTRY CONCERNED AT THE TIME OF THE NOTIFICATION OF THIS DIRECTIVE.

2. NOTWITHSTANDING ARTICLE 8, MEMBER STATES SHALL, FOR A PERIOD OF THREE YEARS FROM THE NOTIFICATION OF THIS DIRECTIVE, CONFINE USE OF THE DESCRIPTION "HALBBITTER" TO CHOCOLATE HAVING A MINIMUM TOTAL DRY COCOA SOLIDS CONTENT OF 50 %, INCLUDING AT LEAST 18 % OF COCOA BUTTER.

ARTICLE 10

1. MEMBER STATES SHALL ADOPT ALL THE MEASURES NECESSARY TO ENSURE THAT TRADE IN THE PRODUCTS REFERRED TO IN ARTICLE 1, WHICH COMPLY WITH THE DEFINITIONS AND RULES LAID DOWN IN THIS DIRECTIVE AND IN ANNEX I THEREOF, CANNOT BE IMPEDED BY THE APPLICATION OF NATIONAL NON-HARMONIZED PROVISIONS GOVERNING THE COMPOSITION, MANUFACTURING SPECIFICATIONS, PACKAGING OR LABELLING OF THESE PRODUCTS IN PARTICULAR OR OF FOODSTUFFS IN GENERAL.

2. PARAGRAPH 1 SHALL NOT BE APPLICABLE TO NON-HARMONIZED PROVISIONS JUSTIFIED ON GROUNDS OF:

- PROTECTION OF PUBLIC HEALTH,
- REPRESSION OF FRAUDS UNLESS SUCH PROVISIONS ARE LIABLE TO IMPEDE THE APPLICATION OF THE DEFINITIONS AND RULES LAID DOWN BY THIS DIRECTIVE,
- PROTECTION OF INDUSTRIAL AND COMMERCIAL PROPERTY, INDICATIONS OF SOURCE, APPLICATIONS OF ORIGIN AND REPRESSION OF UNFAIR COMPETITION.

ARTICLE 11

THE FOLLOWING SHALL BE DETERMINED IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 12:

(a) THE SAMPLING PROCEDURES AND METHODS OF ANALYSIS NEEDED TO VERIFY THAT THE PURITY CRITERIA REFERRED TO IN ARTICLE 5 (1) (b) ARE SATISFIED;

(b) THE SAMPLING PROCEDURES AND METHODS OF ANALYSIS NEEDED TO VERIFY THAT THE RULES RELATING TO THE COMPOSITION AND MANUFACTURING SPECIFICATIONS OF THESE PRODUCTS LAID DOWN IN ANNEX I ARE FULFILLED.

ARTICLE 12

1. WHERE THE PROCEDURE LAID DOWN IN THIS ARTICLE IS TO BE FOLLOWED, THE MATTER SHALL BE REFERRED TO THE STANDING COMMITTEE ON FOODSTUFFS SET UP BY THE COUNCIL DECISION OF 13 NOVEMBER 1969 (1) (HEREINAFTER CALLED "THE COMMITTEE") BY ITS CHAIRMAN, EITHER ON HIS OWN INITIATIVE OR AT THE REQUEST OF A REPRESENTATIVE OF A MEMBER STATE.

2. THE REPRESENTATIVE OF THE COMMISSION SHALL SUBMIT TO THE COMMITTEE A DRAFT OF THE MEASURES TO BE TAKEN. THE COMMITTEE SHALL GIVE ITS OPINION ON THAT DRAFT WITHIN A TIME LIMIT SET BY THE CHAIRMAN HAVING REGARD TO THE URGENCY OF THE MATTER. OPINIONS SHALL BE DELIVERED BY A MAJORITY OF " fifty-four " **[10]** VOTES, THE VOTES OF THE MEMBER STATES BEING WEIGHTED AS PROVIDED IN ARTICLE 148 (2) OF THE TREATY. THE CHAIRMAN SHALL NOT VOTE.

3. (a) WHERE THE MEASURES ENVISAGED ARE IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE, THE COMMISSION SHALL ADOPT THEM.

(b) WHERE THE MEASURES ENVISAGED ARE NOT IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE, OR IF NO OPINION IS DELIVERED, THE COMMISSION SHALL WITHOUT DELAY SUBMIT TO THE COUNCIL A PROPOSAL ON THE MEASURES TO BE TAKEN. THE COUNCIL SHALL ACT BY A QUALIFIED MAJORITY.

(c) IF WITHIN THREE MONTHS OF THE PROPOSAL BEING SUBMITTED TO IT, THE COUNCIL HAS NOT ACTED, THE PROPOSED MEASURES SHALL BE ADOPTED BY THE COMMISSION.

ARTICLE 13

THE PROVISIONS OF ARTICLE 12 SHALL APPLY " FOR A PERIOD OF TWO YEARS FROM THE DATE ON WHICH THE MATTER WAS FIRST REFERRED TO THE COMMITTEE AFTER 1 JANUARY 1985 " **[9]** UNDER ARTICLE 12 (1).

ARTICLE 14

1. THIS DIRECTIVE SHALL ALSO APPLY TO PRODUCTS IMPORTED FROM THIRD COUNTRIES AND INTENDED FOR CONSUMPTION WITHIN THE COMMUNITY.

2. THIS DIRECTIVE SHALL NOT AFFECT THE PROVISIONS OF NATIONAL LAWS:

(a) AT PRESENT AUTHORIZING OR PROHIBITING THE ADDITION OF VEGETABLE FATS OTHER THAN COCOA-BUTTER TO THE CHOCOLATE PRODUCTS DEFINED IN ANNEX I. AT THE END OF A PERIOD OF THREE YEARS FROM THE NOTIFICATION OF THIS DIRECTIVE THE COUNCIL SHALL DECIDE, ON A PROPOSAL FROM THE COMMISSION, ON THE POSSIBILITIES AND THE FORMS OF EXTENDING THE USE OF THESE FATS TO THE WHOLE OF THE COMMUNITY;

(b) AUTHORIZING OR PROHIBITING THE RETAIL SALE OF THE VARIOUS CHOCOLATE PRODUCTS WITHOUT WRAPPING;

(c) " PROHIBITING THE MARKETING OF PRODUCTS PRESENTED IN THE FORM OF BARS OR TABLETS WEIGHING MORE THAN 75 g AND NOT MORE THAN 85 g. " **[3]** THE COUNCIL SHALL DECIDE LATER ON A PROPOSAL FROM THE COMMISSION THE MEASURES TO BE APPLIED FOR THIS PURPOSE THREE YEARS AFTER THE NOTIFICATION OF THIS DIRECTIVE;

(d) LAYING DOWN LESS STRINGENT REGULATIONS ON LABELLING IN THE RETAIL SALE OF FANCY PRODUCTS SUCH AS FIGURINES, CIGARETTES, EGGS AND LOOSE CHOCOLATES; IN SUCH CASES THE PROVISIONS MAY ONLY REQUIRE THE PLACING OF A NOTICE NEAR THE DISPLAYED PRODUCT;

(e) APPLICABLE TO DIETARY PRODUCTS, UNTIL COMMUNITY PROVISIONS CONCERNING THESE ARE PUT INTO EFFECT;

(f) AUTHORIZING THE OFFERING FOR SALE OF CHOCOLATE PRODUCTS OTHER THAN THOSE DEFINED IN ANNEX I UNDER THE NAMES "CREAM CHOCOLATE" OR "SKIMMED-MILK CHOCOLATE".

" (g) authorizing the marketing under the name of "chocolate familiar a la taza" and "chocolate a la taza" of chocolate containing flours and/or starches and intended for consumption with milk after cooking, not defined in Annex I; " **[11]**

3. THIS DIRECTIVE SHALL NOT APPLY TO PRODUCTS LISTED IN ANNEX I (1) INTENDED FOR EXPORT FROM THE COMMUNITY.

ARTICLE 15

" BY " 1 JULY 1975 " **[2]** MEMBER STATES SHALL, IF NECESSARY, AMEND THEIR LAWS IN ACCORDANCE WITH THE PROVISIONS OF THIS DIRECTIVE AND SHALL FORTHWITH INFORM THE COMMISSION THEREOF. " **[1]** " THE LAWS THUS AMENDED SHALL BE APPLIED IN SUCH A WAY AS TO:

- PERMIT TRADE IN PRODUCTS COMPLYING WITH THE PROVISIONS LAID DOWN IN THIS DIRECTIVE, AS FROM 1 JANUARY 1976,
- PROHIBIT TRADE IN PRODUCTS NOT COMPLYING WITH THE PROVISIONS LAID DOWN IN THIS DIRECTIVE, AS FROM 1 JANUARY 1977. " **[3]**

ARTICLE 16

THIS DIRECTIVE SHALL APPLY IN THE FRENCH OVERSEAS DEPARTMENTS.

ARTICLE 17

THIS DIRECTIVE IS ADDRESSED TO THE MEMBER STATES.

ANNEX I

1. FOR THE PURPOSES OF THIS DIRECTIVE, THE FOLLOWING DEFINITIONS SHALL APPLY:

1.1 COCOA BEANS

THE SEEDS OF THE CACAO-TREE (THEOBROMA CACAO L) FERMENTED AND DRIED;

1.2 COCOA NIB

COCOA BEANS, ROASTED OR UNROASTED, WHEN CLEANED, SHELLED AND HAVING UNDERGONE GERM SEPARATION, CONTAINING, WITHOUT PREJUDICE TO THE PROVISIONS OF PARAGRAPH 2, A MAXIMUM RESIDUE OF 5 % SHELL OR GERM AND A MAXIMUM CONTENT OF 10 % ASH - THESE PERCENTAGES TO BE BASED ON THE WEIGHT OF DRY DEFATTED MATTER;

1.3 COCOA DUST, COCOA FINES

PIECES OF COCOA BEAN IN THE FORM OF TINY PARTICLES, COLLECTED SEPARATELY DURING WINNOWING, WITH A MINIMUM FAT CONTENT OF 20 % BASED ON THE WEIGHT OF THE DRY MATTER;

1.4 COCOA MASS

COCOA NIB REDUCED TO A PASTE BY A MECHANICAL PROCESS WITHOUT LOSING ANY OF ITS NATURAL FAT CONTENT;

1.5 COCOA PRESS CAKE

COCOA NIB OR COCOA MASS CONVERTED INTO A CAKE BY A MECHANICAL PROCESS, CONTAINING, WITHOUT PREJUDICE TO THE DEFINITION OF FAT-REDUCED COCOA PRESS CAKE, AT LEAST 20 % OF COCOA BUTTER - THIS PERCENTAGE TO BE BASED ON THE WEIGHT OF THE DRY MATTER - AND A MAXIMUM OF 9 % OF WATER;

1.6 FAT-REDUCED COCOA PRESS CAKE

COCOA PRESS CAKE CONTAINING A MINIMUM OF 8 % OF COCOA BUTTER, BASED ON THE WEIGHT OF THE DRY MATTER;

1.7 EXPELLER COCOA PRESS CAKE

COCOA BEANS, COCOA DUST, WITH OR WITHOUT COCOA NIB OR COCOA PRESS CAKE, CONVERTED INTO CAKE BY THE EXPELLER PROCESS;

1.8 COCOA, COCOA POWDER

COCOA PRESS CAKE OBTAINED BY HYDRAULIC PRESSURE, CONVERTED INTO POWDER BY A MECHANICAL PROCESS AND CONTAINING, WITHOUT PREJUDICE TO THE DEFINITION OF FAT-REDUCED COCOA POWDER, AT LEAST 20 % OF COCOA BUTTER - THIS PERCENTAGE TO BE BASED ON THE WEIGHT OF THE DRY MATTER - AND A MAXIMUM OF 9 % OF WATER;

1.9 FAT-REDUCED COCOA, FAT-REDUCED COCOA POWDER

COCOA POWDER CONTAINING A MINIMUM OF 8 % OF COCOA BUTTER BASED ON THE WEIGHT OF THE DRY MATTER;

1.10 SWEETENED COCOA, SWEETENED COCOA POWDER

THE PRODUCT OBTAINED BY MIXING COCOA POWDER AND SUCROSE SO THAT 100 g OF THE MIXTURE CONTAINS AT LEAST 32 g OF COCOA POWDER;

1.11 DRINKING CHOCOLATE

THE PRODUCT OBTAINED BY MIXING COCOA POWDER AND SUCROSE SO THAT 100 g OF THE MIXTURE CONTAINS AT LEAST 25 g OF COCOA POWDER;

1.12 SWEETENED FAT-REDUCED COCOA, SWEETENED FAT-REDUCED COCOA POWDER

THE PRODUCT OBTAINED BY MIXING FAT-REDUCED COCOA POWDER AND SUCROSE SO THAT 100 g OF THE MIXTURE CONTAINS AT LEAST 32 g OF FAT-REDUCED COCOA POWDER;

1.13 FAT-REDUCED DRINKING CHOCOLATE

THE PRODUCT OBTAINED BY MIXING FAT-REDUCED COCOA POWDER AND SUCROSE SO THAT 100 g OF THE MIXTURE CONTAINS AT LEAST 25 g OF FAT-REDUCED COCOA POWDER;

1.14 COCOA BUTTER

THE FAT OBTAINED FROM COCOA BEANS OR PARTS OF COCOA BEANS WHICH COMPLIES WITH THE FOLLOWING PROVISIONS: COCOA BUTTER SHALL BE PRESENTED IN ONE OF THE FOLLOWING FORMS AND UNDER ONE OF THE FOLLOWING NAMES:

- PRESS COCOA BUTTER OR COCOA BUTTER

COCOA BUTTER OBTAINED BY PRESSURE FROM ONE OR MORE OF THE FOLLOWING RAW MATERIALS: COCOA NIB, COCOA MASS, COCOA PRESS CAKE, FAT-REDUCED COCOA PRESS CAKE.
IT SHALL HAVE THE FOLLOWING CHARACTERISTICS:

-- LEVEL OF UNSAPONIFIABLE MATTER DETERMINED USING PETROLEUM ETHER: NOT MORE THAN 0,35 %
-- " FREE FATTY ACID CONTENT " **[3]** : NOT MORE THAN 1,75 % (EXPRESSED AS OLEIC ACID)

- EXPELLER COCOA BUTTER

COCOA BUTTER OBTAINED BY TORSION (THE EXPELLER PROCESS) FROM COCOA BEANS OR FROM COCOA BEANS COMBINED WITH COCOA NIB, COCOA MASS, COCOA PRESS CAKE, OR FAT-REDUCED COCOA PRESS CAKE.
IT SHALL HAVE THE FOLLOWING CHARACTERISTICS:

-- LEVEL OF UNSAPONIFIABLE MATTER DETERMINED USING PETROLEUM ETHER: NOT MORE THAN 0,50 %
-- " FREE FATTY ACID CONTENT " **[3]** : NOT MORE THAN 1,75 % (EXPRESSED AS OLEIC ACID)

- REFINED COCOA BUTTER

COCOA BUTTER OBTAINED BY PRESSURE, BY TORSION (THE EXPELLER PROCESS), BY EXTRACTION USING A SOLVENT OR BY A COMBINATION OF THESE PROCESSES, FROM ONE OR MORE OF THE FOLLOWING RAW MATERIALS:

COCOA BEANS, COCOA NIB, COCOA DUST, COCOA MASS, COCOA PRESS CAKE, FAT-REDUCED COCOA PRESS CAKE, EXPELLER PRESS CAKE, AND REFINED IN ACCORDANCE WITH THE PROVISIONS OF PARAGRAPH 3 (b); WHERE COCOA FAT, PREPARED EITHER BY THE PRODUCER OF "REFINED COCOA BUTTER" HIMSELF OR BY ANOTHER PRODUCER, IS EMPLOYED AS A SECONDARY RAW MATERIAL, IT MUST HAVE BEEN OBTAINED FROM THE RAW MATERIALS LISTED ABOVE.
IT SHALL HAVE THE FOLLOWING CHARACTERISTICS:

-- LEVEL OF UNSAPONIFIABLE MATTER DETERMINED USING PETROLEUM ETHER: NOT MORE THAN 0,50 %
-- " FREE FATTY ACID CONTENT " **[3]** : NOT MORE THAN 1,75 % (EXPRESSED AS OLEIC ACID)
-- LEVEL OF FAT OBTAINED FROM SHELLS AND GERMS: NOT EXCEEDING IN PROPORTION TO COCOA BUTTER THE LEVEL EXISTING NATURALLY IN COCOA BEANS.

1.15 COCOA FAT

FAT OBTAINED FROM COCOA BEANS OR FROM PARTS OF COCOA BEANS NOT HAVING THE CHARACTERISTICS LAID DOWN FOR THE VARIOUS CATEGORIES OF COCOA BUTTER;

1.16 CHOCOLATE

THE PRODUCT OBTAINED FROM COCOA NIB, COCOA MASS, COCOA POWDER OR FAT-REDUCED COCOA POWDER AND SUCROSE WITH OR WITHOUT ADDED COCOA BUTTER, HAVING, WITHOUT PREJUDICE TO THE DEFINITION OF CHOCOLATE VERMICELLI, GIANDUJA NUT CHOCOLATE AND COUVERTURE CHOCOLATE, A MINIMUM TOTAL DRY COCOA SOLIDS CONTENT OF 35 % - AT LEAST 14 % OF DRY NON-FAT COCOA SOLIDS AND 18 % OF COCOA BUTTER - THESE PERCENTAGES TO BE CALCULATED AFTER THE WEIGHT OF THE ADDITIONS PROVIDED FOR IN PARAGRAPHS 5 TO 8 HAS BEEN DEDUCTED;

1.17 PLAIN CHOCOLATE

THE PRODUCT OBTAINED FROM COCOA NIB, COCOA MASS, COCOA POWDER OR FAT-REDUCED COCOA POWDER AND SUCROSE WITH OR WITHOUT ADDED COCOA BUTTER, HAVING A MINIMUM TOTAL DRY COCOA SOLIDS CONTENT OF 30 % - AT LEAST 12 % OF DRY NON-FAT COCOA SOLIDS AND 18 % OF COCOA BUTTER - THESE PERCENTAGES TO BE CALCULATED AFTER THE WEIGHT OF THE ADDITIONS REFERRED TO IN PARAGRAPHS 5 TO 8 HAS BEEN DEDUCTED;

1.18 VERMICELLI CHOCOLATE, CHOCOLATE FLAKES

CHOCOLATE IN THE FORM OF GRANULES OR FLAKES HAVING A MINIMUM TOTAL DRY COCOA SOLIDS CONTENT OF 32 % INCLUDING 12 % OF COCOA BUTTER;

1.19 " GIANDUJA (OR ONE OF THE DERIVATIVES OF THE WORD "GIANDUJA") NUT CHOCOLATE

THE PRODUCT OBTAINED FIRSTLY FROM CHOCOLATE HAVING A MINIMUM TOTAL DRY COCOA SOLIDS CONTENT OF 32 % INCLUDING A MINIMUM DRY NON-FAT COCOA SOLIDS CONTENT OF 8 %, AND SECONDLY FROM FINELY GROUND HAZELNUTS IN SUCH QUANTITIES THAT 100 g OF THE PRODUCT CONTAIN NOT LESS THAN 20 g AND NOT MORE THAN 40 g OF NUTS.
THE FOLLOWING MAY ALSO BE ADDED:

- MILK OR DRY MATTER PRODUCED BY THE PARTIAL OR COMPLETE DEHYDRATION OF WHOLE MILK OR PARTIALLY OR FULLY SKIMMED MILK IN A PROPORTION SUCH THAT THE FINISHED PRODUCT CONTAINS NO MORE THAN A TOTAL OF 5 % BY WEIGHT OF DRY MILK SOLIDS INCLUDING NOT MORE THAN 1.25 % OF BUTTERFAT,
- ALMONDS, HAZELNUTS AND OTHER NUT VARIETIES, EITHER WHOLE OR BROKEN, IN SUCH QUANTITIES THAT, TOGETHER WITH THE GROUND HAZELNUTS, THEY DO NOT EXCEED 60 % OF THE TOTAL WEIGHT OF THE PRODUCT; " **[5]**

1.20 COUVERTURE CHOCOLATE

CHOCOLATE CONTAINING A MINIMUM OF 31 % OF COCOA BUTTER AND 2,5 % OF DRY NON-FAT COCOA SOLIDS; IF COUVERTURE CHOCOLATE IS DESCRIBED AS "DARK COUVERTURE CHOCOLATE" IT SHALL CONTAIN A MINIMUM OF 31 % OF COCOA BUTTER AND 16 % OF DRY NON-FAT COCOA SOLIDS;

1.21 " MILK CHOCOLATE

THE PRODUCT OBTAINED FROM COCOA NIB, COCOA MASS, COCOA POWDER OR FAT-REDUCED COCOA POWDER AND SUCROSE, WITH OR WITHOUT ADDED COCOA BUTTER, AND ALSO FROM MILK OR FROM SOLIDS OBTAINED BY PARTIALLY OR TOTALLY DEHYDRATING WHOLE MILK OR FROM PARTIALLY OR WHOLLY SKIMMED MILK, AND WHERE APPROPRIATE, FROM CREAM, PARTIALLY OR TOTALLY DEHYDRATED CREAM, BUTTER OR BUTTER FAT; IT SHALL HAVE THE FOLLOWING CHARACTERISTICS, SUBJECT TO THE DEFINITIONS OF MILK CHOCOLATE VERMICELLI, GIANDUJA NUT MILK CHOCOLATE AND COUVERTURE MILK CHOCOLATE:

- TOTAL DRY COCOA SOLIDS: NOT LESS THAN 25 %
- DRY NON-FAT COCOA SOLIDS: NOT LESS THAN 2.5 %
- TOTAL DRY MILK SOLIDS DERIVED FROM THE INGREDIENTS LISTED ABOVE: NOT LESS THAN 14 %
- BUTTER FAT: NOT LESS THAN 3.5 %
- TOTAL FAT: NOT LESS THAN 25 %
- SUCROSE: NOT MORE THAN 55 %;

THESE PERCENTAGES BEING CALCULATED AFTER THE WEIGHT OF THE ADDITIONS PROVIDED FOR IN PARAGRAPHS 5 TO 8 HAS BEEN DEDUCTED. " **[3]**

1.22 " MILK CHOCOLATE WITH HIGH MILK CONTENT

THE PRODUCT OBTAINED FROM COCOA NIB, COCOA MASS, COCOA POWDER OR FAT-REDUCED COCOA POWDER AND SUCROSE, WITH OR WITHOUT ADDED COCOA BUTTER, AND ALSO FROM MILK OR FROM SOLIDS OBTAINED BY PARTIALLY OR TOTALLY DEHYDRATING WHOLE MILK OR FROM PARTIALLY OR WHOLLY SKIMMED MILK, AND, POSSIBLY, FROM CREAM, PARTIALLY OR TOTALLY DEHYDRATED CREAM, BUTTER OR BUTTER FAT; IT SHALL HAVE THE FOLLOWING CHARACTERISTICS:

- TOTAL DRY COCOA SOLIDS: NOT LESS THAN 20 %
- DRY NON-FAT COCOA SOLIDS: NOT LESS THAN 2.5 %
- TOTAL DRY MILK SOLIDS DERIVED FROM THE INGREDIENTS LISTED ABOVE: NOT LESS THAN 20 %
- BUTTER FAT: NOT LESS THAN 5 %
- TOTAL FAT: NOT LESS THAN 25 %
- SUCROSE: NOT MORE THAN 55 %;

THESE PERCENTAGES BEING CALCULATED AFTER THE WEIGHT OF THE ADDITIONS PROVIDED FOR IN PARAGRAPHS 5 TO 8 HAS BEEN DEDUCTED. " **[3]**

1.23 " MILK CHOCOLATE VERMICELLI, MILK CHOCOLATE FLAKES

MILK CHOCOLATE IN THE FORM OF GRANULES OR FLAKES HAVING THE FOLLOWING CHARACTERISTICS WHICH DIFFER FROM THOSE LAID DOWN IN PARAGRAPH 1, HEADING 1.21:

- TOTAL DRY COCOA SOLIDS: NOT LESS THAN 20 %
- TOTAL DRY MILK SOLIDS DERIVED FROM THE INGREDIENTS LISTED IN HEADING 1.21: NOT LESS THAN 12 %
- BUTTER FAT: NOT LESS THAN 3 %
- TOTAL FAT: NOT LESS THAN 12 %
- SUCROSE: NOT MORE THAN 66 %. " **[3]**

1.24 " GIANDUJA (OR ONE OF THE DERIVATIVES OF THE WORD "GIANDUJA") NUT MILK CHOCOLATE

THE PRODUCT OBTAINED, FIRSTLY, FROM MILK CHOCOLATE HAVING A MINIMUM DRY MILK SOLIDS CONTENT OF 10 % AND, SECONDLY, FROM FINELY GROUND HAZELNUTS SUCH THAT 100 g OF THE PRODUCT CONTAIN NOT MORE THAN 40 g AND NOT LESS THAN 15 g OF HAZELNUTS. ALMONDS, HAZELNUTS AND OTHER NUT VARIETIES MAY ALSO BE ADDED, EITHER WHOLE OR BROKEN, IN SUCH QUANTITIES THAT, TOGETHER WITH THE GROUND HAZELNUTS, THEY DO NOT EXCEED 60 % OF THE TOTAL WEIGHT OF THE PRODUCT. " **[3]**

1.25 COUVERTURE MILK CHOCOLATE

MILK CHOCOLATE HAVING A MINIMUM CONTENT OF 31 % OF FAT;

1.26 " WHITE CHOCOLATE

THE PRODUCT FREE OF COLOURING MATTERS, OBTAINED FROM COCOA BUTTER, SUCROSE AND FROM MILK OR SOLIDS OBTAINED BY PARTIALLY OR TOTALLY DEHYDRATING WHOLE MILK OR PARTIALLY OR WHOLLY SKIMMED MILK, AND, POSSIBLY, FROM CREAM, PARTIALLY OR WHOLLY DEHYDRATED CREAM, BUTTER OR BUTTER FAT; IT SHALL HAVE THE FOLLOWING CHARACTERISTICS:

- COCOA BUTTER: NOT LESS THAN 20 %
- TOTAL DRY MILK SOLIDS DERIVED FROM THE INGREDIENTS LISTED ABOVE: NOT LESS THAN 14 %
- BUTTER FAT: NOT LESS THAN 3.5 %
- SUCROSE: NOT MORE THAN 55 %;

THESE PERCENTAGES BEING CALCULATED AFTER THE WEIGHT OF THE ADDITIONS PROVIDED FOR IN PARAGRAPHS 5 TO 8 HAS BEEN DEDUCTED. " **[3]**

1.27 FILLED CHOCOLATE

WITHOUT PREJUDICE TO THE PROVISIONS APPLICABLE TO THE FILLING USED, THE FILLED PRODUCT - EXCEPTING FLOUR CONFECTIONERY OR BISCUIT PRODUCTS - THE OUTER PART OF WHICH CONSISTS OF CHOCOLATE, PLAIN CHOCOLATE, GIANDUJA NUT CHOCOLATE, COUVERTURE CHOCOLATE, MILK CHOCOLATE, MILK CHOCOLATE WITH HIGH MILK CONTENT, GIANDUJA NUT MILK CHOCOLATE, COUVERTURE MILK CHOCOLATE OR WHITE CHOCOLATE AND CONSTITUTES AT LEAST 25 % OF THE TOTAL WEIGHT OF THE PRODUCT;

1.28 A CHOCOLATE

THE PRODUCT IN SINGLE-MOUTHFUL SIZE, CONSISTING EITHER:

- OF FILLED CHOCOLATE, OR
- OF A COMBINATION OF CHOCOLATE, PLAIN CHOCOLATE, GIANDUJA NUT CHOCOLATE, COUVERTURE CHOCOLATE, MILK CHOCOLATE, MILK CHOCOLATE WITH HIGH MILK CONTENT, GIANDUJA NUT MILK CHOCOLATE, COUVERTURE MILK CHOCOLATE OR WHITE CHOCOLATE IN CONJUNCTION WITH OTHER EDIBLE SUBSTANCES, IN SO FAR AS THE CHOCOLATE PARTS ARE CLEARLY VISIBLE AT LEAST PARTIALLY, AND CONSTITUTE AT LEAST 25 % OF THE TOTAL WEIGHT OF THE PRODUCT OR, OF A MIXTURE OF CHOCOLATE, PLAIN CHOCOLATE, COUVERTURE CHOCOLATE, MILK CHOCOLATE, MILK CHOCOLATE WITH HIGH MILK CONTENT, OR COUVERTURE MILK CHOCOLATE AND OTHER EDIBLE SUBSTANCES, EXCEPTING,

-- FLOUR OR STARCHES
-- WITHOUT PREJUDICE TO ARTICLE 14 (2) (a), FATS OTHER THAN COCOA BUTTER AND MILK FATS

PROVIDED THAT THE CHOCOLATE PRODUCTS CONSTITUTE AT LEAST 25 % OF THE TOTAL WEIGHT OF THE PRODUCT.

2. COCOA BEANS, COCOA NIB, COCOA DUST, COCOA MASS, COCOA PRESS CAKE, FAT-REDUCED COCOA PRESS CAKE, EXPELLER COCOA PRESS CAKE, COCOA POWDER AND FAT-REDUCED COCOA POWDER MAY BE ALKALIZED ONLY BY ONE OR MORE OF THE FOLLOWING PRODUCTS: ALKALINE CARBONATES, ALKALINE HYDROXIDES, MAGNESIUM CARBONATE, MAGNESIUM OXIDE, AMMONIA SOLUTIONS, PROVIDED THAT THE AMOUNT OF ALKALIZING AGENT ADDED, EXPRESSED AS POTASSIUM CARBONATE, DOES NOT EXCEED 5 % OF THE WEIGHT OF THE DRY DEFATTED MATTER.
A QUANTITY OF CITRIC ACID OR TARTARIC ACID NOT EXCEEDING 0.5 % OF THE TOTAL WEIGHT OF THE PRODUCT MAY BE ADDED TO THE PRODUCTS THUS TREATED.
IF THE PRODUCT HAS BEEN TREATED AS DESCRIBED ABOVE, ITS ASH CONTENT SHALL NOT EXCEED 14 % OF THE DRY DEFATTED MATTER.

3. (a) COCOA BUTTER MAY BE TREATED BY THE FOLLOWING PROCESSES ONLY:

- FILTRATION, CENTRIFUGING AND OTHER PHYSICAL PROCESSES COMMONLY EMPLOYED FOR THE PURPOSE OF DEMUCILAGINATION;
- TREATMENT BY SUPER-HEATED STEAM UNDER VACUUM AND OTHER PHYSICAL PROCESSES COMMONLY EMPLOYED FOR THE PURPOSE OF DEODORIZATION.

(b) FOR REFINED COCOA BUTTER THE FOLLOWING ARE ALSO PERMISSIBLE:

- TREATMENT BY AN ALKALINE WASH OR SIMILAR SUBSTANCE COMMONLY EMPLOYED FOR THE PURPOSES OF NEUTRALIZATION;
- TREATMENT WITH ONE OR MORE OF THE FOLLOWING SUBSTANCES:

-- BENTONITE,
-- ACTIVE CARBONS,
-- OTHER SIMILAR SUBSTANCES COMMONLY EMPLOYED AS A DECOLORANT.

4. THE PRODUCTS LISTED IN PARAGRAPH 1 MAY CONTAIN INSTEAD OF SUCROSE:

- CRYSTALLIZED GLUCOSE (DEXTROSE), FRUCTOSE, LACTOSE OR MALTOSE AMOUNTING TO A TOTAL OF 5 % OF THE TOTAL WEIGHT OF THE PRODUCT, WITHOUT IT BEING NECESSARY FOR THIS TO BE STATED;
- CRYSTALLIZED GLUCOSE (DEXTROSE) IN A PROPORTION OF MORE THAN 5 % BUT NOT OVER 20 % OF THE TOTAL WEIGHT OF THE PRODUCT. IN THIS CASE THE NAME OF THE PRODUCT SHALL BE ACCOMPANIED BY THE DECLARATION "WITH CRYSTALLIZED GLUCOSE" OR "WITH DEXTROSE".

5. (a) FOODSTUFFS HAVING A FLAVOURING EFFECT, NATURAL FLAVOURING SUBSTANCES AND SYNTHETIC OR ARTIFICIAL FLAVOURING SUBSTANCES THE CHEMICAL COMPOSITION OF WHICH IS IDENTICAL TO THAT OF THE PRINCIPAL ELEMENTS OF NATURAL FLAVOURING SUBSTANCES (WITH THE EXCEPTION OF FLAVOURING PREPARATIONS SUGGESTING THE TASTE OF NATURAL CHOCOLATE OR MILK FAT), AND ETHYL VANILLIN MAY BE ADDED TO COCOA MASS, TO THE VARIOUS KINDS OF COCOA POWDER, CHOCOLATE AND MILK CHOCOLATE, TO WHITE CHOCOLATE AND TO CHOCOLATES.

(b) WITHOUT PREJUDICE TO THE PROVISIONS OF PARAGRAPH 7, A DECLARATION OF THIS ADDITION SHALL ACCOMPANY THE NAME OF:

- COCOA MASS, COUVERTURE CHOCOLATE AND COUVERTURE MILK CHOCOLATE;
- THE VARIOUS KIND OF COCOA POWDER, CHOCOLATE AND MILK CHOCOLATE APART FROM COUVERTURE CHOCOLATE, AND WHITE CHOCOLATE, WHEN THE TASTE OF THE FOODSTUFF HAVING A FLAVOURING EFFECT OR OF THE FLAVOURING SUBSTANCE IS THE PREDOMINANT ONE.

THIS DECLARATION SHALL BE MADE:
- WHERE A FOODSTUFF HAVING A FLAVOURING EFFECT IS EMPLOYED, BY GIVING ITS NAME,
" - WHERE FLAVOURING SUBSTANCES OTHER THAN ETHYL VANILLIN ARE EMPLOYED, BY ADDING TO THE NAME THE STATEMENT "... TASTE" OR "... FLAVOUR" WITH A STATEMENT, IN CHARACTERS OF EQUAL SIZE, INDICATING THE NATURE OF THE TASTE OR FLAVOUR. ANY REFERENCE TO A NATURAL SOURCE SHOULD BE RESTRICTED TO NATURAL FLAVOURING SUBSTANCES; " **[3]**
- WHERE ETHYL VANILLIN IS EMPLOYED, BY THE STATEMENT "WITH ETHYL VANILLIN" OR "ETHYL VANILLIN FLAVOUR".

6. TECHNICALLY PURE VEGETABLE LECITHIN WITH A PEROXIDE LEVEL (EXPRESSED IN MILLIEQUIVALENTS PER kg) NOT EXCEEDING 10, MAY BE ADDED TO THE PRODUCTS LISTED IN PARAGRAPH 1 EXCEPT COCOA NIB.
THE NAME OF THE PRODUCT SHALL BE ACCOMPANIED BY A DECLARATION OF THIS ADDITION AND ITS PERCENTAGE, EXCEPT WHEN LECITHIN IS ADDED TO THE VARIOUS KINDS OF CHOCOLATE REFERRED TO UNDER HEADINGS 1.16 TO 1.28.
PRODUCTS LISTED IN PARAGRAPH 1 MAY NOT CONTAIN MORE THAN 0.5 % OF THEIR TOTAL WEIGHT OF PHOSPHATIDES; HOWEVER, THIS PERCENTAGE SHALL BE INCREASED TO 1 % FOR THE VARIOUS KINDS OF COCOA POWDER, MILK CHOCOLATE WITH HIGH MILK CONTENT AND CHOCOLATE FLAKES, AND TO 5 % FOR THE VARIOUS KINDS OF COCOA POWDER INTENDED FOR PRODUCTION OF INSTANT PREPARATIONS, IN SO FAR AS THE PROVISIONS RELATING TO THEM ALLOW AND PROVIDED THAT THIS PURPOSE IS INDICATED ON THE PACKINGS AND IN COMMERCIAL DOCUMENTS.

7. (a) WITHOUT PREJUDICE TO ARTICLE 14 (2) (a), EDIBLE SUBSTANCES, ITH THE EXCEPTION OF FLOUR AND STARCHES AND OF FATS AND FAT PREPARATIONS NOT DERIVED EXCLUSIVELY FROM MILK, MAY BE ADDED TO CHOCOLATE, PLAIN CHOCOLATE, COUVERTURE CHOCOLATE, MILK CHOCOLATE, MILK CHOCOLATE WITH HIGH MILK CONTENT, COUVERTURE MILK CHOCOLATE AND TO WHITE CHOCOLATE.
THE AMOUNT OF THESE SUBSTANCES, IN RELATION TO THE TOTAL WEIGHT OF THE FINISHED PRODUCT, MAY NOT BE:

(i) LESS THAN 5 % OR MORE THAN A TOTAL OF 40 % IF ADDED IN CLEARLY VISIBLE AND SEPARABLE PIECES;

(ii) MORE THAN A TOTAL OF 30 % IF ADDED IN A FORM WHICH IS FOR PRACTICAL PURPOSES INDISCERNIBLE;

(iii) WITHOUT PREJUDICE TO (i) ABOVE, MORE THAN A TOTAL OF 40 %, IF THEY ARE ADDED BOTH IN CLEARLY-VISIBLE AND SEPARABLE PIECES AND IN A FORM WHICH IS FOR PRACTICAL PURPOSES INDISCERNIBLE.

(b) A DECLARATION RELATING TO THE EDIBLE SUBSTANCES ADDED SHALL ACCOMPANY THE NAME OF THE CHOCOLATE PRODUCTS REFERRED TO UNDER (a).
SUCH A DECLARATION SHALL HOWEVER, BE PROHIBITED IN RESPECT OF THE FOLLOWING:

" (i) MILK AND MILK PRODUCTS WHEN THE FINISHED PRODUCT IS NOT MILK CHOCOLATE, MILK CHOCOLATE WITH HIGH MILK CONTENT, COUVERTURE MILK CHOCOLATE OR WHITE CHOCOLATE; " **[3]**

(ii) COFFEE AND SPIRITS, WHEN THE AMOUNT OF EACH OF THESE SUBSTANCES IS LESS THAN 1 % OF THE TOTAL WEIGHT OF THE FINISHED PRODUCT;

(iii) OTHER EDIBLE SUBSTANCES, INCORPORATED IN A FORM WHICH IS FOR PRACTICAL PURPOSES INDISCERNIBLE, WHEN THE AMOUNT OF EACH OF THESE SUBSTANCES IS LESS THAN 5 % OF THE TOTAL WEIGHT OF THE FINISHED PRODUCT.

(c) IN THE CASE OF FILLED CHOCOLATE AND CHOCOLATES, THE ADDED EDIBLE MATTER REFERRED TO IN PARAGRAPH (a) SHALL NOT BE INCLUDED IN THE CHOCOLATE PRODUCT PARTS, WHICH, PURSUANT TO HEADINGS 1.27 AND 1.28, MUST REPRESENT AT LEAST 25 % OF THE TOTAL WEIGHT.

8. CHOCOLATE, PLAIN CHOCOLATE, MILK CHOCOLATE, MILK CHOCOLATE WITH HIGH MILK CONTENT, WHITE CHOCOLATE, FILLED CHOCOLATE AND CHOCOLATES MAY BE PARTIALLY COATED WITH EDIBLE SUBSTANCES REPRESENTING A MAXIMUM OF 10 % OF THEIR TOTAL WEIGHT. IN THIS CASE:

(a) THE UPPER LIMITS OF 40 % AND 30 % FIXED IN PARAGRAPH 7 (a) AND (b) SHALL INCLUDE THE COATING SUBSTANCES,

(b) THE LOWER LIMIT OF 25 % FIXED FOR THE CONTENT OF VARIOUS KINDS OF CHOCOLATE IN FILLED CHOCOLATE AND IN CHOCOLATES SHALL RELATE TO THE TOTAL WEIGHT OF THE PRODUCT, COATING INCLUDED.

ANNEX II

" SPECIAL MEASURES " **[6]**

1. NOTWITHSTANDING ARTICLE 2 OF THIS DIRECTIVE, IRELAND SHALL BE EXEMPT FROM APPLYING TO PRODUCTS MARKETED IN ITS TERRITORY THE PROVISIONS LAID DOWN IN ARTICLE 6 DURING THE WHOLE PERIOD FOR WHICH THE UNITS OF WEIGHT LEGALLY USED IN THAT COUNTRY AT THE TIME OF ITS ACCESSION TO THE EUROPEAN ECONOMIC COMMUNITY REMAIN AUTHORIZED.

" 1a. MEMBER STATES MAY AUTHORIZE THE ADDITION OF AMMONIUM SALTS OF PHOSPHATIDIC ACIDS TO THE COCOA AND CHOCOLATE PRODUCTS REFERRED TO IN ANNEX I (1) WITH THE EXCEPTION OF COCOA NIB.
THE NAME OF THE PRODUCT SHALL BE ACCOMPANIED BY THE DECLARATION OF THIS ADDITION AND ITS PERCENTAGE, EXCEPT WHEN AMMONIUM SALTS OF PHOSPHATIDIC ACIDS ARE ADDED TO THE VARIOUS KINDS OF CHOCOLATE REFERRED TO IN ANNEX I UNDER HEADINGS 1.16 TO 1.28.
IF AMMONIUM SALTS OF PHOSPHATIDIC ACIDS ARE USED, THE MAXIMUM PERCENTAGES LAID DOWN IN THE THIRD SUBPARAGRAPH OF ANNEX I (6) SHALL ALSO APPLY.
THE COUNCIL MAY, IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 100 OF THE TREATY, INCLUDE THIS SUBSTANCE IN ANNEX I. " **[8]**

2. " (a) THIS DIRECTIVE SHALL NOT AFFECT THOSE PROVISIONS OF NATIONAL LAWS WHICH ARE IN FORCE ON 1 AUGUST 1973 AND WHICH AUTHORIZE THE USE OF:

(i) PHOSPHORIC ACID AS A NEUTRALIZING AGENT IN COCOA PRODUCTS ALKALIZED IN ACCORDANCE WITH ANNEX I, PARAGRAPH 2;

(ii) FLAVOURING SUBSTANCES OTHER THAN THOSE REFERRED TO IN PARAGRAPH 5 (a) OF ANNEX I, IN THE COCOA AND CHOCOLATE PRODUCTS REFERRED TO IN THAT PARAGRAPH;

" (iii) POLYGLYCEROL POLYRICINOLEATE AND SORBITAN TRISTEARATE IN THE COCOA AND CHOCOLATE PRODUCTS REFERRED TO IN THE FIRST SUBPARAGRAPH OF ANNEX I (6). " **[8]**

(b) THE DEROGATION PROVIDED FOR:

(i) IN (a) (i) SHALL END ON 30 JUNE 1981; HOWEVER, BEFORE THAT DATE, THE COUNCIL MAY, IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 100 OF THE TREATY, INCLUDE IN ANNEX I THE SUBSTANCE SPECIFIED IN POINT (a) (i); A DECISION TO INCLUDE THIS SUBSTANCE IN ANNEX I MAY BE ADOPTED ONLY IF SCIENTIFIC RESEARCH HAS ESTABLISHED THAT IT IS NOT HARMFUL TO HUMAN HEALTH AND IF ITS USE IS NECESSARY ON ECONOMIC GROUNDS;

(ii) IN POINT (a) (ii) SHALL END ON A DATE TO BE FIXED BY THE COUNCIL BEFORE 1 JANUARY 1983, IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 100 OF THE TREATY AND AT ANY RATE AT THE TIME OF THE ENTRY INTO FORCE OF COMMUNITY RULES LISTING THE FLAVOURING SUBSTANCES WHICH MAY BE USED IN FOODSTUFFS;

(iii) IN POINT (a) (iii) SHALL END ON " 31 DECEMBER 1983 " **[8]** ; BEFORE THAT DATE, HOWEVER, THE COUNCIL MAY, IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 100 OF THE TREATY, INCLUDE THE SUBSTANCES SPECIFIED IN POINT (a) (iii) IN THE FIRST SUBPARAGRAPH OF PARAGRAPH 6 OF ANNEX I. " **[6]**

(1) OJ No L 291, 19/11/1969, p. 9.

SUGARS

373L0437

73/437/EEC: COUNCIL DIRECTIVE OF 11 DECEMBER 1973 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES CONCERNING CERTAIN SUGARS INTENDED FOR HUMAN CONSUMPTION

OFFICIAL JOURNAL NO L 356, 27/12/1973, P. 71
DATE OF NOTIFICATION: 13/12/1973
DATE OF TRANSPOSITION: 13/12/1974; SEE ART. 15

AMENDED BY

179H
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE HELLENIC REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES [1]
OFFICIAL JOURNAL NO L 291, 19/11/1979, P. 110

185I
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE KINGDOM OF SPAIN AND THE PORTUGUESE REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES [2]
OFFICIAL JOURNAL NO L 302, 15/11/1985, P. 216

ARTICLE 1

WITHIN THE MEANING OF THIS DIRECTIVE:

1. SEMI-WHITE SUGAR

MEANS PURIFIED AND CRYSTALLIZED SUCROSE, OF SOUND AND FAIR MARKETABLE QUALITY WITH THE FOLLOWING CHARACTERISTICS:

(a) POLARIZATION: NOT LESS THAN 99.5°

(b) INVERT SUGAR CONTENT: NOT MORE THAN 0.10 % BY WEIGHT

(c) LOSS ON DRYING: NOT MORE THAN 0.10 % BY WEIGHT

(d) RESIDUAL SULPHUR DIOXIDE CONTENT: NOT MORE THAN 15 mg/kg.

2. SUGAR OR WHITE SUGAR

MEANS PURIFIED AND CRYSTALLIZED SUCROSE, OF SOUND AND FAIR MARKETABLE QUALITY, WITH THE FOLLOWING CHARACTERISTICS:

(a) POLARIZATION: NOT LESS THAN 99.7°

(b) INVERT SUGAR CONTENT: NOT MORE THAN 0.04 % BY WEIGHT

(c) LOSS ON DRYING: NOT MORE THAN 0.10 % BY WEIGHT

(d) RESIDUAL SULPHUR DIOXIDE CONTENT: NOT MORE THAN 15 mg/kg

(e) TYPE OF COLOUR: NOT MORE THAN 12 POINTS DETERMINED ACCORDING TO ANNEX UNDER (a).

3. EXTRA WHITE SUGAR

MEANS THE PRODUCT HAVING THE CHARACTERISTICS REFERRED TO IN POINT 2 (a) TO (d) AND IN RESPECT OF WHICH THE TOTAL NUMBER OF POINTS DETERMINED ACCORDING TO THE PROVISIONS OF THE ANNEX DOES NOT EXCEED A TOTAL OF 8 OR NOT MORE THAN:

- 4 FOR THE COLOUR TYPE
- 6 FOR THE ASH CONTENT
- 3 FOR THE COLOUR IN SOLUTION.

4. SUGAR SOLUTION

MEANS THE AQUEOUS SOLUTION OF SUCROSE WITH THE FOLLOWING CHARACTERISTICS:

(a) DRY MATTER: NOT LESS THAN 62 % BY WEIGHT

(b) INVERT SUGAR CONTENT (RATIO OF FRUCTOSE TO DEXTROSE: 1.0 ± 0.2): NOT MORE THAN 3 % BY WEIGHT OF DRY MATTER

(c) CONDUCTIVITY ASH: NOT MORE THAN 0.1 % BY WEIGHT OF DRY MATTER, DETERMINED ACCORDING TO THE ANNEX UNDER (b)

(d) COLOUR IN SOLUTION NOT MORE THAN 45 ICUMSA UNITS DETERMINED ACCORDING TO THE ANNEX UNDER (c)

(e) RESIDUAL SULPHUR DIOXIDE CONTENT NOT MORE THAN 15 mg/kg OF DRY MATTER.

5. INVERT SUGAR SOLUTION

MEANS THE AQUEOUS SOLUTION OF SUCROSE PARTIALLY INVERTED BY HYDROLYSIS, IN WHICH THE PROPORTION OF INVERT SUGAR DOES NOT PREDOMINATE, WITH THE FOLLOWING CHARACTERISTICS:

(a) DRY MATTER: NOT LESS THAN 62 % BY WEIGHT

(b) INVERT SUGAR CONTENT (RATIO OF FRUCTOSE TO DEXTROSE: 1.0 ± 0.1): MORE THAN 3 % BUT NOT MORE THAN 50 %, BY WEIGHT OF DRY MATTER

(c) CONDUCTIVITY ASH: NOT MORE THAN 0.4 % BY WEIGHT OF DRY MATTER DETERMINED ACCORDING TO THE ANNEX UNDER (b)

(d) RESIDUAL SULPHUR DIOXIDE CONTENT: NOT MORE THAN 15 mg/kg OF DRY MATTER.

6. INVERT SUGAR SYRUP

MEANS THE AQUEOUS SOLUTION, POSSIBLY CRYSTALLIZED, OF SUCROSE PARTIALLY INVERTED BY HYDROLYSIS, IN WHICH THE PROPORTION OF INVERT SUGAR IS PREDOMINANT, WITH THE FOLLOWING CHARACTERISTICS:

(a) DRY MATTER: NOT LESS THAN 62 % BY WEIGHT

(b) INVERT SUGAR CONTENT (RATIO OF FRUCTOSE TO DEXTROSE: 1.0 ± 0.1): MORE THAN 50 % BY WEIGHT OF DRY MATTER

(c) CONDUCTIVITY ASH: NOT MORE THAN 0.4 % BY WEIGHT OF DRY MATTER DETERMINED ACCORDING TO THE ANNEX UNDER (b)

(d) RESIDUAL SULPHUR DIOXIDE CONTENT: NOT MORE THAN 15 mg/kg OF DRY MATTER.

7. GLUCOSE SYRUP

MEANS THE PURIFIED AND CONCENTRATED AQUEOUS SOLUTION OF NUTRITIVE SACCHARIDES OBTAINED FROM STARCH, WITH THE FOLLOWING CHARACTERISTICS:

(a) DRY MATTER: NOT LESS THAN 70 % BY WEIGHT

(b) DEXTROSE EQUIVALENT: NOT LESS THAN 20 % BY WEIGHT OF DRY MATTER AND EXPRESSED AS D-GLUCOSE

(c) SULPHATED ASH: NOT MORE THAN 1.0 % BY WEIGHT OF DRY MATTER

(d) TOTAL SULPHUR DIOXIDE CONTENT

- IN GENERAL: NOT MORE THAN 20 mg/kg
- FOR USE EXCLUSIVELY IN SUGAR CONFECTIONERY PRODUCTS: THE MEMBER STATES MAY, WITHOUT PREJUDICE TO THE NATIONAL OR COMMUNITY PROVISIONS WHICH DETERMINE THE MAXIMUM SULPHUR DIOXIDE CONTENT FOR THE VARIOUS CONFECTIONERY PRODUCTS, FIX THE TOLERANCE FOR GLUCOSE SYRUP OFFERED FOR SALE IN THEIR OWN TERRITORY AT MORE THAN 20 mg/kg BUT NOT MORE THAN 400 mg/kg
- FOR USE IN OTHER SPECIFIED FOODSTUFFS: THE MEMBER STATES MAY, IN ACCORDANCE WITH NATIONAL PROVISIONS GOVERNING THESE FOODSTUFFS, AND WITHOUT PREJUDICE TO COMMUNITY PROVISIONS, FIX THE TOLERANCES FOR GLUCOSE SYRUP OFFERED FOR SALE IN THEIR OWN TERRITORY AT MORE THAN 20 mg/kg, BUT NOT MORE THAN 400 mg/kg PROVIDED THAT THESE TOLERANCES ARE JUSTIFIED BY TECHNOLOGICAL REQUIREMENTS.

8. DRIED GLUCOSE SYRUP

MEANS GLUCOSE SYRUP PARTIALLY DRIED WITH THE FOLLOWING CHARACTERISTICS:

(a) DRY MATTER: NOT LESS THAN 93 % BY WEIGHT

(b) DEXTROSE EQUIVALENT: NOT LESS THAN 20 % BY WEIGHT OF DRY MATTER EXPRESSED AS D-GLUCOSE

(c) SULPHATED ASH: NOT MORE THAN 1.0 % BY WEIGHT OF DRY MATTER

(d) TOTAL SULPHUR DIOXIDE CONTENT

- IN GENERAL: NOT MORE THAN 20 mg/kg
- FOR USE EXCLUSIVELY IN SUGAR CONFECTIONERY: NOT MORE THAN 150 mg/kg. THIS TOLERANCE, HOWEVER, SHALL NOT AFFECT NATIONAL OR COMMUNITY PROVISIONS WHICH FIX THE MAXIMUM SULPHUR DIOXIDE CONTENT FOR THE VARIOUS CONFECTIONERY PRODUCTS
- FOR USE IN OTHER SPECIFIED FOODSTUFFS: THE MEMBER STATES MAY, IN ACCORDANCE WITH NATIONAL PROVISIONS GOVERNING THESE FOODSTUFFS, AND WITHOUT PREJUDICE TO COMMUNITY PROVISIONS, FIX THE TOLERANCES FOR GLUCOSE SYRUP OFFERED FOR SALE IN THEIR OWN TERRITORY AT MORE THAN 20 mg/kg BUT NOT MORE THAN 150 mg/kg PROVIDED THAT THESE TOLERANCES ARE JUSTIFIED BY TECHNOLOGICAL REQUIREMENTS.

9. DEXTROSE MONOHYDRATE

MEANS PURIFIED AND CRYSTALLIZED D-GLUCOSE CONTAINING ONE MOLECULE OF WATER OF CRYSTALLIZATION, WITH THE FOLLOWING CHARACTERISTICS:

(a) DEXTROSE (D-GLUCOSE): NOT LESS THAN 99.5 % BY WEIGHT OF DRY MATTER

(b) DRY MATTER: NOT LESS THAN 90.0 % BY WEIGHT

(c) SULPHATED ASH: NOT MORE THAN 0.25 % BY WEIGHT OF DRY MATTER

(d) TOTAL SULPHUR DIOXIDE CONTENT: NOT MORE THAN 15 mg/kg.

10. DEXTROSE ANHYDROUS

MEANS PURIFIED AND CRYSTALLIZED D-GLUCOSE NOT CONTAINING WATER OF CRYSTALLIZATION, WITH THE FOLLOWING CHARACTERISTICS:

(a) DEXTROSE (D-GLUCOSE): NOT LESS THAN 99.5 % BY WEIGHT OF DRY MATTER

(b) DRY MATTER: NOT LESS THAN 98.0 % BY WEIGHT

(c) SULPHATED ASH: NOT MORE THAN 0.25 % BY WEIGHT OF DRY MATTER

(d) TOTAL SULPHUR DIOXIDE CONTENT: NOT MORE THAN 15 mg/kg.

ARTICLE 2

MEMBER STATES SHALL TAKE ALL MEASURES NECESSARY TO ENSURE THAT THE PRODUCTS REFERRED TO IN ARTICLE 1 MAY BE OFFERED FOR SALE ONLY IF THEY CONFORM TO THE DEFINITIONS AND RULES LAID DOWN IN THIS DIRECTIVE AND IN THE ANNEX THERETO.

ARTICLE 3

1. THE NAMES LISTED IN ARTICLE 1 SHALL BE APPLIED ONLY TO THE PRODUCTS DEFINED THEREIN AND MUST BE USED IN TRADE TO DESIGNATE THEM; THE DESCRIPTION REFERRED TO IN ARTICLE 1 (2) MAY ALSO BE USED TO DESIGNATE THE PRODUCTS DEFINED IN ARTICLE 1 (3).
FURTHERMORE, THE DESCRIPTION "WHITE" SHALL BE RESERVED:

(a) FOR SUGAR SOLUTION WHERE THE COLOUR IN SOLUTION DOES NOT EXCEED 25 ICUMSA UNITS, DETERMINED ACCORDING TO THE METHOD PROVIDED FOR IN THE ANNEX, UNDER (c);

(b) FOR INVERT SUGAR SOLUTION AND FOR INVERT SUGAR SYRUP OF WHICH:

- THE ASH CONTENT DOES NOT EXCEED 0.1 %
- THE COLOUR IN SOLUTION DOES NOT EXCEED 25 ICUMSA UNITS DETERMINED ACCORDING TO THE METHOD PROVIDED FOR IN THE ANNEX UNDER (c).

2. THE PROVISIONS OF PARAGRAPH 1 SHALL NOT HOWEVER AFFECT ARRANGEMENTS WHEREBY THESE NAMES CAN BE USED, ADDITIONALLY, IN ACCORDANCE WITH CUSTOM, TO INDICATE OTHER PRODUCTS, WHICH CANNOT BE CONFUSED WITH THOSE DEFINED IN ARTICLE 1.

3. MOREOVER, AS REGARDS THE USE OF THE WORD "SUGAR" WITHOUT ANY OTHER QUALIFYING TERM, PARAGRAPH 1 SHALL APPLY ONLY TO DIRECT TRADE IN FOOD SUGARS AS SUCH, AND NOT TO COMPOUND PRODUCTS IN WHICH SUCH SUGARS HAVE BEEN USED.

ARTICLE 4

BY WAY OF DEROGATION FROM ARTICLE 1, POINTS (7) AND (8), A MAXIMUM RESIDUAL SULPHUR DIOXIDE CONTENT EQUIVALENT TO 40 mg/kg IN THE PRODUCTS DEFINED IN THE AFOREMENTIONED POINTS SHALL BE AUTHORIZED FOR A PERIOD OF THREE YEARS FROM THE NOTIFICATION OF THIS DIRECTIVE.

ARTICLE 5

BY WAY OF DEROGATION FROM ARTICLE 1, POINTS (1), (2), (3), (4), (5), (6), (9) AND (10) AND FOR A PERIOD OF FIVE YEARS FROM THE NOTIFICATION OF THIS DIRECTIVE, MEMBER STATES MAY CONTINUE TO APPLY NATIONAL PROVISIONS AUTHORIZING A MAXIMUM RESIDUAL SULPHUR DIOXIDE CONTENT UP TO 20 mg/kg IN RESPECT OF PRODUCTS MARKETED IN THEIR TERRITORY.

ARTICLE 6

WITHOUT PREJUDICE TO ANY RELEVANT NATIONAL PROVISIONS, THE PRODUCTS REFERRED TO IN ARTICLE 1, POINTS (7) AND (8), WHICH CONTAIN A QUANTITY OF SULPHUR DIOXIDE EXCEEDING 20 mg/kg MAY NOT BE OFFERED FOR RETAIL SALE.

ARTICLE 7

THE PRODUCTS REFERRED TO IN ARTICLE 1:

- MAY NOT BE SUBMITTED TO THE BLUEING PROCESS,
- MAY CONTAIN COLORANTS IN SO FAR AS THEY ARE INTENDED FOR USE IN OTHER FOODSTUFFS, IN ACCORDANCE WITH THE PROVISIONS APPLICABLE TO THE SAID FOODSTUFFS AND TO THE USE OF COLOURING AGENTS THEREIN.

ARTICLE 8

1. THE PRODUCTS REFERRED TO IN ARTICLE 1, POINTS (1) TO (3) WHEN PACKED AT A NET INDIVIDUAL WEIGHT OF BETWEEN 100 g AND 5 kg SHALL BE OFFERED FOR SALE ONLY AT THE FOLLOWING INDIVIDUAL NET WEIGHTS: 125 g, 250 g, 500 g, 750 g, 1 kg, 1.5 kg, 2 kg , 2.5 kg, 3 kg, 4 kg AND 5 kg.

2. ON A TRANSITIONAL BASIS, FOR A PERIOD OF NOT MORE THAN FIVE YEARS AFTER NOTIFICATION OF THIS DIRECTIVE, WEIGHTS, NET OR GROSS, OTHER THAN THOSE LISTED IN PARAGRAPH 1 SHALL ALSO BE ALLOWED IF THESE WEIGHTS COMPLY WITH THE NATIONAL PROVISIONS IN FORCE OR WITH PRACTICES EXISTING AT THE TIME OF NOTIFICATION OF THIS DIRECTIVE.

ARTICLE 9

1. THE ONLY INFORMATION WHICH IS COMPULSORY ON THE PACKAGES, CONTAINERS OR LABELS OF THE PRODUCTS DEFINED IN ARTICLE 1 SHALL BE THE FOLLOWING:

(a) THE DESCRIPTION BY WHICH THE PRODUCTS ARE DESIGNATED IN ARTICLE 1; HOWEVER:

- THE EXPRESSIONS "MONOHYDRATE" AND "ANHYDROUS" SHALL BE OPTIONAL FOR THE RETAIL TRADE DESCRIPTION OF THE PRODUCTS DEFINED IN ARTICLE 1, POINTS (9) AND (10),
- THE QUALIFYING EXPRESSION "INCLUDES COLOURING AGENTS" SHALL BE OBLIGATORY IN THE DESCRIPTION OF PRODUCTS CONTAINING COLOURING AGENTS, IN CONFORMITY WITH ARTICLE 6, AND THE TERM "WHITE" SHALL BE PROHIBITED IN THIS CASE;

(b) THE NET WEIGHT, UNLESS THE PRODUCTS WEIGH LESS THAN 50 g; THIS EXCEPTION SHALL NOT APPLY TO PRODUCTS WEIGHING LESS THAN 50 g EACH PRESENTED IN PACKAGES CONTAINING

TWO OR MORE SUCH PRODUCTS WHOSE NET WEIGHT INCLUSIVE OF PACKAGING IS NOT LESS THAN 50 g, IN WHICH CASE, THE TOTAL NET WEIGHT OF THE PRODUCTS CONTAINED IN THE OUTER PACKAGE MUST BE INDICATED THEREON; HOWEVER, AS REGARDS THE PRODUCTS REFERRED TO IN ARTICLE 1, POINTS (1), (2), (3), (9) AND (10) THE INDICATION OF NET WEIGHT MAY BE REPLACED BY THAT OF THE MINIMUM NET WEIGHT IF THE PRODUCTS ARE OFFERED FOR SALE IN PIECES OR IN SMALL SACHETS;

(c) THE NAME OR TRADE NAME AND THE ADDRESS OR REGISTERED OFFICE OF THE MANUFACTURER OR PACKER, OR OF A SELLER ESTABLISHED WITHIN THE COMMUNITY; THIS PROVISION DOES NOT AFFECT THE RIGHT OF THE MANUFACTURER TO REQUIRE THAT EITHER HIS NAME OR HIS TRADE NAME BE MENTIONED;

(d) AN INDICATION OF THE TRUE CONTENT OF DRY MATTER AND INVERT SUGAR IN THE CASE OF SUGAR SOLUTION, INVERT SUGAR SOLUTION, AND INVERT SUGAR SYRUP;

(e) THE QUALIFYING TERM "CRYSTALLIZED" FOR INVERT SUGAR SYRUP INCORPORATING CRYSTALS IN THE SOLUTION;

(f) THE DESCRIPTION OF GLUCOSE SYRUP OR DRIED GLUCOSE SYRUP OF WHICH THE SULPHUR DIOXIDE CONTENT EXCEEDS 20 mg/kg OR, IN THE CIRCUMSTANCES REFERRED TO IN ARTICLE 4, EXCEEDS 40 mg/kg, SHALL BE FOLLOWED BY A REFERENCE TO THE FOODSTUFF FOR THE MANUFACTURE OF WHICH IT IS INTENDED, THE MAXIMUM SULPHUR DIOXIDE CONTENT OF THE PRODUCT BEING INDICATED ON THE ACCOMPANYING DOCUMENTS.

2. THE SPECIFICATIONS REFERRED TO IN PARAGRAPH 1 MUST BE CONSPICUOUS, CLEARLY LEGIBLE AND INDELIBLE.

3. THE PROVISIONS OF PARAGRAPH 1 SHALL NOT PRECLUDE THE PRODUCTS DEFINED IN ARTICLE 1 BEARING, IN ADDITION TO THE OBLIGATORY DESCRIPTION, OTHER DESCRIPTIONS CURRENT IN THE VARIOUS MEMBER STATES PROVIDED THAT THE LATTER DESCRIPTIONS ARE NOT LIABLE TO MISLEAD CONSUMERS.

4. WHERE THE PRODUCTS DEFINED IN ARTICLE 1 ARE MADE UP INTO PACKAGES OR IN CONTAINERS OF A NET WEIGHT EQUAL TO OR EXCEEDING 10 kg AND ARE NOT OFFERED FOR RETAIL SALE, THE DESCRIPTIONS REFERRED TO IN PARAGRAPH 1 (b), (d), (e) AND (f) MAY IF DESIRED APPEAR ONLY ON THE ACCOMPANYING DOCUMENTS.

5. BY WAY OF DEROGATION FROM PARAGRAPH 1, AND WITHOUT PREJUDICE TO THE PROVISIONS TO BE ADOPTED BY THE COMMUNITY ON THE LABELLING OF FOODSTUFFS, MEMBER STATES MAY RETAIN NATIONAL PROVISIONS WHICH REQUIRE INDICATION OF:

(a) THE FACTORY, IN RESPECT OF HOME PRODUCTION;

(b) THE COUNTRY OF ORIGIN, ALTHOUGH THIS INFORMATION MAY NOT BE REQUIRED FOR PRODUCTS MANUFACTURED WITHIN THE COMMUNITY.

6. MEMBER STATES SHALL REFRAIN FROM STATING, APART FROM WHAT IS LAID DOWN IN PARAGRAPHS 1 AND 2, HOW THE INFORMATION REFERRED TO IN PARAGRAPH 1 IS TO BE GIVEN. HOWEVER, MEMBER STATES MAY FORBID TRADE ON THEIR TERRITORY IN THE PRODUCTS DEFINED IN ARTICLE 1 IF THE MARKINGS LAID DOWN IN PARAGRAPH 1 (a), (d), (e) AND (f) ARE NOT SHOWN ON ONE SIDE OF THE WRAPPING OR CONTAINER IN THE NATIONAL LANGUAGE OR LANGUAGES OR, AS PROVIDED IN PARAGRAPH 4, IN THE ACCOMPANYING DOCUMENTS.
HOWEVER, IN IRELAND AND THE UNITED KINGDOM DURING THE TRANSITIONAL PERIOD PROVIDED FOR IN ARTICLE 8 (2) ANY WEIGHTS OTHER THAN METRIC SHALL, IF THOSE MEMBER STATES SO REQUIRE, BE LABELLED WITH THEIR METRIC EQUIVALENTS.

7. PARAGRAPHS 1 TO 6 SHALL APPLY WITHOUT PREJUDICE TO THE PROVISIONS TO BE LAID DOWN BY THE COMMUNITY ON LABELLING.

ARTICLE 10

1. MEMBER STATES SHALL ADOPT ALL THE NECESSARY MEASURES TO ENSURE THAT TRADE IN THE PRODUCTS REFERRED TO IN ARTICLE 1, WHICH COMPLY WITH THE DEFINITIONS AND RULES LAID DOWN IN THIS DIRECTIVE AND THE ANNEX THERETO, SHALL NOT BE IMPEDED BY THE APPLICATION OF NATIONAL NON-HARMONIZED PROVISIONS GOVERNING THE COMPOSITION, MANUFACTURING SPECIFICATIONS, PACKAGING OR LABELLING OF THESE PRODUCTS IN PARTICULAR OR OF FOODSTUFFS IN GENERAL.

2. PARAGRAPH 1 SHALL NOT BE APPLICABLE TO NON-HARMONIZED PROVISIONS JUSTIFIED ON GROUNDS OF:

- PROTECTION OF PUBLIC HEALTH,
- REPRESSION OF FRAUDS, UNLESS SUCH PROVISIONS ARE LIABLE TO IMPEDE THE APPLICATION OF THE DEFINITIONS AND RULES LAID DOWN BY THIS DIRECTIVE,
- PROTECTION OF INDUSTRIAL AND COMMERCIAL PROPERTY, OF INDICATIONS OF SOURCE, APPLICATIONS OF ORIGIN AND THE REPRESSION OF UNFAIR COMPETITION.

ARTICLE 11

THE SAMPLING PROCEDURES AND METHODS OF ANALYSIS NEEDED TO VERIFY THE RULES RELATING TO THE COMPOSITION AND MANUFACTURING SPECIFICATIONS OF THE PRODUCTS DEFINED IN ARTICLE 1 SHALL BE DETERMINED IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 12.

ARTICLE 12

1. WHERE THE PROCEDURE LAID DOWN IN THIS ARTICLE IS TO BE FOLLOWED, THE MATTER SHALL BE REFERRED TO THE STANDING COMMITTEE ON FOODSTUFFS, SET UP BY THE COUNCIL DECISION OF 13 NOVEMBER 1969 (1) (HEREINAFTER CALLED "THE COMMITTEE") BY ITS CHAIRMAN, EITHER ON HIS OWN INITIATIVE OR AT THE REQUEST OF A REPRESENTATIVE OF A MEMBER STATE.

2. THE REPRESENTATIVE OF THE COMMISSION SHALL SUBMIT TO THE COMMITTEE A DRAFT OF THE MEASURES TO BE TAKEN. THE COMMITTEE SHALL GIVE ITS OPINION ON THAT DRAFT WITHIN THE TIME LIMIT SET BY THE CHAIRMAN HAVING REGARD TO THE URGENCY OF THE MATTER. OPINIONS SHALL BE ADOPTED BY A MAJORITY OF " fifty-four " **[2]** VOTES THE VOTES OF THE MEMBER STATES BEING WEIGHTED AS PROVIDED IN ARTICLE 148 (2) OF THE TREATY. THE CHAIRMAN SHALL NOT VOTE.

3. (a) WHERE THE MEASURES ENVISAGED ARE IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE, THE COMMISSION SHALL ADOPT THEM.

(b) WHERE THE MEASURES ENVISAGED ARE NOT IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE, OR IF NO OPINION IS DELIVERED, THE COMMISSION SHALL WITHOUT DELAY SUBMIT TO THE COUNCIL A PROPOSAL ON THE MEASURES TO BE TAKEN. THE COUNCIL SHALL ACT BY A QUALIFIED MAJORITY.

(c) IF, WITHIN THREE MONTHS OF THE PROPOSAL BEING SUBMITTED TO IT, THE COUNCIL HAS NOT ACTED, THE PROPOSED MEASURES SHALL BE ADOPTED BY THE COMMISSION.

ARTICLE 13

THE PROVISIONS OF ARTICLE 12 SHALL APPLY FOR A PERIOD OF EIGHTEEN MONTHS FROM THE DATE ON WHICH THE MATTER WAS FIRST REFERRED TO THE COMMITTEE, UNDER ARTICLE 12 (1).

ARTICLE 14

THIS DIRECTIVE SHALL NOT APPLY TO:

(a) PRODUCTS DEFINED IN ARTICLE 1 IN SO FAR AS THEY TAKE THE FOLLOWING FORMS:

- IMPALPABLE SUGARS,
- CANDY SUGARS,
- SUGARS IN LOAF FORM;

(b) PRODUCTS INTENDED FOR EXPORT TO COUNTRIES OUTSIDE THE COMMUNITY.

ARTICLE 15

MEMBER STATES SHALL, IF NECESSARY, WITHIN ONE YEAR FOLLOWING THE NOTIFICATION OF THIS DIRECTIVE, AMEND THEIR LAWS IN ACCORDANCE WITH THE PROVISIONS OF THIS DIRECTIVE AND SHALL FORTHWITH INFORM THE COMMISSION THEREOF. THE LAWS THUS AMENDED SHALL APPLY TO THE PRODUCTS OFFERED FOR SALE IN THE MEMBER STATES TWO YEARS AFTER THE NOTIFICATION OF THIS DIRECTIVE.

ARTICLE 16

THIS DIRECTIVE IS ADDRESSED TO THE MEMBER STATES.

ANNEX

METHOD OF DETERMINING THE COLOUR TYPE, ASH CONTENT, AND THE COLOUR IN SOLUTION OF SUGAR (WHITE) AND OF EXTRA-WHITE SUGAR DEFINED IN ARTICLE 1 (2) AND (3)

A "POINT" CORRESPONDS:

(a) IN THE CASE OF THE COLOUR TYPE, TO 0.5 UNITS, CALCULATED BY THE METHOD OF THE BRUNSWICK INSTITUTE FOR AGRICULTURAL AND SUGAR INDUSTRY TECHNOLOGY AS SET OUT IN A, PARAGRAPH (2) OF THE ANNEX TO COMMISSION REGULATION (EEC) No 1265/69 OF 1 JULY 1969 ESTABLISHING METHODS FOR DETERMINING THE QUALITY OF SUGAR BOUGHT IN BY INTERVENTION AGENCIES (2);

(b) IN THE CASE OF ASH CONTENT, TO 0.0018 % CALCULATED BY THE METHOD OF THE INTERNATIONAL COMMISSION FOR UNIFORM METHODS OF SUGAR ANALYSIS (ICUMSA) AS SET OUT IN A , PARAGRAPH (1) OF THE ANNEX TO THE SAID REGULATION;

(c) IN THE CASE OF THE COLOUR IN SOLUTION, TO 7.5 UNITS CALCULATED BY THE ICUMSA METHOD AS SET OUT IN A, PARAGRAPH (3) OF THE ANNEX TO THE SAID REGULATION.

(1) OJ No L 291, 19/11/1969, p. 9.
(2) OJ No L 163, 04/07/1969, p. 1.

FIRST COMMISSION DIRECTIVE

of 26 July 1979

Laying down Community methods of analysis for testing certain sugars intended for human consumption

(79/786/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 73/437/EEC of 11 December 1973 on the approximation of the laws of the Member States concerning certain sugars intended for human consumption (1), and in particular Article 11 thereof,

Whereas Article 11 of that Directive lays down that the composition of certain sugars shall be verified by Community methods of analysis;

Whereas it is desirable to adopt an initial series of methods in respect of which studies have been completed;

Whereas the method of determining the colour type for sugar or white sugar and for extra-white sugar, the method of measuring the conductivity ash in extra-white sugar, in sugar solution, in invert sugar solution and in invert sugar syrup, and the method of determining the colour in solution of extra-white sugar and sugar solution are laid down in the Annex to Directive 73/437/EEC;

Whereas, on the other hand, pending the formulation of further Community methods for the determination of reducing sugars, it would be advisable to allow the Member States the option of continuing to authorize the use of the Lane and Eynon method (methods 7 and 8 in Annex II, III.3 and III.4) instead of the Luff-Schoorl method (method 6 in Annex II, III.3 and III.4);

Whereas the methods of analysis provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. Member States shall require that the analyses necessary for verification of the criteria set out in Annex I be performed according to the methods described in Annex II to this Directive.

2. Without prejudice to the second subparagraph, the Luff-Schoorl method (Annex II, method 6) shall be used to determine the reducing sugars in the following sugars:

— sugar solution,
— white sugar solution,
— invert sugar solution,
— white invert sugar solution,
— invert sugar syrup,
— glucose syrup,
— dried glucose syrup,
— dextrose monohydrate,
— dextrose anhydrous.

Member States may, however, require the use in their territory of the Lane and Eynon method (Annex II, methods 7 and/or 8 as appropriate) to determine the reducing sugars in one or more of the sugars listed above.

3. If a Member State makes use of the option provided for in the second subparagraph of paragraph 2, it shall forthwith inform the Commission and the other Member States thereof.

Article 2

Member States shall bring into force the laws, regulations or administrative provisions necessary to

(1) OJ No L 356, 27. 12. 1973, p. 71.

comply with this Directive not later than 18 months following its notification. They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 26 July 1979.

For the Commission

Étienne DAVIGNON

Member of the Commission

ANNEX I

SCOPE OF THE COMMUNITY METHODS OF ANALYSIS FOR CERTAIN SUGARS INTENDED FOR HUMAN CONSUMPTION

I. Determination of the loss of mass on drying in:

— semi-white sugar — sugar or white sugar — extra-white sugar	(using method 1, Annex II)

II. Dry matter determination in:

II.1. — glucose syrup — dried glucose syrup — dextrose monohydrate — dextrose anhydrous	(using method 2, Annex II)
II.2. — sugar solution or white sugar solution — invert sugar solution or white invert sugar solution — invert sugar syrup or white invert sugar syrup	(using method 3, Annex II)

III. Measurement of reducing sugars in:

III.1. — semi-white sugar	(using method 4, Annex II)
III.2. — sugar or white sugar — extra-white sugar	(using method 5, Annex II)
III.3. — sugar solution — white sugar solution — invert sugar solution — white invert sugar solution — invert sugar syrup — white invert sugar syrup	(using method 6 or 7, Annex II)
III.4. — glucose syrup — dried glucose syrup — dextrose monohydrate — dextrose anhydrous	(using method 6 or 8, Annex II)

IV. Sulphated ash determination in:

— glucose syrup — dried glucose syrup — dextrose monohydrate — dextrose anhydrous	(using method 9, Annex II)

V. Determination of polarization in:

— semi-white sugar — sugar or white sugar — extra-white sugar	(using method 10, Annex II)

ANNEX II

METHODS OF ANALYSIS TO VERIFY THE COMPOSITION OF CERTAIN SUGARS INTENDED FOR HUMAN CONSUMPTION

INTRODUCTION

1. **Preparation of the sample for analysis**

Thoroughly mix the sample received at the laboratory.

Remove a sub-sample of at least 200 g and transfer immediately to a clean, dry, moisture-tight vessel fitted with an airtight closure.

2. **Reagents and apparatus**

In the description of the apparatus, reference is made only to special instruments and apparatus or to those calling for special standards.

Wherever mention is made of water, this means distilled water or demineralized water of at least equivalent purity.

All reagents shall be of analytical reagent quality unless otherwise specified.

Wherever reference is made to a reagent solution without further qualification, an aqueous solution is meant.

3. **Expression of results**

The result referred to in the official analysis report shall be the mean value of at least two satisfactory replicate determinations.

Unless otherwise stated the results shall be expressed as a percentage by mass of the original sample as received at the laboratory.

The number of significant figures in the result so expressed shall be governed by the precision of the method.

METHOD 1

DETERMINATION OF THE LOSS OF MASS ON DRYING

1. **Scope and field of application**

The method determines the loss of mass on drying in:

— semi-white sugar,
— sugar or white sugar,
— extra-white sugar.

2. **Definition**

'Loss of mass on drying': the value of the loss of mass on drying as determined by the method specified.

3. **Principle**

The loss of mass on drying is determined by drying at a temperature of 103 ± 2 °C.

4. **Apparatus**

4.1. *Analytical balance,* accurate to within 0·1 mg.

4.2. Oven, suitably ventilated, thermostatically controlled, and capable of being maintained at 103 ± 2 °C.

4.3. *Metal weighing dish,* flat-bottomed, resistant to attack by the samples and the conditions of test, diameter at least 100 mm, depth at least 30 mm.

4.4. *Desiccator,* containing freshly activated silica gel or an equivalent desiccant, with a water content indicator.

5. **Procedure**

N.B.: The operations described in sections 5.3 to 5.7 must be performed immediately after opening the sample container.

5.1. Dry the dish (4.3) to constant weight in the oven (4.2) at 103 ± 2 °C.

5.2. Allow the dish to cool in the desiccator (4.4) for at least 30 to 35 minutes and then weigh to the nearest 0·1 mg.

5.3. Weigh accurately, to the nearest 0·1 mg, approximately 20 to 30 g of the sample into the dish.

5.4. Place the dish in the oven (4.2) at 103 ± 2 °C for three hours.

5.5. Allow the dish to cool in a desiccator (4.4) and weigh to the nearest 0·1 mg.

5.6. Replace the dish in the oven at 103 ± 2 °C for 30 minutes.

Allow to cool in the desiccator (4.4) and weigh to the nearest 0·1 mg. Repeat this operation if the difference between two weighings is more than 1 mg. Should an increase in mass occur, the lowest recorded reading will be used in the calculation.

5.7. Do not exceed four hours total drying time.

6. **Expression of results**

6.1. *Formula and method of calculation*

The loss of mass on drying, as a percentage by mass of the sample, is given by the following formula:

$$\frac{(m_o - m_1)}{m_o} \times 100$$

where:

m_0 is the initial mass, in grams, of the test portion,

m_1 is the mass, in grams, of the test portion after drying.

6.2. *Repeatability*

The difference between the results of two determinations when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 0·02 g per 100 g of sample.

METHOD 2

DETERMINATION OF DRY MATTER

Vacuum oven method

1. **Scope and field of application**

The method determines the dry matter content in:

— glucose syrup,
— dried glucose syrup,
— dextrose monohydrate,
— dextrose anhydrous.

2. **Definition**

'The dry matter content': the content of dry matter as determined by the method specified.

3. Principle

The dry matter is determined at a temperature of 70 ± 1 °C using a vacuum oven at a pressure not exceeding 3·3 kPa (34 mbar). The test portions in the case of glucose syrup or dried glucose syrups, are prepared by mixing with water and kieselguhr before drying.

4. Reagents

4.1. *Kieselguhr:* place in a Buchner funnel and purify by repeated washings with dilute hydrochloric acid (1 ml of concentrated acid, density at 20 °C = 1·19 g/ml per litre of water). The treatment is complete when the washings remain definitely acid. Wash with water until the pH value of the filtered water is greater than 4. Dry in an oven at 103 ± 2 °C and store in an airtight container.

5. Apparatus

5.1. *Vacuum drying oven,* leak tight, thermostatically controlled and equipped with a thermometer and a vacuum manometer. The oven design must be such that the heat is rapidly transferred to the weighing dishes placed on the shelves.

5.2. *Air-drying train* consisting of a glass tower filled with freshly activated dry silica gel or an equivalent desiccant containing a water content indicator. This tower is mounted in series with a gas scrubber containing concentrated sulphuric acid connected to the air intake of the oven.

5.3. *Vaccum pump* capable of maintaining the presure in the oven at 3·3 kPa (34 mbar) or less.

5.4. *Metal weighing dish,* flat-bottomed, resistant to attack by the samples and the conditions of test, diameter at least 100 mm, depth at least 300 mm.

5.5. *Glass rod* of a length such that it cannot completely fall into the container.

5.6. *Desiccator* containing freshly activated dry silica gel, or an equivalent desiccant, with a water content indicator.

5.7. *Analytical balance* accurate to within 0·1 mg.

6. Procedure

6.1. Pour approximately 30 g of kieselguhr (4.1) into the weighing dish (5.4) equipped with a glass rod (5.5). Place the whole in the oven (5.1) at 70 ± 1 °C and reduce the pressure to 3·3 kPa (34 mbar) or less.

Dry for at least five hours, drawing a slow stream of air into the oven through the drying train. Check the pressure from time to time and correct it if necessary.

6.2. Restore atmospheric pressure in the oven by cautiously increasing the intake of dry air. Immediately place the dish together with the glass rod in the desiccator (5.6). Allow to cool and then weigh.

6.3. Accurately weigh to the nearest 1 mg approximately 10 g of the sample to be analyzed into a 100 ml beaker.

6.4. Dilute the test portion with 10 ml of warm water and transfer the solution quantitatively into the weighing dish, using the glass rod (5.5).

6.5. Place the dish containing the test portion and the glass rod in the oven and reduce the pressure to 3·3 kPa (34 mbar) or less. Dry at 70 ± 1 °C, allowing a slow stream of dry air to pass through the oven.

The drying operation should proceed for 20 hours; the bulk of the loss should occur towards the end of the first day. It will be necessary to keep the vacuum pump working at a preset pressure and allow a slow stream of dry air to enter the oven so as to maintain a pressure of approximately 3·3 kPa (34 mbar) or less during the night.

6.6. Restore atmospheric pressure in the oven by cautiously increasing the intake of dry air. Immediately place the weighing dish and contents in the desiccator. Allow to cool and then weigh to the nearest 1 mg.

6.7. Continue operation (6.5) for a further four hours. Restore atmospheric pressure in the oven and immediately place the dish in the desiccator. Allow to cool and then weigh. Ascertain whether constant mass has been reached. It is considered that constant mass has been satisfactorily attained if the difference between the two weighings of the same dish does not exceed 2 mg. If the difference is greater, repeat operation 6.7.

6.8. For the determination of the dry matter in dextrose anhydrous or dextrose monohydrate samples the use of kieselguhr and water is not required.

7. **Expression of results**

7.1. *Formula and method of calculation*

The dry matter content, expressed as a percentage by mass of the sample is given by:

$$(m_1 - m_2) \times \frac{100}{m_o}$$

where:

m_0 = the initial mass, in grams, of the test portion,

m_1 = the mass, in grams, of the weighing dish plus the kieselguhr, the glass rod and the residue of the test portion after drying,

m_2 = the mass, in grams, of the weighing dish plus the kieselguhr and the glass rod.

7.2. *Repeatability*

The difference between the results of two determinations when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 0·12 g per 100 g of sample.

METHOD 3

DETERMINATION OF TOTAL DRY MATTER

(Refractometric method)

1. **Scope and field of application**

The method determines the dry-matter content in:

— sugar solution,
— white sugar solution,
— invert sugar solution,
— white invert sugar solution,
— invert sugar syrup,
— white invert sugar syrup.

2. **Definition**

'Dry matter content': the content of dry matter as determined by the method specified.

3. **Principle**

The refractive index of a test portion is determined at 20 °C and converted into dry matter content by reference to tables showing the concentration as a function of the refractive index.

4. **Apparatus**

4.1. *Refractometer,* accurate to four decimal places, provided with a thermometer and a water-circulation pump connected to a water-bath thermostatically controlled at 20 ± 0·5 °C.

4.2. *Light source* consisting of a sodium vapour lamp.

5. **Procedure**

5.1. If any crystals are present in the sample, redissolve them by diluting the sample in the ratio 1 : 1 (m/m).

5.2. Measure the refractive index of the sample at 20 °C in the refractometer (4.1).

6. Expression and calculation of results

6.1. Calculate the dry matter content from the refractive indices for sucrose solutions at 20 °C in the table given and correct for the presence of invert sugars by adding to the result obtained from the tables, 0·022 for every 1% of invert sugar present in the sample as analyzed.

6.2. If the sample was diluted to 1 : 1 (m/m) with water, the calculated dry matter content must be multiplied by two.

6.3. *Repeatability*

The difference between the results of two determinations when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 0·2 g dry matter per 100 g of sample.

REFERENCE TABLES

Refractive indices (*n*) of sucrose solutions at 20 °C (1)

n (20 °C)	Sucrose (%)	*n* (20 °C)	Sucrose (%)	*n* (20 °C)	Sucrose (%)	*n* (20 °C)	Sucrose (%)	*n* (20 °C)	Sucrose (%)
1·3330	0·009	1·3365	2·436	1·3400	4·821	1·3435	7·164[2]	1·3470	9·466
1·3331	0·078	1·3366	2·505	1·3401	4·888	1·3436	7·230	1·3471	9·531
1·3332	0·149	1·3367	2·574	1·3402	4·956	1·3437	7·296	1·3472	9·596
1·3333	0·218	1·3368	2·642	1·3403	5·023	1·3438	7·362	1·3473	9·661
1·3334	0·288	1·3369	2·711	1·3404	5·091	1·3439	7·429	1·3474	9·726
1·3335	0·358	1·3370	2·779	1·3405	5·158	1·3440	7·495	1·3475	9·791
1·3336	0·428	1·3371	2·848	1·3406	5·225	1·3441	7·561	1·3476	9·856
1·3337	0·498	1·3372	2·917	1·3407	5·293	1·3442	7·627	1·3477	9·921
1·3338	0·567	1·3373	2·985	1·3408	5·360	1·3443	7·693	1·3478	9·986
1·3339	0·637	1·3374	3·053	1·3409	5·427	1·3444	7·759	1·3479	10·051
1·3340	0·707	1·3375	3·122	1·3410	5·494	1·3445	7·825	1·3480	10·116
1·3341	0·776	1·3376	3·190	1·3411	5·562	1·3446	7·891	1·3481	10·181
1·3342	0·846	1·3377	3·259	1·3412	5·629	1·3447	7·957	1·3482	10·246
1·3343	0·915	1·3378	3·327	1·3413	5·696	1·3448	8·023	1·3483	10·311
1·3344	0·985	1·3379	3·395	1·3414	5·763	1·3449	8·089	1·3484	10·375
1·3345	1·054	1·3380	3·463	1·3415	5·830	1·3450	8·155	1·3485	10·440
1·3346	1·124	1·3381	3·532	1·3416	5·897	1·3451	8·221	1·3486	10·505
1·3347	1·193	1·3382	3·600	1·3417	5·964	1·3452	8·287	1·3487	10·570
1·3348	1·263	1·3383	3·668	1·3418	6·031	1·3453	8·352	1·3488	10·634
1·3349	1·332	1·3384	3·736	1·3419	6·098	1·3454	8·418	1·3489	10·699
1·3350	1·401	1·3385	3·804	1·3420	6·165	1·3455	8·484	1·3490	10·763
1·3351	1·470	1·3386	3·872	1·3421	6·231	1·3456	8·550	1·3491	10·828
1·3352	1·540	1·3387	3·940	1·3422	6·298	1·3457	8·615	1·3492	10·892
1·3353	1·609	1·3388	4·008	1·3423	6·365	1·3458	8·681	1·3493	10·957
1·3354	1·678	1·3389	4·076	1·3424	6·432	1·3459	8·746	1·3494	11·021
1·3355	1·747	1·3390	4·144	1·3425	6·498	1·3460	8·812	1·3495	11·086
1·3356	1·816	1·3391	4·212	1·3426	6·565	1·3461	8·878	1·3496	11·150
1·3357	1·885	1·3392	4·279	1·3427	6·632	1·3462	8·943	1·3497	11·215
1·3358	1·954	1·3393	4·347	1·3428	6·698	1·3463	9·008	1·3498	11·279
1·3359	2·023	1·3394	4·415	1·3429	6·765	1·3464	9·074	1·3499	11·343
1·3360	2·092	1·3395	4·483	1·3430	6·831	1·3465	9·139	1·3500	11·407
1·3361	2·161	1·3396	4·550	1·3431	6·898	1·3466	9·205	1·3501	11·472
1·3362	2·230	1·3397	4·618	1·3432	6·964	1·3467	9·270	1·3502	11·536
1·3363	2·299	1·3398	4·686	1·3433	7·031	1·3468	9·335	1·3503	11·600
1·3364	2·367	1·3399	4·753	1·3434	7·097	1·3469	9·400	1·3504	11·664

(1) *n* values in these tables are calculated from the equation developed by K. Rosenhauer for ICUMSA, programed and computed by Frank G. Carpenter of UDSA, and published in *Sugar J.* 33, 15-22 (June 1970). Refractive index was measured at 20 °C with D line of Na. Brix (% sucrose by weight) was obtained by weighing at 20 °C in air at 760 Torr (mm Hg) pressure and 50% relative humidity. It replaces the previous table, 47.012, 11th edition, taken from *Intern. Sugar J.* 39, 225 (1937).

n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)
1·3505	11·728	1·3560	15·207	1·3615	18·595	1·3670	21·896	1·3725	25·114
1·3506	11·792	1·3561	15·269	1·3616	18·655	1·3671	21·955	1·3726	25·172
1·3507	11·856	1·3562	15·332	1·3617	18·716	1·3672	22·014	1·3727	25·230
1·3508	11·920	1·3563	15·394	1·3618	18·777	1·3673	22·073	1·3728	25·287
1·3509	11·984	1·3564	15·456	1·3619	18·837	1·3674	22·132	1·3729	25·345
1·3510	12·048	1·3565	15·518	1·3620	18·898	1·3675	22·192	1·3730	25·403
1·3511	12·112	1·3566	15·581	1·3621	18·959	1·3676	22·251	1·3731	25·460
1·3512	12·176	1·3567	15·643	1·3622	19·019	1·3677	22·310	1·3732	25·518
1·3513	12·240	1·3568	15·705	1·3623	19·080	1·3678	22·369	1·3733	25·576
1·3514	12·304	1·3569	15·767	1·3624	19·141	1·3679	22·428	1·3734	25·633
1·3515	12·368	1·3570	15·829	1·3625	19·201	1·3680	22·487	1·3735	25·691
1·3516	12·431	1·3571	15·891	1·3626	19·262	1·3681	22·546	1·3736	25·748
1·3517	12·495	1·3572	15·953	1·3627	19·322	1·3682	22·605	1·3737	25·806
1·3518	12·559	1·3573	16·016	1·3628	19·382	1·3683	22·664	1·3738	25·863
1·3519	12·623	1·3574	16·078	1·3629	19·443	1·3684	22·723	1·3739	25·921
1·3520	12·686	1·3575	16·140	1·3630	19·503	1·3685	22·781	1·3740	25·978
1·3521	12·750	1·3576	16·201	1·3631	19·564	1·3686	22·840	1·3741	26·035
1·3522	12·813	1·3577	16·263	1·3632	19·624	1·3687	22·899	1·3742	26·093
1·3523	12·877	1·3578	16·325	1·3633	19·684	1·3688	22·958	1·3743	26·150
1·3524	12·940	1·3579	16·387	1·3634	19·745	1·3689	23·017	1·3744	26·207
1·3525	13·004	1·3580	16·449	1·3635	19·805	1·3690	23·075	1·3745	26·265
1·3526	13·067	1·3581	16·511	1·3636	19·865	1·3691	23·134	1·3746	26·322
1·3527	13·131	1·3582	16·573	1·3637	19·925	1·3692	23·193	1·3747	26·379
1·3528	13·194	1·3583	16·634	1·3638	19·985	1·3693	23·251	1·3748	26·436
1·3529	13·258	1·3584	16·696	1·3639	20·045	1·3694	23·310	1·3749	26·493
1·3530	13·321	1·3585	16·758	1·3640	20·106	1·3695	23·369	1·3750	26·551
1·3531	13·384	1·3586	16·819	1·3641	20·166	1·3696	23·427	1·3751	26·608
1·3532	13·448	1·3587	16·881	1·3642	20·226	1·3697	23·486	1·3752	26·665
1·3533	13·511	1·3588	16·943	1·3643	20·286	1·3698	23·544	1·3753	26·722
1·3534	13·574	1·3589	17·004	1·3644	20·346	1·3699	23·603	1·3754	26·779
1·3535	13·637	1·3590	17·066	1·3645	20·406	1·3700	23·661	1·3755	26·836
1·3536	13·700	1·3591	17·127	1·3646	20·466	1·3701	23·720	1·3756	26·893
1·3537	13·763	1·3592	17·189	1·3647	20·525	1·3702	23·778	1·3757	26·950
1·3538	13·826	1·3593	17·250	1·3648	20·585	1·3703	23·836	1·3758	27·007
1·3539	13·890	1·3594	17·311	1·3649	20·645	1·3704	23·895	1·3759	27·064
1·3540	13·953	1·3595	17·373	1·3650	20·705	1·3705	23·953	1·3760	27·121
1·3541	14·016	1·3596	17·434	1·3651	20·765	1·3706	24·011	1·3761	27·178
1·3542	14·079	1·3597	17·496	1·3652	20·825	1·3707	24·070	1·3762	27·234
1·3543	14·141	1·3598	17·557	1·3653	20·884	1·3708	24·128	1·3763	27·291
1·3544	14·204	1·3599	17·618	1·3654	20·944	1·3709	24·186	1·3764	27·348
1·3545	14·267	1·3600	17·679	1·3655	21·004	1·3710	24·244	1·3765	27·405
1·3546	14·330	1·3601	17·741	1·3656	21·063	1·3711	24·302	1·3766	27·462
1·3547	14·393	1·3602	17·802	1·3657	21·123	1·3712	24·361	1·3767	27·518
1·3548	14·456	1·3603	17·863	1·3658	21·183	1·3713	24·419	1·3768	27·575
1·3549	14·518	1·3604	17·924	1·3659	21·242	1·3714	24·477	1·3769	27·632
1·3550	14·581	1·3605	17·985	1·3660	21·302	1·3715	24·535	1·3770	27·688
1·3551	14·644	1·3606	18·046	1·3661	21·361	1·3716	24·593	1·3771	27·745
1·3552	14·707	1·3607	18·107	1·3662	21·421	1·3717	24·651	1·3772	27·802
1·3553	14·769	1·3608	18·168	1·3663	21·480	1·3718	24·709	1·3773	27·858
1·3554	14·832	1·3609	18·229	1·3664	21·540	1·3719	24·767	1·3774	27·915
1·3555	14·894	1·3610	18·290	1·3665	21·599	1·3720	24·825	1·3775	27·971
1·3556	14·957	1·3611	18·351	1·3666	21·658	1·3721	24·883	1·3776	28·028
1·3557	15·019	1·3612	18·412	1·3667	21·718	1·3722	24·941	1·3777	28·084
1·3558	15·082	1·3613	18·473	1·3668	21·777	1·3723	24·998	1·3778	28·141
1·3559	15·144	1·3614	18·534	1·3669	21·836	1·3724	25·056	1·3779	28·197

n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)
1·3780	28·253	1·3835	31·317	1·3890	34·310	1·3945	37·233	1·4000	40·091
1·3781	28·310	1·3836	31·372	1·3891	34·363	1·3946	37·286	1·4001	40·142
1·3782	28·366	1·3837	31·428	1·3892	34·417	1·3947	37·338	1·4002	40·194
1·3783	28·422	1·3838	31·482	1·3893	34·471	1·3948	37·391	1·4003	40·245
1·3784	28·479	1·3839	31·537	1·3894	34·524	1·3949	37·443	1·4004	40·296
1·3785	28·535	1·3840	31·592	1·3895	34·578	1·3950	37·495	1·4005	40·348
1·3786	28·591	1·3841	31·647	1·3896	34·632	1·3951	37·548	1·4006	40·399
1·3787	28·648	1·3842	31·702	1·3897	34·685	1·3952	37·600	1·4007	40·450
1·3788	28·704	1·3843	31·757	1·3898	34·739	1·3953	37·653	1·4008	40·501
1·3789	28·760	1·3844	31·812	1·3899	34·793	1·3954	37·705	1·4009	40·553
1·3790	28·816	1·3845	31·867	1·3900	34·846	1·3955	37·757	1·4010	40·604
1·3791	28·872	1·3846	31·922	1·3901	34·900	1·3956	37·810	1·4011	40·655
1·3792	28·928	1·3847	31·976	1·3902	34·953	1·3957	37·862	1·4012	40·706
1·3793	28·984	1·3848	32·031	1·3903	35·007	1·3958	37·914	1·4013	40·757
1·3794	29·040	1·3849	32·086	1·3904	35·060	1·3959	37·967	1·4014	40·808
1·3795	29·096	1·3850	32·140	1·3905	35·114	1·3960	38·019	1·4015	40·860
1·3796	29·152	1·3851	32·195	1·3906	35·167	1·3961	38·071	1·4016	40·911
1·3797	29·208	1·3852	32·250	1·3907	35·220	1·3962	38·123	1·4017	40·962
1·3798	29·264	1·3853	32·304	1·3908	35·274	1·3963	38·175	1·4018	41·013
1·3799	29·320	1·3854	32·359	1·3909	35·327	1·3964	38·228	1·4019	41·064
1·3800	29·376	1·3855	32·414	1·3910	35·380	1·3965	38·280	1·4020	41·115
1·3801	29·432	1·3856	32·468	1·3911	35·434	1·3966	38·332	1·4021	41·166
1·3802	29·488	1·3857	32·523	1·3912	35·487	1·3967	38·384	1·4022	41·217
1·3803	29·544	1·3858	32·577	1·3913	35·540	1·3968	38·436	1·4023	41·268
1·3804	29·600	1·3859	32·632	1·3914	35·593	1·3969	38·488	1·4024	41·318
1·3805	29·655	1·3860	32·686	1·3915	35·647	1·3970	38·540	1·4025	41·369
1·3806	29·711	1·3861	32·741	1·3916	35·700	1·3971	38·592	1·4026	41·420
1·3807	29·767	1·3862	32·795	1·3917	35·753	1·3972	38·644	1·4027	41·471
1·3808	29·823	1·3863	32·849	1·3918	35·806	1·3973	38·696	1·4028	41·522
1·3809	29·878	1·3864	32·904	1·3919	35·859	1·3974	38·748	1·4029	41·573
1·3810	29·934	1·3865	32·958	1·3920	35·912	1·3975	38·800	1·4030	41·623
1·3811	29·989	1·3866	33·013	1·3921	35·966	1·3976	38·852	1·4031	41·674
1·3812	30·045	1·3867	33·067	1·3922	36·019	1·3977	38·904	1·4032	41·725
1·3813	30·101	1·3868	33·121	1·3923	36·072	1·3978	38·955	1·4033	41·776
1·3814	30·156	1·3869	33·175	1·3924	36·125	1·3979	39·007	1·4034	41·826
1·3815	30·212	1·3870	33·230	1·3925	36·178	1·3980	39·059	1·4035	41·877
1·3816	30·267	1·3871	33·284	1·3926	36·231	1·3981	39·111	1·4036	41·928
1·3817	30·323	1·3872	33·338	1·3927	36·284	1·3982	39·163	1·4037	41·978
1·3818	30·378	1·3873	33·392	1·3928	36·337	1·3983	39·214	1·4038	42·029
1·3819	30·434	1·3874	33·446	1·3929	36·389	1·3984	39·266	1·4039	42·080
1·3820	30·489	1·3875	33·500	1·3930	36·442	1·3985	39·318	1·4040	42·130
1·3821	30·544	1·3876	33·555	1·3931	36·495	1·3986	39·370	1·4041	42·181
1·3822	30·600	1·3877	33·609	1·3932	36·548	1·3987	39·421	1·4042	42·231
1·3823	30·655	1·3878	33·663	1·3933	36·601	1·3988	39·473	1·4043	42·282
1·3824	30·711	1·3879	33·717	1·3934	36·654	1·3989	39·525	1·4044	42·332
1·3825	30·766	1·3880	33·771	1·3935	36·706	1·3990	39·576	1·4045	42·383
1·3826	30·821	1·3881	33·825	1·3936	36·759	1·3991	39·628	1·4046	42·433
1·3827	30·876	1·3882	33·879	1·3937	36·812	1·3992	39·679	1·4047	42·484
1·3828	30·932	1·3883	33·933	1·3938	36·865	1·3993	39·731	1·4048	42·534
1·3829	30·987	1·3884	33·987	1·3939	36·917	1·3994	39·782	1·4049	42·585
1·3830	31·042	1·3885	34·040	1·3940	36·970	1·3995	39·834	1·4050	42·635
1·3831	31·097	1·3886	34·094	1·3941	37·023	1·3996	39·885	1·4051	42·685
1·3832	31·152	1·3887	34·148	1·3942	37·075	1·3997	39·937	1·4052	42·736
1·3833	31·207	1·3888	34·202	1·3943	37·128	1·3998	39·988	1·4053	42·786
1·3834	31·262	1·3889	34·256	1·3944	37·180	1·3999	40·040	1·4054	42·836

n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)
1·4055	42·887	1·4110	45·623	1·4165	48·302	1·4220	50·928	1·4275	53·501
1·4056	42·937	1·4111	45·672	1·4166	48·350	1·4221	50·975	1·4276	53·548
1·4057	42·987	1·4112	45·721	1·4167	48·399	1·4222	51·022	1·4277	53·594
1·4058	43·037	1·4113	45·770	1·4168	48·447	1·4223	51·069	1·4278	53·640
1·4059	43·088	1·4114	45·820	1·4169	48·495	1·4224	51·116	1·4279	53·686
1·4060	43·138	1·4115	45·869	1·4170	48·543	1·4225	51·164	1·4280	53·733
1·4061	43·188	1·4116	45·918	1·4171	48·591	1·4226	51·211	1·4281	53·779
1·4062	43·238	1·4117	46·967	1·4172	48·639	1·4227	51·258	1·4282	53·825
1·4063	43·288	1·4118	46·016	1·4173	48·687	1·4228	51·305	1·4283	53·871
1·4064	43·338	1·4119	46·065	1·4174	48·735	1·4229	51·352	1·4284	53·918
1·4065	43·388	1·4120	46·114	1·4175	48·784	1·4230	51·399	1·4285	53·964
1·4066	43·439	1·4121	46·163	1·4176	48·832	1·4231	51·446	1·4286	54·010
1·4067	43·489	1·4122	46·212	1·4177	48·880	1·4232	51·493	1·4287	54·056
1·4068	43·539	1·4123	46·261	1·4178	48·928	1·4233	51·540	1·4288	54·102
1·4069	43·589	1·4124	46·310	1·4179	48·976	1·4234	51·587	1·4289	54·148
1·4070	43·639	1·4125	46·359	1·4180	49·023	1·4235	51·634	1·4290	54·194
1·4071	43·689	1·4126	46·408	1·4181	49·071	1·4236	51·681	1·4291	54·241
1·4072	43·739	1·4127	46·457	1·4182	49·119	1·4237	51·728	1·4292	54·287
1·4073	43·789	1·4128	46·506	1·4183	49·167	1·4238	51·775	1·4293	54·333
1·4074	43·838	1·4129	46·555	1·4184	49·215	1·4239	51·822	1·4294	54·379
1·4075	43·888	1·4130	46·604	1·4185	49·263	1·4240	51·869	1·4295	54·425
1·4076	43·938	1·4131	46·652	1·4186	49·311	1·4241	51·916	1·4296	54·471
1·4077	43·988	1·4132	46·701	1·4187	49·359	1·4242	51·963	1·4297	54·517
1·4078	44·038	1·4133	46·750	1·4188	49·407	1·4243	52·010	1·4298	54·563
1·4079	44·088	1·4134	46·799	1·4189	49·454	1·4244	52·057	1·4299	54·609
1·4080	44·138	1·4135	46·848	1·4190	49·502	1·4245	52·104	1·4300	54·655
1·4081	44·187	1·4136	46·896	1·4191	49·550	1·4246	52·150	1·4301	54·701
1·4082	44·237	1·4137	46·945	1·4192	49·598	1·4247	52·197	1·4302	54·746
1·4083	44·287	1·4138	46·994	1·4193	49·645	1·4248	52·244	1·4303	54·792
1·4084	44·337	1·4139	47·043	1·4194	49·693	1·4249	52·291	1·4304	54·838
1·4085	44·386	1·4140	47·091	1·4195	49·741	1·4250	52·338	1·4305	54·884
1·4086	44·436	1·4141	47·140	1·4196	49·788	1·4251	52·384	1·4306	54·930
1·4087	44·486	1·4142	47·188	1·4197	49·836	1·4252	52·431	1·4307	54·976
1·4088	44·535	1·4143	47·237	1·4198	49·884	1·4253	52·478	1·4308	55·022
1·4089	44·585	1·4144	47·286	1·4199	49·931	1·4254	52·524	1·4309	55·067
1·4090	44·635	1·4145	47·334	1·4200	49·979	1·4255	52·571	1·4310	55·113
1·4091	44·684	1·4146	47·383	1·4201	50·027	1·4256	52·618	1·4311	55·159
1·4092	44·734	1·4147	47·431	1·4202	50·074	1·4257	52·664	1·4312	55·205
1·4093	44·783	1·4148	47·480	1·4203	50·122	1·4258	52·711	1·4313	55·250
1·4094	44·833	1·4149	47·528	1·4204	50·169	1·4259	52·758	1·4314	55·296
1·4095	44·882	1·4150	47·577	1·4205	50·217	1·4260	52·804	1·4315	55·342
1·4096	44·932	1·4151	47·625	1·4206	50·264	1·4261	52·851	1·4316	55·388
1·4097	44·981	1·4152	47·674	1·4207	50·312	1·4262	52·897	1·4317	55·433
1·4098	45·031	1·4153	47·722	1·4208	50·359	1·4263	52·944	1·4318	55·479
1·4099	45·080	1·4154	47·771	1·4209	50·407	1·4264	52·990	1·4319	55·524
1·4100	45·130	1·4155	47·819	1·4210	50·454	1·4265	53·037	1·4320	55·570
1·4101	45·179	1·4156	47·868	1·4211	50·502	1·4266	53·083	1·4321	55·616
1·4102	45·228	1·4157	47·916	1·4212	50·549	1·4267	53·130	1·4322	55·661
1·4103	45·278	1·4158	47·964	1·4213	50·596	1·4268	53·176	1·4323	55·707
1·4104	45·327	1·4159	48·013	1·4214	50·644	1·4269	53·223	1·4324	55·752
1·4105	45·376	1·4160	48·061	1·4215	50·691	1·4270	53·269	1·4325	55·798
1·4106	45·426	1·4161	48·109	1·4216	50·738	1·4271	53·316	1·4326	55·844
1·4107	45·475	1·4162	48·158	1·4217	50·786	1·4272	53·362	1·4327	55·889
1·4108	45·524	1·4163	48·206	1·4218	50·833	1·4273	53·408	1·4328	55·935
1·4109	45·574	1·4164	48·254	1·4219	50·880	1·4274	53·455	1·4329	55·980

n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)
1·4330	56·026	1·4385	58·503	1·4440	60·935	1·4495	63·324	1·4550	65·672
1·4331	56·071	1·4386	58·547	1·4441	60·979	1·4496	63·367	1·4551	65·714
1·4332	56·116	1·4387	58·592	1·4442	61·023	1·4497	63·410	1·4552	65·756
1·4333	56·162	1·4388	58·637	1·4443	61·066	1·4498	63·453	1·4553	65·798
1·4334	56·207	1·4389	58·681	1·4444	61·110	1·4499	63·496	1·4554	65·841
1·4335	56·253	1·4390	58·726	1·4445	61·154	1·4500	63·539	1·4555	65·883
1·4336	56·298	1·4391	58·770	1·4446	61·198	1·4501	63·582	1·4556	65·925
1·4337	56·343	1·4392	58·815	1·4447	61·241	1·4502	63·625	1·4557	65·967
1·4338	56·389	1·4393	58·859	1·4448	61·285	1·4503	63·668	1·4558	66·010
1·4339	56·434	1·4394	58·904	1·4449	61·329	1·4504	63·711	1·4559	66·052
1·4340	56·479	1·4395	58·948	1·4450	61·372	1·4505	63·754	1·4560	66·094
1·4341	56·525	1·4396	58·993	1·4451	61·416	1·4506	63·797	1·4561	66·136
1·4342	56·570	1·4397	59·037	1·4452	61·460	1·4507	63·840	1·4562	66·178
1·4343	56·615	1·4398	59·082	1·4453	61·503	1·4508	63·882	1·4563	66·221
1·4344	56·660	1·4399	59·126	1·4454	61·547	1·4509	63·925	1·4564	66·263
1·4345	56·706	1·4400	59·170	1·4455	61·591	1·4510	63·968	1·4565	66·305
1·4346	56·751	1·4401	59·215	1·4456	61·634	1·4511	64·011	1·4566	66·347
1·4347	56·796	1·4402	59·259	1·4457	61·678	1·4512	64·054	1·4567	66·389
1·4348	56·841	1·4403	59·304	1·4458	61·721	1·4513	64·097	1·4568	66·431
1·4349	56·887	1·4404	59·348	1·4459	61·765	1·4514	64·139	1·4569	66·473
1·4350	56·932	1·4405	59·392	1·4460	61·809	1·4515	64·182	1·4570	66·515
1·4351	56·977	1·4406	59·437	1·4461	61·852	1·4516	64·225	1·4571	66·557
1·4352	57·022	1·4407	59·481	1·4462	61·896	1·4517	64·268	1·4572	66·599
1·4353	57·067	1·4408	59·525	1·4463	61·939	1·4518	64·311	1·4573	66·641
1·4354	57·112	1·4409	59·569	1·4464	61·983	1·4519	64·353	1·4574	66·683
1·4355	57·157	1·4410	59·614	1·4465	62·026	1·4520	64·396	1·4575	66·725
1·4356	57·202	1·4411	59·658	1·4466	62·070	1·4521	64·439	1·4576	66·767
1·4357	57·247	1·4412	59·702	1·4467	62·113	1·4522	64·481	1·4577	66·809
1·4358	57·292	1·4413	59·746	1·4468	62·156	1·4523	64·524	1·4578	66·851
1·4359	57·337	1·4414	59·791	1·4469	62·200	1·4524	64·567	1·4579	66·893
1·4360	57·382	1·4415	59·835	1·4470	62·243	1·4525	64·609	1·4580	66·935
1·4361	57·427	1·4416	59·879	1·4471	62·287	1·4526	64·652	1·4581	66·977
1·4362	57·472	1·4417	59·923	1·4472	62·330	1·4527	64·695	1·4582	67·019
1·4363	57·517	1·4418	59·967	1·4473	62·373	1·4528	64·737	1·4583	67·061
1·4364	57·562	1·4419	60·011	1·4474	62·417	1·4529	64·780	1·4584	67·103
1·4365	57·607	1·4420	60·056	1·4475	62·460	1·4530	64·823	1·4585	67·145
1·4366	57·652	1·4421	60·100	1·4476	62·503	1·4531	64·865	1·4586	67·186
1·4367	57·697	1·4422	60·144	1·4477	62·547	1·4532	64·908	1·4587	67·228
1·4368	57·742	1·4423	60·188	1·4478	62·590	1·4533	64·950	1·4588	67·270
1·4369	57·787	1·4424	60·232	1·4479	62·633	1·4534	64·993	1·4589	67·312
1·4370	57·832	1·4425	60·276	1·4480	62·677	1·4535	65·035	1·4590	67·354
1·4371	57·877	1·4426	60·320	1·4481	62·720	1·4536	65·078	1·4591	67·396
1·4372	57·921	1·4427	60·364	1·4482	62·763	1·4537	65·120	1·4592	67·437
1·4373	57·966	1·4428	60·408	1·4483	62·806	1·4538	65·163	1·4593	67·479
1·4374	58·011	1·4429	60·452	1·4484	62·849	1·4539	65·205	1·4594	67·521
1·4375	58·056	1·4430	60·496	1·4485	62·893	1·4540	65·248	1·4595	67·563
1·4376	58·101	1·4431	60·540	1·4486	62·936	1·4541	65·290	1·4596	67·604
1·4377	58·145	1·4432	60·584	1·4487	62·979	1·4542	65·333	1·4597	67·646
1·4378	58·190	1·4433	60·628	1·4488	63·022	1·4543	65·375	1·4598	67·688
1·4379	58·235	1·4434	60·672	1·4489	63·065	1·4544	65·417	1·4599	67·729
1·4380	58·279	1·4435	60·716	1·4490	63·108	1·4545	65·460	1·4600	67·771
1·4381	58·324	1·4436	60·759	1·4491	63·152	1·4546	65·502	1·4601	67·813
1·4382	58·369	1·4437	60·803	1·4492	63·195	1·4547	65·544	1·4602	67·854
1·4383	58·413	1·4438	60·847	1·4493	63·238	1·4548	65·587	1·4603	67·896
1·4384	58·458	1·4439	60·891	1·4494	63·281	1·4549	65·629	1·4604	67·938

n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)
1·4605	67·979	1·4660	70·249	1·4715	72·482	1·4770	74·678	1·4825	76·841
1·4606	68·021	1·4661	70·290	1·4716	72·522	1·4771	74·718	1·4826	76·880
1·4607	68·063	1·4662	70·331	1·4717	72·562	1·4772	74·758	1·4827	76·919
1·4608	68·104	1·4663	70·372	1·4718	72·602	1·4773	74·797	1·4828	76·958
1·4609	68·146	1·4664	70·413	1·4719	72·643	1·4774	74·837	1·4829	76·997
1·4610	68·187	1·4665	70·453	1·4720	72·683	1·4775	74·876	1·4830	77·036
1·4611	68·229	1·4666	70·494	1·4721	72·723	1·4776	74·916	1·4831	77·075
1·4612	68·270	1·4667	70·535	1·4722	72·763	1·4777	74·956	1·4832	77·113
1·4613	68·312	1·4668	70·576	1·4723	72·803	1·4778	74·995	1·4833	77·152
1·4614	68·353	1·4669	70·617	1·4724	72·843	1·4779	75·035	1·4834	77·191
1·4615	68·395	1·4670	70·658	1·4725	72·884	1·4780	75·074	1·4835	77·230
1·4616	68·436	1·4671	70·698	1·4726	72·924	1·4781	75·114	1·4836	77·269
1·4617	68·478	1·4672	70·739	1·4727	72·964	1·4782	75·153	1·4837	77·308
1·4618	68·519	1·4673	70·780	1·4728	73·004	1·4783	75·193	1·4838	77·347
1·4619	68·561	1·4674	70·821	1·4729	73·044	1·4784	75·232	1·4839	77·386
1·4620	68·602	1·4675	70·861	1·4730	73·084	1·4785	75·272	1·4840	77·425
1·4621	68·643	1·4676	70·902	1·4731	73·124	1·4786	75·311	1·4841	77·463
1·4622	68·685	1·4677	70·943	1·4732	73·164	1·4787	75·350	1·4842	77·502
1·4623	68·726	1·4678	70·984	1·4733	73·204	1·4788	75·390	1·4843	77·541
1·4624	68·768	1·4679	71·024	1·4734	73·244	1·4789	75·429	1·4844	77·580
1·4625	68·809	1·4680	71·065	1·4735	73·285	1·4790	75·469	1·4845	77·619
1·4626	68·850	1·4681	71·106	1·4736	73·325	1·4791	75·508	1·4846	77·657
1·4627	68·892	1·4682	71·146	1·4737	73·365	1·4792	75·547	1·4847	77·696
1·4628	68·933	1·4683	71·187	1·4738	73·405	1·4793	75·587	1·4848	77·735
1·4629	68·974	1·4684	71·228	1·4739	73·445	1·4794	75·626	1·4849	77·774
1·4630	69·016	1·4685	71·268	1·4740	73·485	1·4795	75·666	1·4850	77·812
1·4631	69·057	1·4686	71·309	1·4741	73·524	1·4796	75·705	1·4851	77·851
1·4632	69·098	1·4687	71·349	1·4742	73·564	1·4797	75·744	1·4852	77·890
1·4633	69·139	1·4688	71·390	1·4743	73·604	1·4798	75·784	1·4853	77·928
1·4634	69·181	1·4689	71·431	1·4744	73·644	1·4799	75·823	1·4854	77·967
1·4635	69·222	1·4690	71·471	1·4745	73·684	1·4800	75·862	1·4855	78·006
1·4636	69·263	1·4691	71·512	1·4746	73·724	1·4801	75·901	1·4856	78·045
1·4637	69·304	1·4692	71·552	1·4747	73·764	1·4802	75·941	1·4857	78·083
1·4638	69·346	1·4693	71·593	1·4748	73·804	1·4803	75·980	1·4858	78·122
1·4639	69·387	1·4694	71·633	1·4749	73·844	1·4804	76·019	1·4859	78·160
1·4640	69·428	1·4695	71·674	1·4750	73·884	1·4805	76·058	1·4860	78·199
1·4641	69·469	1·4696	71·714	1·4751	73·924	1·4806	76·098	1·4861	78·238
1·4642	69·510	1·4697	71·755	1·4752	73·963	1·4807	76·137	1·4862	78·276
1·4643	69·551	1·4698	71·795	1·4753	74·003	1·4808	76·176	1·4863	78·315
1·4644	69·593	1·4699	71·836	1·4754	74·043	1·4809	76·215	1·4864	78·353
1·4645	69·634	1·4700	71·876	1·4755	74·083	1·4810	76·254	1·4865	78·392
1·4646	69·675	1·4701	71·917	1·4756	74·123	1·4811	76·294	1·4866	78·431
1·4647	69·716	1·4702	71·957	1·4757	74·162	1·4812	76·333	1·4867	78·469
1·4648	69·757	1·4703	71·998	1·4758	74·202	1·4813	76·372	1·4868	78·508
1·4649	69·798	1·4704	72·038	1·4759	74·242	1·4814	76·411	1·4869	78·546
1·4650	69·839	1·4705	72·078	1·4760	74·282	1·4815	76·450	1·4870	78·585
1·4651	69·880	1·4706	72·119	1·4761	74·321	1·4816	76·489	1·4871	78·623
1·4652	69·921	1·4707	72·159	1·4762	74·361	1·4817	76·528	1·4872	78·662
1·4653	69·962	1·4708	72·199	1·4763	74·401	1·4818	76·567	1·4873	78·700
1·4654	70·003	1·4709	72·240	1·4764	74·441	1·4819	76·607	1·4874	78·739
1·4655	70·044	1·4710	72·280	1·4765	74·480	1·4820	76·646	1·4875	78·777
1·4656	70·085	1·4711	72·320	1·4766	74·520	1·4821	76·685	1·4876	78·816
1·4657	70·126	1·4712	72·361	1·4767	74·560	1·4822	76·724	1·4877	78·854
1·4658	70·167	1·4713	72·401	1·4768	74·599	1·4823	76·763	1·4878	78·892
1·4659	70·208	1·4714	72·441	1·4769	74·639	1·4824	76·802	1·4879	78·931

n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)	n (20 °C)	Sucrose (%)
1·4880	78·969	1·4920	80·497	1·4960	82·007	1·5000	83·500	1·5040	84·976
1·4881	79·008	1·4921	80·534	1·4961	82·044	1·5001	83·537	1·5041	85·013
1·4882	79·046	1·4922	80·572	1·4962	82·082	1·5002	83·574	1·5042	85·049
1·4883	79·084	1·4923	80·610	1·4963	82·119	1·5003	83·611	1·5043	85·086
1·4884	79·123	1·4924	80·648	1·4964	82·157	1·5004	83·648	1·5044	85·123
1·4885	79·161	1·4925	80·686	1·4965	82·194	1·5005	83·685	1·5045	85·159
1·4886	79·199	1·4926	80·724	1·4966	82·232	1·5006	83·722	1·5046	85·196
1·4887	79·238	1·4927	80·762	1·4967	82·269	1·5007	83·759	1·5047	85·233
1·4888	79·276	1·4928	80·800	1·4968	82·307	1·5008	83·796	1·5048	85·269
1·4889	79·314	1·4929	80·838	1·4969	82·344	1·5009	83·833	1·5049	85·306
1·4890	79·353	1·4930	80·876	1·4970	82·381	1·5010	83·870	1·5050	85·343
1·4891	79·391	1·4931	80·913	1·4971	82·419	1·5011	83·907	1·5051	85·379
1·4892	79·429	1·4932	80·951	1·4972	82·456	1·5012	83·944	1·5052	85·416
1·4893	79·468	1·4933	80·989	1·4973	82·494	1·5013	83·981	1·5053	85·452
1·4894	79·506	1·4934	81·027	1·4974	82·531	1·5014	84·018	1·5054	85·489
1·4895	79·544	1·4935	81·065	1·4975	82·569	1·5015	84·055	1·5055	85·525
1·4896	79·582	1·4936	81 103	1·4976	82·606	1·5016	84·092	1·5056	85·562
1·4897	79·620	1·4937	81·140	1·4977	82·643	1·5017	84·129	1·5057	85·598
1·4898	79·659	1·4938	81·178	1·4978	82·681	1·5018	84·166	1·5058	85·635
1·4899	79·697	1·4939	81·216	1·4979	82·718	1·5019	84·203	1·5059	85·672
1·4900	79·735	1·4940	81·254	1·4980	82·755	1·5020	84·240	1·5060	85·708
1·4901	79·773	1·4941	81·291	1·4981	82·793	1·5021	84·277	1·5061	85·744
1·4902	79·811	1·4942	81·329	1·4982	82·830	1·5022	84·314	1·5062	85·781
1·4903	79·850	1·4943	81·367	1·4983	82·867	1·5023	84·351	1·5063	85·817
1·4904	79·888	1·4944	81·405	1·4984	82·905	1·5024	84·388	1·5064	85·854
1·4905	79·926	1·4945	81·442	1·4985	82·942	1·5025	84·424	1·5065	85·890
1·4906	79·964	1·4946	81·480	1·4986	82·979	1·5026	84·461	1·5066	85·927
1·4907	80·002	1·4947	81·518	1·4987	83·016	1·5027	84·498	1·5067	85·963
1·4908	80·040	1·4948	81·555	1·4988	83·054	1·5028	84·535	1·5068	86·000
1·4909	80·078	1·4949	81·593	1·4989	83·091	1·5029	84·572	1·5069	86·036
1·4910	80·116	1·4950	81·631	1·4990	83·128	1·5030	84·609	1·5070	86·072
1·4911	80·154	1·4951	81·668	1·4991	83·165	1·5031	84·645	1·5071	86·109
1·4912	80·192	1·4952	81·706	1·4992	83·202	1·5032	84·682	1·5072	86·145
1·4913	80·231	1·5953	81·744	1·4993	83·240	1·5033	84·719	1·5073	86·182
1·4914	80·269	1·4954	81·781	1·4994	83·277	1·5034	84·756	1·5074	86·218
1·4915	80·307	1·4955	81·819	1·4995	83·314	1·5035	84·792	1·5075	86·254
1·4916	80·345	1·4956	81·856	1·4996	83·351	1·5036	84·829	1·5076	86·291
1·4917	80·383	1·4957	81·894	1·4997	83·388	1·5037	84·866	1·5077	86·327
1·4918	80·421	1·4958	81·932	1·4998	83·425	1·5038	84·903	1·5078	86·363
1·4919	80·459	1·4959	81·969	1·4999	83·463	1·5039	84·939	1·5079	86·399

METHOD 4

MEASUREMENT OF REDUCING SUGARS EXPRESSED AS INVERT SUGARS

(Berlin Institute method)

Scope and field of application

1. The method determines the reducing sugar content expressed as invert sugar in semi-white sugar.

2. **Definitions**

'Reducing sugars expressed as invert sugar': the content of reducing sugars as determined by the method specified.

3. **Principle**

The sample solution containing reducing sugars is used to reduce a solution of copper II complex. The copper I oxide formed is then oxidized with standard iodine solution, the excess of which is determined by back-titration with standardized sodium thiosulphate solution.

4. **Reagents**

4.1. *Copper II solution* (Muller's solution)

4.1.1. Dissolve 35 g of copper II sulphate, pentahydrate ($CuSO_4.5H_2O$) in 400 ml of boiling water. Allow to cool.

4.1.2. Dissolve 173 g of sodium potassium tartrate tetrahydrate (Rochelle salt or Seignette salt; $KNaC_4H_4O_6{\cdot}4H_2O$) and 68 g of anhydrous sodium carbonate in 500 ml of boiling water. Allow to cool.

4.1.3. Transfer both solutions (4.1.1 and 4.1.2) to a one litre volumetric flask and make up to one litre with water. Add 2 g of activated carbon, shake, allow to stand for several hours and filter through thick filter paper or a membrane filter.

If small amounts of copper I oxide appear during storage, the solution should be re-filtered.

4.2. *Acetic acid solution* 5 mol/litre.

4.3. *Iodine solution* 0·01665 mol/litre (i.e. 0·0333 N, 4·2258 g/litre).

4.4. *Sodium thiosulphate solution* 0·0333 mol/litre.

4.5. *Starch solution:* to one litre of boiling water add a mixture of 5 g of soluble starch slurried in 30 ml of water. Boil for three minutes, allow to cool and add, if required, 10 mg of mercury II iodide as a preservative.

5. **Apparatus**

5.1. *Conical flask,* 300 ml; precision burettes and pipettes.

5.2. *Water-bath,* boiling.

6. **Procedure**

6.1. Weigh a portion of the sample (10 g or less) containing not more than 30 mg of invert sugar in a 300 ml conical flask and dissolve in about 100 ml of water.

Pipette 10 ml of the copper II solution (4.1), into the flask containing the sample solution. Mix the contents of the flask by swirling and place it in the boiling water-bath (5.2) for exactly 10 minutes.

The level of the solution in the conical flask should be at least 20 mm below the level of the water in the water-bath. Cool the flask rapidly in a stream of cold running water. During this operation the solution should not be stirred otherwise atmospheric oxygen will reoxidize some precipitated copper I oxide.

Add 5 ml of 5 mol/litre acetic acid (4.2) by pipette without shaking and immediately add an excess (between 20 and 40 ml) of the iodine solution 0·01665 mol/litre (4.3) from a burette.

Stir to dissolve the copper precipitate. Titrate the excess iodine against the sodium thiosulphate solution 0·0333 mol/litre (4.4) using the starch solution (4.5) as indicator. The indicator is added towards the end of the titration.

6.2. Carry out a blank test with water. This is to be carried out with each new copper II solution (4.4). The titration shall not exceed 0·1 ml.

6.3. Carry out a control test under cold conditions with the sugar solution. Allow to stand at room temperature for 10 minutes to permit any reducing agents such as sulphur dioxide which may by present to react.

7. **Expression of results.**

7.1. *Formula and method of calculation*

Volume of iodine consumed = ml 0·01665 mol/litre iodine added in excess minus ml 0·0333 mol/litre sodium thiosulphate used in titration.

The volume (in ml) of 0·01665 ml/litre iodine consumed is corrected by subtracting:

7.1.1. The number of ml consumed in the blank test carried out with water (6.2).

7.1.2. The number of ml consumed in the cold test with the sugar solution (6.3).

7.1.3. A value of 2·0 ml for every 10 g of sucrose present in the aliquot used, or a proportionate quantity where the sample contains less than 10 g sucrose (correction for sucrose).

After these corrections are made each ml of iodine solution (4.3) which has reacted corresponds to 1 mg of of invert sugar.

The invert sugar contents, as a percentage of the sample, is given by the formula:

$$\frac{V_1}{10 \times m_o}$$

where:

V_1 = the number of ml of iodine solution (4.3) after correction,

m_0 = the mass, in grams, of the sample used.

7.2. *Repeatability*

The difference between the results of two determinations when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 0·02 g per 100 g of sample.

METHOD 5

MEASUREMENT OF REDUCING SUGARS EXPRESSED AS INVERT SUGAR

(Knight and Allen method)

1. Scope and field of application

The method determines the reducing sugar content expressed as invert sugar in:

— sugar or white sugar,

— extra white sugar.

2. Definition

'Reducing sugars expressed as invert sugar': the content of reducing sugars as determined by the method specified.

3. Principle

Copper II reagent is added in excess to the sample solution, reduced and the unreduced portion is back-titrated with EDTA solution.

4. Reagents

4.1. *Ethylene diamine tetra-acetic acid solution* (disodium salt) (EDTA) 0·0025 mol/litre: dissolve 0·930 g of EDTA in water and make up to one litre with water.

4.2. *Murexide indicator solution:* add 0·25 g of murexide to 50 ml of water and mix with 20 ml of a 0·2 g /100 ml aqueous solution of methylene blue.

4.3. *Alkaline copper reagent:* dissolve 25 g of anhydrous sodium carbonate and 25 g of potassium sodium tartrate tetrahydrate in about 600 ml of water containing 40 ml of 1·0 mol/litre sodium hydroxide. Dissolve 6·0 g of copper II sulphate pentahydrate ($CuSO_4.5H_2O$) in about 100 ml of water, and add to the tartrate solution. Dilute to one litre with water.

N.B.: the solution has a limited life (one week).

4.4. *Standard invert sugar solution:* dissolve 23·750 g of pure sucrose (4.5) in about 120 ml of water in a 250 ml graduated flask, add 9 ml of hydrochloric acid (ζ = 1·16) and allow to stand for eight days at room temperature. Make the solution up to 250 ml and check for completion of hydrolysis by a polarimeter or saccharimeter reading in a 200 mm tube. This should be − 11·80° ± 0·05 °S (see Note 8). Pipette 200 ml of this solution into a 2 000 ml graduated flask. Dilute with water and while shaking (to avoid excessive local alkalinity) add 71·4 ml of sodium hydroxide solution (1 mol/litre) in which 4 g of benzoic acid has been dissolved. Make up to 2 000 ml to give a 1 g/100 ml solution of invert sugar. This solution should be approximately pH 3.

This stable stock solution should only be diluted immediately before use.

4.5. *Pure sucrose:* sample of pure sucrose with an invert sugar content not greater than 0·001 g/100 g.

5. Apparatus

5.1. *Test tubes,* 150 × 20 mm.

5.2. *White porcelain dish.*

5.3. *Analytical balance,* accurate to within 0·1 mg.

6. Procedure

6.1. Dissolve 5 g of sugar sample in 5 ml of cold water in the test tube (5.1). Add 2·0 ml of the copper reagent (4.3) and mix. Immerse the tube in a boiling water bath for five minutes and then cool in cold water.

6.2. Transfer quantitatively the solution in the test tube to the white porcelain dish (5.2) using as little water as possible, add three drops of indicator (4.2) and titrate with EDTA solution (4.1). V_0 is the number of ml of EDTA used in the titration.

Just before the end-point the colour of the solution changes from green through grey to purple at the end-point. The purple colour will disappear slowly because of oxidation of copper I oxide to copper II oxide at a rate dependent on the concentration of reduced copper present. The end-point of the titration shall therefore be approached fairly rapidly.

6.3. Construct a calibration graph by adding known amounts of invert sugar (as solution 4.4 appropriately diluted) to 5 g of pure sucrose (4.5) and add sufficient cold water so that a total of 5 ml of solution is added. Plot the titration volumes (in ml) against the percentage of invert sugar added to the 5 g of sucrose: the resultant graph is a straight line over the range 0·001 to 0·019 g/100 g invert sugar/100 g sample.

7. Expression of results

7.1. *Method of calculation*

Read on the calibration curve the percentage of invert sugar corresponding to the value V_0 ml of EDTA determined when analyzing the sample.

7.2. When a concentration greater than 0·017 g invert sugar/100 g sample is expected in the sample to be analyzed, the sample size taken in Procedure (6.1) must be appropriately reduced but the analysis sample made up to 5 g with pure sucrose (4.5).

7.3. *Repeatability*

The difference between the results of two determinations when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 0·005 g per 100 g of sample.

8. Note

Divide by 2·889 to convert °S to polarmetric degrees of arc (precision tubes of 200 mm; light source consisting of a sodium vapour lamp; the instrument must be installed in a room where the temperature may be maintained close to 20 °C).

METHOD 6

DETERMINATION OF REDUCING SUGARS EXPRESSED AS INVERT SUGAR OR DEXTROSE EQUIVALENT

(Luff-Schoorl method)

1. Scope and field of application

The method determines:

1.1. The reducing sugars content expressed as invert sugar in:

— sugar solution,
— white sugar solution,
— invert sugar solution,
— white invert sugar solution,
— invert sugar syrup,
— white invert sugar syrup.

1.2. The reducing sugar content, expressed and calculated (on the dry matter) as the dextrose equivalent in:

— glucose syrup,
— dried glucose syrup

1.3. The reducing sugar content expressed as D-glucose in:

— dextrose monohydrate,
— dextrose anhydrous

2. Definition

'Reducing sugars expressed as invert sugars, D-glucose or dextrose equivalent': the content of reducing sugars expressed or calculated as invert sugar, D-glucose or dextrose equivalent as determined by the method specified.

3. Principle

The reducing sugars in the sample (clarified if necessary) are heated to boiling point under standardized conditions with a copper II solution, which is partially reduced to copper I. The excess copper II is subsequently determined iodometrically.

4. Reagents

4.1. *Carrez solution I:* dissolve 21·95 g of zinc acetate dihydrate ($Zn(CH_3COO)_2.2H_2O$) (or 24 g of zinc acetate trihydrate ($Zn(CH_3COO)_2 \cdot 3H_2O$) and 3 ml of glacial acetic acid in water and make up to 100 ml with water.

4.2. *Carrez solution II:* dissolve 10·6 g of potassium hexacyanoferrate II trihydrate $K_4[Fe(CN)_6].3H_2O$ in water and make up to 100 ml with water.

4.3. *Luff-Schoorl reagent:* prepare the following solutions:

4.3.1. Copper II sulphate solution: dissolve 25 g of iron-free copper II sulphate pentahydrate ($CuSO_4.5H_2O$) in 100 ml water.

4.3.2. Citric acid solution: dissolve 50 g of citric acid monohydrate ($C_6H_8O_7.H_2O$) in 50 ml of water.

4.3.3. Sodium carbonate solution: dissolve 143·8 g of anhydrous sodium carbonate in about 300 ml of warm water and allow to cool.

4.3.4. Add the citric acid solution (4.3.2) to the sodium carbonate solution (4.3.3) in a one litre volumetric flask with gentle swirling. Swirl until effervescence ceases and then add the copper II sulphate solution (4.3.1) and make up to 1 000 ml with water. Allow the solution to stand overnight and then filter if necessary. Check the molarity of the reagent thus obtained by the method described in 6.1 (Cu 0·1 mol/litre; Na_2CO_3 1 mol/litre).

4.4. *Sodium thiosulphate solution,* 0·1 mol/litre.

4.5. *Starch solution:* to one litre of boiling water add a mixture of 5 g of soluble starch slurried in 30 ml of water. Boil for three minutes, allow to cool and add, if required, 10 mg of mercury II iodide as a preservative.

4.6. *Sulphuric acid,* 3 mol/litre.

4.7. *Potassium iodide solution,* 30% (m/v).

4.8. *Pumice chips,* boiled in hydrochloric acid, washed free of acid with water and then dried.

4.9. *Isopentanol*

4.10. *Sodium hydroxide,* 0·1 mol/litre.

4.11. *Hydrochloric acid,* 0·1 mol/litre.

4.12. *Phenolphthalein solution,* 1% (m/v) in ethanol.

5. Apparatus

5.1. *Conical flask,* 300 ml, fitted with a reflux condenser.

5.2. *Stop-watch.*

6. Procedure

6.1. *Standardization of the Luff-Schoorl reagent* (4.3)

6.1.1. To 25 ml of Luff-Schoorl reagent (4.3) add 3 g of potassium iodide and 25 ml of 3 mol/litre sulphuric acid (4.6).

Titrate with 0·1 mol/litre sodium thiosulphate (4.4) using starch solution (4.5) as indicator added towards the end of the titration. If the volume of 0·1 mol/litre sodium thiosulphate used is not 25 ml the reagent must be made up afresh.

6.1.2. Pipette 10 ml of the reagent into a 100 ml volumetric flask and dilute to volume with water.

Pipette 10 ml of the diluted reagent into 25 ml of 0·1 mol/litre hydrochloric acid (4.11) in a conical flask and heat for one hour in a boiling water-bath. Cool, make up to the original volume with freshly boiled water and titrate with 0·1 mol/litre sodium hydroxide (4.10) using phenolphthalein (4.12) as indicator.

The volume of 0·1 mol/litre sodium hydroxide (4.10) used must be between 5·5 and 6·5 ml.

6.1.3. Titrate 10 ml of the diluted reagent (6.1.2) with 0·1 mol/litre hydrochloric acid (4.11) using phenolphthalein (4.12) as indicator. The end-point is characterized by the disappearance of the violet colour.

The volume of 0·1 mol/litre hydrochloric acid (4.11) used must be between 6·0 and 7·5 ml.

6.1.4. The pH of the Luff-Schoorl reagent must be between 9·3 and 9·4 at 20 °C.

6.2. *Preparation of the solution*

6.2.1. Accurately weigh, to the nearest 1 mg, 5 g of the sample and transfer quantitatively to a 250 ml volumetric flask, with 200 ml water. Clarify, if necessary, by adding 5 ml of Carrez solution I (4.1) followed by 5 ml of Carrez solution II (4.2). Mix after each addition. Make up to 250 ml with water. Mix well. Filter if necessary.

6.2.2. Dilute the solution (6.2.1) so that 25 ml of the solution contains not less than 15 mg and not more than 60 mg of reducing sugars expressed as glucose.

6.3. *Titration by the Luff-Schoorl method*

Pipette 25 ml of Luff-Schoorl reagent (4.3) into a 300 ml conical flask (5.1). Pipette 25 ml of the sugar solution (6.2.2) into the conical flask and introduce two pumice chips (4.8). Fit a reflux condenser to the conical flask (5.1) and immediately place the apparatus on an asbestos wire gauze over a Bunsen flame. The gauze shall have a hole cut in the asbestos part of the same diameter as the base of the flask. Heat the liquid to boiling point over a period of about two minutes and simmer gently for exactly 10 minutes. Cool immediately in cold water and after five minutes titrate as follows:

Add 10 ml of potassium iodide solution (4.7) then immediately add with caution (because of effervescence) 25 ml of 3 mol/litre sulphuric acid (4.6). Titrate with 0·1 mol/litre sodium thiosulphate solution (4.4) until the solution is almost colourless, then add a few ml of starch solution (4.5) as indicator and continue titrating until the blue colour disappears.

Carry out a control test, using 25 ml of water in place of the 25 ml of sugar solution (6.2.2).

7. Expression of results

7.1. *Formula and method of calculation*

From the table below, find (interpolating if necessary) the weight of glucose or of invert sugar in mg corresponding to the difference between the two titration readings, expressed in ml of 0·1 mol/litre sodium thiosulphate.

Express the result in terms of invert sugar or D-glucose as percentage (m/m) of the dry matter.

7.2. *Repeatability*

The difference between the results of two titrations when carried out simultaneously or in rapid succession on the same sample by the same analyst, under the same conditions, shall not exceed 0·2 ml.

8. Note

A small volume of isopentanol (4·9) may be added before acidifying with sulphuric acid to reduce foaming.

Table of values according to Luff-Schoorl reagent

0·1 mol/litre $Na_2S_2O_3$	Glucose, fructose, invert sugars $C_6H_{12}O_6$	
ml	mg	difference
1	2·4	
2	4·8	2·4
3	7·2	2·4
4	9·7	2·5
5	12·2	2·5
6	14·7	2·5
7	17·2	2·5
8	19·8	2·6
9	22·4	2·6
10	25·0	2·6
11	27·6	2·6
12	30·3	2·7
13	33·0	2·7
14	35·7	2·7
15	38·5	2·8
16	41·3	2·8
17	44·2	2·9
18	47·1	2·9
19	50·0	2·9
20	53·0	3·0
21	56·0	3·0
22	59·1	3·1
23	62·2	3·1

METHOD 7

MEASUREMENT OF REDUCING SUGARS EXPRESSED AS INVERT SUGAR

(Lane and Eynon constant volume modification)

1. Scope and field of application

The method determines the reducing sugars, expressed as invert sugar, in:

— sugar solution,
— white sugar solution,
— invert sugar solution,
— white invert sugar solution,
— invert sugar syrup,
— white invert sugar syrup.

2. **Definition**

'Reducing sugars expressed as invert sugar': the content of reducing sugars as determined by the method specified.

3. **Principle**

The sample solution is titrated at the boiling point against a specified volume of Fehling's solution, using methylene blue as internal indicator.

4. Reagents

4.1. *Fehling's solution:*

4.1.1. Solution A:

Dissolve 69·3 g of copper II sulphate pentahydrate ($CuSO_4.5H_2O$) in water and make up to 1 000 ml.

4.1.2. Solution B:

Dissolve 346·0 g of double sodium potassium tartrate tetrahydrate ($KNaC_4H_4O_6.4H_2O$) with 100·0 g of sodium hydroxide in water and make up to 1 000 ml. The clear solution should be decanted from a sediment that may form from time to time.

Note:

These two solutions should be stored in brown or amber bottles.

4.2. *Sodium hydroxide solution,* 1 mol/litre.

4.3. *Standard invert sugar solution:* dissolve 23·750 g of pure sucrose in about 120 ml of water in a 250 ml graduated flask, add 9 ml of hydrochloric acid (ζ = 1·16) and allow to stand for eight days at room temperature. Make the solution up to 250 ml and check for completion of hydrolysis by a polarimeter or saccharimeter reading in a 200 mm tube. This should be − 11·80° ± 0·05 °S (see note 8). Pipette 200 ml of this solution into a 2 000 ml graduated flask. Dilute with water and while shaking (to avoid excessive local alkalinity) add 71·4 ml of sodium hydroxide solution (1 mol/litre)(4.2) in which 4 g of benzoic acid has been dissolved. Make up to 2 000 ml to give a 1 g/100 ml solution of invert sugar. This solution should be a pH of approximately 3.

This stable stock solution should only be diluted immediately before use.

To make up the 0·25 g/100 ml invert sugar solution, fill a 250 ml graduated flask to the mark with the stock 1 g/100 ml invert solution at 20 °C. Wash the contents of this flask into a 1 000 ml graduated flask and dilute to the mark with water again at 20 °C.

4.4. *Methylene blue solution,* 1 g/100 ml.

5. Apparatus

5.1. *Narrow-necked laboratory boiling flasks,* 500 ml.

5.2. *Burette,* 50 ml, with tap and offset tip, graduated to 0·05 ml.

5.3. *Pipettes* graduated at 20, 25 and 50 ml.

5.4. *One mark volumetric flasks,* 250, 1 000 and 2 000 ml.

5.5. *A heating device,* suitable for maintaining boiling according to the conditions described in 6.1, permitting the observation of the end-point colour change without the necessity of removing the boiling flask (5.1) from the source of heat.

5.6. *Stop-watch,* indicating to within at least one second.

6. **Procedure**

6.1. *Standardization of Fehling's solution*

6.1.1. Pipette 50 ml of solution B (4.1.2) and then 50 ml of solution A (4.1.1) into a clean dry beaker and mix well.

6.1.2. Rinse and fill the burette with 0·25 % (0·25 g/100 ml) standard invert sugar solution (4.3).

6.1.3. Pipette a 20 ml aliquot of the mixed solutions A and B (6.1.1) into a 500 ml boiling flask (5.1). Add 15 ml of water to the flask. Run in, from the burette, 39 ml of the invert sugar solution, add a small quantity of anti-bumping granules and mix the contents of the flask by gentle swirling.

6.1.4. Heat the flask and contents till boiling and allow to boil for exactly two minutes; the flask must not be removed from the heat source during the course of the rest of the procedure, or allowed to cease boiling.

Add three or four drops of methylene blue solution (4.4) at the end of the two-minute boiling period: the solution should be a definite blue colour.

6.1.5. Continue the standardization by adding, from the burette, the standard invert sugar solution in small increments, initially of 0·2 ml; then 0·1 ml and finally in single drops until the end-point is reached. This is indicated by the disappearance of the blue colour imparted by the methylene blue. The solution has then assumed the reddish colour associated with a suspension of copper I oxide.

6.1.6. The end-point should be reached at the end of three minutes from when the solution started to boil. The final titre, V_o, shall be between 39·0 and 41·0 ml. If V_0 lies outside these limits, adjust the copper concentration of Fehling's solution A (4.1.1) and repeat the standardization process.

6.2. *Preparation of sample solutions*

The concentration of the sample test solution should be such that it contains between 250 and 400 mg invert sugar per 100 ml.

6.3. *Preliminary test*

6.3.1. A preliminary test must be carried out to ensure that the quantity of water to be added to the 20 ml of mixed solutions A and B is sufficient to ensure that a final volume after titration of 75 ml is obtained.

The same procedure as described in 6.1.4 is carried out except that the sample solution is used instead of the standard invert sugar solution, i.e. 25 ml of the sample solution is run into the flask from the burette. 15 ml of water is added, and the solution is allowed to boil for two minutes and then titrated until the end-point is reached as described in 6.1.5.

6.3.2. If, after the addition of the methylene blue solution, the reddish colour persists, the sample solution used is too concentrated. In this case, the test is discarded but repeated using a less concentrated sample solution.

If more than 50 ml of sample solution are required to obtain the reddish colour, a more concentrated solution of the sample must be used.

Calculate the quantity of water to be added by subtracting the volumes of mixed Fehling's solution (20 ml) and of the sample solution from 75 ml.

6.4. *Final analysis of sample solution*

6.4.1. Pipette into the boiling flask 20 ml of mixed Fehling's solution and the quantity of water determined as in 6.3.

6.4.2. Add, from the burette, the observed titre of the sample solution (as determined in 6.3) less 1 ml. Add some anti-bumping granules, mix the contents of the flask by swirling, boil the flask and contents and titrate as previously (6.3). The end-point should be reached one minute from the time of addition of the methylene blue solution. Final titre = V_1.

7. **Expression of results**

7.1. *Formula and method of calculation*

The reducing sugars content of the sample calculation as invert sugar, is given by:

$$\% \text{ reducing sugars (as invert sugar} = \frac{V_o \times 25 \times f}{C_o \times V_1}$$

where:

C = the concentration of the sample test solution in g per 100 ml.

V_0 = the volume in ml of the standard invert solution used in the standardization titration,

V_1 = the volume in ml of the sample test solution used in the accurate analysis in 6.4.2,

f = the correction factor to take account of the sucrose concentration in the sample test solution. Values are shown in the table below:

Sucrose (g in boiling mixture)	Correction factor f
0	1·000
0·5	0·982
1·0	0·971
1·5	0·962
2·0	0·954
2·5	0·946
3·0	0·939
3·5	0·932
4·0	0·926
4·5	0·920
5·0	0·915
5·5	0·910
6·0	0·904
6·5	0·898
7·0	0·893
7·5	0·888
8·0	0·883
8·5	0·878
9·0	0·874
9·5	0·869
10·0	0· 64

Corrections for varying sucrose contents of the sample test solution may be calculated from the table by interpolation.

Note:

The approximate sucrose concentration may be found by subtraction of the dissolved solids concentration due to the invert sugar (estimated for the purposes of this calculation f as 1·0), from the total dissolved solids concentration, expressed as sucrose, obtained from the refractive index of the solution using method three of this document.

7.2. *Repeatability*

The difference between the results of two determinations, carried out simultaneously or in rapid succession on the same sample by the same analyst under the same conditions, shall not exceed 1·0 % of their arithmetic mean.

8. Note

Divide by 2·889 to convert °S to polarmetric degrees of arc (precision tubes of 200 mm; light source consisting of a sodium vapour lamp; the instrument must be installed in a room where the temperature may be maintained close to 20 °C).

METHOD 8

DETERMINATION OF DEXTROSE EQUIVALENT

(Lane and Eynon constant)

1. **Scope and field of application**

This method determines the dextrose equivalent of:

— glucose syrup,
— dried glucose syrup,
— dextrose monohydrate,
— dextrose anhydrous.

2. **Definition**

2.1. 'Reducing power': the reducing sugar content, determined by the method specified, expressed in terms of anhydrous dextrose (D-glucose) and calculated as a percentage by mass of the sample.

2.2. 'Dextrose equivalent': the reducing power, calculated as a percentage by mass of the dry matter in the sample.

3. **Principle**

The test solution is titrated at the boiling point against a specified volume of mixed Fehling's solution, under strictly specified conditions, using methylene blue as an internal indicator.

4. **Reagents**

4.1. *Fehling's solution:*

4.1.1. Solution A:

Dissolve 69·3 g of copper II sulphate pentahydrate ($CuSO_4.5H_2O$) in water and make up to volume in a 1 000 ml volumetric flask.

4.1.2. Solution B:

Dissolve 346·0 g of sodium potassium tartrate tetrahydrate ($KNaC_4H_4O_6.4H_2O$) and 100 g of sodium hydroxide in water. Make up to volume in a 1 000 ml volumetric flask. Decant the clear solution from any sediment that may from time to time form.

Note:

These two solutions (4.1.1 and 4.1.2) should be stored in brown or amber bottles.

4.1.3. Preparation of the mixed Fehling's solution

Pipette 50 ml of solution B (4.1.2) and then 50 ml of solution A (4.1.1) into a clean dry beaker and mix well.

Note:

Mixed Fehling's solution shall not be stored but made up afresh every day and standardized (6.1).

4.2. *Anhydrous dextrose* (D-glucose) ($C_6H_{12}O_6$)

This material shall be dried before use for four hours in a vacuum oven at 100 ± 1 °C or less, and an internal pressure of approximately 10 kPa (103 mbar).

4.3. *Standard dextrose solution,* 0·600 g/100 ml

Weigh, to the nearest 0·1 mg, 0·6 g of anhydrous dextrose (4.2), dissolve it in water, transfer the solution quantitatively into a 100 ml volumetric flask (5.4), dilute to the mark and mix.

This solution shall be freshly prepared on each day of use.

4.4. *Methylene blue solution,* 0·1 g/100 ml

Dissolve 0·1 g of methylene blue in 100 ml water.

5. Apparatus

5.1. *Narrow necked laboratory boiling flasks,* 250 ml.

5.2. *Burette,* 50 ml, with tap and offset tip, graduated to 0·05 ml.

5.3. *One mark pipettes,* 25 ml and 50 ml.

5.4. *One mark volumetric flasks,* 100 and 500 ml.

5.5. *A heating device,* suitable for maintaining boiling according to the conditions described in 6·1, permitting the observation of the end-point colour change without the necessity of removing the boiling flask (5.1) from the source of heat (see 6.1, note 3).

5.6. *A stop-watch,* indicating to at least the nearest second.

6. Procedure

6.1. *Standardization of the Fehling's solution*

6.1.1. Pipette 25 ml of Fehling's solution (4.1.3) into a clean, dry boiling flask (5.1).

6.1.2. Fill the burette (5.2) with standard dextrose solution (4.3) and adjust the meniscus to the zero mark.

6.1.3. Run into the boiling flask (5.1) from the burette 18 ml of standard dextrose solution (4.3). Swirl the flask to mix contents.

6.1.4. Place the boiling flask on the heating device (5.5), previously adjusted so that boiling commences in 120 ± 15 seconds.

The heating device shall not be further adjusted during the whole of the titration (see note 1).

6.1.5. When boiling commences, start the stop-watch from zero.

6.1.6. Boil the contents of the flask for 120 seconds, as timed by the stop-watch.
Add 1 ml of methylene blue solution (4.4) towards the end of this period.

6.1.7. After boiling has continued for 120 seconds (by the stop-watch) start adding standard dextrose solution to the boiling flask (5.1) from the burette (6.1.2) in 0·5 ml increments until the colour of the methylene blue is discharged (see notes 2 and 3).
Note the total volume of standard dextrose solution added up to and including the penultimate 0·5 ml increment (X ml).

6.1.8. Repeat 6.1.1 and 6.1.2.

6.1.9. Run into the boiling flask (5.1) from the burette a volume of standard dextrose solution equal to (X–0·3) ml.

6.1.10 Repeat 6.1.4, 6.1.5 and 6.1.6.

6.1.11. After boiling has continued for 120 seconds (by the stop-watch), start adding standard dextrose solution to the boiling flask (5.1) from the burette, initially in 0·2 ml increments and finally dropwise, until the colour of the methylene blue is just discharged.
Towards the end of this action the time between successive additions of standard dextrose solution shall be 10 to 15 seconds.
These additions shall be completed within 60 seconds, making the total time to boiling no longer than 180 seconds.
A third titration with a slightly larger, appropriately adjusted, initial addition of standard dextrose solution (6.1.9) may be necessary to achieve this.

6.1.12. Note the volume (V_0 ml) of standard dextrose solution used up to the end-point of the final titration (see note 4).

6.1.13. V_0 shall be between 19·0 and 21·0 ml standard dextrose solution (4.3).
If V_0 lies outside these limits, adjust the concentration of the Fehling's solution A (4.1.1) appropriately and repeat the standardization process.

6.1.14. For the day-to-day standardization of the mixed Fehling's solution, as V_0 is known with accuracy, a single titration only is necessary, using an initial addition of (V_0 — 0·5) ml standard dextrose solution.

Note 1:

This ensures that once boiling has commenced the evolution of steam is brisk and continuous throughout the whole of the titration process, thus preventing to the maximum possible extent the entrance of air into the titration flask with consquent re-oxidation of its contents.

Note 2:

The disappearance of the colour of the methylene blue is best seen by looking at the upper layers and the meniscus of the contents of the titration flask, as these will be relatively free from the precipiated, red copper I oxide. The colour disappearance is more easily seen when indirect lighting is used. A white screen behind the titration flask is helpful.

Note 3:

The burette should be isolated as much as possible from the source of heat during the determination.

Note 4:

As there is always a personal factor involved, each operator shall carry out his own standardization titration and use his own value of V_0 in the calculation (7.1).

6.2. *Preliminary examination of the prepared sample*

6.2.1. Unless the reducing power (2.1) of the prepared sample is known approximately, it is necessary to carry out a preliminary examination in order to obtain an approximate figure for it so that the mass of the test portion (6.3) can be calculated.
This examination is carried out as follows:

6.2.2. Prepare a 2% m/v solution of the sample, 'Z' having an estimated value.

6.2.3. As 6.1.2, using the sample solution (6.2.2) in place of the standard dextrose solution.

6.2.4. As 6.1.1.

6.2.5. As 6.1.3, using 10·0 ml sample solution instead of 18·0 ml standard dextrose solution.

6.2.6. As 6.1.4.

6.2.7. Heat the contents of the flask to boiling. Add 1 ml methylene blue solution (4.4).

6.2.8. Immediately boiling has started, start the stop-watch (5.6) from zero and commence adding sample solution to the flask from the burette in 1·0 ml increments at intervals of approximately 10 seconds until the blue colour of the methylene blue is discharged.

Note the total volume of sample solution added up to and including the penultimate increment (Y ml).

6.2.9. 'Y' must not exceed 50 ml. If it does, increase the concentration of the sample solution and repeat the titration.

6.2.10. The approximate reducing power of the prepared sample in percent by mass is given by:

$$\frac{60 \times V_0}{Y \times Z}$$

6.3. *Test portion*

Weigh out, to the nearest 0·1 mg, a mass of the prepared sample (mg) which contains between 2·85 and 3·15 g reducing sugars, expressed as anhydrous dextrose (D-glucose) using in the calculation either known approximate figure for the reducing power (2.1) or the approximate figure obtained in 6.2.10.

6.4. *Test solution*

Dissolve the test portion in water and make up to 500 ml in a volumetric flask.

6.5. *Determination*

6.5.1. As 6.1.1.

6.5.2. Fill the burette (5.2) with test solution (6.4) and adjust the meniscus to the zero mark.

6.5.3. Run into the boiling flask from the burette 18·5 ml test solution. Swirl the flask to mix the contents.

6.5.4. As 6.1.4.

6.5.5. As 6.1.5.

6.5.6. As 6.1.6.

6.5.7. As 6.1.7, using test solution in place of standard dextrose solution.

6.5.8. As 6.1.8.

6.5.9. As 6.1.9, using test solution in place of standard dextrose solution.

6.5.10. As 6.1.10.

6.5.11. As 6.1.11, using test solution in place of standard dextrose solution.

6.5.12. Note the volume (V_1) of test solution used up to the end-point of the final titration.

6.5.13. V_1 shall be between 19·0 and 21·0 ml test solution.

If V_1 lies outside these limits, adjust the concentration of the test solution appropriately and repeat 6.5.1 to 6.5.12.

6.5.14. Carry out two determinations on the same test solution.

6.6. *Dry matter content*

Determine the dry matter content of the prepared sample by method 2.

7. Expression of results

7.1. *Formulae and method of calculation*

7.1.1. Reducing power

The reducing power, calculated as a percentage by mass of the prepared sample, is given by:

$$\frac{300 \times V_0}{V_1 \times M}$$

where:

V_0 = the volume, in ml, of the standard dextrose solution (4.3) used in the standardization titration (6.1),

V_1 = the volume, in ml, of the test solution (6.4) used in the determination titration (6.5),

M = the mass, in grams, of the test portion (6.3) used to make 500 ml test solution.

7.1.2. Dextrose equivalent

The dextrose equivalent, calculated as a percentage by mass of the dry matter in the prepared sample, is given by:

$$\frac{RP \times 100}{D}$$

where:

RP = the reducing power, calculated as a percent by mass of the prepared sample (7.1.1),

D = the dry matter content of the prepared sample in percent by mass.

7.1.3. Take as the result the arithmetic mean of the two determinations provided that the requirement concerning repeatability (7.2) is satisfied.

7.2. *Repeatability*

The difference between the results of two determinations when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 1·0 % of their arithmetic mean.

METHOD 9

DETERMINATION OF SULPHATED ASH

1. Scope and field of application

The method determines the sulphated ash content in:

— glucose syrup,
— dried glucose syrup,
— dextrose monohydrate,
— dextrose anhydrous.

2. Definition

'Sulphated ash content': the content of sulphated ash as determined by the method specified.

3. Principle

The residual mass of a test portion is determined after incineration in an oxidizing atmosphere at 525 °C in the presence of sulphuric acid and calculated as a percentage by mass of the sample.

4. Reagents

4.1. *Sulphuric acid,* dilute solution: slowly and cautiously add 100 ml of concentrated sulphuric acid (density at 20 °C = 1·84 g/ml; 96% m/m) to 300 ml water with stirring and cooling.

5. Apparatus

5.1. *Electric muffle furnace,* equipped with a pyrometer and capable of operating at a temperature of 525 ± 25 °C.

5.2. *Analytical balance,* accurate to 0·1 mg.

5.3. *Ashing crucibles,* platinum or quartz, of suitable capacity.

5.4. *Desiccator,* containing freshly activated silica gel or an equivalent desiccant with a water content indicator.

6. Procedure

Heat a crucible (5.3) to the ashing temperature, cool in a desiccator and weigh. Accurately weigh, to the nearest 0·1 mg, 5 g of glucose syrup or dried glucose syrup, or about 10 g of dextrose monohydrate or dextrose anhydrous into the crucible.

Add 5 ml of sulphuric acid solution (4.1) (see note 8.1) and carefully heat the sample in the crucible over a flame or on a hotplate until it is completely carbonized. This carbonization process, during which vapours are burnt off from the sample (see note 8.2), should be carried out in a fume cupboard.

Place the crucible (5.3) in the muffle furnace (5.1) heated to 525 ± 25° C until a white ash is obtained. This normally takes two hours (see note 8.3).

Allow the sample to cool for about 30 minutes in a desiccator (5.4) and then weigh.

7. Expression

7.1. *Formula and method of calculation*

The sulphated ash content expressed as a percentage by mass of the sample to be analyzed is given by:

$$S = \frac{m_1}{m_0} \times 100$$

where:

m_1 = the mass, in grams, of the ash,

m_0 = the mass, in grams, of the test portion.

7.2. *Repeatability*

The difference between the results of two determinations when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 2% of their arithmetic mean.

8. Notes

8.1. The sulphuric acid is added in small quantities to prevent excessive foaming.

8.2. Every relevant precaution must be taken during the first carbonization to prevent losses of sample or of ash through excessive swelling of the sample.

8.3. If the sample is difficult to ash completely (i.e. black particles remain) the crucible should be removed from the muffle furnace and the residue moistened, after cooling, with a few drops of water before being returned to the furnace.

METHOD 10

DETERMINATION OF POLARIZATION

1. Scope and field of application

The method determines the polarization in:

— semi-white sugar,

— sugar or white sugar,

— extra-white sugar.

2. Definition

The polarization is the rotation of the polarized light plane by a sugar solution with 26 g of sugar per 100 ml contained in a tube of 200 mm in length.

3. Principle

The polarization is determined by using a saccharimeter or a polarimeter according to the conditions described in the following method.

4. Reagents

4.1. *Clarification agent:* basic lead acetate solution.

Add 560 g of dry basic lead acetate to about 1 000 ml of freshly boiled water. Boil the mixture for 30 minutes and then leave it to stand overnight.

Decant the supernatant liquid and dilute with freshly boiled water to obtain a solution of density of 1·25 g/ml, at 20 °C.

Protect this solution from contact with air.

4.2. *Diethyl ether*

5. **Apparatus**

5.1. *Saccharimeter graduated for the normal weight of 26 g of sucrose, or polarimeter*

This instrument must be installed in a room where the temperature may be maintained close to 20 °C. Calibrate the instrument against standard quartz plates.

5.2. *Light source,* consisting of a sodium vapour lamp.

5.3. *Precision polarimeter tubes,* length 200 mm, error not exceeding ± 0·02 mm.

5.4. *Analytical balance,* accurate to within 0·1 mg.

5.5. *Individually calibrated 100 ml volumetric flasks stoppered.* Flasks with a real capacity in the range 100·00 ± 0·01 ml may be used without correction. Flasks with a capacity outside those limits must be used with an appropriate correction to adjust the capacity to 100 ml.

5.6. *Water-bath,* controlled thermostatically at 20 ± 0·1 °C.

6. **Procedure**

6.1. *Preparation of the solution*

Weigh as quickly as possible 26 ± 0·002 g of the sample and transfer it quantitatively into a 100 ml volumetric flask (5.5) with approximately 60 ml of water.

Dissolve by swirling but without heating.

Where clarification is necessary, add 0·5 ml of lead acetate reagent (4.1).

Mix the solution by rotating the flask and wash the flask walls, until the volume is such that the meniscus is about 10 mm below the calibration mark.

Place the flask in the water-bath controlled (5.6) at 20 ± 0·1 °C until the temperature of the sugar solution is constant.

Eliminate any bubbles formed at the surface of the liquid with a drop of diethyl ether (4.2).

Make up to volume with water.

Stopper and mix thoroughly by inverting the flask at least three times.

Allow to stand for five minutes.

6.2. *Polarization*

Maintain the temperature at 20 ± 1 °C for all subsequent operations.

6.2.1. Obtain the zero correction of the apparatus.

6.2.2. Filter the sample through a filter paper. Discard the first 10 ml of the filtrate. Collect the next 50 ml of the filtrate.

6.2.3. Wash the polarimeter tube by rinsing twice with the sample solution to be examined (6.2.2).

6.2.4. Fill the tube carefully at 20 ± 0·1 °C with the sample solution to be examined.

Remove all air bubbles when sliding the end-plate into position. Place the filled tube in the cradle of the instrument.

6.2.5. Read the rotation to within 0·05 °S or 0·02 angular degrees. Repeat a further four times. Take the mean of the five readings.

7. **Expression of results**

7.1. *Formula and method of calculation*

The results are expressed in degrees S to the nearest 0·1 °S. To convert the angular degrees into degrees S, the following formula is used:

$$°S = \text{degree of arc} \times 2{\cdot}889$$

7.2. *Repeatability*

The difference between the results of two determinations when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, and each representing the mean of five readings, must not exceed 0·1 °S.

HONEY

374L0409

74/409/EEC: COUNCIL DIRECTIVE OF 22 JULY 1974 ON THE HARMONIZATION OF THE LAWS OF THE MEMBER STATES RELATING TO HONEY

OFFICIAL JOURNAL NO L 221, 12/08/1974, P. 10
DATE OF NOTIFICATION: 23/07/1974
DATE OF TRANSPOSITION: 23/07/1975; SEE ART. 14

AMENDED BY

179H
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE HELLENIC REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES [1]
OFFICIAL JOURNAL NO L 291, 19/11/1979, P. 110

185I
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE KINGDOM OF SPAIN AND THE PORTUGUESE REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES [2]
OFFICIAL JOURNAL NO L 302, 15/11/1985, P. 216

ARTICLE 1

1. FOR THE PURPOSES OF THIS DIRECTIVE "HONEY" SHALL MEAN THE FOODSTUFF WHICH IS PRODUCED BY THE HONEY-BEE FROM THE NECTAR OF BLOSSOMS OR SECRETIONS OF OR ON LIVING PARTS OF PLANTS, AND WHICH THE BEES COLLECT, TRANSFORM, COMBINE WITH SPECIFIC SUBSTANCES OF THEIR OWN AND STORE AND LEAVE TO MATURE IN HONEY COMBS. THIS FOODSTUFF MAY BE FLUID, VISCOUS OR CRYSTALLIZED.

2. THE MAIN TYPES OF HONEY ARE AS FOLLOWS:

(a) ACCORDING TO ORIGIN

BLOSSOM HONEY: HONEY OBTAINED PREDOMINANTLY FROM THE NECTAR OF BLOSSOMS;

HONEYDEW HONEY: HONEY OBTAINED PREDOMINANTLY FROM SECRETIONS OF OR ON LIVING PARTS OF PLANTS; ITS COLOUR VARIES FROM LIGHT OR GREENISH BROWN TO ALMOST BLACK;

(b) ACCORDING TO MODE OF PRESENTATION

COMB HONEY: HONEY STORED BY BEES IN THE CELLS OF FRESHLY BUILT BROODLESS COMBS AND SOLD IN SEALED WHOLE COMBS OR SECTIONS OF SUCH COMBS;

CHUNK HONEY: HONEY WHICH CONTAINS ONE OR MORE PIECES OF COMB HONEY;

DRAINED HONEY: HONEY OBTAINED BY DRAINING DECAPPED BROODLESS COMBS;

EXTRACTED HONEY: HONEY OBTAINED BY CENTRIFUGING DECAPPED BROODLESS COMBS;

PRESSED HONEY: HONEY OBTAINED BY PRESSING BROODLESS COMBS WITH OR WITHOUT THE APPLICATION OF MODERATE HEAT;

ARTICLE 2

MEMBER STATES SHALL TAKE ALL MEASURES NECESSARY TO ENSURE THAT HONEY MAY BE OFFERED FOR SALE ONLY IF IT CONFORMS TO THE DEFINITIONS AND RULES LAID DOWN IN THIS DIRECTIVE AND IN THE ANNEX THERETO.

ARTICLE 3

1. THE TERM "HONEY" SHALL BE APPLIED ONLY TO THE PRODUCT DEFINED IN ARTICLE 1 (1) AND MUST BE USED IN TRADE TO DESIGNATE THAT PRODUCT, WITHOUT PREJUDICE TO THE PROVISIONS LAID DOWN IN ARTICLE 7 (1) (a) AND (2).

2. THE NAMES REFERRED TO IN ARTICLE 1 (2) SHALL BE APPLIED ONLY TO THE PRODUCTS DEFINED THEREIN.

ARTICLE 4

BY WAY OF DEROGATION FROM ARTICLE 3 (1) THE TERMS "KUNSTHONNING" AND "KUNSTHONIG" MAY CONTINUE TO BE USED IN DENMARK AND IN GERMANY RESPECTIVELY FOR A PERIOD OF FIVE YEARS STARTING FROM THE DATE OF NOTIFICATION OF THIS DIRECTIVE, TO DESCRIBE A PRODUCT OTHER THAN HONEY, IN ACCORDANCE WITH THE NATIONAL PROVISIONS GOVERNING THIS PRODUCT IN FORCE AT THE TIME OF THE NOTIFICATION OF THIS DIRECTIVE.

ARTICLE 5

NO PRODUCT OTHER THAN HONEY MAY BE ADDED TO HONEY OFFERED FOR SALE AS SUCH.

ARTICLE 6

1. WHEN IT IS MARKETED THE HONEY SHALL COMPLY WITH THE COMPOSITIONAL CRITERIA LISTED IN THE ANNEX.
HOWEVER, BY WAY OF DEROGATION FROM THE SECOND INDENT OF PARAGRAPH 2 OF THE SAID ANNEX, MEMBER STATES MAY AUTHORIZE IN THEIR OWN TERRITORY:

(a) THE MARKETING OF HEATHER HONEY WITH A MAXIMUM MOISTURE CONTENT OF 25 %, IF THIS IS THE RESULT OF NATURAL CONDITIONS OF PRODUCTION,

(b) THE MARKETING OF "BAKER'S HONEY" OR "INDUSTRIAL HONEY" WITH A MOISTURE CONTENT OF NOT MORE THAN 25 %, IF THIS IS THE RESULT OF NATURAL CONDITIONS OF PRODUCTION.

2. IN ADDITION:

(a) HONEY SHALL, AS FAR AS PRACTICABLE, BE FREE FROM ORGANIC OR INORGANIC MATTERS FOREIGN TO ITS COMPOSITION, SUCH AS MOULD, INSECTS, INSECT DEBRIS, BROOD OR GRAINS OF SAND, WHEN THE HONEY IS MARKETED AS SUCH OR IS USED IN ANY PRODUCT FOR HUMAN CONSUMPTION;

(b) HONEY SHALL NOT:

(i) HAVE ANY FOREIGN TASTES OR ODOURS;

(ii) HAVE BEGUN TO FERMENT OR EFFERVESCE;

(iii) HAVE BEEN HEATED TO SUCH AN EXTENT THAT ITS NATURAL ENZYMES ARE DESTROYED OR MADE INACTIVE;

(iv) HAVE AN ARTIFICIALLY CHANGED ACIDITY;

(c) HONEY MAY UNDER NO CIRCUMSTANCES CONTAIN SUBSTANCES IN SUCH QUANTITY AS TO ENDANGER HUMAN HEALTH.

3. BY WAY OF DEROGATION FROM PARAGRAPHS 1 AND 2, HONEY MAY BE MARKETED AS "BAKER'S HONEY" OR "INDUSTRIAL HONEY" IF, ALTHOUGH SUITABLE FOR HUMAN CONSUMPTION:

(a) IT DOES NOT COMPLY WITH THE REQUIREMENTS REFERRED TO IN PARAGRAPH 2 (b), (i), (ii), (iii), OR

(b) ITS DIASTASE ACTIVITY OR HYDROXYMETHYLFURFURAL CONTENT DO NOT COMPLY WITH THE SPECIFICATIONS LAID DOWN IN THE ANNEX.

HOWEVER, IN THE CASE REFERRED TO UNDER (b) A MEMBER STATE MAY REFRAIN FROM MAKING USE OF THIS TERM COMPULSORY AND ALLOW THE TERM "HONEY" TO BE USED. WITHIN FIVE YEARS FROM THE DATE OF NOTIFICATION OF THIS DIRECTIVE THE COUNCIL SHALL DECIDE, ON A PROPOSAL FROM THE COMMISSION, ON PROVISIONS DESIGNED TO LAY DOWN IDENTICAL TECHNICAL SPECIFICATIONS FOR THE ENTIRE COMMUNITY.

ARTICLE 7

1. THE ONLY INFORMATION WHICH IS COMPULSORY ON THE PACKAGES, CONTAINERS OR LABELS OF HONEY, WHICH INFORMATION MUST BE CONSPICUOUS, CLEARLY LEGIBLE AND INDELIBLE, SHALL BE THE FOLLOWING:

(a) THE TERM "HONEY" OR ONE OF THE NAMES LISTED IN ARTICLE 1 (2); "COMB HONEY" AND "CHUNK HONEY" MUST, HOWEVER, BE DESCRIBED AS SUCH; IN THE CASES REFERRED TO IN SUBPARAGRAPH (b) OF THE SECOND PARAGRAPH OF ARTICLE 6 (1) AND IN THE FIRST PARAGRAPH OF ARTICLE 6 (3), THE NAME OF THE PRODUCT SHALL BE "BAKER'S HONEY" OR "INDUSTRIAL HONEY";

(b) THE NET WEIGHT EXPRESSED IN GRAMMES OR KILOGRAMMES;

(c) THE NAME OR TRADE NAME AND THE ADDRESS OR REGISTERED OFFICE OF THE PRODUCER OR PACKER, OR OF A SELLER ESTABLISHED WITHIN THE COMMUNITY.

2. THE MEMBER STATES MAY REQUIRE IN THEIR OWN TERRITORY USE OF THE NAME "HONEYDEW HONEY" FOR HONEY WHICH IS PREDOMINANTLY HONEYDEW HONEY, WHICH HAS THE ORGANOLEPTIC, PHYSICO-CHEMICAL AND MICROSCOPIC CHARACTERISTICS OF SUCH HONEY AND FOR WHICH THERE IS GIVEN NO INDICATION OF A SPECIFIC PLANT ORIGIN, SUCH AS "PINE HONEY".

3. BY WAY OF DEROGATION FROM PARAGRAPH 1, THE MEMBER STATES MAY RETAIN ANY NATIONAL PROVISIONS WHICH REQUIRE INDICATION OF THE COUNTRY OF ORIGIN. THIS INFORMATION, HOWEVER, MAY NO LONGER BE REQUIRED FOR HONEY ORIGINATING IN THE COMMUNITY.

4. THE TERM "HONEY" REFERRED TO IN PARAGRAPH 1 (a) OR ONE OF THE NAMES REFERRED TO IN ARTICLE 1 (2) MAY BE SUPPLEMENTED INTER ALIA BY:

(a) A REFERENCE TO THE ORIGIN, WHETHER BLOSSOM OR PLANT, PROVIDED THE PRODUCT COMES PREDOMINANTLY FROM THE SOURCE INDICATED AND HAS THE APPROPRIATE ORGANOLEPTIC, PHYSICO-CHEMICAL, AND MICROSCOPIC CHARACTERISTICS;

(b) A REGIONAL, TERRITORIAL OR TOPOGRAPHICAL NAME, PROVIDED THE PRODUCT ORIGINATES ENTIRELY IN THE AREA INDICATED.

5. WHERE HONEY IS PUT UP IN PACKAGES OR CONTAINERS OF A NET WEIGHT EQUAL TO OR EXCEEDING 10 KILOGRAMMES AND IS NOT RETAILED, THE INFORMATION REFERRED TO IN PARAGRAPH 1 (b) AND (c) MAY, IF DESIRED, APPEAR ONLY ON THE ACCOMPANYING DOCUMENTS.

6. MEMBER STATES SHALL REFRAIN FROM STATING, APART FROM WHAT IS LAID DOWN IN PARAGRAPH 1, HOW THE INFORMATION REFERRED TO IN THAT PARAGRAPH IS TO BE GIVEN. HOWEVER, MEMBER STATES MAY FORBID TRADE IN HONEY IN THEIR TERRITORY IF THE MARKINGS LAID DOWN IN PARAGRAPH 1 (a) ARE NOT SHOWN ON ONE SIDE OF THE PACKAGE OR CONTAINER IN THE NATIONAL LANGUAGE OR LANGUAGES.

7. UNTIL THE END OF THE TRANSITIONAL PERIOD DURING WHICH THE IMPERIAL UNITS OF MEASUREMENT CONTAINED IN ANNEX II TO COUNCIL DIRECTIVE NO 71/354/EEC OF 18 OCTOBER 1971 RELATING TO UNITS OF MEASUREMENT WHICH MAY BE USED IN THE COMMUNITY (1), MEMBER STATES MAY REQUIRE THAT THE WEIGHT SHOULD ALSO BE EXPRESSED IN IMPERIAL UNITS OF MEASUREMENT.

8. PARAGRAPHS 1 TO 7 SHALL APPLY WITHOUT PREJUDICE TO SUBSEQUENT PROVISIONS LAID DOWN BY THE COMMUNITY ON LABELLING.

ARTICLE 8

1. MEMBER STATES SHALL ADOPT ALL THE MEASURES NECESSARY TO ENSURE THAT TRADE IN THE PRODUCTS REFERRED TO IN ARTICLE 1, WHICH COMPLY WITH THE DEFINITIONS AND RULES LAID DOWN IN THIS DIRECTIVE AND IN ANNEX I THERETO, SHALL NOT BE IMPEDED BY THE APPLICATION OF NATIONAL NON-HARMONIZED PROVISIONS GOVERNING THE COMPOSITION, MANUFACTURING SPECIFICATIONS, PACKAGING OR LABELLING OF THESE PRODUCTS IN PARTICULAR OR OF FOODSTUFFS IN GENERAL.

2. PARAGRAPH 1 SHALL NOT BE APPLICABLE TO NON-HARMONIZED PROVISIONS JUSTIFIED ON GROUNDS OF:

- PROTECTION OF PUBLIC HEALTH,
- REPRESSION OF FRAUDS UNLESS SUCH PROVISIONS ARE LIABLE TO IMPEDE THE APPLICATION OF THE DEFINITIONS AND RULES LAID DOWN BY THIS DIRECTIVE,
- PROTECTION OF INDUSTRIAL AND COMMERCIAL PROPERTY, OF INDICATIONS OF SOURCE, DESIGNATIONS OF ORIGIN AND THE REPRESSION OF UNFAIR COMPETITION.

ARTICLE 9

THE METHODS OF SAMPLING AND ANALYSIS NECESSARY FOR CHECKING THE COMPOSITION AND CHARACTERISTICS OF HONEY SHALL BE DETERMINED IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 10.

ARTICLE 10

1. WHERE THE PROCEDURE LAID DOWN IN THIS ARTICLE IS TO BE FOLLOWED, THE MATTER SHALL BE REFERRED TO THE STANDING COMMITTEE ON FOODSTUFFS SET UP BY THE COUNCIL DECISION OF 13 NOVEMBER 1969 (2) (HEREINAFTER CALLED THE "COMMITTEE") BY ITS CHAIRMAN, EITHER ON HIS OWN INITIATIVE OR AT THE REQUEST OF A REPRESENTATIVE OF A MEMBER STATE.

2. THE REPRESENTATIVE OF THE COMMISSION SHALL SUBMIT TO THE COMMITTEE A DRAFT OF THE MEASURES TO BE TAKEN. THE COMMITTEE SHALL GIVE ITS OPINION ON THAT DRAFT WITHIN A TIME LIMIT SET BY THE CHAIRMAN HAVING REGARD TO THE URGENCY OF THE MATTER. OPINIONS SHALL BE DELIVERED BY A MAJORITY OF " fifty-four " **[2]** VOTES, THE VOTES OF THE MEMBER STATES BEING WEIGHTED AS PROVIDED IN ARTICLE 148 (2) OF THE TREATY. THE CHAIRMAN SHALL NOT VOTE.

3. (a) WHERE THE MEASURES ENVISAGED ARE IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE, THE COMMISSION SHALL ADOPT THEM.

(b) WHERE THE MEASURES ENVISAGED ARE NOT IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE OR IF NO OPINION IS DELIVERED, THE COMMISSION SHALL WITHOUT DELAY SUBMIT TO THE COUNCIL A PROPOSAL ON THE MEASURES TO BE TAKEN. THE COUNCIL SHALL ACT BY A QUALIFIED MAJORITY.

(c) IF WITHIN THREE MONTHS OF THE PROPOSAL BEING SUBMITTED TO IT, THE COUNCIL HAS NOT ACTED, THE PROPOSED MEASURES SHALL BE ADOPTED BY THE COMMISSION.

ARTICLE 11

THE PROVISIONS OF ARTICLE 10 SHALL APPLY FOR 18 MONTHS FROM THE DATE ON WHICH THE MATTER WAS FIRST REFERRED TO THE COMMITTEE, UNDER ARTICLE 10 (1).

ARTICLE 12

THIS DIRECTIVE SHALL NOT AFFECT NATIONAL PROVISIONS RELATING TO THE SCALES OF WEIGHTS ACCORDING TO WHICH HONEY MUST BE MARKETED; THE COUNCIL, ON A PROPOSAL FROM THE COMMISSION, SHALL ADOPT THE APPROPRIATE COMMUNITY PROVISIONS BEFORE 1 JANUARY 1979.

ARTICLE 13

THIS DIRECTIVE SHALL NOT APPLY TO PRODUCTS INTENDED FOR EXPORT FROM THE COMMUNITY.

ARTICLE 14

MEMBER STATES SHALL, IF NECESSARY, WITHIN A PERIOD OF ONE YEAR FOLLOWING NOTIFICATION OF THIS DIRECTIVE, AMEND THEIR LAWS IN ACCORDANCE WITH THE PROVISIONS OF THIS DIRECTIVE AND SHALL FORTHWITH INFORM THE COMMISSION THEREOF. THE LAWS THUS AMENDED SHALL APPLY TO THE PRODUCTS OFFERED FOR SALE IN THE MEMBER STATES TWO YEARS AFTER THE NOTIFICATION OF THIS DIRECTIVE.

ARTICLE 15

THIS DIRECTIVE IS ADDRESSED TO THE MEMBER STATES.

ANNEX

COMPOSITIONAL CRITERIA FOR HONEY

1. Apparent reducing sugar content, calculated as invert sugar	
— Blossom honey	not less than 65 %
— Honeydew honey and blends of honeydew honey and blossom honey	not less than 60 %
2. Moisture content	
— In general	not more than 21 %
— Heather honey (Calluna) and clover honey (Trifolium sp.)	not more than 23 %
3. Apparent sucrose content	
— In general	not more than 5 %
— Honeydew honey, and blends of honeydew honey and blossom honey, acacia, lavender and banksia menziesii honeys	not more than 10 %
4. Water-insoluble solids content	
— In general	not more than 0·1 %
— Pressed honey	not more than 0·5 %
5. Mineral content (ash)	
— In general	not more than 0·6 %
— Honeydew honey, and blends of honeydew honey and blossom honey	not more than 1 %
6. Acidity	not more than 40 milli-equivalents acid per 1 000 grammes
7. Diastase activity and hydroxymethylfurtural content (HMF) determined after processing and blending	
(a) *Diastase activity (Schade* scale)	
— In general	not less than 8
— Honeys with low natural enzyme content (e.g. citrus) and a HMF content not more than 15 mg/kg	not less than 3
(b) *HMF*	not more than 40 mg/kg (subject to the provisions of paragraph (a) second indent)

(1) OJ No L 243, 29/10/1971, p. 29.
(2) OJ No L 291, 19/11/1969, p. 9.

FRUIT JUICE

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE 93/77/EEC

of 21 September 1993

relating to fruit juices and certain similar products

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 43 and 100a thereof,

Having regard to the proposal from the Commission,

In cooperation with the European Parliament (1),

Having regard to the opinion of the Economic and Social Committee (2),

Whereas Council Directive 75/726/EEC of 17 November 1975 on the approximation of the laws of the Member States concerning fruit juices and certain similar products (3) has been frequently and substantially amended; whereas for reasons of clarity and rationality the said Directive should be consolidated;

Whereas in order to contribute towards the establishment of a single market for fruit juices and fruit nectars, to lay down conditions of production which take account of consumer requirements and to facilitate trade relations on the basis of fair competition, common rules must be adopted governing composition, use of reserved descriptions, manufacturing specifications and labelling of the products concerned;

Whereas existing differences between national provisions governing these products constitute barriers to free movement and create unfair conditions of competition;

Whereas it is essential to establish manufacturing and labelling rules for juices and nectars intended for direct human consumption and to lay down rules for their raw materials while ensuring that the reserved descriptions in this Directive cannot be abused;

Whereas these provisions should, pursuant to the second paragraph of Article 20 of Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (4), be adapted to the rules laid down in the said Directive;

Whereas, pending the adoption of Community provisions in this field, Member States should, for the time being, be free to lay down rules governing the labelling of products not for sale either to the ultimate consumer or to mass caterers;

Whereas the establishment of the characteristics of the products referred to by this Directive must be capable of being adapted to scientific and technical developments; whereas the adoption thereof should be entrusted to the Commission so as to simplify and expedite the procedure;

Whereas the same applies to the determination of methods of analysis for checking the purity criteria of the additives and processing aid used in the manufacture of fruit juices and nectars and to the determination of the sampling procedure and the methods of analysis required for checking the composition and the manufacturing specifications of these juices and nectars;

(1) OJ No C 305, 23. 11. 1992, p. 109 and Decision of 23 June 1993 (not yet published in the Official Journal).
(2) OJ No C 313, 30. 11. 1992, p. 24.
(3) OJ No L 311, 1. 12. 1975, p. 40. Directive as last amended by Directive 89/394/EEC (OJ No L 186, 30. 6. 1989, p. 14).
(4) OJ No L 33, 8. 2. 1979, p. 1. Directive as last amended by Directive 91/72/EEC (OJ No L 42, 16. 2. 1991, p. 27).

Whereas it is desirable that for all cases where the Community empowers the Commission to implement rules relating to foodstuffs provision should be made for establishing close cooperation between the Member States and the Commission within the Standing Committee on Foodstuffs set up by Decision 69/414/EEC (1);

Whereas in some cases national provisions must be maintained and a review clause applied;

Whereas in particular the conditions governing the possible use of L-Malic and DL-Malic acids in fruit juices and nectars must be examined in the context of more general rules governing the use of certain acids in foodstuffs;

Whereas it has appeared necessary, in view of the production conditions obtaining in certain Member States, to make it possible for such Member States to authorize the addition of citric acid to apple juice;

Whereas it is not possible to extract the juice of certain tropical fruits without the pulp; whereas it therefore appears necessary to provide for the possible use of fruit purée in the manufacture of certain fruit juices;

Whereas the option of replacing all sugars by honey within the limits laid down should be extended to all fruit nectars, and the option of using sugars and honey together in certain nectars should be removed;

Whereas the sweetening of certain concentrated fruit juices should be authorized only if they are intended for direct sale to the consumer, since the sweetening may not exceed the permitted limits at the final stage;

Whereas Member States must be free not to adopt in their entirety the lists of additives and processing aid provided for in this Directive until the identification and purity criteria for these products have been established;

Whereas this Directive must not affect the obligations of the Member States concerning the deadlines for transposal of Directive 75/726/EEC and the Directives that amended it,

HAS ADOPTED THIS DIRECTIVE:

Article 1

For the purposes of this Directive, the following definitions shall apply:

1. *Fruit:*

Fruit, fresh or preserved by chilling, sound, free from deterioration, containing all the essential constituents needed for the production of fruit juices and nectars and of a suitable degree of ripeness. Tomatoes are not regarded as fruit;

2. *Fruit purée:*

The fermentable but unfermented product obtained by sieving the edible part of whole or peeled fruit without removing the juice;

3. *Concentrated fruit purée:*

The product obtained from fruit purée by the physical removal of a specific proportion of its water content;

4. *Sugars:*

(a) For the production of fruit juice

- — semi-white sugar,
- — sugar (white sugar),
- — extra white sugar,
- — dextrose monohydrate,
- — dextrose anhydrous,
- — dried glucose syrup,
- — fructose;

(b) for the production of fruit juice made from concentrated fruit juice and the production of fruit nectar, in addition to the sugars referred to in (a):

- — glucose syrup,
- — sugar solution,
- — invert sugar solution,
- — invert sugar syrup,
- — the aqueous solution of sucrose with the following characteristics:
  - (aa) dry matter: not less than 62 % by weight,
  - (bb) invert sugar content (ratio of fructose to dextrose: 1,0 ± 0,2): not more than 3 % by weight of dry matter,
  - (cc) conductivity ash: not more than 0,3 % by weight of dry matter;
  - (dd) colour in solution: not more than 75 ICUMSA units,
  - (ee) residual sulphur dioxide content: not more than 15 mg/kg of dry matter;

5. *Fruit juice:*

(a) The juice obtained from fruit by mechanical processes, fermentable but unfermented, having the characteristic colour, aroma and flavour typical of the juice from the fruit from which it comes.

(1) OJ No L 291, 19. 11. 1969, p. 9.

In the case of citrus fruits, the fruit juice shall come from the endocarp; lime-juice, however, may be obtained from the whole fruit, by suitable production processes whereby by proportion of constituents of the outer part of the fruit is reduced to a minimum.

(b) The product obtained from concentrated fruit juice by:

— the restoration of the proportion of water extracted from the juice when it was concentrated, the water which is added having the appropriate characteristics, particularly from the chemical, microbiological and organoleptic viewpoints, for guaranteeing the essential qualities of the juice, and

— the restoration of its aroma by means of the volatiles collected during the concentration of the fruit juice in question or from the juice of fruits of the same kind,

and which has organoleptic and analytical characteristics equivalent to those of juice obtained from fruit of the same kind in accordance with (a);

6. *Concentrated fruit juice:*

The product obtained from fruit juice by the physical removal of a specific proportion of the water content. If the product is for direct consumption, the reduction in volume shall not be less than 50 %;

7. *Fruit nectar:*

The unfermented but fermentable product obtained by the addition of water and sugars to fruit juice, concentrated fruit juice, fruit purée, concentrated fruit purée or to a mixture of these products which also conforms with Annex I.

However, it may be decided under the procedure laid down in Article 15 that, in the case of certain fruits whose juice has a high natural sugar content, nectar may be produced from them without the addition of sugars;

8. *Dried fruit juice:*

The product obtained from fruit juice by the physical removal of almost all the water content.

Article 2

1. Member States shall take all measures necessary to ensure that the products referred to in Article 1 (5) to (8) may be marketed only if they conform to the definitions and rules laid down in this Directive.

2. Articles 4 to 13 shall apply only to fruit juice, concentrated fruit juice, fruit nectar and dried fruit juice intended for direct consumption, concentrated fruit juice used for the production of fruit juice or nectar intended for direct consumption and fruit juice used for the production of fruit nectar intended for direct consumption.

Article 3

1. The descriptions referred to in Article 1 (5) to (8) shall be reserved for the products defined therein and, without prejudice to Article 10 (2) (a), must be used in trade to describe them.

2. The use of the following descriptions shall also be reserved:

(a) 'Vruchtendrank', for fruit nectars;

(b) 'Süßmost', for fruit nectars obtained exclusively from fruit juices, concentrated fruit juices or a mixture of these products inedible in the natural state because of their high natural acidity;

(c) — 'succo e polpa', for fruit nectars obtained exclusively from fruit purée and/or concentrated fruit purée,

— 'sumo e polpa' for fruit nectars obtained exclusively from fruit juice and fruit purée and/or concentrated fruit purée;

(d) 'æblemost', for apple juice with no added sugars;

(e) 'Sur ... saft', together with the name (in Danish) of the fruit used, for juices with no added sugars and obtained from blackcurrants, cherries, redcurrants, whitecurrants, raspberries, strawberries or elderberries.

3. If the product comes from a single variety of fruit, the name of the latter shall be substituted for the word 'fruit' or shall accompany any descriptions not containing the word 'fruit'.

4. Paragraph 1 shall not prevent the expressions 'sød ... saft' or 'sødet ... saft', together with the name of fruit used, from being employed in Denmark to describe a product consisting of:

— juices obtained from blackcurrants, cherries, redcurrants, whitecurrants, raspberries, strawberries or elderberries and,

— added sugars in a quantity exceeding 200 grams per litre,

provided that the quantity of added sugars and the conditions of use of the product are shown.

Article 4

1. Only the following shall be authorized for the production of fruit juices:

(a) the mixing of one or more kinds of fruit juices and/or fruit purées;

(b) treatment with:

— L-Ascorbic acid (E 300) in the amount necessary to produce an anti-oxidant effect,

— nitrogen,

— carbon dioxide (E 290),

— pectolytic enzymes,

— proteolytic enzymes,

— amylolytic enzymes,

— edible gelatine,

— tannins,

— bentonite,

— silica aerogel,

— kaolin,

— charcoal,

— inert filtration adjuvants (perlite, asbestos, washed diatomite, cellulose, insoluble polyamide);

(c) the usual physical processes and treatments such as heat treatments, centrifuging and filtering; the use of some of these processes and treatments may be restricted or prohibited by the Council acting unanimously on a proposal from the Commission.

2. The following shall also be authorized:

(a) in the case of fruit juices other than pear and grape the addition of sugars in accordance with the following conditions:

(i) in a quantity, expressed as dry matter, not greater than 15 grams per litre of juice, in order to correct them;

(ii) in a quantity, expressed as dry matter, not greater than:

— 40 grams per litre of juice in the case of apple juice, although this addition may be prohibited by Member States,

— 200 grams per litre of juice in the case of lemon, lime, bergamot, and red, white and blackcurrant juices,

— 100 grams per litre of juice in other cases,

for the purpose of sweetening;

(b) in the case of grape juice:

— treatment with:

— sulphur dioxide (E 220),

— sodium sulphite (E 221),

— acid sodium sulphite (sodium bisulphite) (E 222),

— sodium disulphite (sodium pyrosulphite or sodium metabisulphite (E 223),

— potassium disulphite (potassium pyrosulphite or potassium metabisulphite) (E 224),

— calcium sulphite (E 226) and

— acid calcium sulphite (calcium bisulphite) (E 227),

— provided that the total amount of these substances expressed as sulphur dioxide in the juice, as sold or delivered to the consumer, is not greater than 10 mg per litre of juice:

— desulphiting by physical processes,

— clarification by means of casein, white of egg and other animal albumins,

— partial deacidification by means of neutral potassium tartrate, or calcium carbonate to which may be added small quantities of double calcium salt of D-Tartaric and L-Malic acids;

(c) in the case of pineapple juice, the addition of citric acid (E 330) in a quantity not greater than 3 grams per litre.

3. The addition of both sugars and acid to the same fruit juice shall be prohibited.

4. If more than one acid is added to the same fruit juice or nectar, the sum of the quantities of each of the acids added, expressed as a percentage of the maximum authorized quantity, must not exceed 100.

Article 5

Except where otherwise provided for in this Directive, the sulphur dioxide content of a fruit juice, as determined by analysis, shall not exceed 10 mg per litre of juice.

Article 6

1. Only the following shall be authorized in the production of fruit nectars:

(a) the mixing of one or more kinds of fruit nectars, with a possible admixture of fruit juice or fruit purée;

(b) the treatments and processes listed in Article 4 (1) (b) and (c).

2. The following shall also be authorized:

(a) the addition of sugars in a quantity not greater than 20 % by weight of the total weight of the finished product;

(b) the addition of water in a quantity such that the fruit juice and/or fruit purée content and the total acidity of the finished product are ot lower than the levels specified in Annex I; in the case of a mixed fruit nectar the juice and/or purée content and the total acidity shall be proportional to the levels specified in Annex I;

(c) the total replacement of sugars with honey, within the 20 % limit specified in (a);

(d) in the case of the production of the fruit nectars referred to in Article 3 (2) (c) which are obtained from apples, pears or peaches or a mixture of these fruits, the addition of citric acid in a quantity not greater than give grams per litre of finished product; the citric acid may, however, be replaced totally or partially by an equivalent quantity of lemon juice.

Article 7

Only the following shall be permitted in the manufacture of concentrated fruit juices:

(a) the treatments and processes listed in Article 4 with the exception of the provisions in paragrahs 2 (a). However, the addition of sugars provided for in that point (a) shall be authorized only for prepackaged concentrated fruit juices intended for the ultimate consumer and provided that the sweetening is indicated in the description; in that case the total quantity of sugars added expressed in relation to the volume of the juice 'obtained from concentrated ...' may not exceed the limit authorized in Article 4 (2) (a).

For a period of 10 years from 14 June 1989, sugar may be added to concentrated orange juice not intended for the ultimate consumer up to a maximum quantity expressed as dry matter of 15 grams per litre for the purpose of correcting it.

In the case referred to in the second subparagraph the processor must be informed of the addition of sugar, in accordance with trade practices.

On expiry of the period referred to in the second subparagraph, the Council shall decide, acting on a proposal from the Commission, whether to continue the exception in the said subparagraph;

(b) the partial dehydration of the fruit juice by a physical treatment or process other than direct flame; the use of certain treatments or processes may be restricted or prohibited by the Council acting unanimously on a proposal from the Commission;

(c) restoration of their aroma by means of the volatiles collected during the concentration of the basic fruit juice or from the juice of fruit of the same kind; the addition of such volatiles shall be obligatory for concentrated fruit juices which are intended for direct consumption.

Article 8

In the manufacture of dried fruit juice the almost total dehydration of fruit juice by a physical treatment or process other than direct flame shall also be authorized; restoration of the essential volatiles from fruits of the same kind, or possibly recovered during dehydration, shall be compulsory.

Article 9

The treatments and processes referred to in Articles 4, 6, 7 and 8 must not result in any substance being allowed to remain in the products treated in quantities which may be dangerous to human health.

Article 10

1. Directive 79/112/EEC shall apply to the products defined in Article 1 (5) to (8), in accordance with the conditions set out in this Article.

2. (a) The names under which the products defined in Article 1 (5) to (8) are sold shall be the name reserved for them pursuant to Article 3 (1), (2) and (3).

However:

(i) the use of the description 'fruit nectar' may be made optional by Member States for one or more of the products referred to in Article 3 (2) where the descriptions listed therein are used to designate these products;

(ii) for the product defined in Article 1 (8), the adjective 'dried' may be replaced by the adjective 'powdered' and may be accompanied or replaced by particulars of the specific process used (eg freeze-dried or any other similar reference);

(b) The names under which they are sold shall be supplemented:

(i) for products manufactured from two or more kinds of fruit, except as regards the use of lemon juice in accordance with Article 6 (2) (d), by a list of the fruits used, in descending order of the weight of the fruit juices or purées included, where appropriate after restoration; the use of the term 'fruit' shall be optional in this case;

(ii) the products with sugar added within the limits laid down in Article 4 (2) (a) (ii), by the description 'sweetened', followed by an indication of the maximum quantity of sugars added, calculated as dry matter and expressed as grams per litre; the quantity indicated may not exceed the actual quantity added by more than 15 %;

(iii) for the fruit nectars referred to in Article 3 (2) (c) which are not designated by the description 'succo e polpa' alone, in accordance with the national provisions referred to in point (a) (i), by the description 'contains fruit pulp' or an equivalent description.

3. An obligation to declare the list of ingredients shall apply, subject to the following:

(a) (i) the restoration to its original state, by means of the substances strictly necessary for this operation:

— of fruit juice from a concentrated fruit juice,

— of a fruit purée from concentrated fruit purée;

(ii) the restoration of the flavour:

— to concentrated fruit juice,

— to dried fruit juice,

shall not involve an obligation to declare the list of the ingredients used for this purpose;

(b) The substances listed in the first indent of Article 4 (2) (b) shall not be considered as ingredients of one of the products defined in Article 1 (5) to (8) where the sulphur dioxide content of these products, as determined by analysis, does not exceed 10 mg per litre.

4. Indication of the following particulars shall also be compulsory on the labelling of the products defined in Article 1 (5) to (8):

(a) for fruit juice and nectar obtained wholly or partially from a concentrated product, the declaration 'contains ... made from concentrate', plus the name of the concentrated product used; this declaration shall appear in the immediate vicinity of the product name, standing out prominently in bold lettering;

(b) for the products defined in Article 1 (5), (6) and (7), the carbon dioxide content of which is greater than 2 grams per litre, the description 'carbonated';

(c) for concentrated fruit juice and dried fruit juice, an indication of the quantity of water to be added to restore the product;

(d) for fruit nectars, the actual minimum content of fruit juice, fruit purée or mixture of these ingredients, by the declaration 'fruit content: ... % minimum'.

5. The particulars referred to in paragraph 4 (a), (b) and (d) shall appear in the same field of vision of those referred to in Article 11 (3) (a) of Directive 79/112/EEC.

6. The addition of L-ascorbic acid as provided for in Article 4 (1) (b) shall not authorize any reference to Vitamin C.

Article 11

Without prejudice to the provisions to be adopted by the Community in this field, Member States shall remain free to determine the labelling rules for the products referred to in Article 2 (2) which are not to be delivered as such to the ultimate consumer or to mass caterers.

Article 12

The amendments necessary to adapt Articles 4, 6, 7 and 8 and Annex I to technical progress shall be adopted in accordance with the procedure laid down in Article 15, with the exception of those concerning additives.

Article 13

1. Member States shall adopt all the measures necessary to ensure that trade in the products defined in Article 1 (5) to (8) which comply with the rules laid down in this Directive cannot be impeded by the application of national non-harmonized provisions governing the composition, manufacturing specifications, packaging or labelling of these products in particular or of food stuffs in general.

2. Paragraph 1 shall not apply to non-harmonized provisions justified on grounds of:

— protection of public health,

— fraud prevention, unless such provisions are liable to impede the application of the definitions and rules laid down by this Directive,

— protection of industrial and commercial property, of indications of source, appellation of origin and the prevention of unfair competition.

Article 14

The identity and purity criteria for the additives and treatment agents referred to in Articles 4 and 6 shall be determined where necessary in accordance with the procedure laid down in Article 15.

Article 15

1. Where the procedure laid down in this Article is to be followed, the chairman shall refer the matter to the Standing Committee for Foodstuffs, either on his own initiative or at the request of the representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

(b) If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 16

1. This Directive shall not affect national provisions whereby:

(a) the vitaminization of the products covered by this Directive is authorized;

(b) processes of diffusion may be authorized for the manufacture of fruit juices other than grape, citrus fruit, pineapple, pear, peach and apricot intended for the manufacture of concentrated fruit juices, provided that the concentrated juices thus obtained comply with the conditions laid down in Article 1 (5) regarding fruit juices obtained from concentrated fruit juices and have organoleptic and analytical characteristics at least equivalent to those of concentrated juices obtained by mechanical processes;

(c) — the substances referred to in the first indent of Article 4 (2) (b) may be added to pineapple, apple, orange and grapefruit juices on condition that the total quantity added, expressed as sulphur dioxide, does not exceed 50 mg per litre;

— the substances referred to in the first indent of Article 4 (2) (b) may be added to lemon and lime juices on condition that the total quantity added, expressed as sulphur dioxide, does not exceed 350 mg per litre;

(d) dimethylpolysiloxane may be used in pineapple juice up to a maximum of 10 mg per litre;

(e) up to 5 grams per litre of lactic acid may be added to the fruit nectar referred to in Article 1 (7), where this is obtained from apples or pears or from a mixture of these fruits;

(f) up to 3 grams per litre of citric acid may be added to:

— grape juice, subject to such addition being authorized up to and including 19 November 1975,

— apple juice;

(g) up to 3 grams per litre, either singly or combined, of L and DL Malic acids may be added to pineapple juice and to the fruit nectars referred to in Article 3 (2) (c) if they are obtained from pears or peaches, subject to such addition being authorized up to and including 19 November 1975.

2. The exceptions regarding additives provided for in paragraph 1 (c), (d), (e), (f) and (g) shall cease to apply once the relevant rules become applicable at Community level.

Article 17

This Directive shall not apply to:

(a) products intended for export from the Community;

(b) foodstuffs for particular nutritional uses.

Article 18

Member States may postpone implementation of Article 4 (1) (b), Article 4 (2) (b) last indent and Article 6 (1) (b) until the identification and purity criteria are laid down under Article 14.

Article 19

1. Directive 75/726/EEC, including Directives which amended it (1), is hereby repealed without prejudice to the obligations of the Member States concerning the deadlines for transposal of such Directives set out in Annex II.

2. References to the repealed Directive shall be construed as references to this Directive and should be read in accordance with the correlation table in Annex III.

Article 20

This Directive is addressed to the Member States.

Done at Brussels, 21 September 1993.

For the Council

The President

A. BOURGEOIS

(1) Directives 79/168/EEC, 81/487/EEC and 89/394/EEC.

ANNEX I

SPECIAL PROVISIONS RELATING TO FRUIT NECTARS

Fruit nectars made from	Minimum total acid concreat expressed as tartaric acid (g/l of finished product)	Minimum juice and/or purée content (% by weight of finished product)
I. Fruits with aid juice unpalatable in the natural state		
Passion fruit *(Passiflora edulis)*	8	25
Quito naranjillos *(Solanum quitoense)*	5	25
Blackcurrants	8	25
Whitecurrants	8	25
Redcurrants	8	25
Gooseberries	9	30
Sallow-thorn berries *(Hippophae)*	9	25
Sloes	8	30
Plums	6	30
Quetsches	6	30
Rowanberries	8	30
Rose hips *(fruits of Rosa sp.)*	8	40
Sour cherries	8	35
Other cherries	6 (1)	40
Bilberries	4	40
Elderberries	7	50
Raspberries	7	40
Apricots	3 (1)	40
Strawberries	5 (1)	40
Mulberries/blackberries	6	40
Cranberries	9	30
Quinces	7	50
Lemons and limes	—	25
Other fruits belonging to this category	—	25
II. Low-acid, pulpy or highly flavoured fruits with juice unpalatable in the natural state		
Mangos	—	35
Bananas	—	25
Guavas	—	25
Papayas	—	25
Lychees	—	25
Azeroles (Neapolitan medlars)	—	25
Soursop *(Annona muricata)*	—	25
Bullock's heart or custard apple *(Annona reticulata)*	—	25
Sugar apples	—	25
Pomegranates	—	25
Cashew fruits	—	25
Spanish plums *(Spondia purpurea)*	—	25
Umbu *(Spondia tuberosa aroda)*	—	30
Other fruits belonging to this category	—	25
III. Fruits with juice palatable in the natural state		
Apples	3 (1)	50
Pears	3 (1)	50
Peaches	3 (1)	45
Citrus fruits except lemons and limes	5	50
Pineapples	4	50
Other fruits belonging to this category	—	50

(1) Limit not applicable in the case of the product referred to in Article 3 (2) (c).

ANNEX II

TIME LIMITS FOR TRANSPOSAL

Directive	Deadlines	
	To permit trade in those products which comply with this Directive	To prohibit trade in those products which do not comply with this Directive
75/726/EEC (OJ No L 311, 1. 12. 1975, p. 40)	18 November 1977	19 November 1978
79/168/EEC (OJ No L 37, 13. 2. 1979, p. 27)		19 November 1981 (*)
81/487/EEC (OJ No L 189, 11. 7. 1981, p. 43)	1 July 1983	1 July 1984
89/394/EEC (OJ No L 186, 30. 6. 1989, p. 14)	14 June 1990	14 June 1991

(*) This time limit may be extended to four years by the Member States (19 November 1982).

ANNEX III

CORRELATION TABLE

This Directive	Directive 75/726/EEC
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3
Article 4	Article 4
—	Article 5
Article 5	Article 6 first subparagraph
—	Article 6 second subparagraph
Article 6	Article 7
Article 7	Article 8
Article 8	Article 9
Article 9	Article 10
Article 10	Article 11
Article 11	Article 11 a
Article 12	Article 11 b
Article 13	Article 12
Article 14	Article 13
Article 15	Article 14
Article 16 (1) (f)	Article 16 (1) (g)
Article 16 (1) (g)	Article 16 (1) (h)
Article 17	Article 17
—	Article 18 (1) and (2)
Article 18	Article 18 (3)
Article 19	—
Article 20	Article 19
Annex I	Annex

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DIRECTIVE 93/45/EEC

of 17 June 1993

concerning the manufacture of nectars without the addition of sugars or honey

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 75/726/EEC of 17 November 1975 on the approximation of the laws of the Member States concerning fruit juices and certain similar products (1), as last amended by Directive 89/394/EEC (2). and in particular Article 1 (7) (b) thereof, which provides that in the case of certain fruits whose juice has a high natural sugar content, nectar may be produced from them without the addition of sugars,

Whereas the fruits listed in points II and III of the Annex to Directive 75/726/EEC, and apricots, can have a naturally high sugar content and thus fall into the category in question;

Whereas, therefore, when the conditions are met, it is appropriate to authorize the production of nectars without the addition of sugars or honey;

Whereas, in view of the scope and effects of the action envisaged, the Community measures laid down by this Directive are not only necessary but also indispensable to the achievement of the objectives set; whereas these objectives cannot be achieved by the Member States individually; whereas, moreover, such Community level objectives are already set out in Directive 75/726/EEC;

Whereas the list laid down by this Directive is in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The fruits set out in points II and III of the Annex to Directive 75/726/EEC, and apricots, can be used, individually or mixed together, to manufacture nectars without the addition of sugars or honey where their naturally high sugar content so warrants.

Article 2

1. Member States shall take the necessary legislative, regulatory and administrative measures to comply with this Directive no later than 31 December 1993.

They shall forthwith inform the Commission thereof.

2. When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 17 June 1993.

For the Commission

Martin BANGEMANN

Member of the Commission

(1) OJ No L 311, 1. 12. 1975, p. 40.
(2) OJ No L 186, 30. 6. 1989, p. 14.

FRUIT JAMS

379L0693

79/693/EEC: COUNCIL DIRECTIVE OF 24 JULY 1979 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO FRUIT JAMS, JELLIES AND MARMALADES AND " SWEETENED CHESTNUT PURÉE " [3]

OFFICIAL JOURNAL NO L 205, 13/08/1979, P. 5
DATE OF NOTIFICATION: 27/07/1979
DATE OF TRANSPOSITION: 27/07/1981; SEE ART. 17
DATE OF TRANSPOSITION: 27/07/1982; SEE ART. 17

AMENDED BY

380L1276
80/1276/EEC: COUNCIL DIRECTIVE OF 22 DECEMBER 1980 **[1]**
OFFICIAL JOURNAL NO L 375, 31/12/1980, P. 77
DATE OF NOTIFICATION: 31/12/1980

185I
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE KINGDOM OF SPAIN AND THE PORTUGUESE REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES **[2]**
OFFICIAL JOURNAL NO L 302, 15/11/1985, P. 217

388L0593
88/593/EEC: COUNCIL DIRECTIVE OF 18 NOVEMBER 1988 **[3]**
OFFICIAL JOURNAL NO L 318, 25/11/1988, P. 44
DATE OF NOTIFICATION: 28/11/1988
DATE OF TRANSPOSITION: 31/12/1989; SEE ART. 2
DATE OF TRANSPOSITION: 01/01/1991; SEE ART. 2

ARTICLE 1

THIS DIRECTIVE SHALL APPLY TO:

1. EXTRA JAM;

2. JAM;

3. EXTRA JELLY;

4. JELLY;

5. MARMALADE;

6. " sweetened chestnut purée " **[3]**; AS THESE PRODUCTS ARE DEFINED IN ANNEX I.

ARTICLE 2

MEMBER STATES SHALL TAKE ALL THE NECESSARY STEPS TO ENSURE THAT THE PRODUCTS DEFINED IN ANNEX I MAY BE MARKETED ONLY IF THEY CONFORM TO THE DEFINITIONS AND RULES LAID DOWN IN THIS DIRECTIVE.

ARTICLE 3

1. THE NAMES LISTED IN ANNEX I SHALL BE USED EXCLUSIVELY TO DENOTE THE PRODUCTS DEFINED THEREIN AND IN SO FAR AS THEIR SOLUBLE DRY MATTER CONTENT IS NOT LESS THAN 60% AS DETERMINED BY REFRACTOMETER.

2. MEMBER STATES MAY ALSO ALLOW THE USE IN THEIR TERRITORY OF THE NAMES LISTED IN ANNEX I FOR PRODUCTS WITH A SOLUBLE DRY MATTER CONTENT OF LESS THAN 60% WHICH COMPLY WITH THE OTHER PROVISIONS OF THIS DIRECTIVE WITH THE EXCEPTION OF THOSE PRESCRIBED IN ANNEX III (B).

" BEFORE 1 JANUARY 1991 THE COUNCIL, ACTING ON A PROPOSAL FROM THE COMMISSION, SHALL DECIDE ON RULES CONCERNING THE COMMUNITY NAMES APPLICABLE TO SUCH PRODUCTS. " **[3]**

3. THE NAMES LISTED IN ANNEX I (A) (2) AND (4) MAY ALSO BE USED TO DESIGNATE THE PRODUCTS DEFINED IN PARAGRAPHS 1 AND 3 OF THAT SECTION.

4. THIS ARTICLE SHALL NOT AFFECT THE PROVISIONS BY WHICH THE NAME "JELLY" MAY, IN ACCORDANCE WITH CUSTOM, ALSO BE USED TO DESIGNATE OTHER PRODUCTS WHICH CANNOT BE CONFUSED WITH THOSE DEFINED IN ANNEX I.

ARTICLE 4

ONLY RAW MATERIALS CORRESPONDING TO THE DEFINITIONS GIVEN IN ANNEX II MAY BE USED IN THE MANUFACTURE OF THE PRODUCTS DEFINED IN ANNEX I.

ARTICLE 5

ONLY THE SUBSTANCES LISTED IN ANNEX III MAY BE ADDED, AND ONLY IN THE MANNER PRESCRIBED THEREIN, TO THE PRODUCTS DEFINED IN ANNEX I.

ARTICLE 6

1. PRODUCTS DEFINED IN ANNEX I MAY NOT CONTAIN ANY SUBSTANCE IN SUCH QUANTITY AS TO ENDANGER HUMAN HEALTH.

2. PRODUCTS DEFINED IN ANNEX I MAY NOT, IN PARTICULAR, CONTAIN SULPHUR DIOXIDE IN AMOUNTS EXCEEDING THE LIMITS FIXED IN ANNEX IV.

ARTICLE 7

1. (a) THE NAME UNDER WHICH A PRODUCT DEFINED IN ANNEX I IS SOLD SHALL BE THE SAME AS THAT USED BY VIRTUE OF ARTICLE 3.

(b) THIS NAME SHALL BE SUPPLEMENTED BY:

(i) AN INDICATION OF THE TYPE OR TYPES OF FRUIT USED IN DESCENDING ORDER OF IMPORTANCE BY WEIGHT OF THE RAW MATERIALS USED; HOWEVER, FOR PRODUCTS MADE FROM THREE OR MORE TYPES OF FRUIT, THE INDICATION OF THE TYPES OF FRUIT USED MAY BE REPLACED BY THE WORDS "MIXED FRUIT" OR BY AN INDICATION OF THE NUMBER OF TYPES OF FRUIT USED;

(ii) AN INDICATION OF THE INGREDIENTS GIVEN IN ANNEX III (A) (2).

2. (a) WHERE APRICOTS INTENDED FOR THE MANUFACTURE OF THE PRODUCT DEFINED IN ANNEX I (A) (2) HAVE BEEN DRIED BY A PROCESS OTHER THAN FREEZE-DRYING, THE WORDS "DRIED APRICOTS" SHALL APPEAR ON THE LIST OF INGREDIENTS.

(b) WHERE RED BEETROOT JUICE HAS BEEN ADDED TO THE PRODUCTS DEFINED IN ANNEX I (A) (2) AND (4) WHICH HAVE BEEN OBTAINED FROM ONE OR MORE OF THE FOLLOWING: STRAWBERRIES, RASPBERRIES, GOOSEBERRIES, REDCURRANTS OR PLUMS, THE WORDS "RED BEETROOT JUICE TO REINFORCE THE COLOUR" SHALL APPEAR IN THE LIST OF INGREDIENTS.

(c) IN THE CASE OF PRODUCTS MADE FROM THREE OR MORE TYPES OF FRUIT, MEMBER STATES MAY ALLOW THE NAMING IN THE LIST OF INGREDIENTS OF THE TYPES OF FRUIT USED TO BE REPLACED BY THE SINGLE WORD "FRUIT".

(d) " WHERE THE RESIDUAL SULPHUR DIOXIDE CONTENT IS MORE THAN 30 mg/kg, THE WORDS "SULPHUR DIOXIDE" SHALL APPEAR IN THE LIST OF INGREDIENTS, ACCORDING TO THE PERCENTAGE BY WEIGHT OF THE RESIDUE IN THE FINISHED PRODUCT. " **[3]**

3. THE LABELLING OF THE PRODUCTS DEFINED IN ANNEX I SHALL ALSO BEAR THE FOLLOWING OBLIGATORY INFORMATION:

(a) THE WORDS "PREPARED WITH ... g OF FRUIT PER 100 g", THE FIGURE SHOWN REPRESENTING THE QUANTITIES PER 100 g OF FINISHED PRODUCT FOR WHICH THE FOLLOWING HAVE BEEN USED:

- PULP, PUREE, JUICE AND AQUEOUS EXTRACTS IN THE MANUFACTURE OF THE PRODUCTS DEFINED IN ANNEX I (A) (1), (2), (3), (4) AND (6), IF APPLICABLE, AFTER DEDUCTION OF THE WEIGHT OF WATER USED IN PREPARING THE AQUEOUS EXTRACTS,
- CITRUS FRUIT USED IN THE MANUFACTURE OF THE PRODUCT DEFINED IN ANNEX I (A) (5);

(b) " THE WORDS "TOTAL SUGAR CONTENT:... g PER 100 g", THE FIGURE SHOWN REPRESENTING THE VALUE DETERMINED BY REFRACTOMETER AT 20 °C FOR THE FINISHED PRODUCT, SUBJECT TO A TOLERANCE OF +/- 3 REFRACTOMETRIC DEGREES. " **[3]**

(c) FOR PRODUCTS HAVING A SOLUBLE DRY MATTER CONTENT OF LESS THAN 63 % THE WORDS "KEEP IN A COOL PLACE ONCE OPENED"; THIS INDICATION SHALL NOT, HOWEVER, BE COMPULSORY FOR PRODUCTS IN SMALL CONTAINERS, THE CONTENT OF WHICH IS NORMALLY CONSUMED AT ONE TIME AND FOR PRODUCTS TO WHICH PRESERVATIVES HAVE BEEN ADDED;

(d) IN THE CASE OF THE PRODUCT DEFINED IN ANNEX I (A) (5):

- CONTAINING PEEL, AN INDICATION OF THE STYLE OF CUT OF THAT PEEL,
- NOT CONTAINING PEEL, AN INDICATION OF THE ABSENCE OF PEEL.

4. THE PARTICULARS REFERRED TO IN PARAGRAPH 3 MUST APPEAR WITHIN THE SAME FIELD OF VISION AS THOSE REFERRED TO IN ARTICLE 11 (3) (a) OF DIRECTIVE 79/112/EEC (1).

5. THE ADDITION OF L-ASCORBIC ACID BY VIRTUE OF ARTICLE 5 AND ANNEX III (B) SHALL NOT AUTHORIZE REFERENCE TO BE MADE TO VITAMIN C.

ARTICLE 8

WITHOUT PREJUDICE TO THE PROVISIONS TO BE ADOPTED BY THE COMMUNITY IN THIS FIELD, MEMBER STATES SHALL BE FREE TO DETERMINE THE RULES GOVERNING THE LABELLING OF THE PRODUCTS WHICH ARE DEFINED IN ANNEX I AND WHICH ARE NOT INTENDED FOR SUPPLY AS SUCH TO THE FINAL CONSUMER.

" ARTICLE 8a

THE AMENDMENTS NECESSARY TO ADAPT THE ANNEXES TO TECHNICAL PROGRESS SHALL BE ADOPTED IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 13, WITH THE EXCEPTION OF THOSE CONCERNING ADDITIVES. " **[3]**

ARTICLE 9

1. MEMBER STATES MAY NOT PROHIBIT TRADE IN PRODUCTS DEFINED IN ANNEX I WHICH COMPLY WITH THE DEFINITIONS AND RULES LAID DOWN IN THIS DIRECTIVE, IN PARTICULAR BY THE APPLICATION OF NON-HARMONIZED NATIONAL PROVISIONS GOVERNING THE COMPOSITION, MANUFACTURING SPECIFICATIONS, PACKAGING OR LABELLING OF THESE PRODUCTS OR OF FOODSTUFFS IN GENERAL.

2. PARAGRAPH 1 SHALL NOT APPLY TO NON-HARMONIZED NATIONAL PROVISIONS JUSTIFIED ON GROUNDS OF:

- PROTECTION OF PUBLIC HEALTH,
- PREVENTION OF FRAUD, UNLESS SUCH PROVISIONS ARE LIABLE TO IMPEDE THE APPLICATION OF THE DEFINITIONS AND RULES LAID DOWN BY THIS DIRECTIVE,
- PROTECTION OF INDUSTRIAL AND COMMERCIAL PROPERTY RIGHTS, INDICATIONS OF SOURCE, REGISTERED DESIGNATION OF ORIGIN AND PREVENTION OF UNFAIR COMPETITION.

ARTICLE 10

1. WHERE A MEMBER STATE, AS A RESULT OF NEW INFORMATION OR OF A RE-ASSESSMENT OF EXISTING INFORMATION MADE SINCE THIS DIRECTIVE WAS ADOPTED, HAS DETAILED GROUNDS FOR ESTABLISHING THAT THE USE, IN THE PRODUCTS DEFINED IN ANNEX I, OF ONE OF THE SUBSTANCES LISTED IN ANNEX III (A) (2) (b), SECOND INDENT, (2) (c) AND (B) AND ANNEX IV OR WHERE THE MAXIMUM LEVEL WHICH MAY BE EMPLOYED ENDANGERS HUMAN HEALTH ALTHOUGH IT COMPLIES WITH THIS DIRECTIVE, THAT MEMBER STATE MAY TEMPORARILY SUSPEND OR RESTRICT APPLICATION OF THE PROVISIONS IN QUESTION IN ITS TERRITORY. IT SHALL IMMEDIATELY INFORM THE OTHER MEMBER STATES AND THE COMMISSION THEREOF AND GIVE REASONS FOR ITS DECISION.

2. THE COMMISSION SHALL EXAMINE AS SOON AS POSSIBLE THE GROUNDS GIVEN BY THE MEMBER STATE CONCERNED, AND CONSULT THE MEMBER STATES WITHIN THE STANDING COMMITTEE FOR FOODSTUFFS, AND SHALL THEN DELIVER ITS OPINION FORTHWITH AND TAKE THE APPROPRIATE MEASURES.

3. IF THE COMMISSION CONSIDERS THAT AMENDMENTS TO THIS DIRECTIVE ARE NECESSARY IN ORDER TO RESOLVE THE DIFFICULTIES MENTIONED IN PARAGRAPH 1 AND TO ENSURE THE PROTECTION OF HUMAN HEALTH, IT SHALL INITIATE THE PROCEDURE LAID DOWN IN ARTICLE

13, WITH A VIEW TO ADOPTING THESE AMENDMENTS; THE MEMBER STATE WHICH HAS ADOPTED SAFEGUARD MEASURES MAY IN THAT EVENT RETAIN THEM UNTIL THE AMENDMENTS ENTER INTO FORCE.

ARTICLE 11

" THE IDENTITY AND PURITY CRITERIA FOR PRODUCTS AND SUBSTANCES APPEARING IN ANNEXES II (B) AND III (B) SHALL BE DETERMINED WHERE NECESSARY IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 13. " **[3]**

ARTICLE 12

"..." **[3]**

ARTICLE 13

" 1. WHERE THE PROCEDURE LAID DOWN IN THIS ARTICLE IS TO BE FOLLOWED, THE CHAIRMAN SHALL REFER THE MATTER TO THE STANDING COMMITTEE FOR FOODSTUFFS EITHER ON HIS OWN INITIATIVE OR AT THE REQUEST OF THE REPRESENTATIVE OF A MEMBER STATE.

2. THE REPRESENTATIVE OF THE COMMISSION SHALL SUBMIT TO THE COMMITTEE A DRAFT OF THE MEASURES TO BE TAKEN. THE COMMITTEE SHALL DELIVER ITS OPINION ON THE DRAFT WITHIN A TIME LIMIT WHICH THE CHAIRMAN MAY LAY DOWN ACCORDING TO THE URGENCY OF THE MATTER. THE OPINION SHALL BE DELIVERED BY THE MAJORITY LAID DOWN IN ARTICLE 148 (2) OF THE TREATY IN THE CASE OF DECISIONS WHICH THE COUNCIL IS REQUIRED TO ADOPT ON A PROPOSAL FROM THE COMMISSION. THE VOTES OF THE REPRESENTATIVES OF THE MEMBER STATES WITHIN THE COMMITTEE SHALL BE WEIGHTED IN THE MANNER SET OUT IN THAT ARTICLE. THE CHAIRMAN SHALL NOT VOTE.

3. (a) THE COMMISSION SHALL ADOPT THE MEASURES ENVISAGED IF THEY ARE IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE.

(b) IF THE MEASURES ENVISAGED ARE NOT IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE, OR IF NO OPINION IS DELIVERED, THE COMMISSION SHALL, WITHOUT DELAY, SUBMIT TO THE COUNCIL A PROPOSAL RELATING TO THE MEASURES TO BE TAKEN. THE COUNCIL SHALL ACT BY A QUALIFIED MAJORITY.
IF, ON THE EXPIRY OF THREE MONTHS FROM THE DATE OF REFERRAL TO THE COUNCIL, THE COUNCIL HAS NOT ACTED, THE PROPOSED MEASURES SHALL BE ADOPTED BY THE COMMISSION. " **[3]**

ARTICLE 14

"..." **[3]**

ARTICLE 15

1. THIS DIRECTIVE SHALL NOT AFFECT NATIONAL PROVISIONS WHEREBY THE FOLLOWING MAY BE AUTHORIZED FOR THE MANUFACTURE OF THE PRODUCTS DEFINED IN ANNEX I:

(a) THE ADDITION OF THE FOLLOWING SUBSTANCES:

(i) MALIC ACID AND ITS SODIUM AND CALCIUM SALTS ACCORDING TO PROPER MANUFACTURING PRACTICE;

(ii) - CALCIUM CARBONATE, CALCIUM CHLORIDE AND CALCIUM GLUCONATE, USED EITHER SEPARATELY OR IN COMBINATION AT NOT MORE THAN 200 mg/kg EXPRESSED AS CALCIUM,
- SODIUM CARBONATE, SODIUM BICARBONATE AND SODIUM HYDROXIDE,
- PHOSPHORIC ACID;

(iii) - PRESERVATIVES, WHERE THE SOLUBLE DRY MATTER CONTENT IS LESS THAN 65 %,
- COLOURING MATTERS; IN THE CASE OF THE PRODUCTS DEFINED IN ANNEX I (A) (1) AND (3) THIS AUTHORIZATION MAY HOWEVER BE GIVEN ONLY WHERE THE PRODUCTS ARE MANUFACTURED FROM ONE OR MORE OF THE FOLLOWING TYPES: STRAWBERRIES, RASPBERRIES, GOOSEBERRIES, REDCURRANTS AND PLUMS,
- ALGINATE AND CARRAGEENAN AT NOT MORE THAN 10 g/kg (SEPARATELY OR IN COMBINATION) AND CAROB MEAL AT NOT MORE THAN 20 g/kg,
- DIMETHYLPOLYSILOXANE AT NOT MORE THAN 10 mg/kg,
- SORBITAN MONOLAURATE AT NOT MORE THAN 25 mg/kg IN THE PRODUCT REFERRED TO IN THE THIRD SUBPARAGRAPH OF ANNEX I (A) (5);

(b) THE TOTAL OR PARTIAL REPLACEMENT OF THE SUGARS GIVEN IN ANNEX II (A) (6) BY HONEY, CANE MOLASSES OR BROWN SUGAR.

2. " THE DEROGATIONS IN RESPECT OF ADDITIVES PROVIDED FOR IN PARAGRAPH 1 (a) SHALL CEASE TO APPLY ONCE RULES ON THE MATTER BECOME APPLICABLE AT COMMUNITY LEVEL. " **[3]**

3. "..." **[3]**

ARTICLE 16

THIS DIRECTIVE:

(a) SHALL NOT APPLY TO PRODUCTS INTENDED FOR EXPORT TO COUNTRIES OUTSIDE THE COMMUNITY;

(b) SHALL NOT AFFECT NATIONAL PROVISIONS RELATING TO DIETETIC PRODUCTS, WITHOUT PREJUDICE TO ANY COMMUNITY PROVISIONS ON THE MATTER;

(c) SHALL NOT APPLY TO PRODUCTS INTENDED FOR THE MANUFACTURE OF FINE BAKERS' WARES, PASTRIES AND BISCUITS.

ARTICLE 17

1. MEMBER STATES SHALL MAKE SUCH AMENDMENTS TO THEIR LAWS AS MAY BE NECESSARY TO COMPLY WITH THIS DIRECTIVE AND SHALL FORTHWITH INFORM THE COMMISSION THEREOF. THE AMENDED LEGISLATION SHALL:

- PERMIT TRADE IN PRODUCTS COMPLYING WITH THIS DIRECTIVE NOT LATER THAN TWO YEARS AFTER ITS NOTIFICATION,

- PROHIBIT TRADE IN PRODUCTS NOT COMPLYING WITH THIS DIRECTIVE THREE YEARS AFTER ITS NOTIFICATION.

2. BY WAY OF DEROGATION FROM THE SECOND INDENT OF PARAGRAPH 1, THE PERIOD AFTER WHICH TRADE IN PRODUCTS WHICH ARE NOT LABELLED IN ACCORDANCE WITH ARTICLE 7 IS FORBIDDEN SHALL BE THAT REFERRED TO IN THE SECOND INDENT OF ARTICLE 22 (1) OF DIRECTIVE 79/112/EEC.

3. THIS ARTICLE SHALL NOT AFFECT APPLICATION OF ARTICLE 22 (2) (b) AND (c) AND THE FIRST INDENT OF ARTICLE 23 (1) (b) OF DIRECTIVE 79/112/EEC.

ARTICLE 18

THIS DIRECTIVE IS ADDRESSED TO THE MEMBER STATES.

ANNEX I

FINISHED PRODUCTS - DEFINITIONS

A. FOR THE PURPOSE OF THIS DIRECTIVE THE FOLLOWING DEFINITIONS SHALL APPLY:

1. EXTRA JAM: A MIXTURE, BROUGHT TO A SUITABLE GELLED CONSISTENCY, OF SUGARS AND THE PULP OF:

- ONE TYPE OF FRUIT, OR
- TWO OR MORE TYPES OF FRUIT, EXCLUDING APPLES, PEARS, CLINGSTONE PLUMS, MELONS, WATER-MELONS, GRAPES, PUMPKINS, CUCUMBERS AND TOMATOES.
" ROSE HIP EXTRA JAM MAY BE OBTAINED ENTIRELY OR IN PART FROM ROSE HIP PUREE. " **[3]**

THE QUANTITY OF FRUIT PULP USED FOR THE MANUFACTURE OF 1 000 g OF FINISHED PRODUCT SHALL NOT BE LESS THAN:

- 450 g AS A GENERAL RULE,
- 350 g FOR BLACKCURRANTS, ROSEHIPS, QUINCES,
- 250 g FOR GINGER,
- 230 g FOR CASHEW APPLES,
- 80 g FOR PASSION FRUIT.

2. JAM: A MIXTURE, BROUGHT TO A SUITABLE GELLED CONSISTENCY, OF SUGARS AND THE PULP AND/OR PUREE OF:

- ONE TYPE OF FRUIT, OR
- TWO OR MORE TYPES OF FRUIT.

THE QUANTITY OF FRUIT PULP AND/OR PUREE USED FOR THE MANUFACTURE OF 1 000 g OF FINISHED PRODUCT SHALL NOT BE LESS THAN:

- 350 g AS A GENERAL RULE,
- 250 g FOR BLACKCURRANTS, ROSEHIPS, QUINCES,
- 150 g FOR GINGER,
- 160 g FOR CASHEW APPLES,
- 60 g FOR PASSION FRUIT.

HOWEVER, FOR A PERIOD OF FIVE YEARS FROM NOTIFICATION OF THIS DIRECTIVE, MEMBER STATES MAY MAKE PROVISION FOR A QUANTITY OF 300 g IN 1 000 g OF FINISHED PRODUCT IN THE CASE OF RASPBERRIES AND GOOSEBERRIES.

3. EXTRA JELLY: AN APPROPRIATELY GELLED MIXTURE OF SUGARS AND THE JUICE AND/OR AQUEOUS EXTRACTS OF:

- ONE TYPE OF FRUIT, OR
- TWO OR MORE TYPES OF FRUIT, EXCLUDING APPLES, PEARS, CLINGSTONE PLUMS, MELONS, WATER-MELONS, GRAPES, PUMPKINS, CUCUMBERS AND TOMATOES.

THE QUANTITY OF JUICE AND/OR AQUEOUS EXTRACTS USED IN THE MANUFACTURE OF 1 000 g OF FINISHED PRODUCT SHALL NOT BE LESS THAN:

- 450 g AS A GENERAL RULE,
- 350 g FOR BLACKCURRANTS, ROSEHIPS, QUINCES,
- 250 g FOR GINGER,
- 230 g FOR CASHEW APPLES,
- 80 g FOR PASSION FRUIT.

THESE QUANTITIES ARE CALCULATED AFTER DEDUCTION OF THE WEIGHT OF WATER USED IN PREPARING THE AQUEOUS EXTRACTS.

4. JELLY: AN APPROPRIATELY GELLED MIXTURE OF SUGARS AND THE JUICE AND/OR AQUEOUS EXTRACTS OF:

- ONE TYPE OF FRUIT, OR
- TWO OR MORE TYPES OF FRUIT.

THE QUANTITY OF JUICE AND/OR AQUEOUS EXTRACTS USED IN THE MANUFACTURE OF 1 000 g OF FINISHED PRODUCT SHALL NOT BE LESS THAN:

- 350 g AS A GENERAL RULE,
- 250 g FOR BLACKCURRANTS, ROSEHIPS, QUINCES,
- 150 g FOR GINGER,
- 160 g FOR CASHEW APPLES,
- 60 g FOR PASSION FRUIT.

THESE QUANTITIES ARE CALCULATED AFTER DEDUCTION OF THE WEIGHT OF WATER USED IN PREPARING THE AQUEOUS EXTRACTS.

5. MARMALADE: A MIXTURE, BROUGHT TO A SUITABLE GELLED CONSISTENCY, OF SUGARS AND ONE OR MORE OF THE FOLLOWING PRODUCTS OBTAINED FROM CITRUS FRUIT: PULP, PUREE, JUICE, AQUEOUS EXTRACTS AND PEEL.

THE QUANTITY OF CITRUS FRUIT USED IN THE PREPARATION OF 1 000 g OF FINISHED PRODUCT SHALL NOT BE LESS THAN 200 g OF WHICH 75 g OR MORE SHALL BE OBTAINED FROM THE ENDOCARP.

MEMBER STATES MAY AUTHORIZE IN THEIR OWN TERRITORY THE NAME "JELLY MARMALADE" WHERE THE PRODUCT CONTAINS NO INSOLUBLE MATTER WITH THE EXCEPTION, OPTIONALLY, OF SMALL QUANTITIES OF FINELY SLICED PEEL.

6. " Sweetened chestnut purée " **[3]**: A MIXTURE, BROUGHT TO A SUITABLE CONSISTENCY OF SUGARS AND PUREED CHESTNUTS.

THE QUANTITY OF PUREED CHESTNUTS USED IN THE MANUFACTURE OF 1 000 g OF FINISHED PRODUCT SHALL NOT BE LESS THAN 380 g.

B. IN THE CASE OF MIXTURES, THE MINIMUM CONTENT OF A GIVEN FRUIT AS LAID DOWN IN SECTION A SHALL BE REDUCED IN PROPORTION TO THE PERCENTAGE OF SUCH FRUIT USED.

ANNEX II

A. RAW MATERIALS - DEFINITIONS

1. FRUIT:

- FRESH, SOUND FRUIT, FREE FROM DETERIORATION, CONTAINING ALL ITS ESSENTIAL CONSTITUENTS AND SUFFICIENTLY RIPE FOR USE IN THE MANUFACTURE OF PRODUCTS AS DEFINED IN ANNEX I, AFTER CLEANING, REMOVAL OF BLEMISHES, TOPPING AND TAILING,
- " FOR THE PURPOSES OF THIS DIRECTIVE, TOMATOES, THE EDIBLE PARTS OF RHUBARB STALKS, CARROTS AND SWEET POTATOES ARE CONSIDERED TO BE FRUIT. " **[3]**
- THE TERM "CHESTNUT" MEANS THE FRUIT OF THE SWEET CHESTNUT TREE (CASTANEA SATIVA),
" - "GINGER" MEANS THE EDIBLE ROOT OF THE GINGER PLANT. " **[3]**

2. FRUIT PULP (PULP): THE EDIBLE PART OF THE WHOLE FRUIT - IF APPROPRIATE, LESS THE PEEL, SKIN, SEEDS, PIPS AND THE LIKE - WHICH MAY HAVE BEEN SLICED OR CRUSHED BUT WHICH HAS NOT BEEN REDUCED TO A PUREE.

3. FRUIT PUREE (PUREE): THE EDIBLE PART OF THE WHOLE FRUIT - LESS THE PEEL, SKIN, SEEDS, PIPS AND THE LIKE - WHICH HAS BEEN REDUCED TO A PUREE BY SIEVING OR A SIMILAR PROCESS.

" 4. FRUIT JUICE (JUICE): FRUIT JUICE, CONCENTRATED FRUIT JUICE AND DEHYDRATED FRUIT JUICE WHICH COMPLY WITH THE REQUIREMENTS OF COUNCIL DIRECTIVE 75/726/EEC OF 17 NOVEMBER 1975 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES CONCERNING FRUIT JUICES AND CERTAIN SIMILAR PRODUCTS (2), AS LAST AMENDED BY THE ACT OF ACCESSION OF SPAIN AND PORTUGAL. " **[3]**

5. AQUEOUS EXTRACTS OF FRUIT (AQUEOUS EXTRACTS): THE AQUEOUS EXTRACTS OF FRUIT WHICH, SUBJECT TO THE LOSSES NECESSARILY OCCURRING IN PROPER MANUFACTURING, CONTAIN ALL THE WATER-SOLUBLE CONSTITUENTS OF THE FRUIT USED.

" 5a. CITRUS PEEL (PEEL): THE PEEL OF CITRUS FRUITS, CLEANED, WITH OR WITHOUT THE ENDOCARP REMOVED. " **[3]**

6. SUGARS: ANY OF THE FOLLOWING:

- SEMI-WHITE SUGAR,
- SUGAR (WHITE SUGAR),
- EXTRA WHITE SUGAR,
- SUGAR SOLUTION,
- INVERT SUGAR SOLUTION,
- INVERT SUGAR SYRUP,
- DEXTROSE MONOHYDRATE,
- DEXTROSE ANHYDROUS,
- GLUCOSE SYRUP,
- DRIED GLUCOSE SYRUP,
- FRUCTOSE,

- THE AQUEOUS SOLUTION OF SUCROSE WITH THE FOLLOWING CHARACTERISTICS:

(a) DRY MATTER: NOT LESS THAN 62 % BY WEIGHT;

(b) INVERT SUGAR CONTENT (RATIO OF FRUCTOSE TO DEXTROSE: 1,0 ± 0,2): NOT MORE THAN 3 % BY WEIGHT OF DRY MATTER;

(c) CONDUCTIVITY ASH: NOT MORE THAN 0,3 % BY WEIGHT OF DRY MATTER,

(d) COLOUR IN SOLUTION : NOT MORE THAN 75 ICUMSA UNITS,

(e) RESIDUAL SULPHUR DIOXIDE CONTENT: NOT MORE THAN 15 mg/kg OF DRY MATTER.

" B. RAW MATERIALS - AUTHORIZED TREATMENT

1. (a) THE PRODUCTS DEFINED IN SECTION A (1), (2), (3), (5) AND (5a) MAY IN ALL CASES BE TREATED IN THE FOLLOWING WAYS:

- HEATED, CHILLED OR FROZEN,
- FREEZE-DRIED,
- CONCENTRATED, TO THE EXTENT THAT IT IS TECHNICALLY POSSIBLE.

(b) IF THE ABOVEMENTIONED PRODUCTS ARE INTENDED FOR THE MANUFACTURE OF PRODUCTS DEFINED IN ANNEX I (A) (2), (4) AND (5), SULPHUR DIOXIDE (E 220) OR ITS SALTS E 221, E 222, E 223, E 224, E 226 AND E 227 MAY ALSO BE ADDED TO THEM.

2. GINGER MAY BE DRIED OR PRESERVED IN SYRUP.

3. APRICOTS FOR THE MANUFACTURE OF THE PRODUCTS DEFINED IN ANNEX I (A) (2) MAY ALSO BE TREATED BY OTHER DEHYDRATION PROCESSES APART FROM FREEZE DRYING.

4. CHESTNUTS MAY BE SOAKED FOR A SHORT TIME IN AN AQUEOUS SOLUTION OF SULPHUR DIOXIDE OR ITS SALTS E 221, E 222, E 223, E 224, E 226 AND E 227.

5. (a) FRUIT JUICE MAY ALSO BE SUBJECTED TO THE TREATMENTS PROVIDED FOR IN DIRECTIVE 75/726/EEC;

(b) IT MAY ALSO BE SUBJECTED TO THE TREATMENT PROVIDED FOR IN 1 (b) WHERE IT IS INTENDED FOR THE MANUFACTURE OF THE PRODUCTS DEFINED IN ANNEX I, POINTS 4 AND 5.

6. CITRUS PEEL MAY BE PRESERVED IN BRINE. " **[3]**

ANNEX III

SUBSTANCES WHICH MAY BE ADDED TO THE PRODUCTS DEFINED IN ANNEX I

A. EDIBLE INGREDIENTS, AROMATICS AND AROMATIC SUBSTANCES

1. Ingredients which need not be specified in the sales description of the finished products

Name	Conditions of use
— Water suitable for food manufacture	In all the products defined in Annex I
— Fruit juices	In all the products defined in Annex I (A) (2)
" —Red fruit juices	In the products defined in Annex I (A) (1) and (2) where they are obtained from one or more of the following fruits: rosehips, strawberries, raspberries, gooseberries, redcurrants and plums " **[3]**
— Red beetroot juice	In the products defined in Annex I (A) (2) and (4) where they are obtained from one or more of the following species: strawberries, raspberries, gooseberries, redcurrants, plums
— Essential oils of citrus fruits	In the products defined in Annex I (A) (5)
— Edible oils and fats	As anti-foaming agents in all the products defined in Annex I
— Liquid pectin (products containing pectin and derived from dried apple pomace or dried peel of citrus fruits, or from a mixture of both, by the action of dilute acid followed by partial neutralization with sodium or potassium salts)	In all the products defined in Annex I

2. Ingredients which must be specified in the sales description of the finished products

Name	Conditions of use
a) Edible ingredients in sufficient quantity to modify flavour:	
— Citrus fruit juice in products obtained from other types of fruit	In the products defined in Annex I (A) (1) and (2)
— Spirits — Wine and liqueur wine — Walnuts, hazelnuts, almonds — Honey — Herbs — Spices	In all the products defined in Annex I
— Others	Subjects to national laws
b) — Citrus peel — Leaves of *pelargonium odoratissimum*	In the products defined in Annex I (A) (1) to (4) where they are obtained from quince
c) — Vanilla — Vanilla extract — Vanillin — Ethyl vanillin	In the products defined in Annex I (A) (1) to (4) where they are obtained from apples, quinces or rosehips and the product defined in Annex I (A) (6)

B. ADDITIVES

Name	Conditions of use
" —Pectin and amidated pectin (E 440)	All the products defined in Annex I; the pectin and/or amidated pectin content of the finished products shall not exceed 1 % " **[3]**
Lactic acid (E 270)	All the products defined in Annex I in the quantities necessary for normalizing the pH
Sodium lactate (E 325)	
Citric acid (E 330)	
Sodium citrates (E 331)	
Calcium citrates (E 333)	
Tartaric acid (E 334)	
Sodium tartrates (E 335)	
Calcium lactate (E 327)	All the products defined in Annex I in accordance with proper manufacturing practice
L-ascorbic acid (E 300)	All the products defined in Annex I in the quantities necessary for anti-oxidant effect
Mono- and diglycerides of fatty acids (E 471)	All the products defined in Annex I

ANNEX IV

MAXIMUM SULPHUR DIOXIDE CONTENT OF PRODUCTS DEFINED IN ANNEX I

THE SULPHUR DIOXIDE CONTENT OF THE PRODUCTS DEFINED MUST NOT EXCEED THE FOLLOWING VALUES:

1. 10 mg/kg FOR PRODUCTS DEFINED IN ANNEX I (A) (1), (3) AND (6);

2. 50 mg/kg FOR ALL OTHER PRODUCTS DEFINED IN ANNEX I;

3. HOWEVER, FOR THE PRODUCTS DEFINED IN ANNEX I (A) (2) AND (5), MEMBER STATES MAY RETAIN ANY NATIONAL LAWS PERMITTING A SULPHUR DIOXIDE CONTENT GREATER THAN 50 mg/kg BUT LESS THAN 100 mg/kg.

AT THE END OF A PERIOD OF FIVE YEARS FROM THE NOTIFICATION OF THIS DIRECTIVE, THE COMMISSION WILL RE-EXAMINE THIS DEROGATION AND WILL PROPOSE TO THE COUNCIL, IF APPROPRIATE, THE AMENDMENT OR ABOLITION OF THIS PROVISON.

(1) OJ No L 33, 08/02/1979, p. 1.
(2) OJ No L 311, 01/12/1975, p. 40.

PRESERVED MILK

376L0118

76/118/EEC: COUNCIL DIRECTIVE OF 18 DECEMBER 1975 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO CERTAIN PARTLY OR WHOLLY DEHYDRATED PRESERVED MILK FOR HUMAN CONSUMPTION

OFFICIAL JOURNAL NO L 24, 30/01/1976, P. 49
DATE OF NOTIFICATION: 22/12/1975
DATE OF TRANSPOSITION: 22/12/1976; SEE ART. 16

AMENDED BY

378L0630
78/630/EEC: COUNCIL DIRECTIVE OF 19 JUNE 1978 **[1]**
OFFICIAL JOURNAL NO L 206, 29/07/1978, P. 12
DATE OF NOTIFICATION: 22/06/1978

179H
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE HELLENIC REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES **[2]**
OFFICIAL JOURNAL NO L 291, 19/11/1979, P. 110

383L0635
83/635/EEC: COUNCIL DIRECTIVE OF 13 DECEMBER 1983 **[3]**
OFFICIAL JOURNAL NO L 357, 21/12/1983, P. 37
DATE OF NOTIFICATION: 20/12/1983
DATE OF TRANSPOSITION: 01/01/1986; SEE ART. 2
DATE OF TRANSPOSITION: 01/01/1987; SEE ART. 2

1851
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE KINGDOM OF SPAIN AND THE PORTUGUESE REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES **[4]**
OFFICIAL JOURNAL NO L 302, 15/11/1985, P. 217

ARTICLE 1

1. THIS DIRECTIVE CONCERNS PARTLY OR WHOLLY DEHYDRATED PRESERVED MILK AS DEFINED IN THE ANNEX.

2. FOR THE PURPOSES OF THIS DIRECTIVE:

(a) "PARTLY DEHYDRATED MILK" MEANS THE LIQUID PRODUCT OBTAINED DIRECTLY BY THE PARTIAL REMOVAL OF WATER FROM MILK, FROM WHOLLY OR PARTLY SKIMMED MILK, OR FROM A MIXTURE OF THESE PRODUCTS, WHICH MAY HAVE AN ADMIXTURE OF CREAM OR OF WHOLLY DEHYDRATED MILK OR OF BOTH, THE ADDITION OF WHOLLY DEHYDRATED MILK NOT TO EXCEED, IN THE FINISHED PRODUCT, 25 % OF TOTAL MILK SOLIDS; HOWEVER, MEMBER STATES MAY MAINTAIN IN THEIR TERRITORY ANY BAN ON THE USE OF WHOLLY DEHYDRATED MILK IN THE PRODUCTION AND MARKETING OF PARTLY DEHYDRATED MILK, IF THE BAN EXISTED PRIOR TO 1 OCTOBER 1974.
WHEN ADOPTING THE QUALITY CRITERIA REFERRED TO IN ARTICLE 11 (1) (d) AND IN ANY CASE NOT LATER THAN TWO YEARS AFTER NOTIFICATION OF THIS DIRECTIVE, THE COUNCIL SHALL DECIDE WHETHER OR NOT TO CONTINUE TO PERMIT THESE PROHIBITIONS;

(b) "WHOLLY DEHYDRATED MILK" MEANS THE SOLID PRODUCT WHOSE MOISTURE CONTENT IS NOT MORE THAN 5 % BY WEIGHT IN THE FINISHED PRODUCT OBTAINED DIRECTLY BY THE REMOVAL OF WATER FROM MILK, WHOLLY OR PARTLY SKIMMED MILK, CREAM OR FROM A MIXTURE OF THESE PRODUCTS.

3. THE PRESERVATION OF THE PRODUCTS DEFINED IN THE ANNEX SHALL BE ACHIEVED AS FOLLOWS:

(i) PRODUCTS IN POINT 1 (a) TO (d) BY STERILIZATION THROUGH HEAT TREATMENT;

(ii) PRODUCTS IN POINT 1 (e) TO (g) BY THE ADDITION OF SUCROSE (SEMI-WHITE SUGAR, SUGAR OR WHITE SUGAR OR EXTRA WHITE SUGAR);

(iii) PRODUCTS IN POINT 2 BY DEHYDRATION.

ARTICLE 2

MEMBER STATES SHALL TAKE ALL MEASURES NECESSARY TO ENSURE THAT THE PRODUCTS DEFINED IN THE ANNEX MAY BE MARKETED ONLY IF THEY CONFORM TO THE DEFINITIONS AND RULES LAID DOWN IN THIS DIRECTIVE AND THE ANNEX THERETO.

ARTICLE 3

1. THE DESIGNATIONS REFERRED TO IN THE ANNEX SHALL APPLY ONLY TO THE PRODUCTS DEFINED THEREIN AND MUST BE USED IN TRADE TO DENOTE SUCH PRODUCTS.

2. THE USE OF THE FOLLOWING DESIGNATIONS MAY ALSO BE RESERVED, IN THEIR TERRITORY, BY THE MEMBER STATES CONCERNED:

(a) "EVAPORATED MILK" IN IRELAND AND THE UNITED KINGDOM TO DENOTE UNSWEETENED CONDENSED MILK CONTAINING, BY WEIGHT, AT LEAST 9 % FAT AND 31 % TOTAL MILK SOLIDS;

(b) "KONDENSERET KAFFEFLØDE" IN DENMARK, "KONDENSIERTE KAFFEESAHNE" IN GERMANY AND "PANNA DA CAFFE" IN ITALY TO DENOTE THE PRODUCT DEFINED IN POINT 1 (d) OF THE ANNEX;

(c) "FLØDEPULVER" IN DENMARK, AND "RAHMPULVER" AND "SAHNEPULVER " IN GERMANY, TO DENOTE THE PRODUCT DEFINED IN POINT 2 (d) OF THE ANNEX.

" (d) "GEËVAPOREERDE HALFVOLLE MELK" IN BELGIUM AND THE NETHERLANDS AND "LAIT DEMI - ÉCRÉMÉ CONCENTRÉ " AND " LAIT DEMI-ÉCRÉMÉ CONCENTRÉ NON SUCRÉ " IN BELGIUM, FRANCE AND LUXEMBOURG, TO DENOTE, IN THE CASE OF SALE BY RETAIL, THE PRODUCT DEFINED IN POINT 1 (c) OF THE ANNEX. " **[1]**

" (e) "LAIT DEMI-ÉCRÉMÉ CONCENTRÉ SUCRÉ" IN BELGIUM, FRANCE AND LUXEMBOURG AND "GECONDENSEERDE HALFVOLLE MELK MET SUIKER" IN BELGIUM AND THE NETHERLANDS, TO DENOTE, IN THE CASE OF RETAIL SALE, THE PRODUCT DEFINED IN POINT 1 (g) OF THE ANNEX;

(f) "LAIT DEMI-ÉCRÉMÉ EN POUDRE" IN BELGIUM, FRANCE AND LUXEMBOURG AND "HALFVOLLEMELKPOEDER" IN BELGIUM AND THE NETHERLANDS, TO DENOTE, IN THE CASE OF RETAIL SALE, THE PRODUCT DEFINED IN POINT 2 (c) OF THE ANNEX AND CONTAINING, BY WEIGHT, BETWEEN 14 AND 16 GRAMS OF FAT PER 100 GRAMS. " **[3]**

" (g) "leite em pó meio gordo" in Portugal to denote dehydrated milk with a fat content superior to 13 % and inferior to 26 %. " **[4]**

3. "..." **[3]**

ARTICLE 4

WITHOUT PREJUDICE TO PROVISIONS CONCERNING HEALTH AND HYGIENE TO BE ADOPTED BY THE COMMUNITY IN RELATION TO THE BASIC MATERIALS REFERRED TO IN ARTICLE 1 (2), SUCH MATERIALS MUST BE SUBJECTED TO HEAT TREATMENT AT LEAST EQUIVALENT TO PASTEURIZATION WHERE THE PROCESS OF MANUFACTURE OF THE PRODUCTS DEFINED IN ARTICLE 1 (1) DOES NOT INCLUDE SUCH TREATMENT.

ARTICLE 5

1. IN THE MANUFACTURE OF THE PRODUCTS DEFINED IN POINT 1 (a) TO (d) OF THE ANNEX, ONLY THE USE OF THE FOLLOWING SHALL BE AUTHORIZED:

SODIUM AND POTASSIUM BICARBONATES,

E 331 SODIUM CITRATES (SODIUM SALTS OF CITRIC ACID),

E 332 POTASSIUM CITRATES (POTASSIUM SALTS OF CITRIC ACID),

E 339 SODIUM ORTHOPHOSPHATES (SODIUM SALTS OF ORTHOPHOSPHORIC ACID),

E 340 POTASSIUM ORTHOPHOSPHATES (POTASSIUM SALTS OF ORTHOPHOSPHORIC ACID), CALCIUM CHLORIDE,

E 450 SODIUM AND POTASSIUM POLYPHOSPHATES:

(a) DIPHOSPHATES,

(b) TRIPHOSPHATES IN THE CASE OF ULTRA HEAT TREATED (UHT) UNSWEETENED PARTLY DEHYDRATED MILK,

(c) LINEAR POLYPHOSPHATES (CONTAINING NOT MORE THAN 8 % CYCLIC COMPOUNDS) IN THE CASE OF ULTRA HEAT TREATED (UHT) UNSWEETENED PARTLY DEHYDRATED MILK;

- PROVIDED THAT THE TOTAL QUANTITY BY WEIGHT OF THESE ADDED SUBSTANCES IN THE FINISHED PRODUCT IS NOT GREATER THAN:

-- 0.2 % FOR PRODUCTS WITH A TOTAL DRY MATTER CONTENT NOT EXCEEDING 28 %,
-- 0.3 % FOR PRODUCTS WITH A TOTAL DRY MATTER CONTENT EXCEEDING 28 %;

- PROVIDED THAT THE TOTAL TRIPHOSPHATE AND LINEAR POLYPHOSPHATE CONTENT BY WEIGHT EXPRESSED AS P_2O_5, IN ULTRA HEAT TREATED (UHT) UNSWEETENED PARTLY DEHYDRATED MILK, IS NOT GREATER THAN 0.1 %;
- PROVIDED THAT THE TOTAL ADDED PHOSPHATE CONTENT EXPRESSED AS P_2O_5 IS NOT GREATER THAN 0.1 % FOR PRODUCTS WHOSE TOTAL DRY MATTER CONTENT DOES NOT EXCEED 28 %, AND IS NOT GREATER THAN 0.15 % FOR PRODUCTS WHOSE TOTAL DRY MATTER CONTENT EXCEEDS 28 %.

2. IN THE MANUFACTURE OF THE PRODUCTS DEFINED IN POINT 1 (e) TO (g) OF THE ANNEX, ONLY THE USE OF THE FOLLOWING SHALL BE AUTHORIZED:

(a) THE SUBSTANCES LISTED IN PARAGRAPH 1, PROVIDED THAT THEIR TOTAL QUANTITY BY WEIGHT IN THE FINISHED PRODUCT IS NOT GREATER THAN 0.2 % AND THAT THE TOTAL ADDED PHOSPHATE CONTENT EXPRESSED AS P_2O_5 DOES NOT EXCEED 0.1 %;

(b) A QUANTITY OF LACTOSE THAT IS NOT GREATER THAN 0.02 % BY WEIGHT OF THE FINISHED PRODUCT WITH THE ADDITION, WHERE APPROPRIATE, OF TRICALCIUM PHOSPHATE, THE QUANTITY OF WHICH MUST NOT EXCEED 10 % OF THE LACTOSE ADDED.

3. IN THE MANUFACTURE OF THE PRODUCTS DEFINED IN POINT 2 OF THE ANNEX, ONLY THE USE OF THE FOLLOWING SHALL BE AUTHORIZED:

(a) THE SUBSTANCES LISTED IN PARAGRAPH 1:

- PROVIDED THAT THEIR TOTAL QUANTITY, BY WEIGHT, IN THE FINISHED PRODUCT IS NOT GREATER THAN 0.5 % OF WHICH THE MAXIMUM CONTENT OF SODIUM AND POTASSIUM BICARBONATE IS 0.2 % . THE LATTER QUANTITY MAY BE A MAXIMUM OF 0.3 % IN THE CASE OF WHOLLY DEHYDRATED MILK OF THE "HATMAKER" OR "ROLLER" TYPES OTHER THAN THAT INTENDED FOR RETAIL SALE AND FOR THE MANUFACTURE OF WHICH NONE OF THE OTHER SUBSTANCES LISTED IN PARAGRAPH 1 IS USED; HOWEVER, THE UNITED KINGDOM MAY AUTHORIZE THE RETAIL SALE OF THIS MILK IN ITS TERRITORY;
- PROVIDED THAT THE TOTAL ADDED PHOSPHATE CONTENT EXPRESSED AS P2O5 DOES NOT EXCEED 0.25 %;

(b) L-ASCORBIC ACID (E 300), SODIUM L-ASCORBATE (E 301) AND ASCORBYL PALMITATE (E 304), SINGLY OR MIXED AT A MAXIMUM LEVEL, BY WEIGHT, OF THE FINISHED PRODUCT, OF 0.05 % EXPRESSED AS ASCORBIC ACID.

4. WHERE THE DESIGNATION OF THE PRODUCTS DEFINED IN POINT 2 (a), (c) AND (d) OF THE ANNEX REFERS TO INSTANT SOLUBILITY, THE USE OF LECITHINS (E 322) SHALL ALSO BE AUTHORIZED FOR THEIR MANUFACTURE AT A MAXIMUM LEVEL, BY WEIGHT, OF 0.5 %.

5. WHERE THIS ARTICLE REFERS TO THE PERCENTAGE OF AN ADDITIVE, THE ANHYDROUS SUBSTANCE IS MEANT.

6. MEMBER STATES MAY AUTHORIZE IN THEIR TERRITORY THE USE OF ADDITIONAL ADDITIVES FOR WHOLLY DEHYDRATED MILK USED IN VENDING MACHINES AND CLEARLY LABELLED AS SUCH.

7. NOTWITHSTANDING PARAGRAPHS 1 TO 3, MEMBER STATES MAY AUTHORIZE IN THEIR TERRITORY THE ADDITION OF VITAMINS TO THE PRODUCTS DEFINED IN THE ANNEX.

ARTICLE 6

WITHOUT PREJUDICE TO THE PROVISIONS ADOPTED UNDER ARTICLE 11 (1), THE LACTATE CONTENT OF THE PRODUCTS DEFINED IN THE ANNEX SHALL NOT BE GREATER THAN 300 mg PER 100 g OF MILK SOLIDS NOT FAT.

ARTICLE 7

" 1. DIRECTIVE 79/112/EEC (1) SHALL APPLY UNDER THE FOLLOWING CONDITIONS TO THE PRODUCTS DEFINED IN THE ANNEX WHICH ARE INTENDED TO BE SUPPLIED IN THE UNALTERED STATE TO THE ULTIMATE CONSUMER.

2. (a) THE DESIGNATION UNDER WHICH THE PRODUCTS DEFINED IN THE ANNEX ARE SOLD IS ONE OF THE DESIGNATIONS RESERVED FOR THE SAID PRODUCTS PURSUANT TO ARTICLE 3.

(b) IN THE CASE REFERRED TO IN ARTICLE 5 (4), THE WORD "INSTANT" SHALL BE ADDED TO THE NAME UNDER WHICH THE PRODUCT IS SOLD.

3. THE NET QUANTITY OF THE PRODUCTS DEFINED IN THE ANNEX SHALL BE EXPRESSED IN UNITS OF MASS AND, IN THE CASE OF THE PRODUCTS DEFINED IN POINT 1 (a), (b), (c) AND (d) OF THE

ANNEX, IF THEY ARE PACKED IN ANYTHING OTHER THAN TUBES OR METAL TINS, IN UNITS OF MASS AND VOLUME.

4. THE FOLLOWING PARTICULARS SHALL FURTHERMORE APPEAR ON THE PACKAGING, CONTAINERS OR LABELS OF THE SAID PRODUCTS:

(a) THE PERCENTAGE OF MILK FAT, EXPRESSED BY WEIGHT IN RELATION TO THE FINISHED PRODUCT , EXCEPT IN THE CASE OF THE PRODUCTS DEFINED IN POINTS 1 (b) AND (f) AND 2 (b) OF THE ANNEX AND THE PERCENTAGE OF FAT-FREE DRIED MILK EXTRACT IN THE CASE OF THE PRODUCTS DEFINED IN POINT 1 OF THE ANNEX;

(b) IN THE CASE OF THE PRODUCTS DEFINED IN POINT 1 OF THE ANNEX, THE RECOMMENDATIONS ON THE METHOD OF DILUTION OR RECONSTITUTION; THESE PARTICULARS MAY BE REPLACED BY RELEVANT INFORMATION ON THE USE OF THE PRODUCTS WHEN THE LATTER ARE INTENDED FOR USE IN THE UNALTERED STATE;

(c) IN THE CASE OF THE PRODUCTS DEFINED IN POINT 2 OF THE ANNEX, THE RECOMMENDATIONS ON THE METHOD OF DILUTION OR RECONSTITUTION, INCLUDING DETAILS OF THE FAT CONTENT OF THE PRODUCT THUS DILUTED OR RECONSTITUTED, EXCEPT IN THE CASE OF THE PRODUCTS DEFINED IN POINT 2 (b) OF THAT ANNEX;

(d) THE EXPRESSIONS "UHT" OR "ULTRA HEAT TREATED" FOR THE PRODUCTS DEFINED IN POINT 1 (a), (b), (c) AND (d) OF THE ANNEX, WHERE THESE PRODUCTS ARE OBTAINED AS A RESULT OF SUCH TREATMENT AND ASEPTICALLY PACKED.

5. PARAGRAPHS 1 TO 4 SHALL APPLY UNDER THE FOLLOWING CONDITIONS:

- THE PARTICULARS SET OUT UNDER PARAGRAPHS 2 AND 4 (a) SHALL APPEAR IN THE SAME FIELD OF VISION AS THOSE LISTED IN ARTICLE 11 (3) (a) OF DIRECTIVE 79/112/EEC,
- WHERE PRODUCTS WEIGHING LESS THAN 20 GRAMS PER UNIT ARE PACKED IN AN OUTER PACKAGING, THE PARTICULARS REQUIRED BY THIS PARAGRAPH NEED APPEAR ON THE OUTER PACKAGING ONLY, EXCEPT FOR THE DESIGNATION UNDER WHICH THE PRODUCT IS SOLD, REQUIRED BY PARAGRAPH 2 (a),
- IN THE CASE REFERRED TO IN ARTICLE 5 (7), MEMBER STATES SHALL BE EMPOWERED TO INSIST ON THE INCLUSION OF DETAILS OF THE NATURE AND QUANTITY OF ADDED VITAMINS,
- THE MEMBER STATES MAY RETAIN NATIONAL PROVISIONS REQUIRING THE INCLUSION OF A SPECIAL WARNING CONCERNING THE USE OF WHOLLY SKIMMED PRODUCTS AS BABY FOOD. " **[3]**

" ARTICLE 7a

1. WITHOUT PREJUDICE TO THE PROVISIONS TO BE ADOPTED BY THE COMMUNITY CONCERNING THE LABELLING OF FOODSTUFFS NOT INTENDED FOR THE ULTIMATE CONSUMER, THE ONLY MANDATORY PARTICULARS TO BE MARKED ON THE PACKAGES, CONTAINERS OR LABELS OF THE PRODUCTS DEFINED IN THE ANNEX, WHICH PARTICULARS MUST BE CLEARLY VISIBLE, EASILY LEGIBLE AND IN INDELIBLE CHARACTERS, SHALL BE AS FOLLOWS:

(a) THE NAME RESERVED FOR THESE PRODUCTS PURSUANT TO ARTICLE 3;

(b) THE NET QUANTITY EXPRESSED IN KILOGRAMS OR GRAMS. UNTIL THE END OF THE TRANSITIONAL PERIOD DURING WHICH USE OF THE IMPERIAL UNITS OF MEASUREMENT CONTAINED IN CHAPTER D OF THE ANNEX TO COUNCIL DIRECTIVE 71/354/EEC OF 18 OCTOBER 1971 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO UNITS OF MEASUREMENT (2), AS LAST AMENDED BY DIRECTIVE 76/770/EEC (3), IS AUTHORIZED IN THE COMMUNITY, IRELAND AND THE UNITED KINGDOM MAY PERMIT THE QUANTITY TO BE EXPRESSED ONLY IN IMPERIAL UNITS OF MEASUREMENT CALCULATED ON THE BASIS OF THE FOLLOWING CONVERSION RATES:

- ONE MILLILITRE = 0,0352 FLUID OUNCES,
- ONE LITRE = 1,760 PINTS OR 0,220 GALLONS,
- ONE GRAM = 0,0353 OUNCES (AVOIRDUPOIS),

- ONE KILOGRAM = 2,205 POUNDS;

(c) THE NAME OR BUSINESS NAME AND THE ADDRESS OF THE MANUFACTURER OR PACKER OR OF A SELLER ESTABLISHED WITHIN THE COMMUNITY.

HOWEVER, IN THE CASE OF THEIR NATIONAL PRODUCTION MEMBER STATES MAY MAINTAIN IN FORCE NATIONAL PROVISIONS REQUIRING DETAILS OF THE MANUFACTURING OR PACKING ESTABLISHMENT TO BE MENTIONED;

(d) IN THE CASE OF PRODUCTS IMPORTED FROM THIRD COUNTRIES, THE NAME OF THE COUNTRY OF ORIGIN;

(e) THE DATE OF MANUFACTURE OR SOME MARKING BY WHICH THE BATCH CAN BE IDENTIFIED.

2. MEMBER STATES SHALL PROHIBIT THE MARKETING IN THEIR TERRITORY OF THE PRODUCTS DEFINED IN THE ANNEX IF THE PARTICULARS REFERRED TO IN PARAGRAPH 1 (a), (d) AND (e) DO NOT APPEAR IN A LANGUAGE EASILY UNDERSTOOD BY THE PURCHASER, UNLESS THE LATTER IS GIVEN SUCH INFORMATION BY OTHER MEANS; THIS PROVISION SHALL NOT PRECLUDE THE APPEARANCE OF THE SAID PARTICULARS IN SEVERAL LANGUAGES.
THE PARTICULARS SPECIFIED IN PARAGRAPH 1 (B) AND (D) NEED APPEAR ONLY ON AN ACCOMPANYING DOCUMENT. " **[3]**

ARTICLE 8

THE PRODUCTS REFERRED TO IN ARTICLE 1 AND DESTINED FOR RETAIL SALE SHALL BE PACKAGED BY THE MANUFACTURER OR PACKER IN SEALED CONTAINERS WHICH PROTECT THE PRODUCT FROM HARMFUL INFLUENCE AND WHICH MUST BE DELIVERED INTACT TO THE CONSUMER.

ARTICLE 9

1. MEMBER STATES SHALL ADOPT ALL THE MEASURES NECESSARY TO ENSURE THAT TRADE IN PRODUCTS REFERRED TO IN ARTICLE 1 WHICH COMPLY WITH THE DEFINITIONS AND RULES LAID DOWN IN THIS DIRECTIVE AND THE ANNEX CANNOT BE IMPEDED BY THE APPLICATION OF NON-HARMONIZED NATIONAL PROVISIONS GOVERNING THE COMPOSITION, MANUFACTURING SPECIFICATIONS, PACKAGING OR LABELLING OF THESE PRODUCTS OR FOODSTUFFS IN GENERAL.

2. PARAGRAPH 1 SHALL NOT BE APPLICABLE TO NON-HARMONIZED PROVISIONS JUSTIFIED ON GROUNDS OF:

- PROTECTION OF PUBLIC HEALTH,
- PREVENTION OF FRAUDS UNLESS SUCH PROVISIONS ARE LIABLE TO IMPEDE THE APPLICATION OF THE DEFINITIONS AND RULES LAID DOWN BY THIS DIRECTIVE,
- PROTECTION OF INDUSTRIAL AND COMMERCIAL PROPERTY, INDICATIONS OF SOURCE, REGISTERED DESIGNATION AND PREVENTION OF UNFAIR COMPETITION.

ARTICLE 10

1. WHERE A MEMBER STATE, AS A RESULT OF NEW INFORMATION OR OF A RE-ASSESSMENT OF EXISTING INFORMATION MADE SINCE THE DIRECTIVE WAS ADOPTED, HAS DETAILED GROUNDS FOR ESTABLISHING THAT THE USE, IN THE PRODUCTS REFERRED TO IN THE ANNEX, OF ONE OF THE SUBSTANCES LISTED IN ARTICLE 5, OR WHERE THE MAXIMUM LEVEL WHICH MAY BE EMPLOYED ENDANGERS HUMAN HEALTH ALTHOUGH IT COMPLIES WITH THE PROVISIONS OF THIS DIRECTIVE, THAT MEMBER STATE MAY TEMPORARILY SUSPEND OR RESTRICT APPLICATION

OF THE PROVISIONS IN QUESTION IN ITS TERRITORY. IT SHALL IMMEDIATELY INFORM THE OTHER MEMBER STATES AND THE COMMISSION THEREOF AND GIVE REASONS FOR ITS DECISION.

2. THE COMMISSION SHALL EXAMINE AS SOON AS POSSIBLE THE GROUNDS GIVEN BY THE MEMBER STATE CONCERNED AND CONSULT THE MEMBER STATES WITHIN THE STANDING COMMITTEE FOR FOODSTUFFS, AND SHALL THEN DELIVER ITS OPINION FORTHWITH AND TAKE THE APPROPRIATE MEASURES.

3. IF THE COMMISSION CONSIDERS THAT AMENDMENTS TO THE DIRECTIVE ARE NECESSARY IN ORDER TO RESOLVE THE DIFFICULTIES MENTIONED IN PARAGRAPH 1 AND TO ENSURE THE PROTECTION OF HUMAN HEALTH, IT SHALL INITIATE THE PROCEDURE LAID DOWN IN ARTICLE 12, WITH A VIEW TO ADOPTING THESE AMENDMENTS; THE MEMBER STATE WHICH HAS ADOPTED SAFEGUARD MEASURES MAY IN THAT EVENT RETAIN THEM UNTIL THE AMENDMENTS ENTER INTO FORCE.

ARTICLE 11

1. THE COUNCIL, ACTING ON A PROPOSAL FROM THE COMMISSION, SHALL LAY DOWN:

(a) AS FAR AS IS NECESSARY, THE PURITY CRITERIA FOR THE ADDITIVES OR PRODUCTS USED AS ADDITIVES REFERRED TO IN ARTICLE 5;

(b) THE HYGIENIC, CHEMICAL AND PHYSICAL CRITERIA FOR THE PRODUCTS DEFINED IN THE ANNEX;

(c) THE MICROBIOLOGICAL CRITERIA FOR THE PRODUCTS DEFINED IN THE ANNEX;

(d) THE QUALITY CRITERIA FOR WHOLLY DEHYDRATED MILK WHICH MAY BE USED IN THE PRODUCTION OF PARTLY DEHYDRATED MILK IN ACCORDANCE WITH ARTICLE 1 (2) (a).

2. THE FOLLOWING SHALL BE DETERMINED IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 12:

(a) THE METHODS OF ANALYSIS NECESSARY FOR CHECKING THE ABOVE PURITY CRITERIA;

(b) THE SAMPLING PROCEDURES AND METHODS OF ANALYSIS NECESSARY FOR CHECKING THE COMPOSITION AND MANUFACTURING SPECIFICATIONS OF THE PRODUCTS DEFINED IN THE ANNEX.

ARTICLE 12

1. WHERE THE PROCEDURE LAID DOWN IN THIS ARTICLE IS TO BE FOLLOWED, THE MATTER SHALL BE REFERRED TO THE STANDING COMMITTEE ON FOODSTUFFS SET UP BY THE COUNCIL DECISION OF 13 NOVEMBER 1969 (4) (HEREINAFTER CALLED "THE COMMITTEE") BY ITS CHAIRMAN, EITHER ON HIS OWN INITIATIVE OR AT THE REQUEST OF A REPRESENTATIVE OF A MEMBER STATE.

2. THE COMMISSION REPRESENTATIVE SHALL SUBMIT TO THE COMMITTEE A DRAFT OF THE MEASURES TO BE TAKEN. THE COMMITTEE SHALL GIVE ITS OPINION ON THIS DRAFT WITHIN A TIME LIMIT SET BY THE CHAIRMAN HAVING REGARD TO THE URGENCY OF THE MATTER. OPINIONS SHALL BE DELIVERED BY A MAJORITY OF " fifty-four " **[4]** VOTES, THE VOTES OF THE MEMBER STATES BEING WEIGHTED IN ACCORDANCE WITH ARTICLE 148 (2) OF THE TREATY. THE CHAIRMAN SHALL NOT VOTE.

3. (a) WHERE THE MEASURES ENVISAGED ARE IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE, THE COMMISSION SHALL ADOPT THEM.

(b) WHERE THE MEASURES ENVISAGED ARE NOT IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE, OR IF NO OPINION IS DELIVERED, THE COMMISSION SHALL WITHOUT DELAY SUBMIT TO THE COUNCIL A PROPOSAL ON THE MEASURES TO BE TAKEN. THE COUNCIL SHALL ACT BY A QUALIFIED MAJORITY.

(c) IF, WITHIN THREE MONTHS OF THE PROPOSALS HAVING BEEN SUBMITTED TO IT, THE COUNCIL HAS NOT ACTED, THE PROPOSED MEASURES SHALL BE ADOPTED BY THE COMMISSION.

ARTICLE 13

THE PROVISIONS OF ARTICLE 12 SHALL APPLY FOR A PERIOD OF 18 MONTHS FROM THE DATE ON WHICH THE MATTER WAS FIRST REFERRED TO THE COMMITTEE UNDER ARTICLE 12 (1).

ARTICLE 14

THIS DIRECTIVE SHALL NOT AFFECT THE LAWS OF THE MEMBER STATES CONCERNING INDICATIONS OF QUALITY APPLICABLE TO PRODUCTS REFERRED TO IN THE ANNEX AND MANUFACTURED IN THEIR TERRITORY.
" IN THE ABSENCE OF RELEVANT COMMUNITY PROVISIONS AS AT 1 APRIL 1986, THE COUNCIL SHALL RE-EXAMINE THE PROVISIONS OF THIS ARTICLE ON THE BASIS OF A REPORT FROM THE COMMISSION, ACCOMPANIED BY ANY APPROPRIATE PROPOSALS. " **[3]**

ARTICLE 15

THIS DIRECTIVE SHALL NOT APPLY:

- WITHOUT PREJUDICE TO ANY PROVISIONS TO BE ADOPTED BY THE COMMUNITY, TO DIETETIC PRODUCTS OR PRODUCTS SPECIFICALLY PREPARED FOR BABIES AND YOUNG CHILDREN;
- TO PRODUCTS INTENDED FOR EXPORT OUTSIDE THE COMMUNITY.

ARTICLE 16

WITHIN A PERIOD OF ONE YEAR FROM NOTIFICATION OF THIS DIRECTIVE, THE MEMBER STATES SHALL, WHERE NECESSARY, AMEND THEIR LAWS TO COMPLY WITH THE PROVISIONS OF THIS DIRECTIVE. THEY SHALL IMMEDIATELY INFORM THE COMMISSION OF THESE AMENDMENTS AND OF THOSE EXCEPTIONS LAID DOWN BY THIS DIRECTIVE OF WHICH THEY AVAIL THEMSELVES. NOT LATER THAN TWO YEARS AFTER NOTIFICATION OF THIS DIRECTIVE THE LAWS THUS AMENDED SHALL APPLY TO THE PRODUCTS PUT ON THE MARKET FOR THE FIRST TIME IN THE MEMBER STATES.

ARTICLE 17

THIS DIRECTIVE IS ADDRESSED TO THE MEMBER STATES.

ANNEX

DESIGNATIONS AND DEFINITIONS OF PRODUCTS

1. PARTLY DEHYDRATED MILK TO WHICH THIS DIRECTIVE IS APPLICABLE

(a) UNSWEETENED CONDENSED MILK PARTLY DEHYDRATED MILK CONTAINING, BY WEIGHT, NOT LESS THAN 7.5 % FAT AND 25 % TOTAL MILK SOLIDS.

(b) UNSWEETENED CONDENSED SKIMMED MILK PARTLY DEHYDRATED MILK CONTAINING, BY WEIGHT, NOT MORE THAN 1 % FAT AND NOT LESS THAN 20 % TOTAL MILK SOLIDS.

(c) UNSWEETENED CONDENSED PARTLY SKIMMED MILK PARTLY DEHYDRATED MILK CONTAINING, BY WEIGHT, NOT LESS THAN 1 % AND NOT MORE THAN 7.5 % FAT, AND NOT LESS THAN 20 % TOTAL MILK SOLIDS. PARTLY DEHYDRATED MILK CONTAINING, BY WEIGHT, BETWEEN 4 AND 4.5 % FAT AND NOT LESS THAN 24 % TOTAL MILK SOLIDS IS THE ONLY MILK WHICH MAY BE SOLD RETAIL WITH THIS DESIGNATION.

(d) UNSWEETENED CONDENSED HIGH-FAT MILK PARTLY DEHYDRATED MILK CONTAINING, BY WEIGHT, NOT LESS THAN 15 % FAT AND NOT LESS THAN 26.5 % TOTAL MILK SOLIDS.

(e) SWEETENED CONDENSED MILK PARTLY DEHYDRATED MILK WITH AN ADMIXTURE OF SUCROSE (SEMI-WHITE SUGAR, SUGAR OR WHITE SUGAR OR EXTRA WHITE SUGAR) AND CONTAINING, BY WEIGHT, NOT LESS THAN 8 % FAT AND 28 % TOTAL MILK SOLIDS. PARTLY DEHYDRATED MILK WITH AN ADMIXTURE OF SUCROSE (SEMI-WHITE SUGAR, SUGAR OR WHITE SUGAR OR EXTRA WHITE SUGAR) AND CONTAINING, BY WEIGHT, NOT LESS THAN 9 % FAT AND 31 % TOTAL MILK SOLIDS IS THE ONLY MILK WHICH MAY BE SOLD RETAIL WITH THIS DESIGNATION.

(f) SWEETENED CONDENSED SKIMMED MILK PARTLY DEHYDRATED MILK WITH AN ADMIXTURE OF SUCROSE (SEMI-WHITE SUGAR, SUGAR OR WHITE SUGAR OR EXTRA WHITE SUGAR) AND CONTAINING, BY WEIGHT, NOT MORE THAN 1 % FAT AND NOT LESS THAN 24 % TOTAL MILK SOLIDS.

(g) SWEETENED CONDENSED PARTLY SKIMMED MILK PARTLY DEHYDRATED MILK WITH AN ADMIXTURE OF SUCROSE (SEMI-WHITE SUGAR, SUGAR OR WHITE SUGAR OR EXTRA WHITE SUGAR) AND CONTAINING BY WEIGHT NOT LESS THAN 1 % AND NOT MORE THAN 8 % FAT AND NOT LESS THAN 24 % TOTAL MILK SOLIDS. PARTLY DEHYDRATED MILK WITH AN ADMIXTURE OF SUCROSE (SEMI-WHITE SUGAR, SUGAR OR WHITE SUGAR OR EXTRA WHITE SUGAR) AND CONTAINING, BY WEIGHT, BETWEEN 4 AND 4.5 % FAT AND NOT LESS THAN 28 % TOTAL MILK SOLIDS IS THE ONLY MILK WHICH MAY BE SOLD RETAIL WITH THIS DESIGNATION.

2. WHOLLY DEHYDRATED MILK TO WHICH THIS DIRECTIVE IS APPLICABLE

(a) DRIED WHOLE MILK OR WHOLE MILK POWDER DEHYDRATED MILK CONTAINING, BY WEIGHT, NOT LESS THAN 26 % FAT.

(b) DRIED SKIMMED MILK OR SKIMMED-MILK POWDER DEHYDRATED MILK CONTAINING, BY WEIGHT, NOT MORE THAN 1.5 % FAT.

(c) DRIED PARTLY SKIMMED MILK OR PARTLY SKIMMED-MILK POWDER DEHYDRATED MILK WITH A FAT CONTENT NOT LESS THAN 1.5 % AND NOT MORE THAN 26 % BY WEIGHT.

(d) DRIED HIGH-FAT MILK OR HIGH-FAT MILK POWDER DEHYDRATED MILK CONTAINING, BY WEIGHT, NOT LESS THAN 42 % FAT.

(1) OJ No L 33, 08/02/1979, p. 1.
(2) OJ No L 243, 29/10/1971, p. 29.
(3) OJ No L 262, 27/09/1976, p. 204.
(4) OJ No L 291, 29/11/1969, p. 9.

FIRST COMMISSION DIRECTIVE

of 13 November 1979

laying down Community methods of analysis for testing certain partly or wholly dehydrated preserved milk for human consumption

(79/1067/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 76/118/EEC of 18 December 1975 on the approximation of the laws of the Member States relating to certain partly or wholly dehydrated preserved milk for human consumption (1), and in particular Article 11 thereof,

Whereas under Article 11 of Directive 76/118/EEC, the composition of certain partly or wholly dehydrated preserved milk is required to be verified by Community methods of analysis;

Whereas it is desirable to adopt an initial series of methods in respect of which studies have been completed;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee of Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Member States shall take all measures necessary to ensure that the analyses necessary for verification of the criteria set out in Annex I are carried out in accordance with the methods described in Annex II.

Article 2

Where alternative methods for a single determination are specified, the sample may be analysed by either method. The test report referred to in Annex II must state the method which has been employed.

Article 3

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive within 18 months of its notification. They shall forthwith inform the Commission thereof.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 13 November 1979.

For the Commission

Etienne DAVIGNON

Member of the Commission

(1) OJ No L 24, 30. 1. 1976, p. 49.

ANNEX I

SCOPE OF THE FIRST COMMUNITY METHODS OF ANALYSIS FOR CERTAIN PARTLY OR WHOLLY DEHYDRATED PRESERVED MILK DIRECTIVE

I. **General provisions**

II. **Determination of dry matter in:**

— unsweetened condensed high fat milk (using method 1, Annex II),
— unsweetened condensed milk (using method 1, Annex II),
— unsweetened condensed partly skimmed milk (using method 1, Annex II),
— unsweetened condensed skimmed milk (using method 1, Annex II),
— sweetened condensed milk (using method 1, Annex II),
— sweetened condensed partly skimmed milk (using method 1, Annex II),
— sweetened condensed skimmed milk (using method 1, Annex II).

III. **Determination of moisture in:**

— dried high fat milk or high fat milk powder (using method 2, Annex II),
— dried whole milk or whole milk powder (using method 2, Annex II),
— dried partly skimmed milk or partly skimmed-milk powder (using method 2, Annex II),
— dried skimmed milk or skimmed-milk powder (using method 2, Annex II).

IV. **Determination of fat in:**

— unsweetened condensed high fat milk (using method 3, Annex II),
— unsweetened condensed milk (using method 3, Annex II),
— unsweetened condensed partly skimmed milk (using method 3, Annex II),
— unsweetened condensed skimmed milk (using method 3, Annex II),
— sweetened condensed milk (using method 3, Annex II),
— sweetened condensed partly skimmed milk (using method 3, Annex II),
— sweetened condensed skimmed milk (using method 3, Annex II),
— dried high fat milk or high fat milk powder (using method 4, Annex II),
— dried whole milk or whole milk powder (using method 4, Annex II),
— dried partly skimmed milk or partly skimmed-milk powder (using method 4, Annex II),
— dried skimmed milk or skimmed-milk powder (using method 4, Annex II).

V. **Determination of sucrose in:**

— sweetened condensed milk (using method 5, Annex II),
— sweetened condensed partly skimmed milk (using method 5, Annex II),
— sweetened condensed skimmed milk (using method 5, Annex II).

VI. **Determination of lactic acid and lactates in:**

— dried high fat milk or high fat milk powder (using method 6, Annex II),
— dried whole milk or whole milk powder (using method 6, Annex II),
— dried partly skimmed milk or partly skimmed-milk powder (using method 6, Annex II),
— dried skimmed milk or skimmed-milk powder (using method 6, Annex II).

VII. **Determination of phosphatase activity in:**

— dried high fat milk or high fat milk powder (using method 7 or 8, Annex II),
— dried whole milk or whole milk powder (using method 7 or 8, Annex II),
— dried partly skimmed milk or partly skimmed-milk powder (using method 7 or 8, Annex II),
— dried skimmed milk or skimmed-milk powder (using method 7 or 8, Annex II).

ANNEX II

METHODS OF ANALYSIS RELATING TO THE COMPOSITION OF CERTAIN PARTLY OR WHOLLY DEHYDRATED PRESERVED MILK PRODUCTS INTENDED FOR HUMAN CONSUMPTION

GENERAL PROVISIONS

1. PREPARATION OF THE SAMPLE FOR CHEMICAL ANALYSIS

1.1. **Unsweetened condensed high fat milk**
Unsweetened condensed milk
Unsweetened condensed partly skimmed milk
Unsweetened condensed skimmed milk

Shake and invert the closed can. Open the can and slowly pour the milk into a second container which can be closed hermetically, mixing by repeated transfer. Ensure that all remaining fat and milk adhering to the wall and the ends of the can are mixed in with the sample. Close the container. If the contents are not homogeneous warm the container in a waterbath at 40 °C. Shake vigorously every 15 minutes. After two hours, remove the container from the waterbath and let it cool to room temperature. Remove the lid and thoroughly mix the contents of the container with a spoon or spatula (if the fat has separated the sample should not be tested). Store in a cool place.

1.2. **Sweetened condensed milk**
Sweetened condensed partly skimmed milk
Sweetened condensed skimmed milk

Cans: Warm the closed can in a waterbath at 30 to 40 °C for about 30 minutes. Open the can and thoroughly mix the contents with a spatula or a spoon by making upward, downward, and circular movements in order to obtain an intimate mixture of the top and bottom layers with all the contents. Ensure that the remaining milk adhering to the wall and end of the can is incorporated in the sample. As far as possible, pour the contents into a second container provided with an air-tight lid. Close the container and store in a cool place.

Tubes: Cut the end and pour the contents into a container provided with an air-tight lid. Next, cut the tube lengthwise. Scrape out all material adhering to the interior and mix it carefully with the rest of the contents. Store the container in a cool place.

1.3. **Dried high fat milk or high fat milk powder**
Dried whole milk or whole milk powder
Dried partly skimmed milk or partly skimmed-milk powder
Dried skimmed milk or skimmed-milk powder

Transfer the milk powder to a clean, dry container (with air-tight lid) of a capacity of twice the volume of the powder. Close the container immediately and thoroughly mix the milk powder by repeatedly shaking and inverting the container. During the preparation of the sample exposure of the milk powder to the atmosphere should be avoided as far as possible to minimize absorption of moisture.

2. REAGENTS

2.1. **Water**

2.1.1. Wherever mention is made of water for dissolution, dilution or washing purposes, distilled water, or demineralized water of at least equivalent purity shall be used.

2.1.2. Wherever reference is made to 'dissolution', 'solution' or 'dilution' without further indication, 'dissolution in water', 'solution in water' and 'dilution in water' is meant.

2.2. **Chemicals**

All chemicals used shall be of recognized analytical reagent quality except where otherwise specified.

3. EQUIPMENT

3.1. Lists of equipment

The lists of equipment contain only those items with a specialized use and items with a particular specification.

3.2. Analytical balance

Analytical balance means a balance capable of weighing to at least 0.1 mg.

4. EXPRESSION OF RESULTS

4.1. Calculation of percentage

Except where otherwise specified, the results shall be calculated as a percentage by mass of the sample as received by the laboratory.

4.2. Number of significant figures

The result shall not contain more significant figures than are justified by the precision of the method of analysis used.

5. TEST REPORT

The test report shall identify the method of analysis used as well as the results obtained. In addition, it shall mention all details of procedure not specified in the method of analysis, or which are optional, as well as any circumstances that may have influenced the results obtained.

The test report shall give all the information necessary for the complete identification of the sample.

METHOD 1: DETERMINATION OF DRY MATTER CONTENT

(oven 99 °C)

1. SCOPE AND FIELD OF APPLICATION

This method determines the dry matter content of:

— unsweetened condensed high fat milk,
— unsweetened condensed milk,
— unsweetened condensed partly skimmed milk,
— unsweetened condensed skimmed milk,
— sweetened condensed milk,
— sweetened condensed partly skimmed milk,
— sweetened condensed skimmed milk.

2. DEFINITION

The dry matter content of condensed milks: dry matter content as determined by the method specified.

3. PRINCIPLE

A known amount of the sample is diluted with water, mixed with sand and dried at a temperature of 99 °C ± 1 °C. The mass after drying is the mass of dry matter and is calculated as a percentage by mass of the sample.

4. REAGENTS

Quartz sand or sea sand, treated with hydrochloric acid (size of the grains: 0.18 to 0.5 mm, that is passing through a 500 micron sieve and retained by a 180 micron sieve). It should meet the following control test:

Heat about 25 g of sand for two hours in the drying oven (5.3) as described in 6.1. to 6.3. Add 5 ml of water, heat again in the oven for two hours, cool and reweigh. The difference between the two masses should not exceed 0.5 mg.

If necessary treat the sand with a 25 % hydrochloric acid solution for three days, mixing occasionally. Wash with water until the acid reaction disappears or the wash water is chloride free. Dry at 160 °C and re-test as above.

5. APPARATUS

5.1. Analytical balance.

5.2. Metal dishes, preferably of nickel, aluminium or stainless steel. The dishes must have lids which fit very well but which are readily removed. Suitable dimensions are: diameter 60 to 80 mm and depth about 25 mm.

5.3. Atmospheric-pressure drying oven, well ventilated, thermostatically controlled with temperature regulated at 99 °C ± 1 °C. The temperature should be uniform throughout the oven.

5.4. Desiccator, containing freshly activated silica gel with a water content indicator or an equivalent desiccant.

5.5. Glass rods, flattened at one end of such a length that they can fit inside the metal dishes (5.2).

5.6. Waterbath, boiling.

6. PROCEDURE

6.1. Place about 25 g sand (4) and a short glass rod (5.5) in the dish (5.2).

6.2. Without covering the dish and contents with the lid, place the dish, contents and lid in the oven (5.3) and heat for two hours.

6.3. Replace lid and transfer the dish to the desiccator (5.4). Allow to cool to room temperature and accurately weigh to the nearest 0.1 mg (M_0).

6.4. Tilt the sand to one side of the dish. Introduce into the clear space about 1.5 g of the sample of sweetened condensed milk and 3.0 g of unsweetened condensed milk. Replace the lid and accurately weigh to the nearest 0.1 mg (M_1).

6.5. Remove the lid, add 5 ml of water and, with the aid of the glass rod, mix the liquids and then the sand and the liquid portion. Leave the rod in the mixture.

6.6. Place the dish on a boiling waterbath (5.6) until the water has evaporated; this usually takes 20 minutes. Stir the mixture from time to time with the rod to keep the mass well aerated so that the mass when dry does not form a cake. Lay the rod inside the dish.

6.7. Place the dish and lid in the oven for one and a half hours.

6.8. Replace the lid, transfer the dish to the desiccator (5.4), allow to cool to room temperature and accurately weigh to the nearest 0.1 mg.

6.9. Replace the dish and lid in the oven, uncover the dish and heat it with its lid for a further hour.

6.10. Repeat process 6.8.

6.11. Repeat the described processes 6.9 and 6.10 until the difference in mass of two successive weighings is less than 0.5 mg or until the mass increases. If an increase in mass occurs use the lowest mass obtained in the calculation (7.1). Let the final weight recorded be M_2 g.

7. EXPRESSION OF RESULTS

7.1. **Method of calculation**

The content of dry matter, calculated as a percentage by mass of the sample, is given by:

$$\frac{M_2 - M_0}{M_1 - M_0} \times 100$$

where:

M_0 = mass, in g of the dish, lid and sand after process 6.3;

M_1 = mass, in g of the dish, lid, sand and sample after process 6.4;

M_2 = mass, in g of the dish, lid, sand and dried sample after process 6.11.

7.2. **Repeatability**

The difference between the results of two determinations carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 0.2 g of dry matter per 100 g of the product.

8. CALCULATION OF TOTAL MILK SOLIDS AND MILK SOLIDS NOT FAT

8.1. **The total milk solids** content of the sweetened condensed milk is given by:

Total dry matter (obtained by method 1, Annex II) — sucrose (obtained by method 5, Annex II).

8.2. **The milk solids not fat** content of the sweetened condensed milks is given by:

Total dry matter (obtained by method 1, Annex II) — (sucrose content obtained by method 5, Annex II) and fat content (obtained by method 3, Annex II).

8.3. **The milk solids not fat** content of unsweetened condensed milks is given by:

Total dry matter (obtained by method 1, Annex II) — fat content (obtained by method 3, Annex II).

METHOD 2: DETERMINATION OF MOISTURE (oven 102 °C)

1. SCOPE AND FIELD OF APPLICATION

This method determines the loss of mass on drying of:

— dried high fat milk or high fat milk powder,
— dried whole milk or whole milk powder,
— dried partly skimmed milk or partly skimmed-milk powder,
— dried skimmed milk or skimmed-milk powder.

2. DEFINITION

Moisture content: the loss of mass on drying as determined by the method specified.

3. PRINCIPLE

The residual mass of a test portion is determined after drying at atmospheric pressure in an oven at 102 °C ± 1 °C to constant mass. The loss of mass is calculated as a percentage by mass of the sample.

4. APPARATUS

4.1. Analytical balance.

4.2. Dishes, preferably of nickel, aluminium, stainless steel or glass. The dishes must have lids which fit very well but which can readily be removed. Suitable dimensions are: diameter 60 to 80 mm and depth about 25 mm.

4.3. Atmospheric-pressure drying oven, well ventilated, thermostatically controlled with temperature regulation (at 102 °C ± 1°C). The temperature should be uniform throughout the oven.

4.4. Desiccator, containing freshly activated silica gel with a water content indicator or an equivalent desiccant.

5. PROCEDURE

5.1. Uncover the dish (4.2) and place it and its lid in the oven (4.3) and heat for about one hour.

5.2. Place the lid on the dish and transfer the covered dish to the desiccator (4.4). Allow it to cool to room temperature and accurately weigh to the nearest 0.1 mg (M_0).

5.3. Introduce approximately 2 g of dried milk sample into the dish, cover the dish with the lid and accurately weigh to the nearest 0.1 mg the covered dish as quickly as possible (M_1).

5.4. Uncover the dish and put it with its lid in the oven for two hours.

5.5. Replace the lid, transfer the covered dish to the desiccator, allow it to cool to room temperature and accurately weigh to the nearest 0.1 mg as quickly as possible.

5.6. Uncover the dish and heat it and its lid for one hour in the oven.

5.7. Repeat process 5.5.

5.8. Repeat processes 5.6 and 5.5 until the decrease in mass between the successive weighings does not exceed 0.5 mg or until the mass increases. If an increase in mass occurs use the lowest mass obtained in the calculation (6.1). Let the final weight recorded be M_2 g.

6. EXPRESSION OF RESULTS

6.1. **Method of calculation**

Calculate the loss of mass on drying of the sample, expressed as a percentage by mass, by the formula:

$$\frac{M_1 - M_2}{M_1 - M_0} \times 100$$

where:

M_0 = mass, in g of the dish and its lid after process 5.2;

M_1 = mass, in g of the dish, its lid and sample after process 5.3;

M_2 = mass, in g of the dish, its lid and final sample after process 5.5.

6.2. **Repeatability**

The difference in results between two determinations carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 0.1 g of moisture per 100 g of product.

METHOD 3: DETERMINATION OF FAT CONTENT IN CONDENSED MILKS (RÖSE-GOTTLIEB METHOD)

1. SCOPE AND FIELD OF APPLICATION

This method determines the fat content of:

— unsweetened condensed high fat milk,
— unsweetened condensed milk,
— unsweetened condensed partly skimmed milk,
— unsweetened condensed skimmed milk,
— sweetened condensed milk,
— sweetened condensed partly skimmed milk,
— sweetened condensed skimmed milk.

2. DEFINITION

The fat content of condensed milks: fat content as determined by the method specified.

3. PRINCIPLE

The fat content is determined by extraction of the fat from an ammoniacal alcoholic solution of the sample with diethyl ether and light petroleum followed by evaporation of the solvents and weighing of the residue and calculation as a percentage by mass of the sample, according to the principle of Röse-Gottlieb.

4. REAGENTS

All reagents should conform to the requirements specified in the blank test (6.1). If necessary, reagents may be redistilled in the presence of about 1 g of butterfat for 100 ml of solvent.

4.1. Ammonia solution, approximately 25 % (m/m) NH_3 (density at 20 °C approximately 0.91 g/ml), or a stronger solution of known concentration.

4.2. Ethanol, 96 ± 2 % (v/v) or, if not available, ethanol denatured with methanol, ethyl methyl ketone or light petroleum.

4.3. Diethyl ether, peroxide-free.

Note 1:
To test for peroxides, add to 10 ml of the ether in a small glass stoppered cylinder, previously rinsed with the ether, 1 ml freshly prepared 10 % potassium iodide solution. Shake and let stand for one minute. No yellow colour should be observed in either layer.

Note 2:
Diethyl ether may be maintained free from peroxides by adding wet zinc foil that has been completely immersed in dilute acidified copper sulphate solution for one minute and subsequently washed with water. Use per litre approximately 8 000 mm^2 zinc foil; cut in strips long enough to reach at least halfway up the container.

4.4. Light petroleum (petroleum ether), with any boiling range between 30 and 60 °C.

4.5. Mixed solvent, prepared shortly before use by mixing equal volume of diethyl ether (4.3) and light petroleum (4.4) (where the use of mixed solvent is indicated, it may be replaced by either diethyl ether or light petroleum alone).

5. APPARATUS

5.1. Analytical balance.

5.2. Suitable extraction tubes or flasks, provided with ground glass stoppers or other closures unaffected by the solvents used.

5.3. Flasks, thin-walled and flat-bottomed, 150 to 250 ml capacity.

5.4. Atmospheric pressure drying oven, well ventilated and thermostatically controlled (adjusted to operate at 102 °C ± 1 °C.

5.5. Anti-bumping granules, fat-free, non porous, non friable in use, e.g. glass beads or pieces of silicon carbide (the use of this material is optional; see clause 6.2.1).

5.6. Siphon, to fit extraction tubes.

5.7. Centrifuge (optional).

6. PROCEDURE

6.1. Blank test

At the same time as the determination of the fat content of the sample, carry out a blank determination on 10 ml of water using the same type of extraction apparatus, the same reagents in the same amounts and the same procedure as described hereafter, excluding clause 6.2.2. If the blank exceeds 0.5 mg, the reagents should be checked and the impure reagent or reagents should be purified or replaced.

6.2. Determination

6.2.1. Dry a flask (5.3) (together with, if required, some anti-bumping granules (5.5) to promote gentle boiling during the subsequent removal of the solvents) in the oven (5.4) for half to one hour. Allow the flask to cool to the temperature of the balance room and accurately weigh the cooled flask to the nearest 0.1 mg.

6.2.2. Stir the prepared sample and immediately weigh, to the nearest 1 mg, 2 to 2.5 g of the sample if sweetened or 4 to 5 g of the sample if unsweetened directly in, or by difference into, the extraction apparatus (5.2). Add water to 10.5 ml and shake gently with slight warming (40 to 50 °C) until the product is completely dispersed. The sample must be dispersed completely otherwise the determination should be repeated.

6.2.3. Add 1.5 ml ammonia (25 %) (4.1) or a corresponding volume of a stronger solution, and mix well.

6.2.4. Add 10 ml ethanol (4.2) and mix the liquids gently but thoroughly in the unclosed apparatus.

6.2.5. Add 25 ml diethyl ether (4.3). Cool under running water. Close the apparatus and shake vigorously and invert repeatedly for one minute.

6.2.6. Remove the stopper carefully and add 25 ml light petroleum (4.4) using the first few millilitres to rinse the stopper and inside of the neck of the apparatus, allowing the rinsings to run into the apparatus. Close by replacing the stopper and shake and invert repeatedly for 30 seconds. Do not shake too vigorously if centrifuging is not to be used in 6.2.7.

6.2.7. Allow the apparatus to stand until the upper liquid layer has become clear and has distinctly separated from the lower aqueous layer. Alternatively carry out the separation using a suitable centrifuge (5.7).

Note:
When a centrifuge which is not driven by a three-phase motor, is used, sparks may occur and care must therefore be taken to avoid an explosion or fire from any ether vapours, coming, for example, from a broken tube.

6.2.8. Remove the stopper, rinse it and the inside of the neck of the apparatus with a few millilitres of mixed solvent (4.5) and allow the rinsings to run into the apparatus. Carefully transfer as much as possible of the supernatant layer by decantation or by means of a siphon (5.6) into the prepared flask (6.2.1).

Note:
If the transfer is not made using a siphon, it may be necessary to add a little water in order to raise the interface between the two layers thus aiding decantation.

6.2.9. Rinse the outside and the inside of the neck of the apparatus or the tip and the lower part of the siphon with a few millilitres of mixed solvent (4.5). Allow the rinsings from the outside of the ap-

paratus to run into the flask and the rinsings from the inside of the neck and from the siphon to run into the extraction apparatus.

6.2.10. Make a second extraction by repeating the procedure of 6.2.5 to 6.2.9 inclusive but using only 15 ml diethyl ether and 15 ml light petroleum.

6.2.11. Make a third extraction by repeating the procedure of 6.2.10 but omit the final rinsing (6.2.9).

Note:
It is not mandatory to carry out this third extraction when analysing skimmed unsweetened condensed milk and skimmed sweetened condensed milk samples.

6.2.12. Carefully evaporate or distil off as much solvent (including the ethanol) as possible. If the flask is of small capacity, it will be necessary to remove some of the solvent as above after each extraction.

6.2.13. When there is no appreciable odour of solvent place the flask on its side in the oven and heat for one hour.

6.2.14. Remove the flask from the oven, allow to cool to the temperature of the balance room and accurately weigh to the nearest 0.1 mg.

6.2.15. Repeat 6.2.13 and 6.2.14 for heating periods of 30 to 60 minutes until the difference in mass of two successive weighings is less than 0.5 mg or until the mass increases. If an increase in mass occurs use the lowest mass obtained in the calculation (7.1). Let the final weight recorded be M_1 g.

6.2.16. Add 15 to 25 ml light petroleum in order to confirm that the extracted matter is wholly soluble. Warm gently and swirl the solvent until all the fat is dissolved.

6.2.16.1. If the extracted matter is wholly soluble in the light petroleum, the mass of fat is the difference between the weights determined at stages 6.2.1 and 6.2.15.

6.2.16.2. If any insoluble matter is present, or in case of doubt, completely extract the fat from the flasks by repeated washing with warm light petroleum, allowing the undissolved material to settle before each decantation. Rinse the outside of the neck of the flask three times. Heat the flask, placed on its side, for one hour in the oven, allow to cool to the temperature of the balance room as before (6.2.1) and weigh to the nearest 0.1 mg. The mass of fat is the difference between the mass obtained at 6.2.15 and this final mass.

7. EXPRESSION OF RESULTS

7.1. Calculation

The mass, in g of fat extracted is:

$$(M_1 - M_2) - (B_1 - B_2)$$

and the fat content of the sample, expressed as a percentage is:

$$\frac{(M_1 - M_2) - (B_1 - B_2)}{S} \times 100$$

where:

M_1 = mass, in g of flask M with fat after stage 6.2.15;

M_2 = mass, in g of flask M after stage 6.2.1 or, in the case of undissolved material or doubt, stage 6.2.16.2;

B_1 = mass, in g of flask B of the blank after stage 6.2.15;

B_2 = mass, in g of flask B after stage 6.2.1 or, in the case of undissolved material or doubt, stage 6.2.16.2;

S = mass, in g of sample used.

7.2. Repeatability

The difference between results of two determinations carried out obtained simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 0.05 g fat per 100 g of the product.

METHOD 4: DETERMINATION OF FAT CONTENT IN DRIED MILKS (RÖSE-GOTTLIEB METHOD)

1. SCOPE AND FIELD AND APPLICATION

This method determines the fat content of:

— dried high fat milk or high fat milk powder,
— dried whole milk or whole milk powder,
— dried partly skimmed milk or partly skimmed-milk powder,
— dried skimmed milk or skimmed-milk powder.

2. DEFINITION

The fat content of dried milks: fat content as determined by the method specified.

3. PRINCIPLE

The fat content is determined by extraction of the fat from an ammoniacal alcoholic solution of sample with diethyl ether and light petroleum, followed by evaporation of the solvents and weighing of the residue and calculation as a percentage by mass of the sample, according to the principle of Röse-Gottlieb.

4. REAGENTS

All reagents should conform to the requirements specified in the blank test (6.1). If necessary, reagents may be redistilled in the presence of about 1 g of butterfat per 100 ml of solvent.

4.1. Ammonia solution, approximately 25 % (m/m) NH_3 (density at 20 °C approximately 0.91 g/ml), or stronger solution of known concentration.

4.2. Ethanol, 96 ± 2 % (v/v) or, if not available, ethanol denatured with methanol, ethyl methyl ketone or light petroleum.

4.3. Diethyl ether, peroxide-free

Note 1:
To test for peroxide, add to 10 ml of the ether in a small glass stoppered cylinder, previously rinsed with the ether, 1 ml freshly prepared 10 % potassium iodide solution. Shake and let stand for one minute. No yellow colour should be observed in either layer.

Note 2:
Diethyl ether may be maintained free from peroxides by adding wet zinc foil that has been completely immersed in dilute acidified copper sulphate solution for one minute and subsequently washed with water. Use per litre approximately 8 000 mm^2 zinc foil cut in strips long enough to reach at least halfway up the container.

4.4. Light petroleum (petroleum ether), with any boiling range between 30 and 60 °C.

4.5. Mixed solvent, prepared shortly before use by mixing equal volumes of diethyl ether (4.3) and light petroleum (4.4) (when the use of mixed solvent is indicated, it may be replaced by either diethyl ether or light petroleum alone).

5. APPARATUS

5.1. Analytical balance.

5.2. Suitable extraction tubes or flasks, provided with ground glass stoppers or other closures unaffected by the solvents used.

5.3. Flasks, thin-walled, flat-bottomed, of 150 to 250 ml capacity.

5.4. Atmospheric pressure drying oven, well ventilated and thermostatically controlled (adjusted to operate at 102 °C ± 1 °C).

5.5. Anti-bumping granules, fat-free, non porous, non friable in use, e.g. glass beads or pieces of silicon carbide (the use of this material is optional: see clause 6.2.1).

5.6. Waterbath, at 60 to 70 °C.

5.7. Siphon to fit extraction tubes.

5.8. Centrifuge (optional).

6. PROCEDURE

6.1. Blank test

At the same time as the determination of the fat content of the sample, carry out a blank determination on 10 ml of water using the same type of extraction apparatus, the same reagents in the same amounts and the same procedure as described hereafter, excluding clause 6.2.2. If blank exceeds 0.5 mg, the reagents should be checked and the impure reagent or reagents should be purified or replaced.

6.2. Determination

6.2.1. Dry the flask (5.3) together with, if required, some anti-bumping granules (5.5) to promote gentle boiling during the subsequent removal of the solvents) in the oven (5.4) for half to one hour. Allow the flask to cool to the temperature of the balance room and accurately weigh the cooled flask to the nearest 0.1 mg.

6.2.2 Accurately weigh, to the nearest 1 mg, directly in, or by difference into, the extraction apparatus (5.2) about 1 g of whole milk powder or about 1.5 g of partly skimmed or skimmed-milk powder. Add 10 ml water and shake gently until the milk powder is completely dispersed (heat may be necessary for some samples).

6.2.3. Add 1.5 ml ammonia (25 %) (4.1) or a corresponding volume of a stronger solution and heat in a waterbath (5.6) for 15 minutes at 60 to 70 °C, shaking occasionally. Cool, for example, in running water.

6.2.4. Add 10 ml ethanol (4.2) and mix the liquids gently but thoroughly in the unclosed apparatus.

6.2.5. Add 25 ml diethyl ether (4.3). Cool in running water. Close the apparatus and shake vigorously and invert repeatedly for one minute.

6.2.6. Remove the stopper carefully and add 25 ml light petroleum (4.4) using the first few millilitres to rinse the stopper and inside of the neck of the apparatus, allowing the rinsings to run into the apparatus. Close by replacing the stopper and shake and invert repeatedly for 30 seconds. Do not shake too vigorously if centrifuging is not to be used in 6.2.7.

6.2.7. Allow the apparatus to stand until the upper liquid layer has become clear and has distinctly separated from the lower aqueous layer. Alternatively carry out the separation using a suitable centrifuge (5.8).

Note:
When a centrifuge which is not driven by a three-phase motor is used, sparks may occur and care must therefore be taken to avoid an explosion or fire from any ether vapours coming, for example, from a broken tube.

6.2.8. Remove the stopper, rinse it and the inside of the neck of the apparatus with a few millilitres of mixed solvent (4.5) and allow the rinsings to run into the apparatus. Carefully transfer as much as possible of the supernatant layer by decantation or by means of a siphon (5.7) into the prepared flask (6.2.1).

Note:
If the transfer is not made using a siphon, it may be necessary to add a little water in order to raise the interface between the two layers thus aiding decantation.

6.2.9. Rinse the outside and the inside of the neck of the apparatus or the tip and the lower part of the siphon with a few millilitres of mixed solvent. Allow the rinsings from the outside of the apparatus to run into the flask and the rinsings from the inside of the neck and from the siphon to run into the extraction apparatus.

6.2.10. Make a second extraction by repeating the procedure of 6.2.5 to 6.2.9 inclusive but using only 15 ml diethyl ether and 15 ml light petroleum.

6.2.11. Make a third extraction by repeating the procedure of 6.2.10 but omit the final rinsing (6.2.9).

Note:
It is not mandatory to carry out this third extraction when analysing dried skimmed milk samples.

6.2.12. Carefully evaporate or distil off as much solvent (including the ethanol) as possible. If the flask is of small capacity it will be necessary to remove some of the solvent as above after each extraction.

6.2.13. When there is no appreciable odour of solvent, place the flask on its side in the oven and heat for one hour.

6.2.14. Remove the flask from the oven, allow to cool to the temperature of the balance room as previously (6.2.1) and accurately weigh to the nearest 0.1 mg.

6.2.15. Repeat 6.2.13 and 6.2.14 for heating periods of 30 to 60 minutes until the difference in mass of two successive weights is less than 0.5 mg or until the mass increases. If an increase in mass occurs use the lowest mass obtained in the calculation (7.1). Let the final weight recorded be M_1 g.

6.2.16. Add 15 to 25 ml light petroleum in order to confirm that the extracted matter is wholly soluble. Warm gently and swirl the solvent until all the fat is dissolved.

6.2.16.1. If the extracted matter is wholly soluble in the light petroleum, the mass of fat is the difference between the weights determined at stages 6.2.1 and 6.2.15.

6.2.16.2. If any insoluble matter is present, or in case of doubt completely extract the fat from the flask by repeated washing with warm light petroleum, allowing the undissolved material to settle before each decantation. Rinse the outside of the neck of the flask three times.

Heat the flask, placed on its side, for one hour in the oven, allow to cool to the temperature of the balance room, as before (6.2.1) and weigh to the nearest 0.1 mg. The mass of fat is the difference between the mass under 6.2.15 and this final mass.

7. EXPRESSION OF RESULTS

7.1. Calculation

The mass, in g of fat extracted is:

$$(M_1 - M_2) - (B_1 - B_2)$$

and the fat content of the sample, expressed as a percentage, is:

$$\frac{(M_1 - M_2) - (B_1 - B_2)}{S} \times 100$$

where:

M_1 = mass, in g of flask M with fat after stage 6.2.15;

M_2 = mass, in g of flask M after stage 6.2.1 or, in the case of undissolved material or doubt, stage 6.2.16.2;

B_1 = mass, in g of flask B of the blank after stage 6.2.15;

B_2 = mass, in g of flask B after stage 6.2.1 or, in the case of undissolved material or doubt, stage 6.2.16.2;

S = mass, in g of sample used.

7.2. **Repeatability**

The difference between results of two determinations carried out simultaneously or in rapid succession on the same sample, the same analyst, under the same conditions, shall not exceed 0.2 g fat per 100 g of product with the exception of skimmed-milk powder for which the difference must not exceed 0.1 g fat per 100 g of product.

METHOD 5: DETERMINATION OF SUCROSE CONTENT (POLARIMETERIC METHOD)

1. SCOPE AND FIELD OF APPLICATION

This method determines the sucrose content of:

— sweetened condensed milk,
— sweetened condensed partly skimmed milk,
— sweetened condensed skimmed milk.

Samples must not contain invert sugar.

2. DEFINITION

The sucrose content of sweetened condensed milks: the sucrose content as determined by the method specified.

3. PRINCIPLE

The method is based on the principle of the Clerget inversion, a mild treatment of the sample with acid which produces complete hydrolysis of sucrose but almost none of lactose or other sugars. The sucrose content is obtained from the change in rotating power of the solution.

A clear filtrate of the sample, without mutarotation by lactose, is prepared by treatment of the solution with ammonia followed by neutralization and clearing by the successive addition of zinc acetate and potassium hexacyanoferrate II solutions.

In a portion of the filtrate the sucrose is hydrolyzed in a specified manner.

From the rotation of the filtrate before and after inversion, the sucrose content is calculated using the appropriate formulae.

4. REAGENTS

4.1. Zinc acetate solution, 1 M: dissolve 21.9 g crystallized zinc acetate dihydrate $Zn(C_2H_3O_2)_2.2H_2O$ and 3 ml glacial acetic acid in water and make up to 100 ml with water.

4.2. Potassium hexacyanoferrate (II) solution, 0.25 M: dissolve 10.6 g crystallized potassium hexacyanoferrate (II) trihydrate $K_4[Fe(CN)_6].3H_2O$ in water and make up to 100 ml with water.

4.3. Hydrochloric acid solution, 6.35 ± 0.20 M (20 to 22 %) or 5.0 ± 0.2 M (16 to 18 %).

4.4. Ammonia solution, 2.0 ± 0.2 M (3.5 %).

4.5. Acetic acid solution, 2.0 ± 0.2 M (12 %).

4.6. Bromothymol blue indicator, 1 % (m/v) solution in ethanol.

5. APPARATUS

5.1. Balance, sensitivity 10 mg.

5.2. Polarimeter tube, 2dm, of exactly calibrated length.

5.3. Polarimeter or saccarimeter:

(a) Polarimeter with sodium light or mercury green light (mercury vapour lamp with prism or the special Wratten Screen No 77 A), to be read with an accuracy of at least 0.05 angular degrees,

(b) Saccarimeter with international sugar scale, using white light passing through a filter of 15 mm of a 6 % solution of potassium bichromate, or sodium light, to be read with an accuracy of at least 0.1 ° on the international sugar scale.

5.4. Water bath, regulated at 60 °C ± 1 °C.

6. PROCEDURE

6.1. Control determination

In order to standardize the procedure, reagents and apparatus, carry out a control determination in duplicate as described below using a mixture of 100 g of milk and 18 g pure sucrose or a mixture of 110 g of skimmed milk and 18 g pure sucrose, each corresponding to 40 g of condensed milk containing 45 % sucrose. Calculate the sugar content using the formulae under 7, substituting for M, F and P respectively in formula 1 the quantity of milk taken and the fat and protein content of this milk, and in formula 2 for M, the value of 40.00. The mean of the values found shall not differ by more than 0.2 % from 45.0 %.

6.2. Determination

6.2.1. Weigh to within 10 mg, approximately 40 g of the well mixed sample into a 100 ml glass beaker. Add 50 ml of hot water (80 to 90 °C) and mix well.

6.2.2. Transfer the mixture quantitatively to a 200 ml measuring flask, rinsing the beaker with successive quantities of water at 60 °C, until the total volume is between 120 and 150 ml. Mix and cool to room temperature.

6.2.3. Add 5 ml of the dilute ammonia solution (4.4). Mix again and then allow to stand for 15 minutes.

6.2.4. Neutralize the ammonia by adding an equivalent quantity of the diluted solution of acetic acid (4.5). Determine the exact number of ml beforehand by titration of the ammonia solution using bromothymol blue as indicator (4.6). Mix.

6.2.5. Add, with gently mixing by rotating the tilted flask, 12.5 ml of zinc acetate solution (4.1).

6.2.6. Add 12.5 ml of potassium hexacyanoferrate (II) solution (4.2) in the same way as for the acetate solution.

6.2.7. Bring the contents of the flask to 20 °C and make up to the 200 ml mark with water at 20 °C.

Note:
During any of the stages so far described all additions of water or reagents should have been made in such manner as to avoid the formation of air bubbles, and with the same object in view, all mixing should have been carried out by rotation of the flask rather than by shaking. If air bubbles are found to be present before making up to 200 ml volume, their removal can be assisted by temporarily connecting the flask to a vacuum pump, and rotating the flask.

6.2.8. Close the flask with a dry stopper and mix thoroughly by vigorous shaking.

6.2.9. Allow to stand for a few minutes and then filter through a dry filter paper, rejecting the first 25 ml of filtrate.

6.2.10. Direct polarization: determine the optical rotation of the filtrate at 20 °C ± 1 °C.

6.2.11. Inversion: pipette 40 ml of the filtrate obtained above into a 50 ml volumetric flask. Add 6.0 ml of 6.35 M hydrochloric acid or 7.5 ml of 5.0 M hydrochloric acid (4.3).

Place the flask in a waterbath of 60 °C for 15 minutes, ensuring that the entire bulb of the flask has been immersed. Mix by a rotatory movement during the first five minutes, in which time the

contents of the flask should have attained the temperature of the bath. Cool to 20 °C, and make up to volume with water at 20 °C. Mix and allow to stand for one hour at this temperature.

6.2.12. *Invert polarization*

Determine the rotation of the inverted solution at 20 °C ± 0.2 °C. (However, if temperature T of the liquid in the polarization tube differs by more than 0.2 °C during the measurement, the temperature correction referred to under 7.2 must be applied.)

7. EXPRESSION OF RESULTS

7.1. Method of calculation

Calculate the sucrose content by means of the following formulae:

$$(1)\quad v = \frac{M}{100}\,(1.08\,F + 1.55\,P)$$

$$(2)\quad S = \frac{D - 1.25\,I}{Q} \times \frac{V - v}{V} \times \frac{V}{L \times M}\ \%$$

where:

S = sucrose content;

M = mass of the weighed sample in grams;

F = percentage of fat in the sample;

P = percentage of protein (N × 6.38) in the sample;

V = volume in ml to which the sample is diluted before filtration;

v = correction in ml for the volume of the precipitate formed during clarification;

D = direct polarimeter reading (polarization before inversion);

I = polarimeter reading after inversion;

L = length in dm of the polarimeter tube;

Q = inversion factor, the values of which are given below.

Remarks:

(a) When exactly 40.00 g of condensed milk are weighed and a polarimeter with sodium light, angular degrees and a 2dm polarimeter tube at 20.0 °C ± 0.1 °C is used the sucrose content of normal condensed milk (C = 9) can be calculated from the following formula:

$$S = (D - 1.25\,I) \times (2.833 - 0.00612\,F - 0.00878\,P)$$

(b) If the invert polarization is measured at a temperature other than 20 °C, the figures should be multiplied by:

$$(1 + 0.0037\,(T - 20).$$

7.2. Values of the inversion factor Q

The following formulae give accurate values for Q, for various sources of light with corrections for concentration and temperature:

Sodium light and polarimeter with angular degrees:
$Q = 0.8825 + 0.0006\,(C - 9) - 0.0033\,(T - 20)$.

Mercury green light and polarimeter with angular degrees:
$Q = 1.0392 + 0.0007\,(C - 9) - 0.0039\,(T - 20)$.

White light with dichromate filter and saccharimeter with international sugar scale degrees:
$Q = 2.549 + 0.0017\,(C - 9) - 0.0095\,(T - 20)$.

In the above formulae:
C = Percentage of total sugars in the inverted solution as polarized,

T = Temperature of the inverted solution in the polarimetric reading.

Note 1:
The percentage of total sugars C in the inverted solution may be calculated from the direct reading and the change on inversion in the usual manner, using the usual values for the specific rotations of sucrose, lactose and invert sugar.

The correction 0.0006 (C – 9) etc., is only accurate when C is approximately 9; for normal condensed milk, this correction can be neglected, C being close to 9.

Note 2:
Variation in temperature from 20 °C of 1 °C makes little difference in the direct reading, but variation of over 0.2 °C in the invert reading necessitates a correction. The correction − 0.0033 (T − 20) etc., is only accurate between 18 °C and 22 °C.

7.3. Repeatability

The difference between results of two determinations carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 0.3 g of sucrose per 100 g of condensed milk.

METHOD 6: DETERMINATION OF LACTIC ACID AND LACTATES CONTENT

1. SCOPE AND FIELD OF APPLICATION

This method determines the lactic acid and lactates, expressed as lactic acid, contents of:

— dried high fat milk or high fat milk powder,
— dried whole milk or whole milk powder,
— dried partly skimmed milk or partly skimmed-milk powder,
— dried skimmed milk or skimmed-milk powder.

2. DEFINITION

Lactic acid and lactates content of dried milks: the lactic acid and lactates, expressed as lactic acid, contents as determined by the method specified.

3. PRINCIPLE

Fat, protein and lactose are simultaneously removed from a solution of the sample by addition of copper sulphate and calcium hydroxide followed by filtration.

The lactic acid and lactates in the filtrate are converted into acetaldehyde by concentrated sulphuric acid in the presence of copper II sulphate.

The lactic acid content is determined colorimetrically using p-hydroxydiphenyl.

The lactic acid and lactates content is expressed as mg of lactic acid per 100 g of solids-non-fat.

4. REAGENTS

4.1. Copper (II) sulphate solution: dissolve 250 g of copper (II) sulphate ($CuSO_4.5H_2O$) in water and dilute to 1 000 ml with water.

4.2. Calcium hydroxide suspension.

4.2.1. Grind 300 g of calcium hydroxide ($Ca(OH)_2$) in a mortar with water, using totally 900 ml. The suspension should be freshly prepared before use.

4.2.2. Calcium hydroxide suspension: grind 300 g of calcium hydroxide ($Ca(OH)_2$) in a mortar with water, using totally 1 400 ml. The suspension should be freshly prepared before use.

4.3. Sulphuric acid — copper (II) sulphate solution: Add to 300 ml of sulphuric acid, 95.9 to 97.0 % (m/m) of H_2SO_4, 0.5 ml of the copper (II) sulphate solution (4.1).

4.4. p-hydroxydiphenyl ($C_6H_5C_6H_4OH$) solution: dissolve, by shaking and by heating slightly 0.75 g of p-hydroxydiphenyl in 5 ml of an aqueous solution of sodium hydroxide, containing 5 g of NaOH per 100 ml. Dilute to 50 ml with water in a volumetric flask. Keep the solution in a brown coloured glass bottle in a dark and cool place. Do not use if the colour changes or tubidity occurs. The maximum shelf life is 72 hours.

4.5. Lactic acid standard solution: dissolve, shortly before use, 0.1067 g of lithium lactate (CH_3 CHOHCOOLi) in water and dilute to 1 000 ml in a volumetric flask. 1 ml of this solution corresponds to 0.1 mg of lactic acid.

4.6. Standard reconstituted milk: analyse in advance several samples of high quality dried milk. For the preparation of the calibration curve select the sample having the lowest lactic acid content, containing not more than 30 mg of lactic acid per 100 g of solids-non-fat. Follow the operating procedure described under 6.2.1 and 6.2.2 below.

5. APPARATUS

5.1. Analytical balance.

5.2. Spectrophotometer suitable for readings at a wavelength of 570 nm.

5.3. Waterbath at 30 °C ± 2 °C.

5.4. Mortar and pestle.

5.5. Filter paper (Schleicher and Schull 595, Whatman 1 or equivalent).

5.6. Test tubes, pyrex or equivalent (dimensions 25 × 150 mm).

Note:
All glassware must be perfectly clean and designated for use solely in this determination. Rinse glassware containing precipitate residues with concentrated hydrochloric acid before washing.

6. PROCEDURE

6.1. **Blank test**

Carry out a blank test by placing 30 ml of water into a 50 ml graduated tube and treating this tube as described under 6.2.4 to 6.2.11 inclusive. If the blank measured against water exceeds an equivalent of 20 mg of lactic acid per 100 g solids-non-fat, the reagents should be checked and the impure reagents or reagent should be replaced. Carry out the blank test at the same time as the analysis of the sample.

6.2. **Determination**

Note: Avoid contamination with impurities especially with saliva and sweat.

6.2.1. Determine the solids-non-fat content (a) g of the sample by subtracting the fat content (obtained by method 4) and the moisture content (obtained by method 2) from 100.

6.2.2. Weigh $\frac{1000}{(a-10)}$ g of the sample to the nearest 0.1 g. Add this quantity of sample to 100 ml of water and mix thoroughly.

6.2.3. Pipette 5 ml of the solution obtained into a 50 ml graduated tube and dilute with water to about 30 ml.

6.2.4. Add slowly while shaking, 5 ml of the copper (II) sulphate solution (4.1) and allow to stand for 10 minutes.

6.2.5. Add slowly while shaking, 5 ml of the calcium hydroxide suspension (4.2.1) or 10 ml of the calcium hydroxide suspension (4.2.2).

6.2.6. Dilute to 50 ml with water, shake vigorously, allow to stand for 10 minutes then filter. Discard the first runnings.

6.2.7. Pipette 1 ml of the filtrate into a test tube (5.6).

6.2.8. Add to the tube by means of a burette or graduated pipette 6.0 ml of the sulphuric acid-copper (II) sulphate solution (4.3). Mix.

6.2.9. Heat in the boiling water bath for five minutes. Cool to ambient temperature under running water.

6.2.10. Add two drops of p-hydroxydiphenyl reagent (4.4) and shake vigorously to spread the reagent evenly throughout the liquid. Place the tube in the waterbath at 30 °C ± 2 °C; leave for 15 minutes shaking from time to time.

6.2.11. Place the tube in the boiling waterbath for 90 seconds. Cool to ambient temperature under running water.

6.2.12. Measure the optical density against the blank test (6.1) within three hours at the wavelength specified under 5.2.

6.2.13. If the optical density exceeds that of the highest point of the standard curve, repeat the test using an adequate dilution of the filtrate obtained under 6.2.6.

6.3. **Preparation of the standard**

6.3.1. Pipette 5 ml of the reconstituted milk (4.6) into five 50 ml graduated tubes. Pipette into these tubes 0, 1, 2, 3 and 4 ml respectively of the standard solution (4.5), so as to obtain a range of standards corresponding to 0, 20, 40, 60 and 80 mg of added lactic acid per 100 g of solids-non-fat, of the dried milk.

6.3.2. Dilute with water to about 30 ml and treat as described under 6.2.4 to 6.2.11.

6.3.3. Measure the optical densities of the standards (6.3.1) against the blank test (6.1) at the wavelength specified under 5.2. Plot in a diagram the optical densities against the quantities of lactic acid given under 6.3.1, i.e. 0 mg, 20 mg, 40 mg, 60 mg and 80 mg per 100 g of solids-non-fat. Draw the best fitting straight line through the points and prepare the standard curve by moving this line parallel to itself in such a way that it passes through the origin.

7. EXPRESSION OF RESULTS

7.1. **Method of calculation**

Convert the optical density measured under 6.2.12 or 6.2.13 into mg of lactic acid per 100 g of solids-non-fat in the sample by reference to the standard curve. Multiply this result by the dilution factor where the filtrate has been diluted according to 6.2.13.

7.2. **Repeatability**

The difference between the results of two determinations carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 8 mg of lactic acid per 100 g of solids-non-fat for contents up to 80 mg. For higher values, this difference may not exceed 10 % of the lowest value.

METHOD 7: DETERMINATION OF PHOSPHATASE ACTIVITY (MODIFIED SANDERS AND SAGER PROCEDURE)

1. SCOPE AND FIELD OF APPLICATION

This method describes the determination of phosphatase activity in:

— dried high fat milk or high fat milk powder,
— dried whole milk or whole milk powder,
— dried partly skimmed milk or partly skimmed-milk powder,
— dried skimmed milk or skimmed-milk powder.

2. DEFINITION

The phosphatase activity of dried milks is a measure of the quantity of active alkaline phosphatase present. It is expressed as the quantity of phenol in µg liberated by 1 ml of reconstituted milk, as determined by the procedure described below.

3. PRINCIPLE

The phosphatase activity of dried milks is determined by the ability of the phosphatase to liberate the phenol from disodiumphenylphosphate. The quantity of phenol liberated under prescribed conditions is determined by a spectrophotometric measurement of the colour developed with Gibb's reagent.

4. REAGENTS

4.1. Solution A

Barium borate hydroxide buffer: pH 10.6 ± 0.1 at 20 °C.

Dissolve: 25.0 g of barium hydroxide ($Ba(OH)_2.8H_2O$) in water and dilute to 500 ml.

Dissolve: 11.0 g of boric acid (H_3BO_3) in water and dilute to 500 ml.

Warm the two solutions to 50 °C and mix.

Shake and cool the mixture to room temperature.

Adjust the pH to 10.6 ± 0.1 with the barium hydroxide solution and filter.

Store the solution in a tightly stoppered container.

Before use, dilute the buffer with an equal quantity of water.

4.2. Solution B:

Colour development buffer.

Dissolve: 6.0 g of sodium metaborate ($NaBO_2$) (or 12.6 g of $NaBO_2.4H_2O$) and 20.0 g of sodium chloride (NaCl) in water and dilute to 1 000 ml with water.

4.3. Solution C

Buffer substrate solution.

4.3.1. Dissolve 0.5 g of disodiumphenylphosphate ($Na_2C_6H_5PO_4.2H_2O$) in 4.5 ml of Solution B (4.2). Add 2 drops of Solution E (4.5) and allow to stand 30 minutes. Extract the colour with 2.5 ml butanol (4.10). If necessary, repeat the colour extraction. After separation, discard the butanol. This solution can be kept for several days in a refrigerator. Develop and extract the colour once more before use.

4.3.2. Pipette 1 ml of this solution into a 100 ml volumetric flask and make up to volume with Solution A. Prepare the buffer solution immediately before use.

4.4. Solution D

Precipitant.

Dissolve 3.0 g of zinc sulphate ($ZnSO_4.7H_2O$) and 0.6 g of copper (II) sulphate ($CuSO_4.5H_2O$) in water and make up to 100 ml with water.

4.5. Solution E

Gibb's reagent.

Dissolve 0.040 g of 2,6-dibromoquinone 1,4 — chloroimide ($O.C_6H_2Br_2.NCl$) in 10 ml of 96 % ethanol. Store the solution in a dark glass bottle kept in a refrigerator. Discard this reagent when it has become discoloured.

4.6. Colour dilution buffer

Dilute 10 ml of Solution B (4.2), colour development buffer, to 100 ml with water.

4.7. Copper sulphate solution

Dissolve 0.05 g of copper (II) sulphate ($CuSO_4.5H_2O$) in water and make to 100 ml with water.

4.8. Phenol standard solution

Dissolve 0.200 ± 0.001 g of pure phenol in water and make up to 100 ml in a volumetric flask with water. This solution can be stored for several months in a refrigerator. Dilute 10 ml of this solution to 100 ml with water. This diluted solution contains 200 µg of phenol in 1 ml and can be used for preparing more dilute solutions.

4.9. Boiled distilled water.

4.10. n-Butanol.

5. APPARATUS

5.1. Analytical balance.

5.2. Waterbath, thermostatically controlled at 37 °C ± 1 °C.

5.3. Spectrophotometer suitable for readings at a wavelength of 610 nm.

5.4. Filter paper (Schleicher and Schull 597, Whatman 42 or equivalent filter paper).

5.5. Waterbath, boiling.

5.6. Aluminium foil.

6. PROCEDURE

Precautions:

1. Avoid direct exposure to sunlight.
2. All the glassware, stoppers and removal material should be perfectly clean. It is recommended that they be rinsed and boiled with water or that they be treated with steam.
3. Avoid using plastic materials (stoppers for example) as they may contain phenols.
4. Saliva contains phosphatase; contamination by traces of saliva must therefore be carefully avoided.

6.1. Preparation of the sample

6.1.1. Weigh, to within 0.1 g, 10 g of the sample and dissolve in 90 ml of water. The temperature for dissolving the powder shall, under no circumstances, exceed 35 °C.

6.2. Determination

6.2.1. Introduce in each of two test tubes 1 ml of reconstituted milk prepared as described in 6.1.1.

6.2.2. Heat one of the tubes in boiling water for two minutes. Cover the tube and the waterbath (5.5) or, for example, a beaker with aluminium foil (5.6) to ensure that the entire tube will be heated. Cool in cold water to room temperature. Use this tube for the blank test. For all subsequent operations treat the two tubes identically.

6.2.3. Add 10 ml of Solution C (4.3.2). Mix and place the tube in the waterbath at 37 °C (5.2).

6.2.4. Incubate for 60 minutes in the waterbath shaking periodically.

6.2.5. Transfer the tubes immediately to a boiling waterbath (5.5) and heat for two minutes; cool to room temperature in cold water.

6.2.6. Add 1 ml of Solution D (4.4), mix and filter through a dry filter paper; discard the first filtrates until a clear liquid is obtained.

6.2.7. Put 5 ml of each filtrate into test tubes, add 5 ml of Solution B (4.2) and 0.1 ml of Solution E (4.5). Mix.

6.2.8. Allow the colour to develop at room temperature for 30 minutes away from direct sunlight.

6.2.9. Measure the optical density of the sample solution, against the blank, at the wavelength indicated in 5.3.

6.2.10. Repeat the determination if the optical density of the solution is above that of the standard sample with 20 µg of phenol prepared according to 7.

If this limit is exceeded, dilute a suitable volume of reconstituted milk according to 6.1.1 with a suitable volume of this milk carefully boiled as indicated in 6.2.2 to inactivate the phosphatase present.

7. PREPARATION OF THE STANDARD CURVE

7.1. Pipette into four 100 ml volumetric flasks, 1, 3, 5 and 10 ml of the standard solution diluted according to 4.8 and make up to volume with water; these dilutions contain respectively 2, 6, 10 and 20 µg of phenol per ml.

7.2. Pipette 1 ml of water or 1 ml of each standard solution (7.1) into the test tubes in order to obtain a series of samples containing 0 (blank value obtained using the 1 ml of water) — 2 — 6 — 10 and 20 µg of phenol.

7.3. Pipette successively into each test tube 1 ml of the solution of copper (II) sulphate (4.7), 5 ml of the colour dilution buffer solution (4.6), 3 ml of water and 0.1 ml of Solution E (4.5). Mix.

7.4. Leave the test tubes for 30 minutes at room temperature away from direct sunlight.

7.5. Measure the absorbance of the solutions in each of the tubes, compared to the blank value, at the wavelength indicated in 5.3.

7.6. Prepare the standard curve by plotting the absorbance values against the quantities of phenol in µg as indicated in 7.2.

8. EXPRESSION OF THE RESULTS

8.1. Calculation

8.1.1. Convert the figures as determined under 6.2.9 to µg of phenol, by reference to the standard curve.

8.1.2. Calculate the phosphatase activity expressed as µg of phenol per ml of reconstituted milk according to the following formula:

Phosphatase activity = 2.4 x P
where P = the quantity of phenol in µg according to 8.1.1.

8.1.3. If it was necessary to dilute as indicated under 6.2.10 multiply the result obtained in 8.1.2 by the dilution factor.

8.2. Repeatability

The difference between the results of two determinations carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 2 µg of phenol liberated by 1 ml of reconstituted milk.

METHOD 8: DETERMINATION OF PHOSPHATASE ACTIVITY (ASCHAFFENBURG AND MÜLLEN PROCEDURE)

1. SCOPE AND FIELD OF APPLICATION

This method describes the determination of phosphatase activity in:

— dried high fat milk or high fat milk powder,
— dried whole milk or whole milk powder,
— dried partly skimmed milk or partly skimmed-milk powder,
— dried skimmed milk or skimmed-milk powder.

2. DEFINITION

The phosphatase activity of dried milks is a measure of the quantity of active alkaline phosphatase present in the product. It is expressed as the quantity of p-nitrophenol in micrograms liberated by 1 ml of the reconstituted sample, under the conditions described.

3. PRINCIPLE

The reconstituted sample is diluted with a buffer substrate at pH 10.2 and incubated at a temperature of 37 °C for two hours. Any alkaline phosphatase present in the sample will, under

these circumstances, liberate p-nitrophenol from added disodium p-nitrophenyl phosphate. The p-nitrophenol liberated is determined by direct comparison with standard colour glasses in a simple comparator using reflected light.

4. REAGENTS

4.1. Sodium carbonate-bicarbonate buffer solution.

Dissolve 3.5 g of anhydrous sodium carbonate and 1.5 g of sodium bicarbonate in water and dilute to 1 000 ml in a volumetric flask with water.

4.2. Buffer substate.

Dissolve 1.5 g of disodium p-nitrophenylphosphate in sodium carbonate-bicarbonate buffer (4.1) and dilute to 1 000 ml in a volumetric flask with buffer (4.1).

This solution is stable if stored in a refrigerator ($\leq 4\ ^{\circ}C$) for one month but a colour control test should be carried out on such stored solutions — see 6, precaution number 3.

4.3. Clarification solutions.

4.3.1. Zinc sulphate solution.

Dissolve 30.0 g of zinc sulphate ($ZnSO_4$) in water and dilute to 100 ml in a volumetric flask with water.

4.3.2. Potassium hexacyanoferrate (II) solution.

Dissolve 17.2 g of potassium hexacyanoferrate (II) trihydrate ($K_4Fe(CN)_6.3H_2O$) and dilute to 100 ml in a volumetric flask with water.

5. APPARATUS

5.1. Analytical balance.

5.2. Waterbath, thermostatically controlled at $37\ ^{\circ}C \pm 1\ ^{\circ}C$.

5.3. Comparator, with special disc containing standard colour glasses calibrated in µg p-nitrophenol per ml milk, and 2 × 25 mm cells.

6. PROCEDURE

Precautions:

1. After use, test tubes must be emptied, rinsed in water, washed in hot water containing an alkaline detergent, followed by thorough rinsing in clean hot tap water. Finally, they must be rinsed in water and dried before use.

   Pipettes must be thoroughly rinsed in clean cold tap water immediately after use, followed by rinsing in water and dried before use.

2. The test tube stoppers must be thoroughly rinsed in hot tap water immediately after use, followed by boiling for two minutes in water.

3. The buffer substrate solution (4.2) should remain stable for at least one month if stored in a refrigerator at 4 °C or less. Any instability is denoted by the formation of a yellow colour. Whilst the test is always read against a boiled product control containing the same buffer substrate solution, it is recommended that the solution should not be used if it gives a colour reading in excess of 10 µg when read in a 25 mm cell in the comparator using distilled water in the other 25 mm cell.

4. Use a separate pipette for each sample and avoid contaminating the pipette with saliva.

5. The test must not be exposed to direct sunlight at any time.

6.1. Preparation of sample

Dissolve 10 g of the powder in 90 ml of water. The temperature for dissolving the powder must not exceed 35 °C.

6.2. **Determination**

6.2.1. Pipette 15 ml of buffer substrate (4.2) into a clean, dry test tube, followed by 2 ml of the reconstituted sample (6.1) to be tested. Stopper the tube, mix by inversion and place in the 37 °C water bath (5.2).

6.2.2. At the same time, place in the water bath a control tube containing 15 ml of buffer substrate and 2 ml of boiled reconstituted sample similar to that under test.

6.2.3. After two hours remove both tubes from the water bath, add 0.5 ml of zinc sulphate precipitant (4.3.1), replace the stopper, shake vigorously and allow to stand for three minutes. Add 0.5 ml of potassium hexacyanoferrate (II) precipitant (4.3.2), mix thoroughly and filter through the fluted filter paper (5.4) and collect the clear filtrate in the clean test tube.

6.2.4. Transfer the filtrate to a 25 mm cell and compare against the filtrate of the boiled sample control in the comparator using the special disc (5.3).

7. EXPRESSION OF RESULTS

7.1. **Calculation**

The direct reading obtained under 6.2.4 is recorded as µg p-nitrophenol per ml sample or per ml of reconstituted sample.

7.2. **Repeatability**

The difference between the results of two determinations carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 2 µg of p-nitrophenol liberated by 1 ml of reconstituted milk.

II

(Acts whose publication is not obligatory)

COMMISSION

FIRST COMMISSION DIRECTIVE

of 6 October 1987

laying down Community methods of sampling for chemical analysis for the monitoring of preserved milk products

(87/524/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 85/591/EEC of 20 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption (1), and in particular Article 1 (1) thereof,

Whereas Council Directive 76/118/EEC of 18 December 1975 on the approximation of the laws of the Member States relating to certain partly or wholly dehydrated preserved milk for human consumption (2), as last amended by the Act of Accession of Spain and Portugal, lays down Community rules governing the composition, use of reserved designations, conditions of manufacture and labelling of the products in question;

Whereas, pursuant to Article 1 (1) of Directive 85/591/EEC, samples of such products must be taken in accordance with Community methods for the purpose of determining their composition, conditions of manufacture, packaging or labelling;

Whereas it is desirable to adopt an initial series of methods of sampling for chemical analysis in respect of which studies have been completed;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Member States shall take all measures necessary to ensure that the taking of samples as referred to in the Annex is carried out in accordance with the methods described therein.

Article 2

Member States shall take all measures necessary to comply with this Directive by 6 April 1989 at the latest. They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 6 October 1987.

For the Commission

COCKFIELD

Vice-President

(1) OJ No L 372, 31. 12. 1985, p. 50.
(2) OJ No L 24, 30. 1. 1976, p. 49.

ANNEX

METHODS OF SAMPLING RELATED TO THE CONTROL OF CHEMICAL ANALYSIS OF CERTAIN PARTLY OR WHOLLY DEHYDRATED PRESERVED MILK PRODUCTS

I. GENERAL PROVISIONS

1. Administrative instructions

1.1. *Personnel*

Sampling shall be performed by an authorized qualified person as specified in the Member State's regulations.

1.2. *Sealing and labelling of samples*

Each sample taken for official use shall be sealed at the place of sampling and identified following the Member State's regulations.

1.3. *Replicate samples*

At least two equivalent samples shall be simultaneously prepared for analysis. Under reservation of Community legislation to be defined, the procedure and number of samples to be taken depending upon the appropriate national legislation for each Member State.

The samples shall be dispatched to the laboratory as soon as possible after sampling.

1.4. *Report*

Samples shall be accompanied by a report, which will be established in accordance with the Member State's legislation.

2. Sampling Equipment

Specifications

All sampling equipment shall be made of suitable material of adequate strength, which does not bring about a change in the sample which may affect any result of the subsequent examination and should not cause any change in the samples while sampling is being carried out. The use of stainless steel is recommended.

All surfaces shall be smooth and free from crevices and all corners shall be rounded. Sampling equipment shall comply with the requirements laid down with respect to each product to be sampled.

3. Sampling containers

Specifications

Sample containers and closures shall be of materials and construction which adequately protect the sample and which do not bring about in the sample a change which may affect any result of the subsequent analysis or examination. Materials which are appropriate include glass, some metals and some plastics. The containers shall preferably be opaque. If transparent or translucent the container with contents shall be stored in a dark place.

Containers and closures shall be clean and dry. The shape and capacity of the container shall be appropriate to the requirements laid down for the product to be sampled.

Single service plastic containers, containers made from plastic, laminates including an aluminium foil or suitable plastic bags, with appropriate methods of closure, may be used.

Containers other than plastic bags shall be securely closed either by means of a suitable stopper or by a screw-cap of metal or plastic material having, if necessary, an air-tight plastic liner. Any stopper or liner used should be insoluble, non-absorbant and greaseproof, and will not influence the odour, flavour, properties or composition of the sample.

Stoppers shall be made of, or covered with, non-absorbant odourless materials.

4. Sampling technique

The sample container shall be closed immediately after sampling.

5. Storage of samples

The recommended storage temperatures of the samples of the various products shall not exceed 25 °C. Storage time and temperature must be considered together and not separately.

6. **Transport of samples**

Samples shall be brought to the laboratory responsible for the tests as soon as possible (preferably within 24 hours of sample taking).

During transit, precautions shall be taken to prevent exposure to contaminating odours, to direct sunlight and to temperatures greater than 25 °C.

II. METHOD 1 : SAMPLING OF PARTLY DEHYDRATED MILKS

1. **Scope and field of application**

— unsweetened condensed high-fat milk,
— unsweetened condensed milk,
— unsweetened condensed partly skimmed milk,
— unsweetened condensed skimmed milk,
— sweetened condensed milk,
— sweetened condensed skimmed milk,
— sweetened condensed partly skimmed milk.

2. **Equipment**

2.1. *General*

See Section 2 of the General Provisions.

2.2. *Plungers and agitators*

Plungers or agitators, for mixing liquids in bulk, shall be of sufficient area to produce adequate disturbance of the product without developing rancid flavour. In view of the different shapes and sizes of containers, no specific design of plunger can be recommended for all purposes, but plungers shall be designed in such a way as to avoid scratching the inner surface of the product containers during agitation.

Suitable material has been described in Section 2 of the General Provisions.

A form of plunger recommended as being suitable for the mixing of liquids in buckets or in cans has the following dimensions (Fig. 1) : a disc 150 millimetres in diameter, perforated with six holes each of 12,5 millimetres in diameter on a circle 100 millimetres in diameter, the disc being fixed centrally to a metallic rod, the other end of which forms a loop handle. The length of the rod, including the handle, shall be approximately 1 metre.

A suitable plunger for use for small tanks, has the following approximate dimensions (Fig. 2) : a rod not less than 2 metres in length, fitted with a disc 300 millimetres in diameter perforated with 12 holes each 30 millimetres in diameter on a circle 230 millimetres in diameter.

For mixing the contents of large vessels, mechanical agitation or agitation by clean compressed air is advisable. Minimal air pressure and volume shall be used to prevent rancid flavour development.

Note : Wherever 'clean compressed air' is required by this guide, it is necessary to use compressed air from which all contaminants (including oil, water and dust) have been excluded.

2.3. *Stirrer*

Broad bladed, of sufficient depth to reach the bottom of the product container, and which preferably has one edge shaped to the contour of the container (see Fig. 3).

2.4. *Dippers*

A dipper of suitable size and shape for collecting the sample is illustrated in Fig. 4. The dipper shall be fitted with a solid handle at least 150 millimetres in length. The capacity of the dipper shall be not less than 50 millilitres. It is an advantage for the handle to be bent over. The tapered form of the cup permits nesting of the dippers.

Alternatively, a dipper of similar capacity may be used, but it should have parallel sides graduated into five equal sections for assistance in sampling proportionately consignments held in more than one container.

2.5. *Rod*

Round, about 1 metre long and 35 millimetres in diameter.

2.6. *Container*

For sub-sampling capacity of 5 litres, wide mouthed.

2.7. *Spoon or spatula*

Broad bladed.

2.8. *Sample containers*

See Section 3 of General Provisions.

3. **Procedure**

3.1. *Sampling of unsweetened partly dehydrated milks*

A sample of not less than 200 grams shall be taken.

3.1.1. The product shall be thoroughly mixed by plunging or stirring, or by mechanical agitation, or by pouring from one container to another, or by the use of clean compressed air (see note 2.2), until sufficient homogeneity is obtained.

Take the sample immediately after mixing by means of a dipper. If obtaining sufficient homogeneity presents difficulties, samples shall be taken from different portions of the product container to a total of not less than 200 grams. (It shall be noted if the sample is a mixture of sub-samples on the sample label and in the accompanying report).

3.1.2. Sampling products packed in small retail containers

The intact and unopened container may constitute the sample. One or more containers with the same batch or code number shall be taken to make up a sample of not less than 200 grams.

3.2. *Sampling of sweetened partly dehydrated milk*

3.2.1. General

The sampling of bulk containers of sweetened partly dehydrated milk may be a matter of extreme difficulty, particularly when the product is not homogeneous and is highly viscous. Problems of sampling may arise through the presence of large crystals of sucrose or lactose, or through precipitation of various salts which may occur throughout the body of the product or adhere to the walls, or through the presence of lumpy matter. Such conditions will become apparent when a sampling rod is introduced into the product container and is withdrawn after exploring as large an area of contact as possible. Provided the size of sugar crystals is not larger than 6 millimetres, difficulties in sampling should not be experienced from this cause. When the product is not homogeneous, this fact shall be noted on the sample label of the accompanying report. Since sweetened condensed milk is frequently stored at atmospheric temperature, it is recommended that in order to obtain a representative sample the contents shall be brought to a temperature of not less than 20 °C.

3.2.2. Procedure

A sample of not less than 200 grams shall be taken.

— Open containers

One end of the container, previously thoroughly cleaned and dried to prevent foreign matter falling into the bulk during the opening process, shall be removed. The contents shall be mixed by using a stirrer (see Fig. 3). The blade shall be scraped around the sides and bottom of the container to remove any adhering product. The contents shall be thoroughly mixed by a combination of rotary and vertical movements, with the stirrer inclined diagonally, taking care to avoid incorporation of air in the sample. The stirrer shall be withdrawn and the condensed milk adhering to it shall be transferred into the 5-litre (2.6) container by means of a spatula or spoon. The mixing and withdrawal shall be repeated until 2 to 3 litres have been collected. This shall be mixed until homogeneous and a sample of not less than 200 grams shall be taken.

— Enclosed drums with bungs at the end, or at the side

For the reasons described in 3.2.1, sampling through the bung hole is suitable only with condensed milk which flows readily and is of uniform consistency. The contents shall be mixed by inserting a rod through the bung hole, and after exploring and stirring as far as possible in all directions, the rod shall be withdrawn and a sample shall be prepared as described in 3.2.1. Alternatively, the contents may be allowed to run into a suitable container, care being taken that as much of the contents as possible be recovered from the drum. After stirring with a stirrer the sample shall be collected as described in 3.2.1.

3.2.3. Sampling products packed in small retail containers

The intact and unopened container may constitute the sample. One or more containers with the same batch or code number shall be taken to make up a sample of not less than 200 grams.

3.3. *Preservation, storage and transport of sample*

See Sections 5 and 6 of the General Provisions.

III. METHOD 2: SAMPLING OF POWDERED PRESERVED MILK PRODUCTS

1. **Scope and field of application**

This method describes the sampling for chemical analysis of:

— dried whole milk or whole milk powder,
— dried skimmed milk or skimmed milk powder,
— dried partly skimmed milk or partly skimmed milk powder,
— dried high-fat milk or high-fat milk powder.

2. **Equipment**

See Section 2 of the General Provisions.

2.1. *Borers of sufficient length to reach the bottom of the product container*

Borers conforming to the description given in Part IV are appropriate.

2.2. *Scoop, spoon or broad-bladed spatula*

2.3. *Sample containers*

See Section 3 of the General Provisions.

3. **Procedure**

3.1. *General*

Care shall be taken to minimize the uptake of atmospheric moisture by the content of the product container or in the period prior to sampling for analysis. The product container shall be securely reclosed after sampling.

3.2. *Sampling*

A sample of not less than 200 grams shall be taken. The clean and dry borer shall be passed through the product, if necessary with the container inclined or laid on its side. The slit shall be oriented downward and an even rate of penetration used. When the borer reaches the bottom of the container it shall be rotated through 180°, withdrawn and the contents discharged into the sample container. One or more borers shall be taken to make a sample of not less than 200 grams. The sample container shall be closed immediately after sampling is complete.

3.2.1. Sampling products packed in small retail packages

The intact and unopened package may constitute the sample. One or more containers with the same batch or code number small be taken to make up a sample of not less than 200 grams.

Note: When products are described as 'instant', a whole unopened package must constitute the sample.

3.3. *Preservation, stockage and transport of sample*

See Sections 5 and 6 of the General Provisions.

IV. BORERS FOR THE SAMPLING OF POWEDERED PRESERVED MILK IN BULK

1. **Types of borer**

Type A: long
Type B: short
(see Fig. 5).

2. **Materials**

Blade and stem shall be made of polished metal, preferably stainless steel.

The grip of the long trype should preferably be made of stainless steel.

The short type borer shall have a detachable grip of wood or plastic, fitted with a bayonet catch in the blade.

3. **Construction**

3.1. Shape, material and finish shall be such as to permit the borer to be easily cleaned.

3.2. The protruding edge of the blade of type A shall be sufficiently sharp to serve as a scraper.

3.3. The point of the blade shall be sufficiently sharp to facilitate sampling.

4. **Principal dimensions**

The borers shall conform to the dimensions (subject to a tolerance of 10 %) given in the table hereafter :

(Dimensions in mm)

	Type A long	Type B short
Length of blade	800	400
Thickness of metal of blade	1 to 2	1 to 2
Inner diameter of blade at point	18	32
Inner diameter of blade at grip or stem	22	28
Slit width at point	4	20
Slit width at grip or stem	14	14

5. **Note on use of borers**

5.1. With less free-flowing powders, the borers can be inserted vertically. Type A borers are then filled completely by turning and can be withdrawn vertically. Type B borers are already filled completely during insertion but must be withdrawn in an oblique position to prevent losses from the lower end.

5.2. In the case of free-flowing powder, the container shall be inclined, the borers inserted nearly horizontally with the slit downwards and withdrawn with the slit upwards.

Dimensions in millimetres

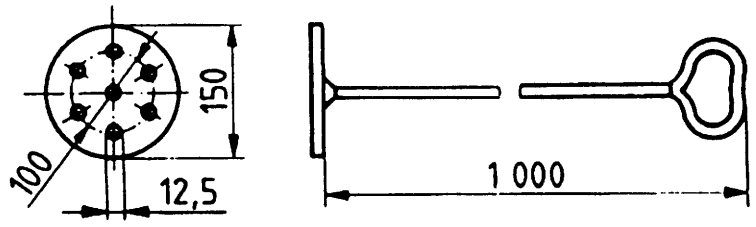


Figure 1: Recommended plunger for cans and buckets

Dimensions in millimetres

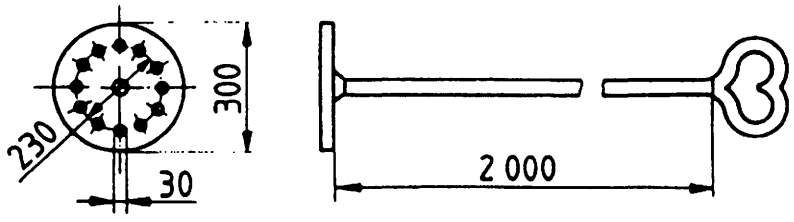


Figure 2: Suitable plunger for small tanks

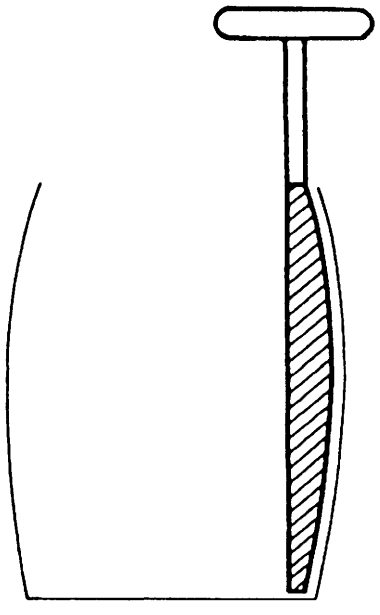


Figure 3: Suitable stirrer for mixing sweetened condensed milk

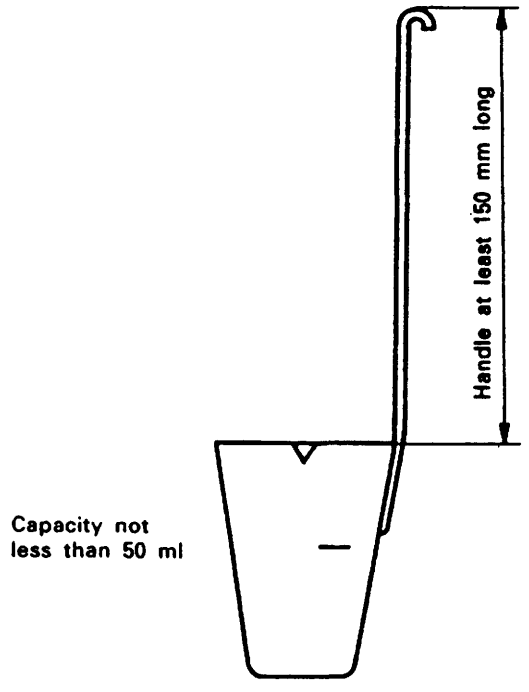


Figure 4: Suitable dipper for liquids

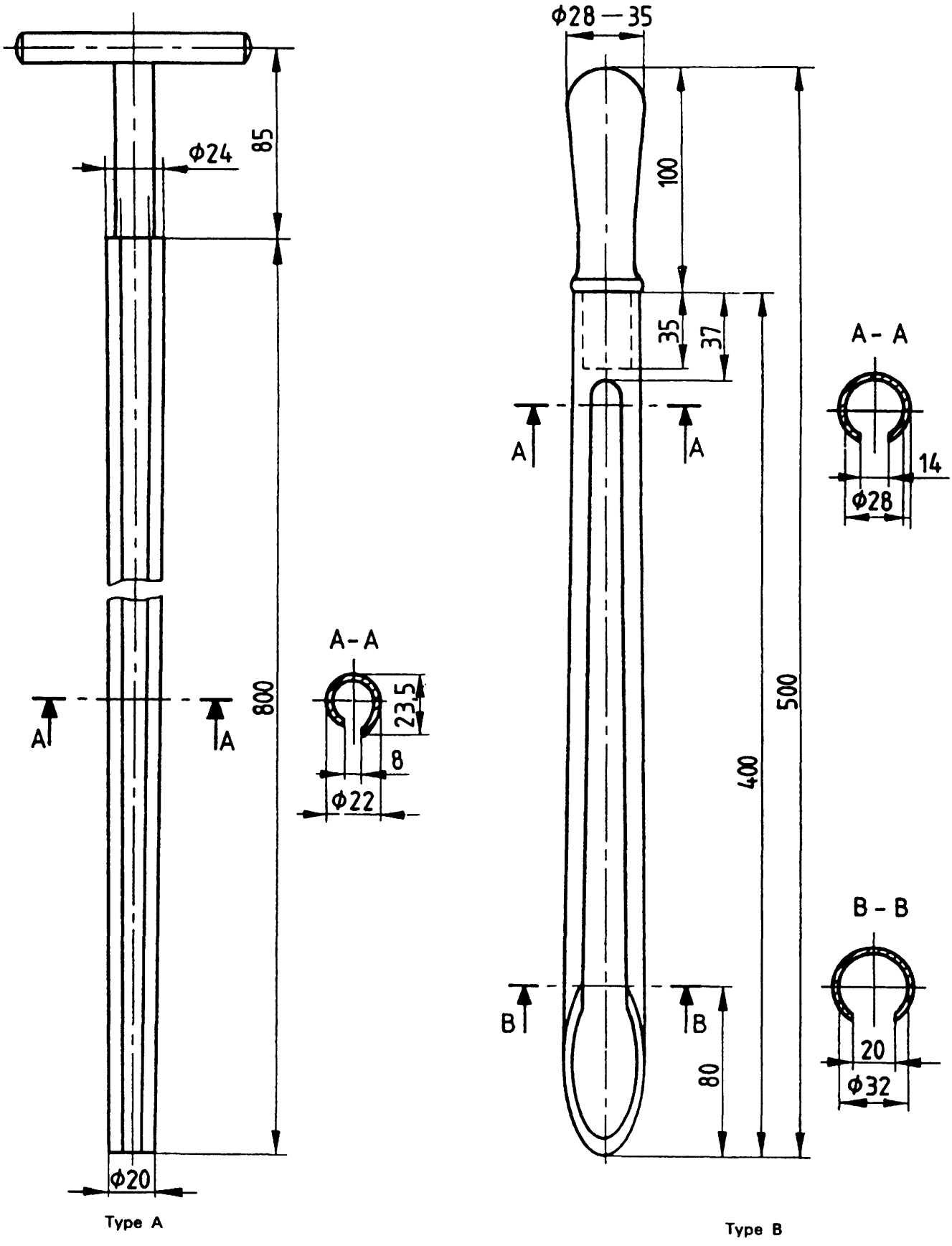


Figure 5: Dried-milk borers (all dimensions in millimetres)

CASEINS AND CASEINATES

383L0417

83/417/EEC: COUNCIL DIRECTIVE OF 25 JULY 1983 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO CERTAIN LACTOPROTEINS (CASEINS AND CASEINATES) INTENDED FOR HUMAN CONSUMPTION

OFFICIAL JOURNAL NO L 237, 26/08/1983, P. 25
DATE OF NOTIFICATION: 02/08/1983
DATE OF TRANSPOSITION: 01/08/1985; SEE ART. 12
DATE OF TRANSPOSITION: 01/08/1986; SEE ART. 12

AMENDED BY

1851
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE KINGDOM OF SPAIN AND THE PORTUGUESE REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES [1]
OFFICIAL JOURNAL NO L 302, 15/11/1985, P. 217

ARTICLE 1

1. THIS DIRECTIVE CONCERNS LACTOPROTEINS, AS DEFINED IN THE ANNEXES, WHICH ARE INTENDED FOR HUMAN CONSUMPTION AND MIXTURES THEREOF.

2. FOR THE PURPOSES OF THIS DIRECTIVE:

- "CASEINS" MEANS THE PRINCIPAL PROTEIN CONSTITUENT OF MILK, WASHED AND DRIED, INSOLUBLE IN WATER AND OBTAINED FROM SKIMMED MILK BY PRECIPITATION:

-- BY THE ADDITION OF ACID, OR
-- BY MICROBIAL ACIDIFICATION, OR
-- BY USING RENNET, OR
-- BY USING OTHER MILK-COAGULATING ENZYMES,
WITHOUT PREJUDICE TO THE POSSIBILITY OF PRIOR USE OF ION EXCHANGE PROCESSES AND CONCENTRATION PROCESSES,

- "CASEINATES" MEANS PRODUCTS OBTAINED BY DRYING CASEINS TREATED WITH NEUTRALIZING AGENTS,
- "SKIMMED MILK" MEANS THE MILK OF ONE OR MORE COWS TO WHICH NOTHING HAS BEEN ADDED AND OF WHICH ONLY THE FAT CONTENT HAS BEEN REDUCED.

ARTICLE 2

THE MEMBER STATES SHALL TAKE ALL THE NECESSARY STEPS TO ENSURE THAT:

- THE PRODUCTS DEFINED IN THE ANNEXES MAY BE MARKETED ONLY IF THEY CONFORM TO THE DEFINITIONS AND RULES LAID DOWN IN THIS DIRECTIVE AND THE ANNEXES THERETO, AND
- PRODUCTS WHICH DO NOT SATISFY THE CRITERIA LAID DOWN IN THE ANNEXES ARE NAMED AND LABELLED IN SUCH A WAY THAT THE BUYER IS NOT MISLED AS TO THEIR NATURE, QUALITY OR USE.

ARTICLE 3

THE NAMES REFERRED TO IN THE ANNEXES SHALL BE RESERVED FOR THE PRODUCTS DEFINED AND MUST BE USED COMMERCIALLY TO DESIGNATE THOSE PRODUCTS.

ARTICLE 4

1. WITHOUT PREJUDICE TO DIRECTIVE 79/112/EEC (1) AND WITHOUT PREJUDICE TO THE PROVISIONS TO BE ADOPTED BY THE COMMUNITY CONCERNING THE LABELLING OF FOODSTUFFS NOT INTENDED FOR THE ULTIMATE CONSUMER, THE ONLY MANDATORY PARTICULARS TO BE MARKED ON THE PACKAGES, CONTAINERS OR LABELS OF THE PRODUCTS DEFINED IN THE ANNEXES, PARTICULARS WHICH MUST BE CLEARLY VISIBLE, EASILY LEGIBLE AND IN INDELIBLE CHARACTERS, SHALL BE AS FOLLOWS:

(a) THE NAME RESERVED FOR THESE PRODUCTS IN ACCORDANCE WITH ARTICLE 3 WITH, IN THE CASE OF CASEINATES, AN INDICATION OF THE CATION OR CATIONS;

(b) IN THE CASE OF PRODUCTS MARKETED AS MIXTURES,

- THE WORDS "MIXTURE OF..." FOLLOWED BY THE NAMES OF THE DIFFERENT PRODUCTS WHICH MAKE UP THE MIXTURE, IN DECREASING ORDER OF WEIGHT,
- AN INDICATION OF THE CATION OR CATIONS IN THE CASE OF CASEINATE OR CASEINATES,
- THE PROTEIN CONTENT IN THE CASE OF MIXTURES CONTAINING CASEINATES;

(c) THE NET QUANTITY EXPRESSED IN THE FOLLOWING UNITS OF MASS: KILOGRAMS OR GRAMS. UNTIL THE END OF THE TRANSITIONAL PERIOD DURING WHICH USE OF THE IMPERIAL UNITS OF MEASUREMENT CONTAINED IN CHAPTER D OF THE ANNEX TO COUNCIL DIRECTIVE 71/354/EEC OF 18 OCTOBER 1971 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO UNITS OF MEASUREMENT (2), AS LAST AMENDED BY DIRECTIVE 76/770/EEC (3), IS AUTHORIZED IN THE COMMUNITY, IRELAND AND THE UNITED KINGDOM MAY PERMIT THE QUANTITY TO BE EXPRESSED ONLY IN IMPERIAL UNITS OF MEASUREMENT CALCULATED ON THE BASIS OF THE FOLLOWING CONVERSION RATES:

- 1 ml = 0,0352 FLUID OUNCES,
- 1 l = 1,760 PINTS OR 0,220 GALLONS,
- 1 g = 0,0353 OUNCES (AVOIRDUPOIS),
- 1 kg = 2,205 POUNDS;

(d) THE NAME OR BUSINESS NAME AND THE ADDRESS OF THE MANUFACTURER OR PACKAGER OR OF A SELLER ESTABLISHED WITHIN THE COMMUNITY;
HOWEVER, IN THE CASE OF THEIR NATIONAL PRODUCTION, MEMBER STATES MAY MAINTAIN IN FORCE NATIONAL PROVISIONS REQUIRING DETAILS OF THE MANUFACTURING OR PACKAGING ESTABLISHMENT TO BE MENTIONED;

(e) IN THE CASE OF PRODUCTS IMPORTED FROM THIRD COUNTRIES, THE NAME OF THE COUNTRY OF ORIGIN;

(f) THE DATE OF MANUFACTURE OR SOME MARKING BY WHICH THE BATCH CAN BE IDENTIFIED.

2. MEMBER STATES SHALL PROHIBIT THE MARKETING OF EDIBLE CASEINS AND CASEINATES IN THEIR TERRITORY IF THE PARTICULARS REFERRED TO IN PARAGRAPHS 1 (a), (b), (e) AND (f) DO NOT APPEAR IN A LANGUAGE EASILY UNDERSTOOD BY THE PURCHASER, UNLESS THE LATTER IS GIVEN SUCH INFORMATION BY OTHER MEANS; THIS PROVISION SHALL NOT PRECLUDE THE APPEARANCE OF THE SAID PARTICULARS IN SEVERAL LANGUAGES.
THE PARTICULARS SPECIFIED IN PARAGRAPH 1 (b), THIRD INDENT, (c), (d) AND (e), NEED APPEAR ONLY IN AN ACCOMPANYING DOCUMENT. FOR TRANSPORT IN BULK, THIS DEROGATION MAY BE EXTENDED TO (b), SECOND INDENT, AND (f).

ARTICLE 5

WITHOUT PREJUDICE TO COMMUNITY PROVISIONS TO BE ADOPTED IN THE FIELD OF HEALTH AND HYGIENE IN CONNECTION WITH THE BASIC MATERIALS REFERRED TO IN ANNEXES I AND II, SUCH PRODUCTS MUST BE SUBJECTED TO HEAT TREATMENT WHICH WILL RENDER THE PHOSPHATASE NEGATIVE.

ARTICLE 6

1. MEMBER STATES SHALL TAKE ALL THE NECESSARY STEPS TO ENSURE THAT TRADE IN PRODUCTS REFERRED TO IN ARTICLE 1 WHICH COMPLY WITH THE DEFINITIONS AND RULES LAID DOWN IN THIS DIRECTIVE AND THE ANNEXES THERETO CANNOT BE IMPEDED BY THE APPLICATION OF NON-HARMONIZED NATIONAL PROVISIONS GOVERNING THE COMPOSITION, MANUFACTURING SPECIFICATIONS, PACKAGING OR LABELLING OF THESE PRODUCTS OR OF FOODSTUFFS IN GENERAL.

2. PARAGRAPH 1 SHALL NOT APPLY TO NON-HARMONIZED PROVISIONS WHICH ARE JUSTIFIED ON THE GROUNDS OF:

- PROTECTION OF PUBLIC HEALTH,
- PREVENTION OF FRAUD UNLESS SUCH PROVISIONS ARE LIABLE TO IMPEDE THE APPLICATION OF THE DEFINITIONS AND RULES LAID DOWN BY THIS DIRECTIVE,
- PROTECTION OF INDUSTRIAL AND COMMERCIAL PROPERTY, INDICATIONS OF SOURCE, REGISTERED DESIGNATION OF ORIGIN AND PREVENTION OF UNFAIR COMPETITION.

ARTICLE 7

1. WHERE, AS A RESULT OF NEW INFORMATION OR OF A REASSESSMENT OF EXISTING INFORMATION MADE SINCE THE DIRECTIVE WAS ADOPTED, A MEMBER STATE FINDS THERE IS DETAILED EVIDENCE THAT THE USE IN THE PRODUCTS DEFINED IN ANNEXES I AND II HERETO OF ONE OF THE SUBSTANCES REFERRED TO THEREIN OR THE MAXIMUM QUANTITY OF SUCH SUBSTANCE THAT MAY BE USED CONSTITUTES A DANGER TO HUMAN HEALTH, EVEN THOUGH IT COMPLIES WITH THE PROVISIONS OF THIS DIRECTIVE, THAT MEMBER STATE MAY TEMPORARILY SUSPEND OR RESTRICT APPLICATION OF THE PROVISIONS IN QUESTION IN ITS TERRITORY. IT SHALL IMMEDIATELY INFORM THE OTHER MEMBER STATES AND THE COMMISSION THEREOF AND GIVE REASONS FOR ITS DECISION.

2. THE COMMISSION SHALL EXAMINE AS SOON AS POSSIBLE THE REASONS GIVEN BY THE MEMBER STATE CONCERNED AND SHALL CONSULT THE MEMBER STATES WITHIN THE STANDING COMMITTEE FOR FOODSTUFFS; IT SHALL THEN DELIVER ITS OPINION FORTHWITH AND TAKE THE APPROPRIATE MEASURES.

3. IF THE COMMISSION CONSIDERS THAT AMENDMENTS TO THE DIRECTIVE ARE NECESSARY IN ORDER TO REMEDY THE DIFFICULTIES REFERRED TO IN PARAGRAPH 1 AND TO PROTECT HUMAN HEALTH, IT SHALL INITIATE THE PROCEDURE PROVIDED FOR IN ARTICLE 10 FOR THE PURPOSE OF ADOPTING SUCH AMENDMENTS. IN THAT CASE, THE MEMBER STATE WHICH HAS ADOPTED SAFEGUARD MEASURES MAY MAINTAIN THEM UNTIL THE AMENDMENTS ENTER INTO FORCE.

ARTICLE 8

THE COUNCIL, ACTING ON A PROPOSAL FROM THE COMMISSION, SHALL ADOPT WHERE NECESSARY PURITY CRITERIA FOR THE TECHNOLOGICAL ADJUVANTS REFERRED TO IN THE ANNEXES.

ARTICLE 9

THE FOLLOWING SHALL BE DETERMINED IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 10:

(a) THE METHODS OF ANALYSIS NECESSARY FOR CHECKING THE PURITY CRITERIA REFERRED TO IN ARTICLE 8;

(b) THE SAMPLING PROCEDURES AND METHODS OF ANALYSIS NECESSARY FOR CHECKING THE COMPOSITION AND MANUFACTURING SPECIFICATIONS AT THE TIME OF MANUFACTURE OF THE PRODUCTS DEFINED IN THE ANNEXES.

ARTICLE 10

1. WHERE THE PROCEDURE LAID DOWN IN THIS ARTICLE IS INVOKED, THE MATTER SHALL BE REFERRED TO THE STANDING COMMITTEE FOR FOODSTUFFS SET UP BY DECISION 69/414/EEC (4), HEREINAFTER REFERRED TO AS "THE COMMITTEE", BY ITS CHAIRMAN, EITHER ON HIS OWN INITIATIVE OR AT THE REQUEST OF A REPRESENTATIVE OF A MEMBER STATE.

2. THE COMMISSION SHALL SUBMIT TO THE COMMITTEE A DRAFT OF THE MEASURES TO BE ADOPTED. THE COMMITTEE SHALL GIVE ITS OPINION ON THE SAID DRAFT WITHIN SUCH TIME AS THE CHAIRMAN OF THE COMMITTEE MAY DETERMINE IN THE LIGHT OF THE URGENCY OF THE MATTER IN QUESTION. THE COMMITTEE SHALL DECIDE BY A MAJORITY OF AT LEAST " fifty-four " [1] VOTES, THE VOTES OF THE MEMBER STATES BEING WEIGHTED IN ACCORDANCE WITH ARTICLE 148 (2) OF THE TREATY. THE CHAIRMAN SHALL NOT TAKE PART IN THE VOTE.

3. (a) THE COMMISSION SHALL ADOPT THE MEASURES CONTEMPLATED WHERE THEY ARE IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE.

(b) WHERE THE MEASURES CONTEMPLATED ARE NOT IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE, OR WHERE NO SUCH OPINION HAS BEEN ISSUED, THE COMMISSION SHALL FORTHWITH SUBMIT TO THE COUNCIL A PROPOSAL ON THE MEASURES TO BE TAKEN. THE COUNCIL SHALL ACT BY A QUALIFIED MAJORITY.

(c) IF, ON EXPIRY OF A PERIOD OF THREE MONTHS FROM THE DATE ON WHICH THE MATTER WAS REFERRED TO THE COUNCIL, THE LATTER HAS NOT ACTED, THE PROPOSED MEASURES SHALL BE ADOPTED BY THE COMMISSION.

ARTICLE 11

THIS DIRECTIVE SHALL NOT APPLY TO PRODUCTS REFERRED TO IN ARTICLE 1 INTENDED FOR EXPORT TO THIRD COUNTRIES.

ARTICLE 12

MEMBER STATES SHALL MAKE SUCH AMENDMENTS TO THEIR LAWS AS MAY BE NECESSARY TO COMPLY WITH THIS DIRECTIVE AND SHALL FORTHWITH INFORM THE COMMISSION THEREOF; THE LAWS THUS AMENDED SHALL BE APPLIED IN SUCH A WAY AS TO:

- PERMIT TRADE IN PRODUCTS COMPLYING WITH THIS DIRECTIVE NOT LATER THAN TWO YEARS AFTER ITS NOTIFICATION (5),
- PROHIBIT TRADE IN PRODUCTS NOT COMPLYING WITH THIS DIRECTIVE THREE YEARS AFTER ITS NOTIFICATION.

ARTICLE 13

THIS DIRECTIVE IS ADDRESSED TO THE MEMBER STATES.

ANNEX I

EDIBLE CASEINS

I. NAMES AND DEFINITIONS

(a) *'edible acid casein'* means edible casein obtained by precipitation using the technological adjuvants and bacterial cultures listed in Section II (d) which comply with the standards laid down in Section II.

(b) *'edible rennet casein'* means edible casein obtained by precipitation using the technological adjuvants listed in Section III (d) which comply with the standards laid down in Section III.

II. STANDARDS APPLICABLE TO 'EDIBLE ACID CASEIN'

(a) Essential factors of composition

1. Maximum moisture content	10,0 % by weight
2. Minimum milk protein content calculated on the dried extract	90 % by weight
of which minimum casein content	95 % by weight
3. Maximum milk fat content calculated on the dried extract	2,25 % by weight
4. Maximum titratable acidity, expressed in ml of decinormal sodium hydroxide solution per g	0,27
5. Maximum ash content (P_2O_5 included)	2,5 % by weight
6. Maximum anhydrous lactose content	1 % by weight
7. Maximum sediment content (burnt particles)	22,5 mg in 25 g

(b) Contaminants

Maximum lead content	1 mg/kg

(c) Impurities

Extraneous matter (such as wood or metal particles, hairs or insect fragments)	nil in 25 g

(d) Harmless technological adjuvants and bacterial cultures suitable for human consumption

(i) — lactic acid (E 270)
— hydrochloric acid
— sulphuric acid
— citric acid (E 330)
— acetic acid (E 260)
— orthophosphoric acid

(ii) — whey
— bacterial cultures producing lactic acid

(e) Organoleptic characteristics

1. *Odour:* No foreign odours
2. *Appearance:* Colour ranging from white to creamy white; the product must not contain any lumps that would not break up under slight pressure.

III. STANDARDS APPLICABLE TO 'EDIBLE RENNET CASEIN'

(a) Essential factors of composition

1. Maximum moisture content	10	% m/m
2. Minimum milk protein content calculated on the dried extract	84	% by weight
of which minimum casein content	95	% by weight
3. Maximum milk fat content calculated on the dried extract	2	% by weight
4. Minimum ash content (P_2O_5 included)	7,50	% by weight
5. Maximum anhydrous lactose content	1	% by weight
6. Maximum sediment content (burnt particles)	22,5	mg in 25 g

(b) Contaminants

Maximum lead content	1	mg/kg

(c) Impurities

Extraneous matter (such as wood or metal particles, hairs or insect fragments)	nil in 25 g

(d) Harmless technological adjuvants suitable for human consumption

— rennet

— other milk-coagulating enzymes

(e) Organoleptic characteristics

1. *Odour:* No foreign odours
2. *Appearance:* Colour ranging from white to creamy white; the product must not contain any lumps that would not break up under slight pressure.

ANNEX II

EDIBLE CASEINATES

I. DENOMINATIONS AND DEFINITIONS

'edible caseinates': means caseinates obtained from edible caseins using neutralizing agents of edible quality listed under Section II (d) and complying with the standards set out in Section II.

II. STANDARDS APPLICABLE TO EDIBLE CASEINATES

(a) **Essential factors of composition**

1. Maximum moisture content	8	% by weight
2. Minimum content of milk protein casein, calculated on the dried extract	88	% by weight
3. Maximum content of milk fat, calculated on the dried extract	2,0	% by weight
4. Maximum anhydrous lactose content	1,0	% by weight
5. pH value	6,0	to 8,0
6. Maximum sediment content (burnt particles)	22,5 mg in 25 g	

(b) **Contaminants**

Maximum lead content	1	mg/kg

(c) **Impurities**

Extraneous matter (such as wood or metal particles, hairs or insect fragments)	nil in 25 g

(d) **Technological adjuvants of edible quality**

(optional neutralizing and buffering agents)

hydroxides carbonates phosphates citrates	of	sodium potassium calcium ammonium magnesium

(e) **Characteristics**

1. *Odour:*	Very slight foreign flavours and odours.
2. *Appearance:*	Colour ranging from white to creamy white; the product must not contain any lumps that do not break under slight pressure.
3. *Solubility:*	Almost entirely soluble in distilled water, except for the calcium caseinate.

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(1) OJ No L 33, 08/02/1979, p. 1.
(2) OJ No L 243, 29/10/1971, p. 29.
(3) OJ No L 262, 27/09/1976, p. 204.
(4) OJ No L 291, 29/11/1969, p. 9.
(5) THIS DIRECTIVE WAS NOTIFIED TO THE MEMBER STATES ON 2 AUGUST 1983.

II

(Acts whose publication is not obligatory)

COMMISSION

FIRST COMMISSION DIRECTIVE
of 25 October 1985
on methods of analysis for edible caseins and caseinates

(85/503/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 83/417/EEC of 25 July 1983 on the approximation of the laws of the Member States relating to certain lactoproteins (caseins and caseinates) intended for human consumption [1], and in particular Article 9 (b) thereof;

Whereas Article 9 (b) of Directive 83/417/EEC requires that Community methods of analysis be determined for checking the composition of certain edible caseins and caseinates;

Whereas it is possible to adopt an initial series of methods in respect of which studies have been completed;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Member States shall take all measures necessary to ensure that the analyses necessary for verification of the criteria set out in Annex I are carried out in accordance with the methods described in Annex II.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 May 1987 at the latest. They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 25 October 1985.

For the Commission
COCKFIELD
Vice-President

[1] OJ No L 237, 26. 8. 1983, p. 25.

ANNEX I

SCOPE OF THE FIRST COMMUNITY METHODS OF ANALYSIS DIRECTIVE FOR EDIBLE CASEINS AND CASEINATES

I. **General Provisions**

II. **Determination of moisture in :**

— acid caseins using method 1, Annex II

— rennet caseins using method 1, Annex II

— caseinates using method 1, Annex II

III. **Determination of protein content in :**

— acid caseins using method 2, Annex II

— rennet caseins using method 2, Annex II

— caseinates using method 2, Annex II

IV. **Determination of titratable acidity in :**

— acid caseins using method 3, Annex II

V. **Determination of ash (including P_2O_5) in :**

— acid caseins using method 4, Annex II

— rennet caseins using method 5, Annex II

VI. **Determination of pH in :**

— caseinates using method 6, Annex II

ANNEX II

METHODS OF ANALYSIS RELATING TO THE COMPOSITION OF EDIBLE CASEINS AND CASEINATES

GENERAL PROVISIONS

1. PREPARATION OF THE ANALYSIS SAMPLE

1.1. **General**

The mass of the sample presented to the laboratory for analysis shall be at least 200 grams.

1.2. **Preparation of the sample for analysis in the laboratory**

1.2.1. Thoroughly mix and break down any lumps, etc., in the laboratory sample by repeatedly shaking and inverting the container (if necessary, after having transferred all of the laboratory sample to an air-tight container of sufficient capacity (twice volume of sample) to allow this operation to be carried out).

1.2.2. Transfer a representative portion of the sample, i. e. about 50 grams of the thoroughly mixed laboratory sample (1.2.1) to the test sieve (3.3).

1.2.3. If the 50 gram portion completely or almost completely passes (at least 95 % by weight) through the sieve (3.3), use for the determination the sample as prepared in 1.2.1.

1.2.4. Otherwise, grind the 50 gram portion, using the grinding device (3.4), until it satisfies the sieving criterion (1.2.3). Immediately transfer all the sieved sample to an air-tight container of sufficient capacity (twice volume of sample) and mix thoroughly by repeated shaking and inverting. During these operations, take precautions to avoid any change in the moisture content of the product.

1.2.5. After the test sample has been prepared, any determination should be proceeded with as soon as possible.

1.3. **Containers**

The sample shall always be kept in an air-tight and moisture-tight container.

2. REAGENTS

2.1. **Water**

2.1.1. Wherever mention is made to water for solution, dilution or washing purposes, distilled water, or demineralized water of at least equivalent purity, shall be used.

2.1.2. Wherever reference is made to 'solution' or 'dilution' without further indication, 'solution in water' or 'dilution with water' is meant.

2.2. **Chemicals**

All chemicals used shall be of recognized analytical reagent quality except where otherwise specified.

3. EQUIPMENT

3.1. **Lists of equipment**

The lists of equipment contain only those items with a specialized use and items to a particular specification.

3.2. **Analytical balance**

Analytical balance means a balance capable of weighing to at least 0,1 mg.

3.3. **Test sieve**

The test sieves to be used are to be fitted with a lid, to be of diameter 200 mm, to be constructed of wire cloth with a nominal aperture size of 500 µm. The aperture tolerances and wire diameters to be permitted are as given in ISO 3310/1. (Test sieves — Technical requirements and testing — Part 1 : Metal wire cloth. ISO 3310/1 — 1975).

The sieves are to be fitted with a receiver.

3.4. **Grinding device**

For grinding the laboratory sample if necessary (see 1.2.4), without development of undue heat and without loss or absorption of moisture, a hammer mill shall not be used.

4. EXPRESSION OF RESULTS

4.1. **Results**

The result stated in the analytical report is to be the mean value obtained from two determinations which satisfy the repeatability criterion for that method.

4.2. **Calculation of percentage**

Except where otherwise specified, the result shall be calculated as a percentage by mass of the sample.

5. TEST REPORT

The test report shall identify the method of analysis used as well as the results obtained. In addition, it shall mention all details of procedure not specified in the method of analysis or which are optional, as well as any circumstances that may have influenced the results obtained. The test report shall give all the information necessary for the complete identification of the sample.

METHOD 1

DETERMINATION OF MOISTURE CONTENT

1. SCOPE AND FIELD OF APPLICATION

This method determines the moisture content in :

— acid caseins
— rennet caseins
— caseinates

2. DEFINITION

The moisture content of caseins and caseinates : the loss of mass as determined by the method specified.

3. PRINCIPLE

The residual mass of a test portion is determined after drying at atmospheric pressure in an oven at 102 °C ± 1 °C to constant mass. The loss of mass is calculated as a percentage by mass of the sample.

4. APPARATUS

4.1. **Analytical balance**

4.2. **Dishes,** flat-bottomed and of material non-corrodible under the conditions of test e.g. nickel, aluminium, stainless steel or glass. The dishes must have lids which fit tightly but which can readily be removed. Suitable dimensions are : diameter 60 to 80 mm and depth about 25 mm.

4.3. **Atmospheric pressure drying oven,** well ventilated, thermostatically controlled with temperature regulation (at 102 °C ± 1 °C). The temperature should be uniform throughout the oven.

4.4. **Desiccator,** containing freshly activated silica gel with a water content indicator or an equivalent desiccant.

4.5. **Suitable device for handling dishes,** e.g. laboratory tongs.

5. PROCEDURE

5.1. **Preparation of the test sample**

As described in Section 1.2 of the General Provisions.

5.2. **Preparation of the dish**

5.2.1. Heat the uncovered dish and its lid (4.2) in the oven (4.3), controlled at 102 °C ± 1 °C, for at least one hour.

5.2.2. Place the lid on the dish, transfer the covered dish to the desiccator (4.4), allow to cool to the temperature of the balance room and weigh to the nearest 0,1 mg (m_0).

5.3. **Test portion**

Place 3 to 5 grams of the test sample (5.1) into the dish, cover with the lid and weigh to the nearest 0,1 mg (m_1).

5.4. **Determination**

5.4.1. Uncover the dish and place it with its lid in the oven (4.3), controlled at 102 °C ± 1 °C, for four hours.

5.4.2. Replace the lid on the dish, transfer to the desiccator, allow to cool to the temperature of the balance room and weigh to the nearest 0,1 mg.

5.4.3. Uncover the dish and heat it again, with its lid, in the oven for one hour. Then repeat operation 5.4.2.

5.4.4. If the mass obtained in 5.4.3 is less than the mass obtained in 5.4.2 by more than 1 mg, repeat operation 5.4.3.

If an increase in mass occurs, use the lowest recorded mass in the calculation (6.1).

Let the final weight recorded be m_2g. The total drying time should not normally exceed six hours.

6. EXPRESSION OF RESULTS

6.1. **Method of calculation**

The loss of mass on drying of the sample, expressed as a percentage by mass, is given by:

$$\frac{m_1 - m_2}{m_1 - m_0} \times 100$$

where:

m_0 = mass, in g of the dish and its lid after process 5.2;

m_1 = mass, in g of the dish, its lid and the test portion before drying (process 5.3);

m_2 = mass, in g of the dish, its lid and the test portion after drying (process 5.4.3 or 5.4.4).

Calculate the loss on drying to the nearest 0,01 %.

6.2. **Repeatability**

The difference in results between two determinations carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 0,1 g of moisture per 100 grams of product.

This repeatability interval should be achieved in 95 % of the times that the method is carried out.

METHOD 2

DETERMINATION OF PROTEIN CONTENT

1. SCOPE AND FIELD OF APPLICATION

This method determines the protein content of:

— acid caseins,

— rennet caseins,

— caseinates,

except those containing ammonium caseinate or other ammonium or nitrogenous non-protein compounds.

2. DEFINITION

The protein content : the nitrogen content as determined by the method specified and then multiplied by 6,38 and expressed as a percentage by mass.

3. PRINCIPLE

A test portion is digested with a mixture of potassium sulphate and sulphuric acid, in the presence of copper (II) sulphate as catalyst, to convert organic nitrogen to ammoniacal nitrogen. The ammonia is distilled and absorbed into boric acid solution and then titrated with standard hydrochloric acid solution. The nitrogen content is converted to protein content by multiplying by 6,38.

4. REAGENTS

4.1. **Sulphuric acid, concentrated,** S_2O 1,84 g/ml.

4.2. **Potassium sulphate, anhydrous** (K_2SO_4).

4.3. **Copper (II) sulphate pentahydrate** ($CuSO_45H_2O$).

4.4. **Sucrose** ($C_{12}H_{22}O_{11}$).

4.5. **Boric acid,** 40-g/l solution.

4.6. **Sodium hydroxide,** concentrated aqueous solution 30 % (m/m), carbonate free.

4.7. **Hydrochloric acid,** 0,1 mol/l.

4.8. **Mixed indicator.** Mix equal volumes of a 2 g/l solution of methyl red in at least 95 % (V/V) ethanol and a 1 g/l solution of methylene blue in at least 95 % (V/V) ethanol.

5. APPARATUS

5.1. **Analytical balance**

5.2. **Kjeldahl flask,** 500 ml capacity.

5.3. **Digestion apparatus** to hold the Kjeldahl flask (5.2) in an inclined position and with a heating device which will not heat the part of the flask above the surface of the liquid contents.

5.4. **Condenser** with straight inner tube.

5.5. **Outlet tube with safety bulb** connected to the lower end of the condenser (5.4) by a ground glass joint or a rubber tube. If rubber tubing is used, the glass ends must be near one another.

5.6. **Splash-head** connected to the Kjeldahl flask (5.2) and to the condenser (5.4) by soft, close-fitting rubber or other appropriate stoppers.

5.7. **Conical flask,** 500 ml capacity.

5.8. **Graduated cylinders,** 50 ml and 100 ml capacity.

5.9. **Burette,** 50 ml capacity, graduated in 0,1 ml.

5.10. **Boiling aids :**

5.10.1. For the digestion : small pieces of hard porcelain, or glass beads.

5.10.2. For the distillation ; freshly calcined pieces of pumice.

6. PROCEDURE

6.1. **Preparation of the test sample**

As described in Section 1.2 of the General Provisions.

6.2. **Test for presence of ammoniacal nitrogen**

If the presence of ammonium caseinate or other ammonium compounds is suspected, carry out the following test. Add to 1 gram of sample in a small conical flask 10 ml of water and 100 mg of magnesium oxide. Rinse down any magnesium oxide adhering to the walls and close the flask with a cork stopper, inserting a piece of moistened red litmus paper between the stopper and the neck of the flask. Mix the contents of the flask carefully and heat the flask in a water bath at 60 to 65 °C. If the litmus paper colours blue within 15 minutes ammonia is present, and the method is not applicable (see Section 1).

6.3. **Blank test**

At the same time as the determination of the nitrogen content of the sample perform a blank determination using 0,5 grams of the sucrose (4.4) instead of the test portion, using the same apparatus, the same quantities of all reagents and the same procedure as described in 6.5. If the titration in the blank determination exceeds 0,5 ml of 0,1 mol/l acid, the reagents shall be checked and the impure reagent or reagents purified or replaced.

6.4. **Test portion**

Transfer to the Kjeldahl flask (5.2) 0,3 to 0,4 grams of the test sample (6.1), weighed to the nearest 0,1 mg.

6.5. **Determination**

6.5.1. Transfer to the flask a few pieces of porcelain or a few glass beads (5.10.1) and about 10 grams of the anhydrous potassium sulphate (4.2).

Add 0,2 g of the copper (II) sulphate (4.3) and wash down the neck of the flask with a little water. Add 20 ml of the concentrated sulphuric acid (4.1). Mix the contents of the flask.

Heat gently on the digestion apparatus (5.3) until any frothing has ceased, boil gently until the solution is clear and a pale green-blue colour persists. During heating, swirl the flask occasionally.

Continue the boiling, regulating the heating so as to condense the vapours in the middle of the flask neck. Continue the heating for 90 minutes avoiding local overheating.

Allow to cool to room temperature. Carefully add about 200 ml of water and a few pieces of pumice (5.10.2). Mix and cool again.

6.5.2. Transfer into the conical flask (5.7) 50 ml of the boric acid solution (4.5) and four drops of the indicator (4.8). Mix. Place the conical flask under the condenser (5.4) so that the tip of the outlet tube (5.5) is immersed in the boric acid solution. Using a graduated cylinder (5.8), add to the Kjeldahl flask 80 ml of the sodium hydroxide solution (4.6). During this operation, hold the flask in an inclined position so that the sodium hydroxide solution runs down the side of the flask to form a bottom layer.

Immediately connect the Kjeldahl flask to the condenser by means of the splash-head (5.6).

Gently rotate the Kjeldahl flask to mix its contents. Boil gently at first, avoiding any frothing. Continue the distillation so that 150 ml of distillate are collected in approximately 30 minutes. The distillate should have a temperature below 25 °C. About two minutes before the end of the distillation, lower the conical flask so that the tip of the outlet tube is no longer immersed in the acid solution, and rinse the tip with a little water. Stop heating, remove the outlet tube and rinse its outer and inner walls with a little water, collecting the washings in the conical flask.

6.5.3. Titrate the distillate in the conical flask, using the standard volumetric hydrochloric acid solution (4.7).

7. EXPRESSION OF RESULTS

7.1. **Formula and method of calculation**

The protein content of the sample, expressed as a percentage by mass, is given by:

$$\frac{(V_1 - V_2) \times T \times 14 \times 100 \times 6{,}38}{m \times 1\,000} = \frac{8{,}932\,(V_1 - V_2) \times T}{m}$$

where :

V_1 is the volume, in millilitres, of the standard volumetric hydrochloric acid solution (4.7) used in the determination (6.5);

V_2 is the volume, in millilitres, of the standard volumetric hydrochloric acid solution (4.7) used in the blank test (6.3);

T is the strength of the standard volumetric hydrochloric acid solution (4.7) in mol/l;

m is the mass, in grams, of the test portion.

Calculate the protein content to the nearest 0,1 %.

7.2. **Repeatability**

The difference between the results of two determinations carried out simultaneously or in rapid succession on the same sample, by the same analyst under the same conditions shall not exceed 0,5 grams of protein per 100 grams of product.

This repeatability interval should be achieved in 95 % of the times that the method is correctly carried out.

METHOD 3

DETERMINATION OF TITRATABLE ACIDITY

1. SCOPE AND FIELD OF APPLICATION

The method determines the titratable acidity of :

— acid caseins.

2. DEFINITION

The titratable acidity of acid caseins : the volume in millilitres, of a 0,1 mol/l standard sodium hydroxide solution required to neutralize an aqueous extract of 1 gram of the product.

3. PRINCIPLE

An aqueous extract of the sample at 60 °C is obtained and filtered. The filtrate is titrated against standard sodium hydroxide using phenolphtalein indicator.

4. REAGENTS

Any water used in the method procedure or in the preparation of reagents shall be freed from carbon dioxide by boiling for 10 minutes before use.

4.1. **Sodium hydroxide solution** : 0,1 Mol/l.

4.2. **Phenolphtalein indicator solution**, 10 g/l in ethanol (95 % V/V) neutralized to the indicator.

5. APPARATUS

5.1. **Analytical balance**

5.2. **Conical flask**, 500 ml capacity, with ground neck and fitted with a ground glass stopper.

5.3. **One-mark pipette**, 100 ml capacity.

5.4. **Pipette**, suitable for measuring 0,5 ml of indicator solution (4.2).

5.5. **Conical flask**, 250 ml capacity.

5.6. **Measuring cylinder**, 250 ml capacity.

5.7. **Burette**, graduated in 0,1 ml.

5.8. **Water bath**, capable of being controlled at a temperature of 60 °C ± 2 °C.

5.9. **Appropriate filter**

6. PROCEDURE

6.1. **Preparation of the test sample**

As described in Section 1.2 of the General Provisions.

6.2. **Test portion**

Weigh about 10 grams of the test sample (6.1) to the nearest 10 mg and transfer it to the conical flask (5.2).

6.3. **Determination**

Using the 250 ml measuring cylinder (5.6), add 200 ml of freshly boiled and cooled water, previously heated to 60 °C. Stopper the flask, mix by swirling and place in the water bath at 60 °C (5.8) for 30 minutes. Shake the flask at intervals of about 10 minutes.

Filter, and cool the filtrate to about 20 °C. The filtrate must be clear.

Transfer 100 ml of the cooled filtrate into the conical flask (5.5), using the pipette (5.3). Add 0,5 ml of the phenolphtalein indicator solution (4.2), using the pipette (5.4). Titrate with the standard volumetric sodium hydroxide solution (4.1), until the appearance of a faint pink colour, persisting for at least 30 seconds. Determine and record the volume used to the nearest 0,01 ml.

7. EXPRESSION OF RESULTS

7.1. **Formula and method of calculation**

The titratable acidity of the acid casein is given by :

$$\frac{20 \times V \times T}{m}$$

where :

V is the volume, in millilitres, of the standard volumetric sodium hydroxide solution (4.1) used ;

T is the strength of the standard volumetric sodium hydroxide solution (4.1) in mol/l ;

m is the mass, in grams, of the test portion.

Calculate the titratable acidity to two decimal places.

7.2. **Repeatability**

The difference in results between two determinations carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 0,02 ml of 0,1 mol/l sodium hydroxide per 1 gram of product.

This repeatability interval should be achieved in 95 % of the times that the method is correctly carried out.

METHOD 4

DETERMINATION OF ASH

(including P_2O_5)

1. SCOPE AND FIELD OF APPLICATION

The method determines the ash (including P_2O_5) content of :

— acid caseins

2. DEFINITION

The ash (including P_2O_5) content : the content of ash as determined by the method specified.

3. PRINCIPLE

A portion of the sample is incinerated at 825 °C ± 25 °C in the presence of magnesium acetate to bind all phosphorus of organic origin. The final ash is calculated after the weighing of the residue and subtraction of the mass of ash originating from the magnesium acetate.

4. REAGENTS

4.1. **Magnesium acetate tetrahydrate solution**, 120 g/l. Dissolve 120 grams of magnesium acetate tetrahydrate [$Mg\ (CH_3\ CO_2)_2\ 4\ H_2\ O$] in water and make up one litre with water.

5. APPARATUS

5.1. **Analytical balance**

5.2. **One-mark pipette**, 5 ml.

5.3. **Silica or platinum dishes**, about 70 mm diameter and 25 to 50 mm deep.

5.4. **Drying oven**, capable of being controlled at 102 °C ± 1 °C.

5.5. **Electrical furnace**, capable of being controlled at 825 °C ± 25 °C.

5.6. **Boiling water bath**

5.7. **Desiccator containing freshly activated silica gel with a water content indicator or an equivalent desiccant.**

6. PROCEDURE

6.1. **Preparation of the test sample**

As described in Section 1.2 of the General Provisions.

6.2. **Preparation of the dishes**

Heat two dishes (A,B) (5.3) in the electrical furnace (5.5), controlled at 825 °C ± 25 °C, for 30 minutes. Allow the dishes to cool somewhat and then place in the desiccator (5.7) to the temperature of the balance room and weigh to the nearest 0,1 mg.

6.3. **Test portion**

Weigh, to the nearest 0,1 mg approximately 3 grams of the test sample (6.1), directly into one of the prepared dishes (A).

6.4. **Determination**

Using the pipette (5.2), add to the dish (A) exactly 5 ml of the magnesium acetate solution (4.1) so as to wet all of the test portion, and allow to stand for 20 minutes.

To the other prepared dish (B), add with the pipette (5.2) exactly 5 ml of the magnesium acetate solution (4.1).

Evaporate the contents of both dishes (A and B) to dryness on the boiling water bath (5.6).

Place both dishes in the oven (5.4), controlled at 102 °C ± 1 °C, for 30 minutes.

Heat dish A with its contents on a low flame, a hot plate or under an I/R lamp, until the test portion is completely charred, taking care that it does not burst into flame.

Transfer both dishes (A and B) to the electrical furnace (5.5), controlled at 825 °C ± 25 °C, and heat for at least one hour until all carbon has disappeared from dish A. Allow both dishes to cool somewhat and then place in the desiccator (5.7) to the temperature of the balance room and weigh to the nearest 0,1 mg.

Repeat the operations of heating for approximately 30 minutes, in the electrical furnace (5.5), cooling and weighing, until the mass remains constant to within 1 mg or begins to increase. Record the minimum mass.

7. EXPRESSION OF RESULTS

7.1. **Method of calculation**

The content of ash, including P_2O_5, in the sample, as a percentage by mass, is given by:

$$\frac{(m_1 - m_2) - (m_3 - m_4)}{m_0} \times 100$$

where:

m_0 is the mass, in grams, of the test portion;

m_1 is the mass, in grams, of dish A and residue;

m_2 is the mass, in grams, of the prepared dish A;

m_3 is the mass, in grams, of dish B and residue;

m_4 is the mass, in grams, of the prepared dish B.

Calculate the final result to the nearest 0,01 %.

7.2. **Repeatability**

The difference in results between the determinations carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 0,1 grams per 100 grams of product.

The repeatability interval should be achieved in 95 % of the times that the method is correctly carried out.

METHOD 5

DETERMINATION OF ASH

(including P_2O_5)

1. SCOPE AND FIELD OF APPLICATION

This method determines the ash (including P_2O_5) content of:

— rennet casein

2. DEFINITION

The ash (including P_2O_5) content: the content of ash as determined by the method specified.

3. PRINCIPLE

A portion of the sample is incinerated at 825 °C ± 25 °C to constant mass. The residue is determined by weighing and calculated as a percentage by mass of the sample.

4. APPARATUS

4.1. **Analytical balance**

4.2. **Silica or platinum dish**, about 70 mm diameter and 25 to 50 mm deep.

4.3. **Electrical furnace** with air circulation, capable of being controlled at 825 °C ± 25 °C.

4.4. **Desiccator**, containing freshly activated silica gel with a water content indicator or an equivalent desiccant.

5. PROCEDURE

5.1. **Preparation of the test sample**

As described in Section 1.2 of the General Provisions.

5.2. **Preparation of the dish**

Heat the dish (4.2) in the electrical furnace (4.3), controlled at 825 °C ± 25 °C, for 30 minutes. Allow the dish to cool somewhat and then place in the desiccator (4.4) to the temperature of the balance room and weigh to the nearest 0,1 mg.

5.3. **Test portion**

Weigh, to the nearest 0,1 mg approximately 3 grams of the test sample (5.1) directly into the prepared dish.

5.4. **Determination**

Heat the dish with its contents on a low flame, a hot plate or an I/R lamp until the test portion is completely charred, taking care that it does not burst into flame.

Transfer the dish to the electrical furnace (4.3), controlled at 825 °C ± 25 °C, and heat for at least one hour until all carbon has disappeared from the dish. Allow the dish to cool somewhat and then place in the desiccator (4.4) to the temperature of the balance room and weigh to the nearest 0,1 mg.

Repeat the operations of heating for approximately 30 minutes, in the electrical furnace (4.3), cooling and weighing, until the mass remains constant to within 1 mg or begins to increase. Record the minimum mass.

6. EXPRESSION OF RESULTS

6.1. **Method of calculation and formula**

The ash content of the sample, including P_2O_5, as a percentage per mass, is given by:

$$\frac{m_1 - m_2}{m_0} \times 100$$

where :

m_0 is the mass, in grams, of the test portion ;

m_1 is the mass, in grams, of the dish and residue ;

m_2 is the mass, in grams, of the prepared dish.

Calculate the final result to the nearest 0,01 %.

6.2. **Repeatability**

The difference between the results of two determinations carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 0,15 grams of ash per 100 grams of product.

This repeatability interval should be achieved in 95 % of the times that the method is correctly carried out.

METHOD 6

DETERMINATION OF pH

1. SCOPE AND FIELD OF APPLICATION

This method determines the pH of :

— caseinates.

2. DEFINITION

The pH of caseinates : the pH, at 20 °C, of an aqueous solution of caseinates, as determined by the method specified.

3. PRINCIPLE

The electrometric determination of pH of an aqueous solution of caseinate, using a pH meter.

4. REAGENTS

Any water used in the preparation of the reagents or in the Procedure (6) shall be recently distilled water that has been protected from carbon dioxide absorption.

4.1. **Buffer solutions**, for calibration of the pH meter (5.2)

Two standard buffer solutions with pH values at 20 °C which are known to the second decimal place and will bracket the pH value of the sample under test, for example phtalate buffer solution of pH approximately 4 and a borax buffer solution of pH approximately 9.

5. APPARATUS

5.1. **Balance**, accuracy 0,1 grams.

5.2. **pH meter**, minimum sensitivity 0,05 pH unit, with a suitably calibrated elecrode, e.g. glass electrode and a calomel or other reference electrodc.

5.3. **Thermometer**, accuracy 0,5 °C.

5.4. **Conical flask**, capacity 100 ml, fitted with a ground glass stopper.

5.5. **Beaker**, capacity 50 ml.

5.6. **Mixer**

5.7. **Beaker**, for the mixer (5.6) of at least 250 ml capacity.

6. PROCEDURE

6.1. **Preparation of the test sample**

As described in Section 1.2 of the General Provisions.

6.2. **Determination**

6.2.1. *Calibration of pH meter*

Adjust the temperature of the buffer solutions (4.1) to 20 °C and calibrate the pH meter in accordance with the manufacturer's instructions.

NOTES

1. The calibration should be carried out while the flasks are standing for 20 mintues (see 6.2.2).

2. If a series of samples is being tested, check the calibration of the pH meter with one or more of the standard buffer solutions at least every 30 minutes.

6.2.2. *Preparation of the test solution*

Transfer to the beaker (5.7) 95 ml of water, add 5,0 grams of the test sample (6.1), and mix using the mixer (5.6) for 30 seconds.

Allow to stand for 20 minutes at about 20 °C, covered with a watch glass.

6.2.3. *Measurement of pH*

6.2.3.1. Pour about 20 ml of the solution into the beaker (5.5) and immediately determine the pH of this liquid, using the pH meter (5.2) after having rinsed the glass electrode carefully with water.

6.2.3.2. Measure the pH.

7. EXPRESSION OF RESULTS

7.1. **Recording of pH**

Record, as the pH of the aqueous solution of caseinate, the value read from the dial of the pH meter to at least two decimal places.

7.2. **Repeatability**

The difference between the results of two determinations carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 0,05 pH unit.

This repeatability interval should be achieved in 95 % of the times that the method is correctly carried out.

II

(Acts whose publication is not obligatory)

COMMISSION

FIRST COMMISSION DIRECTIVE

of 15 July 1986

laying down methods of sampling for chemical analysis of edible caseins and caseinates

(86/424/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to the Council Directive 83/417/EEC of 25 July 1983 on the approximation of the laws of the Member States relating to certain lactoproteins (caseins and caseinates) included for human consumption [1] and in particular Article 9 thereof,

Whereas under Article 9 of Directive 83/417/EEC, caseins and caseinates are required to be sampled according to Community procedures;

Whereas it is desirable to adopt an initial series of methods of sampling for chemical analysis in request of which studies are completed;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The sampling requirements referred to in Article 9, paragraph (b) of Directive 83/417/EEC shall be those outlined in the Annex to the present Directive.

Article 2

Member States shall take all necessary measures in order to comply with the present Directive by 15 January 1988 [2] at the latest. They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to all the Member States.

Done at Brussels, 15 July 1986.

For the Commission

COCKFIELD

Vice-President

[1] OJ No L 237, 26. 8. 1983, p. 25.

[2] Date corresponding to 18 months after adoption of the present Directive.

ANNEX

METHODS OF SAMPLING RELATED TO THE CONTROL OF CHEMICAL ANALYSIS OF CERTAIN EDIBLE CASEINS AND CASEINATES INTENDED FOR HUMAN CONSUMPTION

I. GENERAL PROVISIONS

1. Administrative instructions

1.1. *Personnel*

Sampling shall be performed by an authorized qualified person as specified in the Member States' regulations.

1.2. *Sealing and labelling of samples*

Each sample taken for official use shall be sealed at the place of sampling and identified following the Member States' regulations.

1.3. *Replicate samples*

At least two equivalent representative samples shall be simultaneously prepared for analysis. Under reservation of Community legislation to be defined the procedure and number of samples to to taken depending upon the appropriate national legislation for each Member State.

The samples shall be dispatched to the laboratory as soon as possible after sampling.

1.4. *Report*

Samples shall be accompanied with a report which will be established following the Member States' legislation.

2. **Sampling equipment**

2.1. *Specifications*

All sampling equipment shall be made of suitable material of adequate strength, which does not bring about a change in the sample which may affect any result of the subsequent examination and should not cause any change in the samples while sampling is carried out. The use of stainless steel is recommended.

All surfaces shall be smooth and free from crevices and all corners shall be rounded. Sampling equipment shall comply with the requirements laid down with respect to each product to be sampled.

3. **Sampling containers**

3.1. *Specifications*

Sample containers and closures shall be of materials and construction which adequately protect the sample and which do not bring about in the sample a change which may affect any result of the subsequent analysis or examination. Materials which are appropriate include glass, some metals and some plastics. The containers shall preferably be opaque. If transparent or translucent the containers with contents shall be stored in a dark place.

Containers and closures shall be clean and dry. The shape and capacity of the container shall be appropriate to the requirements laid down for the product to be sampled.

Single service plastic containers, containers made from plastic, laminates including an aluminium foil or suitable plastic bags, with appropriate methods of closure, may be used.

Containers other than plastic bags shall be securely closed either by means of a suitable stopper or by a screw-cap of metal or plastic material having, if necessary, an air-tight plastic liner. Any stopper or liner used should be insoluble, non-absorbant and greaseproof, and will not influence the odour, flavour, properties or composition of the sample.

Stoppers shall be made of, or covered with, non-absorbant odourless materials.

4. **Sampling technique**

The sample container shall be closed immediately after sampling.

5. **Storage of samples**

The recommended storage temperatures of the samples of the various caseins and caseinates shall not exceed 25 °C.

6. **Transport of samples**

Samples shall be brought to the laboratory responsible for the tests as soon as possible (preferably within 24 hours of sample taking).

During transit, precautions shall be taken to prevent exposure to contaminating odours, to direct sunlight and to temperatures greater than 25 °C.

II. METHOD — SAMPLING OF EDIBLE CASEINS AND CASEINATES

1. **Scope and field of application**

This method describes the sampling for chemical analysis of:

— edible acid caseins,
— edible rennet caseins,
— edible caseinates.

2. **Equipment**

See Section 2 of General Provisions.

2.1. *Borers*

Of sufficient length to reach the bottom of the product container. Borers conforming to the description given in Part III of this Directive are appropriate.

2.2. *Spoon, spatula or scoop*

Broad-loaded.

2.3. *Sample containers*

See Section 3 of General Provisions.

3. **Procedure**

3.1. *General*

Care shall be taken to minimize the uptake of atmospheric moisture by the content of the product container during or in the period prior to sampling for analysis. The product container shall be securely reclosed after sampling.

3.2. *Procedure*

3.2.1. Sampling

A sample of not less than 200 grams shall be taken. The clean and dry borer shall be passed through the product, if necessary with the container inclined or laid on its side. The slit shall be oriented downward and an even rate of penetration used. When the borer reaches the bottom of the container it shall be rotated through 180°, withdrawn and the contents discharged into the sample container. One or more bores shall be taken to make a sample of not less than 200 grams. The sample container shall be closed immediately after sampling is complete. Such sampling shall be carried out on the same batch.

3.2.2. Sampling products packed in small retail packages

The intact and unopened package may constitute the sample. As far as possible one or more packages of the same batch should be taken to form a sample of not less than 200 grams.

If this is not possible, use another method to constitute a representative sample.

3.2.3. Preservation, storage and transport of sample

Sections 5 and 6 of the General Provisions.

III. BORERS FOR THE SAMPLING OF EDIBLE CASEINS AND CASEINATES IN BULK

1. **Types of borer**

Type A: Long (see fig. 1);
Type B: Short (see fig. 1).

2. **Materials**

Blade and stem shall be made of polished metal, preferably stainless steel. The grip of the long type should preferably be made of stainless steel. The short type borer shall have a detachable grip of wood or plastic, fitted with a bayonet-catch in the blade.

3. **Construction**

3.1. Shape, material and finish shall be such as to permit the borer to be easily cleaned.

3.2. The protruding edge of the blade of type A shall be sufficiently sharp to serve as a scraper.

3.3. The point of the blade shall be sufficiently sharp as to facilitate sampling.

4. **Principal dimensions**

The borers shall conform to the dimensions (subject to a tolerance of 10 %) given in the table below:

(in mm)

	Type A Long	Type B Short
Length of blade	800	400
Thickness of metal of blade	1 to 2	1 to 2
Inner diameter of blade at point	18	32
Inner diameter of blade at grip or stem	22	28
Slit width at point	4	20
Slit width at grip or stem	14	14

5. **Note on use of borers**

5.1. With less free-flowing powders, the borers can be inserted vertically. Type A borers are filled completely by turning and then can be withdrawn vertically.

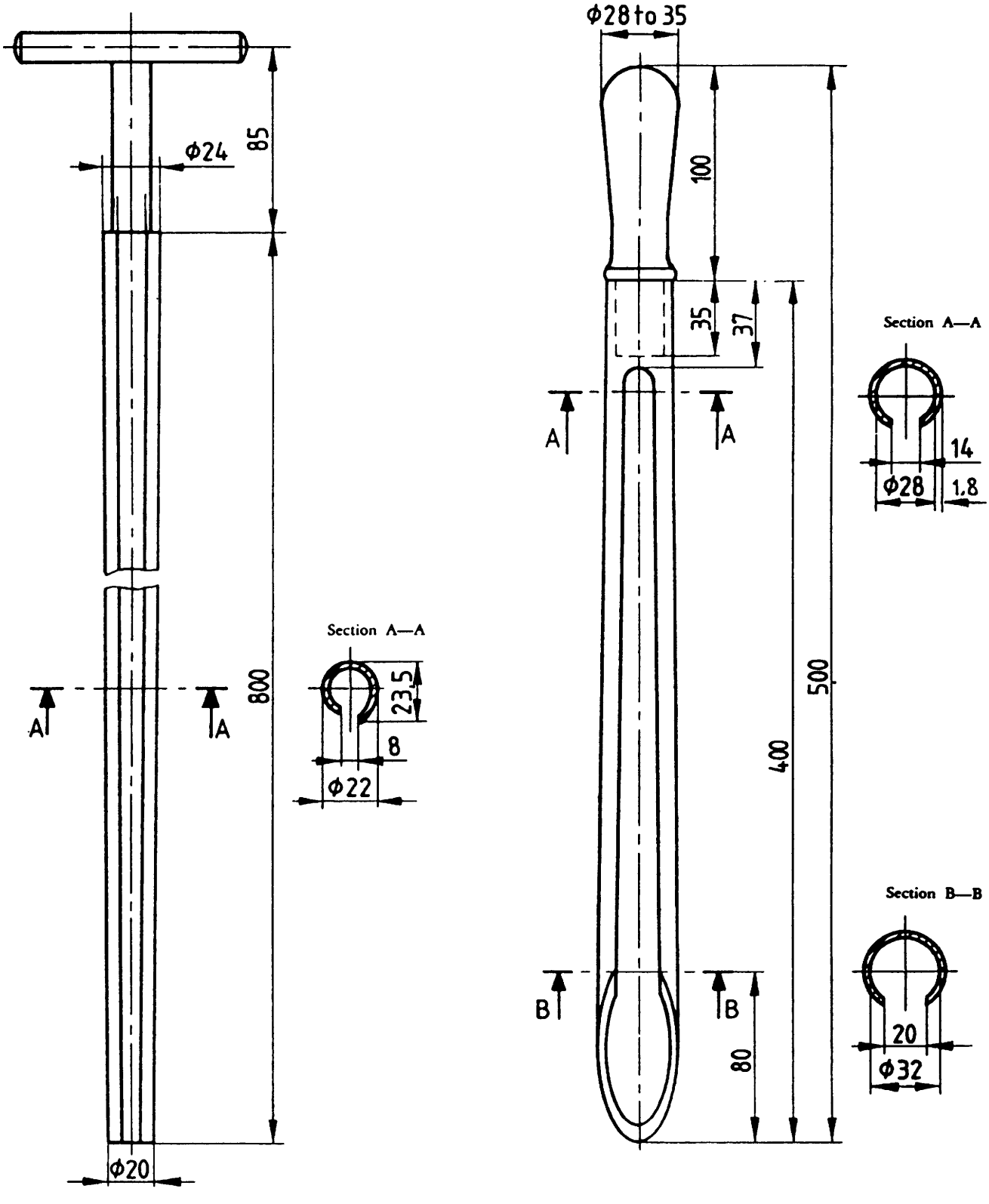
Type B borers are already filled completely during insertion but must be withdrawn in an oblique position to prevent losses from the lower end.

5.2. In the case of free-flowing powder, the containers shall be inclined, the borers inserted nearly horizontally with the slit downwards and withdrawn with the slit upwards.

Figure

BORERS SUITABLE FOR THE SAMPLING OF CASEINS AND CASEINATES

(Dimensions in millimetres)



Type A

Type B

NATURAL MINERAL WATERS

380L0777

80/777/EEC: COUNCIL DIRECTIVE OF 15 JULY 1980 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO THE EXPLOITATION AND MARKETING OF NATURAL MINERAL WATERS

OFFICIAL JOURNAL NO L 229, 30/08/1980, P. 1
DATE OF NOTIFICATION: 17/07/1980
DATE OF TRANSPOSITION: 17/07/1982; SEE ART. 15
DATE OF TRANSPOSITION: 17/07/1984; SEE ART. 15

AMENDED BY

380L1276
80/1276/EEC: COUNCIL DIRECTIVE OF 22 DECEMBER 1980 [1]
OFFICIAL JOURNAL NO L 375, 31/12/1980, P. 77
DATE OF NOTIFICATION: 31/12/1980

385L0007
85/7/EEC: COUNCIL DIRECTIVE OF 19 DECEMBER 1984 [2]
OFFICIAL JOURNAL NO L 2, 03/01/1985, P. 22
DATE OF NOTIFICATION: 27/12/1984

185I
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE KINGDOM OF SPAIN AND THE PORTUGUESE REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES [3]
OFFICIAL JOURNAL NO L 302, 15/11/1985, P. 217

ARTICLE 1

1. THIS DIRECTIVE CONCERNS WATERS EXTRACTED FROM THE GROUND OF A MEMBER STATE AND RECOGNIZED BY THE RESPONSIBLE AUTHORITY OF THAT MEMBER STATE AS NATURAL MINERAL WATERS SATISFYING THE PROVISIONS OF ANNEX I, SECTION I.

2. THIS DIRECTIVE ALSO CONCERNS WATERS EXTRACTED FROM THE GROUND OF A THIRD COUNTRY, IMPORTED INTO THE COMMUNITY AND RECOGNIZED AS NATURAL MINERAL WATERS BY THE RESPONSIBLE AUTHORITY OF A MEMBER STATE.
THE WATERS REFERRED TO IN THE FIRST SUBPARAGRAPH MAY BE SO RECOGNIZED ONLY IF THE RESPONSIBLE AUTHORITY IN THE COUNTRY OF EXTRACTION HAS CERTIFIED THAT THEY SATISFY ANNEX I, SECTION I, AND THAT REGULAR CHECKS ARE MADE ON THE APPLICATION OF THE PROVISIONS OF ANNEX II, PARAGRAPH 2.
THE VALIDITY OF THE CERTIFICATION REFERRED TO IN THE SECOND SUBPARAGRAPH MAY NOT EXCEED A PERIOD OF TWO YEARS. IT SHALL NOT BE NECESSARY TO REPEAT THE RECOGNITION PROCEDURE REFERRED TO IN THE FIRST SUBPARAGRAPH IF THE CERTIFICATION IS RENEWED BEFORE THE END OF THE SAID PERIOD.

3. THIS DIRECTIVE SHALL NOT APPLY:

- TO WATERS WHICH ARE MEDICINAL PRODUCTS WITHIN THE MEANING OF DIRECTIVE 65/65/EEC (1),
- TO NATURAL MINERAL WATERS USED AT SOURCE FOR CURATIVE PURPOSES IN THERMAL OR HYDROMINERAL ESTABLISHMENTS.

4. THE GROUNDS FOR GRANTING THE RECOGNITION REFERRED TO IN PARAGRAPHS 1 AND 2, SHALL BE STATED IN DUE FORM BY THE RESPONSIBLE AUTHORITY OF THE MEMBER STATE AND SHALL BE OFFICIALLY PUBLISHED.

5. EACH MEMBER STATE SHALL INFORM THE COMMISSION OF THE CASES WHERE THE RECOGNITION REFERRED TO IN PARAGRAPHS 1 AND 2 HAS BEEN GRANTED OR WITHDRAWN. THE LIST OF NATURAL MINERAL WATERS SO RECOGNIZED SHALL BE PUBLISHED IN THE OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITIES.

ARTICLE 2

MEMBER STATES SHALL TAKE THE MEASURES NECESSARY TO ENSURE THAT ONLY THE WATERS REFERRED TO IN ARTICLE 1 WHICH COMPLY WITH THE PROVISIONS OF THIS DIRECTIVE MAY BE MARKETED AS NATURAL MINERAL WATERS.

ARTICLE 3

NATURAL MINERAL WATER SPRINGS MAY BE EXPLOITED AND THEIR WATERS BOTTLED ONLY IN ACCORDANCE WITH ANNEX II.

ARTICLE 4

1. NATURAL MINERAL WATER, IN ITS STATE AT SOURCE, MAY NOT BE THE SUBJECT OF ANY TREATMENT OR ADDITION OTHER THAN:

(a) THE SEPARATION OF ITS UNSTABLE ELEMENTS, SUCH AS IRON AND SULPHUR COMPOUNDS, BY FILTRATION OR DECANTING, POSSIBLY PRECEDED BY OXYGENATION, IN SO FAR AS THIS TREATMENT DOES NOT ALTER THE COMPOSITION OF THE WATER AS REGARDS THE ESSENTIAL CONSTITUENTS WHICH GIVE IT ITS PROPERTIES;

(b) THE TOTAL OR PARTIAL ELIMINATION OF FREE CARBON DIOXIDE BY EXCLUSIVELY PHYSICAL METHODS;

(c) THE INTRODUCTION OR THE REINTRODUCTION OF CARBON DIOXIDE UNDER THE CONDITIONS LAID DOWN IN ANNEX I, SECTION III;

2. IN PARTICULAR ANY DISINFECTION TREATMENT BY WHATEVER MEANS AND, SUBJECT TO PARAGRAPH 1 (c), THE ADDITION OF BACTERIOSTATIC ELEMENTS OR ANY OTHER TREATMENT LIKELY TO CHANGE THE VIABLE COLONY COUNT OF THE NATURAL MINERAL WATER SHALL BE PROHIBITED.

3. PARAGRAPH 1 SHALL NOT CONSTITUTE A BAR TO THE UTILIZATION OF NATURAL MINERAL WATER IN THE MANUFACTURE OF SOFT DRINKS.

ARTICLE 5

1. THE REVIVABLE TOTAL COLONY COUNT OF A NATURAL MINERAL WATER AT SOURCE SHALL CONFORM TO ITS NORMAL VIABLE COLONY COUNT AND GIVE SATISFACTORY EVIDENCE OF THE PROTECTION OF THE SOURCE AGAINST ALL CONTAMINATION. THIS TOTAL COLONY COUNT SHALL BE DETERMINED UNDER THE CONDITIONS LAID DOWN IN ANNEX I, SECTION II, POINT 1.3.3.
AFTER BOTTLING, THE TOTAL COLONY COUNT AT SOURCE MAY NOT EXCEED 100 PER MILLILITRE AT 20 TO 22 °C IN 72 HOURS ON AGAR-AGAR OR AN AGAR-GELATINE MIXTURE AND 20 PER MILLILITRE AT 37 °C IN 24 HOURS ON AGAR-AGAR. THE TOTAL COLONY COUNT SHALL BE MEASURED WITHIN THE 12 HOURS FOLLOWING BOTTLING, THE WATER BEING MAINTAINED AT 4 °C ± 1 °C DURING THIS 12-HOUR PERIOD.
AT SOURCE, THESE VALUES SHOULD NOT NORMALLY EXCEED 20 PER MILLILITRE AT 20 TO 22 °C IN 72 HOURS AND 5 PER MILLILITRE AT 37 °C IN 24 HOURS RESPECTIVELY, ON THE UNDERSTANDING THAT THEY ARE TO BE CONSIDERED AS GUIDE FIGURES AND NOT AS MAXIMUM PERMITTED CONCENTRATIONS.

2. AT SOURCE AND DURING ITS MARKETING, A NATURAL MINERAL WATER SHALL BE FREE FROM:

(a) PARASITES AND PATHOGENIC MICRO-ORGANISMS;

(b) ESCHERICHIA COLI AND OTHER COLIFORMS AND FAECAL STREPTOCOCCI IN ANY 250 ml SAMPLE EXAMINED;

(c) SPORULATED SULPHITE-REDUCING ANAEROBES IN ANY 50 ml SAMPLE EXAMINED;

(d) PSEUDOMONAS AERUGINOSA IN ANY 250 ml SAMPLE EXAMINED.

3. WITHOUT PREJUDICE TO PARAGRAPHS 1 AND 2 AND THE CONDITIONS OF EXPLOITATION LAID DOWN IN ANNEX II, AT THE MARKETING STAGE:

- THE REVIVABLE TOTAL COLONY COUNT OF A NATURAL MINERAL WATER MAY ONLY BE THAT RESULTING FROM THE NORMAL INCREASE IN THE BACTERIA CONTENT WHICH IT HAD AT SOURCE,
- THE NATURAL MINERAL WATER MAY NOT CONTAIN ANY ORGANOLEPTIC DEFECTS.

ARTICLE 6

ANY CONTAINERS USED FOR PACKAGING NATURAL MINERAL WATERS SHALL BE FITTED WITH CLOSURES DESIGNED TO AVOID ANY POSSIBILITY OF ADULTERATION OR CONTAMINATION.

ARTICLE 7

1. THE SALES DESCRIPTION OF NATURAL MINERAL WATERS SHALL BE "NATURAL MINERAL WATER" OR, IN THE CASE OF AN EFFERVESCENT NATURAL MINERAL WATER AS DEFINED IN ANNEX I, SECTION III, AS APPROPRIATE, "NATURALLY CARBONATED NATURAL MINERAL WATER", "NATURAL MINERAL WATER FORTIFIED WITH GAS FROM THE SPRING" OR "CARBONATED NATURAL MINERAL WATER".
THE SALES DESCRIPTION OF NATURAL MINERAL WATERS WHICH HAVE UNDERGONE ANY OF THE TREATMENTS REFERRED TO IN ARTICLE 4 (1) (b) SHALL HAVE ADDED TO IT AS APPROPRIATE THE INDICATION "FULLY DE-CARBONATED" OR "PARTIALLY DE-CARBONATED".

2. LABELS ON NATURAL MINERAL WATERS SHALL ALSO GIVE THE FOLLOWING MANDATORY INFORMATION:

(a) - EITHER THE WORDS: "COMPOSITION IN ACCORDANCE WITH THE RESULTS OF THE OFFICIALLY RECOGNIZED ANALYSIS OF... (DATE OF ANALYSIS)",

- OR A STATEMENT OF THE ANALYTICAL COMPOSITION GIVING ITS CHARACTERISTIC CONSTITUENTS;

(b) THE PLACE WHERE THE SPRING IS EXPLOITED AND THE NAME OF THE SPRING.

3. MEMBER STATES MAY ALSO:

(a) RETAIN THE PROVISIONS WHICH REQUIRE THE COUNTRY OF ORIGIN TO BE INDICATED, ALTHOUGH THIS INFORMATION CANNOT BE DEMANDED IN THE CASE OF NATURAL MINERAL WATERS FROM A SPRING IN THE TERRITORY OF THE COMMUNITY;

(b) INTRODUCE PROVISIONS WHICH REQUIRE INFORMATION ON ANY TREATMENTS REFERRED TO IN ARTICLE 4 (1) (a).

ARTICLE 8

1. THE NAME OF A LOCALITY, HAMLET OR PLACE MAY OCCUR IN THE WORDING OF A TRADE DESCRIPTION PROVIDED THAT IT REFERS TO A NATURAL MINERAL WATER THE SPRING OF WHICH IS EXPLOITED AT THE PLACE INDICATED BY THAT DESCRIPTION AND PROVIDED THAT IT IS NOT MISLEADING AS REGARDS THE PLACE OF EXPLOITATION OF THE SPRING.

2. IT SHALL BE FORBIDDEN TO MARKET NATURAL MINERAL WATER FROM ONE AND THE SAME SPRING UNDER MORE THAN ONE TRADE DESCRIPTION.

3. WHEN THE LABELS OR INSCRIPTIONS ON THE CONTAINERS IN WHICH THE NATURAL MINERAL WATERS ARE OFFERED FOR SALE INCLUDE A TRADE DESCRIPTION DIFFERENT FROM THE NAME OF THE SPRING OR THE PLACE OF ITS EXPLOITATION, THIS PLACE OR THE NAME OF THE SPRING SHALL BE INDICATED IN LETTERS AT LEAST ONE AND A HALF TIMES THE HEIGHT AND WIDTH OF THE LARGEST OF THE LETTERS USED FOR THAT TRADE DESCRIPTION.
THE FIRST SUBPARAGRAPH SHALL APPLY, MUTATIS MUTANDIS AND WITH THE SAME INTENTION AS REGARDS THE IMPORTANCE ATTRIBUTED TO THE NAME OF THE SPRING OR THE PLACE OF ITS EXPLOITATION, WITH REGARD TO THE TRADE DESCRIPTION USED IN ADVERTISING, IN WHATSOEVER FORM, RELATING TO NATURAL MINERAL WATERS.

ARTICLE 9

1. IT SHALL BE FORBIDDEN, BOTH ON PACKAGING OR LABELS AND IN ADVERTISING IN WHATSOEVER FORM, TO USE DESIGNATIONS, PROPRIETARY NAMES, TRADE MARKS, BRAND NAMES, ILLUSTRATIONS OR OTHER SIGNS, WHETHER EMBLEMATIC OR NOT, WHICH:

(a) IN THE CASE OF A NATURAL MINERAL WATER, SUGGEST A CHARACTERISTIC WHICH THE WATER DOES NOT POSSESS, IN PARTICULAR AS REGARDS ITS ORIGIN, THE DATE OF THE AUTHORIZATION TO EXPLOIT IT, THE RESULTS OF ANALYSES OR ANY SIMILAR REFERENCES TO GUARANTEES OF AUTHENTICITY;

(b) IN THE OF DRINKING WATER PACKAGED IN CONTAINERS WHICH DOES NOT SATISFY THE PROVISIONS OF ANNEX I, SECTION I, ARE LIABLE TO CAUSE CONFUSION WITH A NATURAL MINERAL WATER, IN PARTICULAR THE DESCRIPTION "MINERAL WATER".

2. (a) ALL INDICATIONS ATTRIBUTING TO A NATURAL MINERAL WATER PROPERTIES RELATING TO THE PREVENTION, TREATMENT OR CURE OF A HUMAN ILLNESS SHALL BE PROHIBITED.

(b) HOWEVER, THE INDICATIONS LISTED IN ANNEX III TO THIS DIRECTIVE SHALL BE AUTHORIZED IF THEY MEET THE RELEVANT CRITERIA LAID DOWN IN THAT ANNEX OR, IN THE ABSENCE THEREOF, CRITERIA LAID DOWN IN NATIONAL PROVISIONS AND PROVIDED THAT THEY HAVE BEEN DRAWN UP ON THE BASIS OF PHYSICO-CHEMICAL ANALYSES AND, WHERE NECESSARY, PHARMACOLOGICAL, PHYSIOLOGICAL AND CLINICAL EXAMINATIONS CARRIED OUT ACCORDING

TO RECOGNIZED SCIENTIFIC METHODS, IN ACCORDANCE WITH SECTION I, PARAGRAPH 2 OF ANNEX I.

(c) MEMBER STATES MAY AUTHORIZE THE INDICATIONS "STIMULATES DIGESTION", "MAY FACILITATE THE HEPATO-BILIARY FUNCTIONS" OR SIMILAR INDICATIONS. THEY MAY ALSO AUTHORIZE THE INCLUSION OF OTHER INDICATIONS, PROVIDED THAT THE LATTER DO NOT CONFLICT WITH THE PRINCIPLES STATED IN (a) AND ARE COMPATIBLE WITH THOSE STATED IN (b).

3. MEMBER STATES MAY ADOPT SPECIAL PROVISIONS REGARDING INFORMATION - BOTH ON PACKAGING OR LABELS AND IN ADVERTISING - CONCERNING THE SUITABILITY OF A NATURAL MINERAL WATER FOR THE FEEDING OF INFANTS. SUCH PROVISIONS MAY ALSO CONCERN THE PROPERTIES OF THE WATER WHICH DETERMINE THE USE OF THE SAID INFORMATION.
MEMBER STATES WHICH INTEND TAKING SUCH MEASURES SHALL INFORM THE OTHER MEMBER STATES AND THE COMMISSION OF THEM BEFOREHAND.

4. NOT LATER THAN THREE YEARS AFTER NOTIFICATION OF THIS DIRECTIVE, THE COMMISSION SHALL SUBMIT TO THE COUNCIL A REPORT AND, WHERE APPROPRIATE, SUITABLE PROPOSALS ON THE APPLICATION OF THE PROVISIONS REFERRED TO IN 1.2.12 OF ANNEX I, SECTION II.

ARTICLE 10

1. MEMBER STATES SHALL ADOPT THE MEASURES NECESSARY TO ENSURE THAT TRADE IN NATURAL MINERAL WATERS WHICH COMPLY WITH THE DEFINITIONS AND RULES LAID DOWN IN THIS DIRECTIVE CANNOT BE IMPEDED BY THE APPLICATION OF NON-HARMONIZED NATIONAL PROVISIONS GOVERNING THE PROPERTIES, COMPOSITION, CONDITIONS OF EXPLOITATION, PACKAGING OR LABELLING OF NATURAL MINERAL WATERS OR FOODSTUFFS IN GENERAL.

2. PARAGRAPH 1 SHALL NOT BE APPLICABLE TO NON-HARMONIZED NATIONAL PROVISIONS JUSTIFIED ON GROUNDS OF:

- PROTECTION OF PUBLIC HEALTH,
- PREVENTION OF FRAUD, UNLESS SUCH PROVISIONS ARE LIKELY TO IMPEDE THE APPLICATION OF THE DEFINITIONS AND RULES LAID DOWN BY THIS DIRECTIVE,
- PROTECTION OF INDUSTRIAL AND COMMERCIAL PROPERTY, INDICATIONS OF SOURCE, DESIGNATIONS OF ORIGIN AND THE PREVENTION OF UNFAIR COMPETITION.

ARTICLE 11

THE SAMPLING PROCEDURES AND THE METHODS OF ANALYSIS NECESSARY FOR CHECKING THE MICROBIOLOGICAL CHARACTERISTICS REFERRED TO IN ARTICLE 5 AND THE COMPOSITIONAL CHARACTERISTICS REFERRED TO IN 1.2 OF ANNEX I, SECTION II, SHALL BE DETERMINED IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 12.

ARTICLE 12

1. WHERE THE PROCEDURE LAID DOWN IN THIS ARTICLE IS TO BE FOLLOWED, THE MATTER SHALL BE REFERRED TO THE STANDING COMMITTEE ON FOODSTUFFS, HEREINAFTER CALLED "THE COMMITTEE", BY ITS CHAIRMAN, EITHER ON HIS OWN INITIATIVE OR AT THE REQUEST OF THE REPRESENTATIVE OF A MEMBER STATE.

2. THE COMMISSION REPRESENTATIVE SHALL SUBMIT A DRAFT OF THE MEASURES TO BE TAKEN TO THE COMMITTEE. THE COMMITTEE SHALL DELIVER ITS OPINION ON THAT DRAFT WITHIN A TIME LIMIT SET BY THE CHAIRMAN HAVING REGARD TO THE URGENCY OF THE MATTER. OPINIONS SHALL BE ARRIVED AT BY A MAJORITY OF " fifty-four " **[3]** VOTES, THE VOTES OF THE

MEMBER STATES BEING WEIGHTED IN ACCORDANCE WITH ARTICLE 148 (2) OF THE TREATY. THE CHAIRMAN SHALL NOT VOTE.

3. (a) WHERE THE MEASURES ENVISAGED ARE IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE THE COMMISSION SHALL ADOPT THEM;

(b) WHERE THE MEASURES ENVISAGED ARE NOT IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE, OR IF NO OPINION IS DELIVERED, THE COMMISSION SHALL FORTHWITH SUBMIT TO THE COUNCIL A PROPOSAL ON THE MEASURES TO BE TAKEN. THE COUNCIL SHALL ACT BY A QUALIFIED MAJORITY;

(c) IF WITHIN THREE MONTHS OF THE MATTER BEING BROUGHT BEFORE IT THE COUNCIL HAS NOT ACTED, THE MEASURES PROPOSED SHALL BE ADOPTED BY THE COMMISSION.

ARTICLE 13

ARTICLE 12 SHALL APPLY " FOR A PERIOD OF TWO YEARS FROM THE DATE ON WHICH THE MATTER WAS FIRST REFERRED TO THE COMMITTEE AFTER 1 JANUARY 1985 " **[2]** UNDER ARTICLE 12 (1).

ARTICLE 14

THIS DIRECTIVE SHALL NOT APPLY TO NATURAL MINERAL WATERS INTENDED FOR EXPORT TO THIRD COUNTRIES.

ARTICLE 15

MEMBER STATES SHALL MAKE SUCH AMENDMENTS TO THEIR LAWS AS MAY BE NECESSARY TO COMPLY WITH THIS DIRECTIVE AND SHALL FORTHWITH INFORM THE COMMISSION THEREOF; THE LAWS THUS AMENDED SHALL BE APPLIED IN SUCH A WAY AS TO:

- PERMIT TRADE IN PRODUCTS COMPLYING WITH THIS DIRECTIVE NOT LATER THAN TWO YEARS AFTER ITS NOTIFICATION,
- PROHIBIT TRADE IN PRODUCTS NOT COMPLYING WITH THIS DIRECTIVE FOUR YEARS AFTER ITS NOTIFICATION.

ARTICLE 16

THIS DIRECTIVE SHALL ALSO APPLY TO THE OVERSEAS DEPARTMENTS OF THE FRENCH REPUBLIC.

ARTICLE 17

THIS DIRECTIVE IS ADDRESSED TO THE MEMBER STATES.

ANNEX I

I. DEFINITION

1. "NATURAL MINERAL WATER" MEANS MICROBIOLOGICALLY WHOLESOME WATER, WITHIN THE MEANING OF ARTICLE 5, ORIGINATING IN AN UNDERGROUND WATER TABLE OR DEPOSIT AND EMERGING FROM A SPRING TAPPED AT ONE OR MORE NATURAL OR BORE EXITS.
NATURAL MINERAL WATER CAN BE CLEARLY DISTINGUISHED FROM ORDINARY DRINKING WATER:

(a) BY ITS NATURE, WHICH IS CHARACTERIZED BY ITS MINERAL CONTENT, TRACE ELEMENTS OR OTHER CONSTITUENTS AND, WHERE APPROPRIATE, BY CERTAIN EFFECTS;

(b) BY ITS ORIGINAL STATE,

BOTH CHARACTERISTICS HAVING BEEN PRESERVED INTACT BECAUSE OF THE UNDERGROUND ORIGIN OF SUCH WATER, WHICH HAS BEEN PROTECTED FROM ALL RISK OF POLLUTION.

2. THESE CHARACTERISTICS, WHICH MAY GIVE NATURAL MINERAL WATER PROPERTIES FAVOURABLE TO HEALTH, MUST HAVE BEEN ASSESSED:

(a) FROM THE FOLLOWING POINTS OF VIEW:

1. GEOLOGICAL AND HYDROLOGICAL,
2. PHYSICAL, CHEMICAL AND PHYSICO-CHEMICAL,
3. MICROBIOLOGICAL,
4. IF NECESSARY, PHARMACOLOGICAL, PHYSIOLOGICAL AND CLINICAL;

(b) ACCORDING TO THE CRITERIA LISTED IN SECTION II;

(c) ACCORDING TO SCIENTIFIC METHODS APPROVED BY THE RESPONSIBLE AUTHORITY.

THE ANALYSES REFERRED TO IN (a) (4) MAY BE OPTIONAL WHERE THE WATER PRESENTS THE COMPOSITIONAL CHARACTERISTICS ON THE STRENGTH OF WHICH IT WAS CONSIDERED A NATURAL MINERAL WATER IN THE MEMBER STATE OF ORIGIN PRIOR TO THE ENTRY INTO FORCE OF THIS DIRECTIVE. THIS IS THE CASE IN PARTICULAR WHEN THE WATER IN QUESTION CONTAINS, PER kg, BOTH AT SOURCE AND AFTER BOTTLING, A MINIMUM OF 1 000 mg OF TOTAL SOLIDS IN SOLUTION OR A MINIMUM OF 250 mg OF FREE CARBON DIOXIDE.

3. THE COMPOSITION, TEMPERATURE AND OTHER ESSENTIAL CHARACTERISTICS OF NATURAL MINERAL WATER MUST REMAIN STABLE WITHIN THE LIMITS OF NATURAL FLUCTUATION; IN PARTICULAR, THEY MUST NOT BE AFFECTED BY POSSIBLE VARIATIONS IN THE RATE OF FLOW.
WITHIN THE MEANING OF ARTICLE 5 (1), THE NORMAL VIABLE COLONY COUNT OF NATURAL MINERAL WATER MEANS THE REASONABLY CONSTANT TOTAL COLONY COUNT AT SOURCE BEFORE ANY TREATMENT, WHOSE QUALITATIVE AND QUANTITATIVE COMPOSITION TAKEN INTO ACCOUNT IN THE RECOGNITION OF THAT WATER IS CHECKED BY PERIODIC ANALYSIS.

II. REQUIREMENTS AND CRITERIA FOR APPLYING THE DEFINITION

1.1. REQUIREMENTS FOR GEOLOGICAL AND HYDROLOGICAL SURVEYS
THERE MUST BE A REQUIREMENT TO SUPPLY THE FOLLOWING PARTICULARS:

1.1.1. THE EXACT SITE OF THE CATCHMENT WITH INDICATION OF ITS ALTITUDE, ON A MAP WITH A SCALE OF NOT MORE THAN 1:1 000;

1.1.2. A DETAILED GEOLOGICAL REPORT ON THE ORIGIN AND NATURE OF THE TERRAIN;

1.1.3. THE STRATIGRAPHY OF THE HYDROGEOLOGICAL LAYER;

1.1.4. A DESCRIPTION OF THE CATCHMENT OPERATIONS;

1.1.5. THE DEMARCATION OF THE AREA OR DETAILS OF OTHER MEASURES PROTECTING THE SPRING AGAINST POLLUTION.

1.2. REQUIREMENTS FOR PHYSICAL, CHEMICAL AND PHYSICO-CHEMICAL SURVEYS
THESE SURVEYS SHALL ESTABLISH:

1.2.1. THE RATE OF FLOW OF THE SPRING;

1.2.2. THE TEMPERATURE OF THE WATER AT SOURCE AND THE AMBIENT TEMPERATURE;

1.2.3. THE RELATIONSHIP BETWEEN THE NATURE OF THE TERRAIN AND THE NATURE AND TYPE OF MINERALS IN THE WATER;

1.2.4. THE DRY RESIDUES AT 180 °C AND 260 °C;

1.2.5. THE ELECTRICAL CONDUCTIVITY OR RESISTIVITY, WITH THE MEASUREMENT TEMPERATURE HAVING TO BE SPECIFIED;

1.2.6. THE HYDROGEN ION CONCENTRATION (PH);

1.2.7. THE ANIONS AND CATIONS;

1.2.8. THE NON-IONIZED ELEMENTS;

1.2.9. THE TRACE ELEMENTS;

1.2.10. THE RADIO-ACTINOLOGICAL PROPERTIES AT SOURCE;

1.2.11. WHERE APPROPRIATE, THE RELATIVE ISOTOPE LEVELS OF THE CONSTITUENT ELEMENTS OF WATER, OXYGEN (16 O - 18 O) AND HYDROGEN (PROTIUM, DEUTERIUM, TRITIUM);

1.2.12. THE TOXICITY OF CERTAIN CONSTITUENT ELEMENTS OF THE WATER, TAKING ACCOUNT OF THE LIMITS LAID DOWN FOR EACH OF THEM.

1.3. CRITERIA FOR MICROBIOLOGICAL ANALYSES AT SOURCE
THESE ANALYSES MUST INCLUDE:

1.3.1. DEMONSTRATION OF THE ABSENCE OF PARASITES AND PATHOGENIC MICRO-ORGANISMS;

1.3.2. QUANTITATIVE DETERMINATION OF THE REVIVABLE COLONY COUNT INDICATIVE OF FAECAL CONTAMINATION:

(a) ABSENCE OF ESCHERICHIA COLI AND OTHER COLIFORMS IN 250 ml AT 37 °C AND 44.5 °C;

(b) ABSENCE OF FAECAL STREPTOCOCCI IN 250 ml;

(c) ABSENCE OF SPORULATED SULPHITE-REDUCING ANAEROBES IN 50 ml;

(d) ABSENCE OF PSEUDOMONAS AERUGINOSA IN 250 ml.

1.3.3. DETERMINATION OF THE REVIVABLE TOTAL COLONY COUNT PER ml OF WATER:

(a) AT 20 TO 22 °C IN 72 HOURS ON AGAR-AGAR OR AN AGAR-GELATINE MIXTURE,

(b) AT 37 °C IN 24 HOURS ON AGAR-AGAR.

1.4. REQUIREMENTS FOR CLINICAL AND PHARMACOLOGICAL ANALYSES

1.4.1. THE ANALYSES, WHICH MUST BE CARRIED OUT IN ACCORDANCE WITH SCIENTIFICALLY RECOGNIZED METHODS, SHOULD BE SUITED TO THE PARTICULAR CHARACTERISTICS OF THE NATURAL MINERAL WATER AND ITS EFFECTS ON THE HUMAN ORGANISM, SUCH AS DIURESIS, GASTRIC AND INTESTINAL FUNCTIONS, COMPENSATION FOR MINERAL DEFICIENCIES.

1.4.2. THE ESTABLISHMENT OF THE CONSISTENCY AND CONCORDANCE OF A SUBSTANTIAL NUMBER OF CLINICAL OBSERVATIONS MAY, IF APPROPRIATE, TAKE THE PLACE OF THE ANALYSES REFERRED TO IN 1.4.1. CLINICAL ANALYSES MAY, IN APPROPRIATE CASES, TAKE THE PLACE OF THE ANALYSES REFERRED TO IN 1.4.1 PROVIDED THAT THE CONSISTENCY AND CONCORDANCE OF A SUBSTANTIAL NUMBER OF OBSERVATIONS ENABLE THE SAME RESULTS TO BE OBTAINED.

III. SUPPLEMENTARY QUALIFICATIONS RELATING TO EFFERVESCENT NATURAL MINERAL WATERS

AT SOURCE OR AFTER BOTTLING, EFFERVESCENT NATURAL MINERAL WATERS GIVE OFF CARBON DIOXIDE SPONTANEOUSLY AND IN A CLEARLY VISIBLE MANNER UNDER NORMAL CONDITIONS OF TEMPERATURE AND PRESSURE. THEY FALL INTO THREE CATEGORIES TO WHICH THE FOLLOWING DESCRIPTIONS RESPECTIVELY SHALL APPLY:

(a) "NATURALLY CARBONATED NATURAL MINERAL WATER" MEANS WATER WHOSE CONTENT OF CARBON DIOXIDE FROM THE SPRING AFTER DECANTING, IF ANY, AND BOTTLING IS THE SAME AS AT SOURCE, TAKING INTO ACCOUNT WHERE APPROPRIATE THE REINTRODUCTION OF A QUANTITY OF CARBON DIOXIDE FROM THE SAME WATER TABLE OR DEPOSIT EQUIVALENT TO THAT RELEASED IN THE COURSE OF THOSE OPERATIONS AND SUBJECT TO THE USUAL TECHNICAL TOLERANCES;

(b) "NATURAL MINERAL WATER FORTIFIED WITH GAS FROM THE SPRING" MEANS WATER WHOSE CONTENT OF CARBON DIOXIDE FROM THE WATER TABLE OR DEPOSIT AFTER DECANTING, IF ANY, AND BOTTLING IS GREATER THAN THAT ESTABLISHED AT SOURCE;

(c) "CARBONATED NATURAL MINERAL WATER" MEANS WATER TO WHICH HAS BEEN ADDED CARBON DIOXIDE OF AN ORIGIN OTHER THAN THE WATER TABLE OR DEPOSIT FROM WHICH THE WATER COMES.

ANNEX II

CONDITIONS FOR THE EXPLOITATION AND MARKETING OF NATURAL MINERAL WATER

1. EXPLOITATION OF A NATURAL MINERAL WATER SPRING SHALL BE SUBJECT TO PERMISSION FROM THE RESPONSIBLE AUTHORITY OF THE COUNTRY WHERE THE WATER HAS BEEN EXTRACTED, AFTER IT HAS BEEN ESTABLISHED THAT THE WATER IN QUESTION COMPLIES WITH THE PROVISIONS LAID DOWN IN POINT 1 OF ANNEX I.

2. EQUIPMENT FOR EXPLOITING THE WATER MUST BE SO INSTALLED AS TO AVOID ANY POSSIBILITY OF CONTAMINATION AND TO PRESERVE THE PROPERTIES, CORRESPONDING TO THOSE ASCRIBED TO IT, WHICH THE WATER POSSESSES AT SOURCE.
TO THIS END, IN PARTICULAR:

(a) THE SPRING OR OUTLET MUST BE PROTECTED AGAINST THE RISKS OF POLLUTION;

(b) THE CATCHMENT, PIPES AND RESERVOIRS MUST BE OF MATERIALS SUITABLE FOR WATER AND SO BUILT AS TO PREVENT ANY CHEMICAL, PHYSICO-CHEMICAL OR MICROBIOLOGICAL ALTERATION OF THE WATER;

(c) THE CONDITIONS OF EXPLOITATION, PARTICULARLY THE WASHING AND BOTTLING PLANT, MUST MEET HYGIENE REQUIREMENTS. IN PARTICULAR, THE CONTAINERS MUST BE SO TREATED

OR MANUFACTURED AS TO AVOID ADVERSE EFFECTS ON THE MICROBIOLOGICAL AND CHEMICAL CHARACTERISTICS OF THE NATURAL MINERAL WATER;

(d) THE TRANSPORT OF NATURAL MINERAL WATER IN CONTAINERS OTHER THAN THOSE AUTHORIZED FOR DISTRIBUTION TO THE ULTIMATE CONSUMER IS PROHIBITED.

HOWEVER, POINT (d) NEED NOT BE APPLIED TO MINERAL WATERS EXPLOITED AND MARKETED IN THE TERRITORY OF A MEMBER STATE IF, IN THAT MEMBER STATE AT THE TIME OF NOTIFICATION OF THIS DIRECTIVE, TRANSPORT OF THE NATURAL MINERAL WATER IN TANKS FROM THE SPRING TO THE BOTTLING PLANT WAS AUTHORIZED.

3. WHERE IT IS FOUND DURING EXPLOITATION THAT THE NATURAL MINERAL WATER IS POLLUTED AND NO LONGER PRESENTS THE MICROBIOLOGICAL CHARACTERISTICS LAID DOWN IN ARTICLE 5, THE PERSON EXPLOITING THE SPRING MUST FORTHWITH SUSPEND ALL OPERATIONS, PARTICULARLY THE BOTTLING PROCESS, UNTIL THE CAUSE OF POLLUTION IS ERADICATED AND THE WATER COMPLIES WITH THE PROVISIONS OF ARTICLE 5.

4. THE RESPONSIBLE AUTHORITY IN THE COUNTRY OF ORIGIN SHALL CARRY OUT PERIODIC CHECKS TO SEE WHETHER:

(a) THE NATURAL MINERAL WATER IN RESPECT OF WHICH EXPLOITATION OF THE SPRING HAS BEEN AUTHORIZED COMPLIES WITH SECTION I OF ANNEX I;

(b) THE PROVISIONS OF PARAGRAPHS 2 AND 3 ARE BEING APPLIED BY THE PERSON EXPLOITING THE SPRING.

ANNEX III

INDICATIONS AND CRITERIA LAID DOWN IN ARTICLE 9 (2)

Indications	Criteria
Low mineral content	Mineral salt content, calculated as a fixed residue, not greater than 500 mg/l
Very low mineral content	Mineral salt content, calculated as a fixed residue, not greater than 50 mg/l
Rich in mineral salts	Mineral salt content, calculated as a fixed residue, greater than 1 500 mg/l
Contains bicarbonate	Bicarbonate content greater than 600 mg/l
Contains sulphate	Sulphate content greater than 200 mg/l
Contains chloride	Chloride content greater than 200 mg/l
Contains calcium	Calcium content greater than 150 mg/l
Contains magnesium	Magnesium content greater than 50 mg/l
Contains fluoride	Fluoride content greater than 1 mg/l
Contains iron	Bivalent iron content greater than 1 mg/l
Acidic	Free carbon dioxide content greater than 250 mg/l
Contains sodium	Sodium content greater than 200 mg/l
Suitable for the preparation of infant food	—
Suitable for a low-sodium diet	Sodium content less than 20 mg/l
May be laxative	—
May be diuretic	—

(1) OJ No 22, 09/02/1965, p. 369/65.

380L0778

80/778/EEC: COUNCIL DIRECTIVE OF 15 JULY 1980 RELATING TO THE QUALITY OF WATER INTENDED FOR HUMAN CONSUMPTION

OFFICIAL JOURNAL NO L 229, 30/08/1980, P. 11
DATE OF NOTIFICATION: 17/07/1980
DATE OF TRANSPOSITION: 17/07/1982; SEE ART. 18
DATE OF TRANSPOSITION: 17/07/1985; SEE ART. 19

AMENDED BY

381L0858
81/858/EEC: COUNCIL DIRECTIVE OF 19 OCTOBER 1981 [1]
OFFICIAL JOURNAL NO L 319, 07/11/1981, P. 19

185I
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE KINGDOM OF SPAIN AND THE PORTUGUESE REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES [2]
OFFICIAL JOURNAL NO L 302, 15/11/1985, P. 219

391L0692
91/692/EEC: COUNCIL DIRECTIVE OF 23 DECEMBER 1991 [3]
OFFICIAL JOURNAL NO L 377, 31/12/1991, P. 48
DATE OF TRANSPOSITION: 01/01/1993; SEE ART. 7

ARTICLE 1

THIS DIRECTIVE CONCERNS STANDARDS FOR WATER INTENDED FOR HUMAN CONSUMPTION.

ARTICLE 2

FOR THE PURPOSES OF THIS DIRECTIVE, WATER INTENDED FOR HUMAN CONSUMPTION SHALL MEAN ALL WATER USED FOR THAT PURPOSE, EITHER IN ITS ORIGINAL STATE OR AFTER TREATMENT, REGARDLESS OF ORIGIN,

- WHETHER SUPPLIED FOR CONSUMPTION, OR
- WHETHER
-- USED IN A FOOD PRODUCTION UNDERTAKING FOR THE MANUFACTURE, PROCESSING, PRESERVATION OR MARKETING OF PRODUCTS OR SUBSTANCES INTENDED FOR HUMAN CONSUMPTION AND
-- AFFECTING THE WHOLESOMENESS OF THE FOODSTUFF IN ITS FINISHED FORM.

ARTICLE 3

WITH REGARD TO WATER REFERRED TO IN THE SECOND INDENT OF ARTICLE 2, MEMBER STATES SHALL APPLY THE VALUES FOR THE TOXIC AND MICROBIOLOGICAL PARAMETERS LISTED IN

TABLES D AND E RESPECTIVELY OF ANNEX I AND THE VALUES FOR THE OTHER PARAMETERS WHICH THE COMPETENT NATIONAL AUTHORITIES CONSIDER ARE LIKELY TO AFFECT THE WHOLESOMENESS OF THE FOODSTUFF IN ITS FINISHED FORM.

ARTICLE 4

1. THIS DIRECTIVE SHALL NOT APPLY TO:

(a) NATURAL MINERAL WATERS RECOGNIZED OR DEFINED AS SUCH BY THE COMPETENT NATIONAL AUTHORITIES;

(b) MEDICINAL WATERS RECOGNIZED AS SUCH BY THE COMPETENT NATIONAL AUTHORITIES.

2. MEMBER STATES MAY NOT PROHIBIT OR IMPEDE THE MARKETING OF FOODSTUFFS ON GROUNDS RELATING TO THE QUALITY OF THE WATER USED WHERE THE QUALITY OF SUCH WATER MEETS THE REQUIREMENTS OF THIS DIRECTIVE UNLESS SUCH MARKETING CONSTITUTES A HAZARD TO PUBLIC HEALTH.

ARTICLE 5

THIS DIRECTIVE SHALL APPLY WITHOUT PREJUDICE TO THE SPECIFIC PROVISIONS OF OTHER COMMUNITY REGULATIONS.

ARTICLE 6

1. MEMBER STATES SHALL SEND THE COMMISSION:

- APPROPRIATE INFORMATION AS TO THE INDUSTRIAL SECTORS IN WHICH THE COMPETENT NATIONAL AUTHORITIES CONSIDER THAT THE WHOLESOMENESS OF THE FINISHED PRODUCT, WITHIN THE MEANING OF ARTICLE 2, IS UNAFFECTED BY THE QUALITY OF THE WATER USED;
- NATIONAL VALUES FOR PARAMETERS OTHER THAN THE TOXIC AND MICROBIOLOGICAL PARAMETERS REFERRED TO IN ARTICLE 3.

2. THE COMMISSION SHALL EXAMINE THIS INFORMATION AND SHALL TAKE ANY MEASURES WHICH MAY BE APPROPRIATE. IT SHALL PERIODICALLY DRAW UP A COMPREHENSIVE REPORT FOR THE MEMBER STATES.

ARTICLE 7

1. MEMBER STATES SHALL FIX VALUES APPLICABLE TO WATER INTENDED FOR HUMAN CONSUMPTION FOR THE PARAMETERS SHOWN IN ANNEX I.

2. MEMBER STATES MAY REFRAIN FROM FIXING, PURSUANT TO THE FIRST PARAGRAPH, THE VALUES OF PARAMETERS IN RESPECT OF WHICH NO VALUE IS SHOWN IN ANNEX I, AS LONG AS THESE VALUES HAVE NOT BEEN DETERMINED BY THE COUNCIL.

3. FOR THE PARAMETERS GIVEN IN TABLES A, B, C, D, AND E OF ANNEX I:

- THE VALUES TO BE FIXED BY THE MEMBER STATES MUST BE LESS THAN OR THE SAME AS THE VALUES SHOWN IN THE "MAXIMUM ADMISSIBLE CONCENTRATION" COLUMN;

- IN FIXING THE VALUES, MEMBER STATES SHALL TAKE AS A BASIS THE VALUES APPEARING IN THE "GUIDE LEVEL" COLUMN.

4. FOR THE PARAMETERS APPEARING IN TABLE F OF ANNEX I, THE VALUES TO BE FIXED BY MEMBER STATES MUST BE NOT LOWER THAN THOSE GIVEN IN THE "MINIMUM REQUIRED CONCENTRATION" COLUMN FOR SOFTENED WATER, OF THE KIND REFERRED TO IN THE FIRST INDENT OF ARTICLE 2.

5. IN THE INTERPRETATION OF THE VALUES SHOWN IN ANNEX I ACCOUNT SHALL BE TAKEN OF THE OBSERVATIONS.

6. MEMBER STATES SHALL TAKE THE STEPS NECESSARY TO ENSURE THAT WATER INTENDED FOR HUMAN CONSUMPTION AT LEAST MEETS THE REQUIREMENTS SPECIFIED IN ANNEX I.

ARTICLE 8

MEMBER STATES SHALL TAKE ALL THE NECESSARY MEASURES TO ENSURE THAT ANY SUBSTANCES USED IN THE PREPARATION OF WATER FOR HUMAN CONSUMPTION DO NOT REMAIN IN CONCENTRATIONS HIGHER THAN THE MAXIMUM ADMISSIBLE CONCENTRATION RELATING TO THESE SUBSTANCES IN WATER MADE AVAILABLE TO THE USER AND, THAT THEY DO NOT, EITHER DIRECTLY OR INDIRECTLY, CONSTITUTE A PUBLIC HEALTH HAZARD.

ARTICLE 9

1. MEMBER STATES MAY MAKE PROVISION FOR DEROGATIONS FROM THIS DIRECTIVE IN ORDER TO TAKE ACCOUNT OF:

(a) SITUATIONS ARISING FROM THE NATURE AND STRUCTURE OF THE GROUND IN THE AREA FROM WHICH THE SUPPLY IN QUESTION EMANATES.
WHERE A MEMBER STATE DECIDES TO MAKE SUCH A DEROGATION, IT SHALL INFORM THE COMMISSION ACCORDINGLY WITHIN TWO MONTHS OF ITS DECISION STATING THE REASONS FOR SUCH DEROGATION;

(b) SITUATIONS ARISING FROM EXCEPTIONAL METEOROLOGICAL CONDITIONS.
WHERE A MEMBER STATE DECIDES TO MAKE SUCH A DEROGATION, IT SHALL INFORM THE COMMISSION ACCORDINGLY WITHIN 15 DAYS OF ITS DECISION STATING THE REASONS FOR THIS DEROGATION AND ITS DURATION.

2. MEMBER STATES SHALL REPORT TO THE COMMISSION ONLY THOSE DEROGATIONS REFERRED TO IN PARAGRAPH 1 WHICH RELATE TO A DAILY WATER SUPPLY OF AT LEAST 1 000 m^3 OR A POPULATION OF AT LEAST 5 000.

3. IN NO CASE SHALL THE DEROGATIONS MADE BY VIRTUE OF THIS ARTICLE RELATE TO TOXIC OR MICROBIOLOGICAL FACTORS OR CONSTITUTE A PUBLIC HEALTH HAZARD.

ARTICLE 10

1. IN THE EVENT OF EMERGENCIES, THE COMPETENT NATIONAL AUTHORITIES MAY, FOR A LIMITED PERIOD OF TIME AND UP TO A MAXIMUM VALUE TO BE DETERMINED BY THEM, ALLOW THE MAXIMUM ADMISSIBLE CONCENTRATION SHOWN IN ANNEX I TO BE EXCEEDED, PROVIDED THAT THIS DOES NOT CONSTITUTE AN UNACCEPTABLE RISK TO PUBLIC HEALTH AND PROVIDED THAT THE SUPPLY OF WATER FOR HUMAN CONSUMPTION CANNOT BE MAINTAINED IN ANY OTHER WAY.

2. WITHOUT PREJUDICE TO THE APPLICATION OF DIRECTIVE 75/440/EEC (1), AND IN PARTICULAR ARTICLE 4 (3) THEREOF, WHEN, FOR ITS SUPPLY OF DRINKING WATER, A MEMBER STATE IS OBLIGED TO RESORT TO SURFACE WATER WHICH DOES NOT REACH THE CONCENTRATIONS REQUIRED OF CATEGORY A3 WATER WITHIN THE MEANING OF ARTICLE 2 OF THE AFORMENTIONED DIRECTIVE AND WHEN IT CANNOT DEVISE SUITABLE TREATMENT TO OBTAIN DRINKING WATER OF THE QUALITY LAID DOWN BY THIS DIRECTIVE, IT MAY, FOR A LIMITED PERIOD OF TIME AND UP TO A MAXIMUM PERMISSIBLE VALUE WHICH IT SHALL DETERMINE, AUTHORIZE THE MAXIMUM ADMISSIBLE CONCENTRATION SHOWN IN ANNEX I TO BE EXCEEDED PROVIDED THAT THIS DOES NOT CONSTITUTE AN UNACCEPTABLE RISK TO PUBLIC HEALTH.

3. MEMBER STATES WHICH HAVE RECOURSE TO THE DEROGATIONS REFERRED TO IN THIS ARTICLE SHALL IMMEDIATELY INFORM THE COMMISSION THEREOF, STATING THE REASONS FOR AND PROBABLE DURATION OF SUCH DEROGATIONS.

ARTICLE 11

MEMBER STATES SHALL ENSURE THAT ALL NECESSARY MEASURES TAKEN TO APPLY THE PROVISIONS TAKEN PURSUANT TO THIS DIRECTIVE SHALL IN NO CASE HAVE THE EFFECT OF ALLOWING, DIRECTLY OR INDIRECTLY, EITHER ANY DETERIORATION IN THE PRESENT QUALITY OF WATER INTENDED FOR HUMAN CONSUMPTION OR AN INCREASE IN THE POLLUTION OF WATERS USED FOR THE PRODUCTION OF DRINKING WATER.

ARTICLE 12

1. MEMBER STATES SHALL TAKE ALL NECESSARY STEPS TO ENSURE REGULAR MONITORING OF THE QUALITY OF WATER INTENDED FOR HUMAN CONSUMPTION.

2. ALL WATER INTENDED FOR HUMAN CONSUMPTION SHALL BE MONITORED AT THE POINT WHERE IT IS MADE AVAILABLE TO THE USER IN ORDER TO CHECK WHETHER IT MEETS THE REQUIREMENTS LAID DOWN IN ANNEX I.

3. THE POINTS OF SAMPLING SHALL BE DETERMINED BY THE COMPETENT NATIONAL AUTHORITIES.

4. FOR SUCH MONITORING, MEMBER STATES SHALL CONFORM WITH ANNEX II.

5. MEMBER STATES SHALL AS FAR AS PRACTICABLE USE THE REFERENCE METHODS OF ANALYSIS SET OUT IN ANNEX III.

LABORATORIES USING OTHER METHODS SHALL ENSURE THAT THE RESULTS THUS OBTAINED ARE EQUIVALENT TO OR COMPARABLE WITH THE RESULTS OBTAINED BY THE METHODS INDICATED IN ANNEX III.

ARTICLE 13

SUCH CHANGES AS ARE NECESSARY FOR ADAPTING THE REFERENCE METHODS OF ANALYSIS SET OUT IN ANNEX III TO SCIENTIFIC AND TECHNICAL PROGRESS SHALL BE ADOPTED IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 15.

ARTICLE 14

(a) A COMMITTEE ON THE ADAPTATION TO SCIENTIFIC AND TECHNICAL PROGRESS, HEREINAFTER CALLED "THE COMMITTEE", IS HEREBY SET UP; IT SHALL CONSIST OF REPRESENTATIVES OF THE MEMBER STATES WITH A REPRESENTATIVE OF THE COMMISSION AS CHAIRMAN.

(b) THE COMMITTEE SHALL ADOPT ITS OWN RULES OF PROCEDURE.

ARTICLE 15

1. WHERE THE PROCEDURE LAID DOWN IN THIS ARTICLE IS TO BE FOLLOWED, THE MATTER SHALL BE REFERRED TO THE COMMITTEE BY ITS CHAIRMAN, EITHER ON HIS OWN INITIATIVE OR AT THE REQUEST OF A REPRESENTATIVE OF A MEMBER STATE.

2. THE REPRESENTATIVE OF THE COMMISSION SHALL SUBMIT TO THE COMMITTEE A DRAFT OF THE MEASURES TO BE TAKEN. THE COMMITTEE SHALL GIVE ITS OPINION ON THAT DRAFT WITHIN A TIME LIMIT SET BY THE CHAIRMAN HAVING REGARD TO THE URGENCY OF THE MATTER. OPINIONS SHALL BE ADOPTED BY A MAJORITY OF " fifty-four " **[2]** VOTES, THE VOTES OF THE MEMBER STATES BEING WEIGHTED AS PROVIDED IN ARTICLE 148 (2) OF THE TREATY. THE CHAIRMAN SHALL NOT VOTE.

3. (a) WHERE THE MEASURES ENVISAGED ARE IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE, THE COMMISSION SHALL ADOPT THEM.

(b) WHERE THE MEASURES ENVISAGED ARE NOT IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE, OR IF NO OPINION IS DELIVERED, THE COMMISSION SHALL WITHOUT DELAY SUBMIT TO THE COUNCIL A PROPOSAL ON THE MEASURES TO BE TAKEN. THE COUNCIL SHALL ACT BY A QUALIFIED MAJORITY.

(c) IF, WITHIN THREE MONTHS OF THE PROPOSAL BEING SUBMITTED TO IT, THE COUNCIL HAS NOT ACTED, THE PROPOSED MEASURES SHALL BE ADOPTED BY THE COMMISSION.

ARTICLE 16

WITHOUT PREJUDICE TO ARTICLE 4 (2), MEMBER STATES MAY LAY DOWN MORE STRINGENT PROVISIONS THAN THOSE PROVIDED FOR IN THIS DIRECTIVE FOR WATER INTENDED FOR HUMAN CONSUMPTION.

ARTICLE 17

MEMBER STATES MAY ADOPT SPECIAL PROVISIONS REGARDING INFORMATION - BOTH ON PACKAGING OR LABELS AND IN ADVERTISING - CONCERNING A WATER'S SUITABILITY FOR THE FEEDING OF INFANTS. SUCH PROVISIONS MAY ALSO CONCERN THE PROPERTIES OF THE WATER WHICH DETERMINE THE USE OF THE SAID INFORMATION. MEMBER STATES WHICH INTEND TAKING SUCH MEASURES SHALL INFORM THE OTHER MEMBER STATES AND THE COMMISSION OF THEM BEFOREHAND.

" Article 17a

At intervals of three years the Member States shall send information to the Commission on the implementation of this Directive, in the form of a sectoral report which shall also cover other pertinent Community Directives. This report shall be drawn up on the basis of a questionnaire or outline drafted by the Commission in accordance with the procedure laid down in Article 6 of Directive 91/692/EEC. The questionnaire or outline shall be sent to the Member States six months before the start of the period covered by the report. The report shall be sent to the Commission within nine months of the end of the three-year period covered by it.
The first report shall cover the period from 1993 to 1995 inclusive.
The Commission shall publish a Community report on the implementation of the Directive within nine months of receiving the reports from the Member States. " **[3]**

ARTICLE 18

1. MEMBER STATES SHALL BRING INTO FORCE THE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS NECESSARY TO COMPLY WITH THIS DIRECTIVE AND ITS ANNEXES WITHIN TWO YEARS FOLLOWING ITS NOTIFICATION. THEY SHALL FORTHWITH INFORM THE COMMISSION THEREOF.

2. MEMBER STATES SHALL COMMUNICATE TO THE COMMISSION THE TEXTS OF THE MAIN PROVISIONS OF NATIONAL LAW WHICH THEY ADOPT IN THE FIELD GOVERNED BY THIS DIRECTIVE.

ARTICLE 19

THE MEMBER STATES SHALL TAKE THE NECESSARY MEASURES TO ENSURE THAT THE QUALITY OF WATER INTENDED FOR HUMAN CONSUMPTION COMPLIES WITH THIS DIRECTIVE WITHIN FIVE YEARS OF ITS NOTIFICATION.

ARTICLE 20

MEMBER STATES MAY, IN EXCEPTIONAL CASES AND FOR GEOGRAPHICALLY DEFINED POPULATION GROUPS, SUBMIT A SPECIAL REQUEST TO THE COMMISSION FOR A LONGER PERIOD FOR COMPLYING WITH ANNEX I.
THIS REQUEST, FOR WHICH GROUNDS MUST BE DULY PUT FORWARD, SHALL SET OUT THE DIFFICULTIES EXPERIENCED AND MUST PROPOSE AN ACTION PROGRAMME WITH AN APPROPRIATE TIMETABLE TO BE UNDERTAKEN FOR THE IMPROVEMENT OF THE QUALITY OF WATER INTENDED FOR HUMAN CONSUMPTION.
THE COMMISSION SHALL EXAMINE THESE PROGRAMMES, INCLUDING THE TIMETABLES. IN THE CASE OF DISAGREEMENT WITH THE MEMBER STATE CONCERNED, THE COMMISSION SHALL SUBMIT APPROPRIATE PROPOSALS TO THE COUNCIL.

ARTICLE 21

THIS DIRECTIVE IS ADDRESSED TO THE MEMBER STATES.

ANNEX I

LIST OF PARAMETERS

A. ORGANOLEPTIC PARAMETERS

	Parameters	Expression of the results (2)	Guide level (GL)	Maximum admissible concentration (MAC)	Comments
1	Colour	mg/l Pt/Co scale	1	20	
2	Turbidity	mg/l SiO_2 Jackson units	1 0·4	10 4	— Replaced in certain circumstances by a transparency test, with a Secchi disc reading in meters: GL: 6 m MAC: 2 m
3	Odour	Dilution number	0	2 at 12 °C 3 at 25 °C	— To be related to the taste tests.
4	Taste	Dilution number	0	2 at 12 °C 3 at 25 °C	— To be related to the odour tests.

B. PHYSICO-CHEMICAL PARAMETERS (in relation to the water's natural structure)

	Parameters	Expression of the results ( )	Guide level (GL)	Maximum admissible concentration (MAC)	Comments
5	Temperature	°C	12	25	
6	Hydrogen ion concentration	pH unit	$6·5 \leq pH \leq 8·5$		— The water should not be aggressive. — The pH values do not apply to water in closed containers. — Maximum admissible value: 9·5.
7	Conductivity	$\mu S\ cm^{-1}$ at 20 °C	400		— Corresponding to the mineralization of the water. — Corresponding relativity values in ohms/cm: 2 500.

	Parameters	Expression of the results	Guide level (GL)	Maximum admissible concentration (MAC)	Comments
8	Chlorides	Cl mg/l	25		— Approximate concentration above which effects might occur: 200 mg/l.
9	Sulphates	SO_4 mg/l	25	250	
10	Silica	SiO_2 mg/l			— See Article 8.
11	Calcium	Ca mg/l	100		
12	Magnesium	Mg mg/l	30	50	
13	Sodium	Na mg/l	20	175 (as from 1984 and with a percentile of 90) 150 (as from 1987 and with a percentile of 80) (these percentiles should be calculated over a reference period of three years)	— The values of this parameter take account of the recommendations of a WHO working party (The Hague, May 1978) on the progressive reduction of the current total daily salt intake to 6 g. — As from 1 January 1984 the Commission will submit to the Council reports on trends in the total daily intake of salt per population. — In these reports the Commission will examine to what extent the 120 mg/l MAC suggested by the WHO working party is necessary to achieve a satisfactory total salt intake level, and, if appropriate, will suggest a new salt MAC value to the Council and a deadline for compliance with that value. — Before 1 January 1984 the Commission will submit to the Council a report on whether the reference period of three years for calculating these percentiles is scientifically well founded.
14	Potassium	K mg/l	10	12	
15	Aluminium	Al mg/l	0·05	0·2	
16	Total hardness				— See Table F, page 23.
17	Dry residues	mg/l after drying at 180 °C		1 500	
18	Dissolved oxygen	% O_2 saturation			— Saturation value > 75 % except for underground water.
19	Free carbon dioxide	CO_2 mg/l			— The water should not be aggressive.

C. PARAMETERS CONCERNING SUBSTANCES UNDESIRABLE IN EXCESSIVE AMOUNTS (3)

	Parameters	Expression of the results (1)	Guide level (GL)	Maximum admissible concentration (MAC)	Comments
20	Nitrates	NO_3 mg/l	25	50	
21	Nitrites	NO_2 mg/l		0·1	
22	Ammonium	NH_4 mg/l	0·05	0·5	
23	Kjeldahl Nitrogen (excluding N in NO_2 and NO_3)	N mg/l		1	
24	(K Mn O_4) Oxidizability	O_2 mg/l	2	5	— Measured when heated in acid medium.
25	Total organic carbon (TOC)	C mg/l			— The reason for any increase in the usual concentration must be investigated.
26	Hydrogen sulphide	S µg/l		undetectable organoleptically	
27	Substances extractable in chloroform	mg/l dry residue	0·1		
28	Dissolved or emulsified hydrocarbons (after extraction by petroleum ether); Mineral oils	µg/l		10	
29	Phenols (phenol index)	C_6H_5OH µg/l		0·5	— Excluding natural phenols which do not react to chlorine.
30	Boron	B µg/l	1 000		
31	Surfactants (reacting with methylene blue)	µg/l (lauryl sulphate)		200	

	Parameters	Expression of the results	Guide level (GL)	Maximum admissible concentration (MAC)	Comments
32	Other organochlorine compounds not covered by parameter No 55	µg/l	1		— Haloform concentrations must be as low as possibile.
33	Iron	Fe µg/l	50	200	
34	Manganese	Mn µg/l	20	50	
35	Copper	Cu µg/l	100 — at outlets of pumping and/or treatment works and their substations 3000 — after the water has been standing for 12 hours in the piping and at the point where the water is made available to the consumer		— Above 3 000 µg/l astringent tast discolouration + corrosion may occur.
36	Zinc	Zn µg/l	100 — at outlets of pumping and/or treatment works and their substations 5 000 — after the water has been standing for 12 hours in the piping and at the point where the water is made available to the consumer		— Above 5 000 µg/l astringent taste, opalescence and sand-like deposits may occur.
37	Phosphorus	P_2O_5 µg/l	400	5 000	

	Parameters	Expression of the results	Guide level (GL)	Maximum admissible concentration (MAC)	Comments
38	Fluoride	F µg/l 8 — 12 °C 25 — 30 °C		1 500 700	— MAC varies according to average temperature in geographical area concerned.
39	Cobalt	Co µg/l			
40	Suspended solids		None		
41	Residual Chlorine	Cl µg/l			— See Article 8.
42	Barium	Ba µg/l	100		
43	Silver	Ag µg/l		10	If, exceptionally, silver is used non-systematically to process the water, a MAC value of 80 µg/l may be authorized.

D. PARAMETERS CONCERNING TOXIC SUBSTANCES

	Parameters	Expression of the results	Guide level (GL)	Maximum admissible concentration (MAC)	Comments
44	Arsenic	As µg/l		50	
45	Beryllium	Be µg/l			
46	Cadmium	Cd µg/l		5	
47	Cyanides	CN µg/l		50	
48	Chromium	Cr µg/l		50	
49	Mercury	Hg µg/l		1	
50	Nickel	Ni µg/l		50	
51	Lead	Pb µg/l		50 (in running water)	Where lead pipes are present, the lead content should not exceed 50 µg/l in a sample taken after flushing. If the sample is taken either directly or after flushing and the lead content either frequently or to an appreciable extent exceeds 100 µg/l, suitable measures must be taken to reduce the exposure to lead on the part of the consumer.

	Parameters	Expression of the results	Guide level (GL)	Maximum admissible concentration (MAC)	Comments
52	Antimony	Sb µg/l		10	
53	Selenium	Se µg/l		10	
54	Vanadium	V µg/l			
55	Pesticides and related products — substances considered separately — total	µg/l		0·1 0·5	'Pesticides and related products' means: — insecticides: — persistent organochlorine compounds — organophosphorous compounds — carbamates — herbicides — fungicides — PCBs and PCTs
56	Polycyclic aromatic hydrocarbons	µg/l		0·2	" — reference substances: - fluoranthene - 3,4 - benzofluoranthene - 11,12 - benzofluoranthene - 3,4 - benzpyrene - 1,12 - benzperylene - indeno (1,2,3 - cd) pyrene " (R1)

E. MICROBIOLOGICAL PARAMETERS

	Parameters	Results: volume of the sample in ml	Guide level (GL)	Maximum admissible concentration (MAC)	
				Membrane filter method	Multiple tube method (MPN)
57	Total coliforms (4)	100	—	0	MPN < 1
58	Fecal coliforms	100	—	0	MPN < 1
59	Fecal streptococci	100	—	0	MPN < 1
60	Sulphite-reducing Clostridia	20	—	—	MPN ≤ 1

Water intended for human consumption should not contain pathogenic organisms.

If it is necessary to supplement the microbiological analysis of water intended for human consumption, the samples should be examined not only for the bacteria referred to in Table E but also for pathogens including:

— salmonella,
— pathogenic staphylococci,
— fecal bacteriophages,
— entero-viruses;

nor should such water contain:

— parasites,
— algas,
— other organisms such as animalcules.

	Parameters		Results: size of sample (in ml)	Guide level (GL)	Maximum admissible concentration (MAC)	Comments
61	Total bacteria counts for water supplied for human consumption	37 °C	1	10 (5) (6)	—	
		22 °C	1	100 (5) (6)	—	
62	Total bacteria counts for water in closed containers	37 °C	1	5	20	On their own responsibility and where parameters 57, 58, 59 and 60 are complied with, and where the pathogen organisms given on page 22 are absent, Member States may process water for their internal use the total bacteria count of which exceeds the MAC values laid down for parameter 62. MAC values should be measured within 12 hours of being put into closed containers with the sample water being kept at a constant temperature during that 12-hour period.
		22 °C	1	20	100	

F. MINIMUM REQUIRED CONCENTRATION FOR SOFTENED WATER INTENDED FOR HUMAN COMSUMPTION

	Parameters	Expression of the results	Minimum required concentration (softened water)	Comments
1	Total hardness	mg/l Ca	60	Calcium or equivalent cations.
2	Hydrogen ion concentration	pH		The water should not be aggressive.
3	Alkalinity	mg/l HCO_3	30	
4	Dissolved oxygen			

NB: — The provisions for hardness, hydrogen ion concentration, dissolved oxygen and calcium also apply to desalinated water.
— If, owing to its excessive natural hardness, the water is softened in acordance with Table F before being supplied for consumption, its sodium content may, in exceptional cases, be higher than the values given in the 'Maximum admissible concentration' column. However, an effort must be made to keep the sodium content at as low a level as possible and the essential requirements for the protection of public health may not be disregarded.

TABLE OF CORRESPONDENCE BETWEEN THE VARIOUS UNITS OF WATER HARDNESS MEASUREMENT

	French degree	English degree	German degree	Milligrams of Ca	Millimoles of Ca
French degree	1	0·70	0·56	4·008	0·1
English degree	1·43	1	0·80	5·73	0·143
German degree	1·79	1·25	1	7·17	0·179
Milligrams of Ca	0·25	0·175	0·140	1	0·025
Millimoles of Ca	10	7	5·6	40·08	1

ANNEX II

PATTERNS AND FREQUENCY OF STANDARD ANALYSES

A. TABLE OF STANDARD PATTERN ANALYSES (Parameters to be considered in monitoring)

	Standard analyses / Parameters to be considered	Minimum monitoring (C 1)	Current monitoring (C 2)	Periodic monitoring (C 3)	Occasional monitoring in special situations or in case of accidents (C 4)
A	ORGANOLEPTIC PARAMETERS	– odour (7) – taste (7)	– odour – taste – turbidity (appearance)	Current monitoring analyses + other parameters as in footnote(10)	The competent national authorities of the Member States will determine the parameters (11) according to circumstances, taking account of all factors which might have an adverse affect on the quality of drinking water supplied to consumers.
B	PHYSICO-CHEMICAL PARAMETERS	– conductivity or other physico-chemical parameter – residual chlorine (9)	– temperature (8) – conductivity or other physico-chemical parameter – pH – residual chlorine (9)		
C	UNDESIRABLE PARAMETERS		– nitrates – nitrites – ammonia		
D	TOXIC PARAMETERS				
E	MICRO-BIOLOGICAL PARAMETERS	– total coliforms or total counts of 22° and 37° – fecal coliforms	– total coliforms – fecal coliforms – total counts of 22° and 37°		

Note: An initial analysis, to be carried out before a source is exploited, should be added. The parameters to be considered would be the current monitoring analyses plus *inter alia* various toxic or undesirable substances presumed present. The list would be drawn up by the competent national authorities.

B. TABLE OF MINIMUM FREQUENCY OF STANDARD ANALYSES (14)

Volume of water produced or distributed in m^3/day	Population concerned (assuming 200 l/day per person)	Analysis C 1	Analysis C 2	Analysis C 3	Analysis C 4
		Number of samples per year	Number of samples per year	Number of samples per year	
100	500	(12)	(12)	(12)	Frequency to be determined by the competent national authorities as the situation requires
1 000	5 000	(12)	(12)	(12)	
2 000	10 000	12	3	(12)	
10 000	50 000	60	6	1	
20 000	100 000	120	12	2	
30 000	150 000	180	18	3	
60 000	300 000	360 (13)	36	6	
100 000	500 000	360 (13)	60	10	
200 000	1 000 000	360 (13)	120 (13)	20 (13)	
1 000 000	5 000 000	360 (13)	120 (13)	20 (13)	

ANNEX III

REFERENCE METHODS OF ANALYSIS

A. ORGANOLEPTIC PARAMETERS

1	Colour	Photometric method calibrated on the Pt/co scale.
2	Turbidity	Silica method — Formazine test — Secchi's method.
3	Odour	Successive dilutions, tested at 12 °C or 25 °C.
4	Taste	Successive dilutions, tested at 12 °C or 25 °C.

B. PHYSICO-CHEMICAL PARAMETERS

5	Temperature	Thermometry.
6	Hydrogen ion concentration	Electrometry.
7	Conductivity	Electrometry.
8	Chlorides	Titrimetry — Mohr's method.
9	Sulphates	Gravimetry — complexometry — spectrophotometry.
10	Silica	Absorption spectrophotometry.
11	Calcium	Atomic absorption — complexometry.
12	Magnesium	Atomic absorption.
13	Sodium	Atomic absorption.
14	Potassium	Atomic absorption.
15	Aluminium	Atomic absorption — absorption spectrophotometry.
16	Total hardness	Complexometry.
17	Dry residue	Dessication at 180 °C and weighing.
18	Dissolved oxygen	Winkler's method — Specific electrode method.
19	Free carbon dioxide	Acidimetry.

C. PARAMETERS CONCERNING UNDESIRABLE SUBSTANCES

20	Nitrates	Absorption spectrophotometry — Specific electrode method.
21	Nitrites	Absorption spectrophotometry.
22	Ammonium	Absorption spectrophotometry.
23	Kjeldahl Nitrogen	Oxidation with Titrimetry or Absorption spectrophotometry.
24	Oxidizability	Boiling for 10 minutes with $KMnO_4$ in acid medium.
25	Total organic carbon (TOC)	—

26 Hydrogen sulphide	Absorption spectrophotometry.
27 Substances extractable in chloroform	Liquid/liquid extraction using purified chloroform at neutral pH, weighing the residue.
28 Hydrocarbons (dissolved or in emulsion); Mineral oils	Infra-red absorption spectrophotometry.
29 Phenols (phenol index)	Absorption spectrophotometry, paranitroaniline method and 4-aminoantipyrine method.
30 Boron	Atomic absorption — Absorption spectrophotometry.
31 Surfactants (reacting with metylene blue)	Absorption spectrophotometry with methylene blue.
32 Other organo-chlorine compounds	Gas-phase or liquid-phase chromatography after extraction by appropriate solvents and purification — Identification of the constituents of mixtures if necessary. Quantitative determination.
33 Iron	Atomic absorption — Absorption spectrophotometry.
34 Manganese	Atomic absorption — Absorption spectrophotometry.
35 Copper	Atomic absorption — Absorption spectrophotometry.
36 Zinc	Atomic absorption — Absorption spectrophotometry.
37 Phosphorus	Absorption spectrophotometry.
38 Fluoride	Absorption spectrophotometry — Specific electrode method.
39 Cobalt	—
40 Suspended solids	Method of filtration on to μ 0·45 porous membrane or centrifuging (for at least 15 minutes with an average acceleration of 2 800 to 3 200 g) dried at 105 °C and weighed.
41 Residual chlorine	Titrimetry — Absorption spectrophotometry.
42 Barium	Atomic absorption.

D. PARAMETERS CONCERNING TOXIC SUBSTANCES

43 Silver	Atomic absorption.
44 Arsenic	Absorption spectrophotometry — Atomic absorption.
45 Beryllium	—
46 Cadmium	Atomic absorption.
47 Cyanides	Absorption spectrophotometry.
48 Chromium	Atomic absorption — Absorption spectrophotometry.
49 Mercury	Atomic absorption.
50 Nickel	Atomic absorption.
51 Lead	Atomic absorption.
52 Antimony	Absorption spectrophotometry.

53 Selenium	Atomic absorption.
54 Vanadium	—
55 Pesticides and related products	See method 32.
56 Polycyclic aromatic hydrocarbons	Measurement of intensity of fluorescence ultraviolet after extraction using hexane — gas-phase chromatography or measurement in ultraviolet after thin layer chromatography — Comparative measurements against a mixture of six standard substances of the same concentration (15)

E. MICROBIOLOGICAL PARAMETERS

57 (16) Total coliforms 58 (16) Fecal coliforms	Fermentation in mutliple tubes. Subculturing of the positive tubes on a confirmation medium. Count according to MPN (most probable number) or Membrane filtration and culture on an appropriate medium such as Tergitol lactose agar, endo agar, 0·4 % Teepol broth, subculturing and identification of the suspect colonies — Incubation temperature for total coliforms: 37 °C Incubation temperature for fecal coliforms: 44 °C
59 (16) Fecal streptococci	Sodium azide method (Litsky). Count according to MPN — Membrane filtration and culture on an appropriate medium.
60 (16) Sulphite-reducing Clostridia	A spore count, after heating the sample to 80 °C by: — seeding in a medium with glucose, sulphite and iron, counting the black-halo colonies; — membrane filtration, deposition of the inverted filter on a medium with glucose, sulphite and iron covered with agar, count of black colonies; — distribution in tubes of differential reinforced clostridial medium (DRCM), subculturing of the black tubes in a medium of litmus-treated milk, count according to MPN.
61/62 (16) Total counts	Inoculation by placing in nutritive agar.

ADDITIONAL TESTS

Salmonella	Concentration by membrane filtration. Inoculation on a pre-enriched medium. Enrichment, subculturing on isolating agar. Identification.
Pathogenic staphylococci	Membrane filtration and culture on a specific medium (e.g. Chapman's hypersaline medium). Test for pathogenic characteristics.

Fecal bacteriophages	Guelin's process.
Enteroviruses	Concentration by filtration, flocculation or centrifuging, and identification.
Protozoa	Concentration by filtration on a membrane, microscopic examination, test for pathogenicity.
Animalcules (worms — larvae)	Concentration by filtration on a membrane. Microscopic examination. Test for pathogenicity.

F. MINIMUM REQUIRED CONCENTRATION

Alkalinity	Acidimetry with Methyl orange

(R1) Corrigenda, OJ No L 220, 06/08/1981, p. 40.

(1) OJ No L 194, 25/07/1975, p. 26.
(2) IF, ON THE BASIS OF DIRECTIVE 71/354/EEC AS LAST AMENDED, A MEMBER STATE USES IN ITS NATIONAL LEGISLATION, ADOPTED IN ACCORDANCE WITH THIS DIRECTIVE, UNITS OF MEASUREMENT OTHER THAN THESE INDICATED IN THIS ANNEX, THE VALUES THUS INDICATED MUST HAVE THE SAME DEGREE OF PRECISION.
(3) CERTAIN OF THESE SUBSTANCES MAY EVEN BE TOXIC WHEN PRESENT IN VERY SUBSTANTIAL QUANTITIES.
(4) PROVIDED A SUFFICIENT NUMBER OF SAMPLES IS EXAMINED (95% CONSISTENT RESULTS).
(5) FOR DISINFECTED WATER THE CORRESPONDING VALUES SHOULD BE CONSIDERABLY LOWER AT THE POINT WHERE IT LEAVES THE PROCESSING PLANT.
(6) IF, DURING SUCCESSIVE SAMPLING, ANY OF THESE VALUES IS CONSISTENTLY EXCEEDED A CHECK SHOULD BE CARRIED OUT.
(7) QUALITATIVE ASSESSMENT.
(8) EXCEPT FOR WATER SUPPLIED IN CONTAINERS.
(9) OR OTHER DISINFECTANTS AND ONLY IN THE CASE OF TREATMENT.
(10) THESE PARAMETERS WILL BE DETERMINED BY THE COMPETENT NATIONAL AUTHORITY, TAKING ACCOUNT OF ALL FACTORS WHICH MIGHT AFFECT THE QUALITY OF DRINKING WATER SUPPLIED TO USERS AND WHICH COULD ENABLE THE IONIC BALANCE OF THE CONSTITUENTS TO BE ASSESSED.
(11) THE COMPETENT NATIONAL AUTHORITY MAY USE PARAMETERS OTHER THAN THOSE MENTIONED IN ANNEX I TO THIS DIRECTIVE.
(12) FREQUENCY LEFT TO THE DISCRETION OF THE COMPETENT NATIONAL AUTHORITIES. HOWEVER, WATER INTENDED FOR THE FOOD-MANUFACTURING INDUSTRIES MUST BE MONITORED AT LEAST ONCE A YEAR.
(13) THE COMPETENT HEALTH AUTHORITIES SHOULD ENDEAVOUR TO INCREASE THIS FREQUENCY AS FAR AS THEIR RESOURCES ALLOW.

(14) (a) IN THE CASE OF WATER WHICH MUST BE DISINFECTED, MICROBIOLOGICAL ANALYSIS SHOULD BE TWICE AS FREQUENT.
(b) WHERE ANALYSES ARE VERY FREQUENT, IT IS ADVISABLE TO TAKE SAMPLES AT THE MOST REGULAR INTERVALS POSSIBLE.
(c) WHERE THE VALUES OF THE RESULTS OBTAINED FROM SAMPLES TAKEN DURING THE PRECEDING YEARS ARE CONSTANT AND SIGNIFICANTLY BETTER THAN THE LIMITS LAID DOWN IN ANNEX I, AND WHERE NO FACTOR LIKELY TO CAUSE A DETERIORATION IN THE QUALITY OF THE WATER HAS BEEN DISCOVERED, THE MINIMUM FREQUENCIES OF THE ANALYSES REFERRED TO ABOVE MAY BE REDUCED:
- FOR SURFACE WATERS, BY A FACTOR OF 2 WITH THE EXCEPTION OF THE FREQUENCIES LAID DOWN FOR MICROBIOLOGICAL ANALYSES;
- FOR GROUND WATERS, BY A FACTOR OF 4, BUT WITHOUT PREJUDICE TO THE PROVISIONS OF POINT (a) ABOVE.
(15) " Standard substances to be considered: fluoranthene, 3,4-benzofluoranthene, 11,12-benzofluoranthene, 3,4-benzpyrene, 1,12-benzperylene, indeno (1,2,3 - cd) pyrene. " (R1)
(16) Comments: The incubation period is generally 24 or 48 hours except for total counts, when it is 48 or 72 hours.

COFFEE AND CHICORY

377L0436

77/436/EEC: COUNCIL DIRECTIVE OF 27 JUNE 1977 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO COFFEE EXTRACTS AND CHICORY EXTRACTS

OFFICIAL JOURNAL NO L 172, 12/07/1977, P. 20
DATE OF NOTIFICATION: 28/06/1977
DATE OF TRANSPOSITION: 28/06/1978; SEE ART. 12
DATE OF TRANSPOSITION: 28/06/1980; SEE ART. 12

AMENDED BY

179H
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE HELLENIC REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES **[1]**
OFFICIAL JOURNAL NO L 291, 19/11/1979, P. 111

385L0007
85/7/EEC: COUNCIL DIRECTIVE OF 19 DECEMBER 1984 **[2]**
OFFICIAL JOURNAL NO L 2, 03/01/1985, P. 22
DATE OF NOTIFICATION: 27/12/1984

185I
ACT CONCERNING THE CONDITIONS OF ACCESSION OF THE KINGDOM OF SPAIN AND THE PORTUGUESE REPUBLIC AND THE ADJUSTMENTS TO THE TREATIES **[3]**
OFFICIAL JOURNAL NO L 302, 15/11/1985, P. 216

385L0573
85/573/EEC: COUNCIL DIRECTIVE OF 19 DECEMBER 1985 **[4]**
OFFICIAL JOURNAL NO L 372, 31/12/1985, P. 22
DATE OF NOTIFICATION: 24/12/1985
DATE OF TRANSPOSITION: 01/01/1987; SEE ART. 2
DATE OF TRANSPOSITION: 01/07/1988; SEE ART. 2

ARTICLE 1

1. THIS DIRECTIVE CONCERNS THE COFFEE EXTRACTS AND CHICORY EXTRACTS REFERRED TO IN THE ANNEX.

2. FOR THE PURPOSES OF THIS DIRECTIVE:

(a) COFFEE EXTRACTS ARE THE PRODUCTS IN ANY CONCENTRATION OBTAINED BY EXTRACTION FROM ROASTED COFFEE USING ONLY WATER AS THE MEDIUM OF EXTRACTION AND EXCLUDING ANY PROCESS OF HYDROLYSIS INVOLVING THE ADDITION OF AN ACID OR A BASE AND,

(i) CONTAINING THE SOLUBLE AND AROMATIC CONSTITUENTS OF COFFEE,

(ii) WHICH MAY CONTAIN INSOLUBLE OILS DERIVED FROM COFFEE, TRACES OF OTHER INSOLUBLE SUBSTANCES DERIVED FROM COFFEE AND INSOLUBLE SUBSTANCES NOT DERIVED FROM COFFEE OR FROM THE WATER USED FOR EXTRACTION;

(b) CHICORY EXTRACTS ARE THE PRODUCTS IN ANY CONCENTRATION OBTAINED BY EXTRACTION FROM ROASTED CHICORY USING ONLY WATER AS THE MEDIUM OF EXTRACTION AND EXCLUDING ANY PROCESS OF HYDROLYSIS INVOLVING THE ADDITION OF AN ACID OR A BASE.

FOR THE PURPOSES OF THIS DIRECTIVE CHICORY IS THE PRODUCT IN GRANULAR OR POWDER FORM OBTAINED FROM ROOTS OF CHICORIUM INTYBUS L, NOT USED FOR THE PRODUCTION OF WITLOOF CHICORY, SUITABLY CLEANED, DRIED AND ROASTED WHETHER OR NOT CONTAINING SMALL QUANTITIES OF ADDED NUTRIENT OILS OR FATS AND/OR SUGARS AND/OR MOLASSES; THEY MAY CONTAIN TRACES OF INSOLUBLE SUBSTANCES NOT DERIVED FROM CHICORY.

ARTICLE 2

1. MEMBER STATES SHALL TAKE ALL MEASURES NECESSARY TO ENSURE THAT THE PRODUCTS LISTED IN THE ANNEX MAY BE OFFERED FOR SALE ONLY IF THEY COMPLY WITH THE DEFINITIONS AND RULES LAID DOWN IN THIS DIRECTIVE AND ITS ANNEX.

2. BLENDS OF COFFEE EXTRACTS AND CHICORY EXTRACTS AND EXTRACTS OF BLENDS OF ROASTED COFFEE AND ROASTED CHICORY MAY BE OFFERED FOR SALE ONLY IF:

- THESE PRODUCTS COMPLY MUTATIS MUTANDIS WITH THE DEFINITIONS LAID DOWN IN THE ANNEX, AND
- SHOULD THEY BE IN SOLID OR PASTE FORM, THEY COMPLY WITH ARTICLE 4.

ARTICLE 3

1. ONLY RAW MATERIALS WHICH ARE SOUND, GENUINE AND OF MERCHANTABLE QUALITY MAY BE USED IN THE MANUFACTURE OF THE PRODUCTS REFERRED TO IN THE ANNEX.

2. ACTING ON A PROPOSAL FROM THE COMMISSION, THE COUNCIL SHALL:

- DETERMINE THE LIST OF AND CRITERIA OF PURITY FOR SOLVENTS WHICH MAY BE USED FOR THE DECAFFEINATION OF THE PRODUCTS REFERRED TO IN PARAGRAPH 1 OF THE ANNEX, AS WELL AS THE MAXIMUM LEVELS FOR RESIDUES FROM THE SAID SOLVENTS,
- "..." **[4]**

3. MEMBER STATES MAY AUTHORIZE WITHIN THEIR TERRITORY THE USE OF ANTI-CAKING AGENTS:

- FOR THE PRODUCTS REFERRED TO IN PARAGRAPH 1 (a) OF THE ANNEX WHEN THEY ARE USED IN VENDING MACHINES AND SPECIFICALLY LABELLED AS SUCH,
- FOR THE PRODUCTS REFERRED TO IN PARAGRAPH 2 (a) OF THE ANNEX.

ARTICLE 4

" Products in solid or in paste form referred to in Article 1, when put up in individual packages of a nominal weight of more than 25 g but not exceeding 10 kg, shall be offered for retail sale in packages of the following nominal weights only: 50 g, 100 g, 200 g, 250 g (for mixtures of coffee and chicory extracts only and for coffee extracts intended exclusively for use in automatic vending machines), 300 g (for coffee extracts only), 500 g, 750 g, 1 kg, 1,5 kg, 2 kg, 2,5 kg, 3 kg and multiples of a kilogram. " **[4]**

ARTICLE 5

THE DESCRIPTIONS SET OUT IN THE ANNEX SHALL APPLY ONLY TO THE PRODUCTS REFERRED TO THEREIN AND MUST BE USED IN TRADE TO DESCRIBE THOSE PRODUCTS.

ARTICLE 6

" 1. Directive 79/112/EEC (1) shall apply in accordance with the following conditions to the products defined in the Annex to this Directive where they are intended to be supplied without further processing to the ultimate consumer:

(1) (a) The name under which a product is sold, as referred to in Article 5 of Directive 79/112/EEC, shall be the description applied to the products concerned pursuant to Article 5 of this Directive;

(b) It may be supplemented by the term "concentrated":

(i) in the case of the product defined in point 1 (c) of the Annex, provided that the coffee-based dry matter content is more than 25% by weight,

(ii) in the case of the product defined in point 2 (c) of the Annex, provided that the chicory-based dry matter content is more than 45% by weight.

(2) The following particulars, in addition to those specified in Article 3 of Directive 79/112/EEC, shall be compulsory on the labelling:

(a) the term "decaffeinated" in the case of the products defined in point 1 of the Annex provided that the anhydrous caffeine content does not exceed 0,3% by weight of the coffee-based dry matter;

(b) in the case of the products defined in points 1 (c) and 2 (c) of the Annex:

(i) the term "roasted with sugar" if the extract is obtained from the raw material roasted with sugar,

(ii) the terms "with sugar", "preserved with sugar" or "with added sugar" if the sugar has been added to the raw material after roasting.

Where sugars of types other than sucrose are used this must be stated instead of the term "sugar";

(c) the minimum coffee-based dry matter content, expressed as a percentage by weight of the finished product, in the case of the products defined in point 1 (b) and (c) of the Annex;

(d) the minimum chicory-based dry matter content, expressed as a percentage by weight of the finished product, in the case of the products defined in point 2 (b) and (c) of the Annex.

(3) The particulars mentioned in point (2) (a) and (b) above shall appear in the same field of vision as those mentioned in Article 11 (3) (a) of Directive 79/112/EEC.

2. The labelling of the products defined in the Annex where they are not intended to be supplied to the ultimate consumer shall include only the following compulsory information:

- the name under which the product is sold, as specified in paragraph 1 (1) (a),
- the nominal net quantity in units of mass or volume, except in the case of products put up for sale in bulk,
- a means of identifying the batch,
- the name or business name and address of the manufacturer or packager, or of a seller established within the Community.

The particulars listed in the first subparagraph shall appear on the packaging or a label affixed to it, or on an accompanying document. " **[4]**

ARTICLE 7

1. MEMBER STATES SHALL ADOPT ALL THE MEASURES NECESSARY TO ENSURE THAT TRADE IN THE PRODUCTS DEFINED IN ARTICLE 1 WHICH COMPLY WITH THE DEFINITIONS AND RULES LAID DOWN BY THIS DIRECTIVE, CANNOT BE IMPEDED BY THE APPLICATION OF NON-HARMONIZED NATIONAL PROVISIONS GOVERNING THE COMPOSITION, MANUFACTURING SPECIFICATIONS, PACKAGING OR LABELLING OF THESE PRODUCTS IN PARTICULAR, OR OF FOODSTUFFS IN GENERAL.

2. PARAGRAPH 1 SHALL NOT APPLY TO NON-HARMONIZED PROVISIONS JUSTIFIED ON GROUNDS OF:

- PROTECTION OF PUBLIC HEALTH,
- REPRESSION OF FRAUDS, UNLESS SUCH PROVISIONS ARE LIABLE TO IMPEDE THE APPLICATION OF THE DEFINITIONS AND RULES LAID DOWN BY THIS DIRECTIVE,
- PROTECTION OF INDUSTRIAL AND COMMERCIAL PROPERTY, INDICATIONS OF SOURCE, APPLICATIONS OF ORIGIN AND THE REPRESSION OF UNFAIR COMPETITION.

ARTICLE 8

THE SAMPLING PROCEDURES AND METHODS OF ANALYSIS NECESSARY TO VERIFY THE COMPOSITION AND MANUFACTURING SPECIFICATIONS OF PRODUCTS FALLING WITHIN THE SCOPE OF THIS DIRECTIVE SHALL BE DETERMINED IN ACCORDANCE WITH THE PROCEDURE LAID DOWN IN ARTICLE 9.

ARTICLE 9

1. WHERE THE PROCEDURE LAID DOWN IN THIS ARTICLE IS TO BE FOLLOWED, THE MATTER SHALL BE REFERRED TO THE STANDING COMMITTEE ON FOODSTUFFS SET UP BY DECISION 69/414/EEC (2), HEREINAFTER CALLED "THE COMMITTEE", BY ITS CHAIRMAN, EITHER ON HIS OWN INITIATIVE OR AT THE REQUEST OF A REPRESENTATIVE OF A MEMBER STATE.

2. THE COMMISSION REPRESENTATIVE SHALL SUBMIT TO THE COMMITTEE A DRAFT OF THE MEASURES TO BE TAKEN. THE COMMITTEE SHALL GIVE ITS OPINION ON THAT DRAFT WITHIN A TIME LIMIT SET BY THE CHAIRMAN HAVING REGARD TO THE URGENCY OF THE MATTER. OPINIONS SHALL BE DELIVERED BY A MAJORITY OF " fifty-four " **[3]** VOTES, THE VOTES OF THE MEMBER STATES BEING WEIGHTED AS PROVIDED IN ARTICLE 148 (2) OF THE TREATY. THE CHAIRMAN SHALL NOT VOTE.

3. (a) WHERE THE MEASURES ENVISAGED ARE IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE, THE COMMISSION SHALL ADOPT THEM.

(b) WHERE THE MEASURES ENVISAGED ARE NOT IN ACCORDANCE WITH THE OPINION OF THE COMMITTEE, OR IF NO OPINION IS DELIVERED, THE COMMISSION SHALL WITHOUT DELAY SUBMIT TO THE COUNCIL A PROPOSAL ON THE MEASURES TO BE TAKEN. THE COUNCIL SHALL ACT BY A QUALIFIED MAJORITY.

(c) IF WITHIN THREE MONTHS OF THE PROPOSAL BEING SUBMITTED TO IT THE COUNCIL HAS NOT ACTED, THE PROPOSED MEASURES SHALL BE ADOPTED BY THE COMMISSION.

ARTICLE 10

ARTICLE 9 SHALL APPLY " FOR A PERIOD OF TWO YEARS FROM THE DATE ON WHICH THE MATTER WAS FIRST REFERRED TO THE COMMITTEE AFTER 1 JANUARY 1985 " **[2]** PURSUANT TO ARTICLE 9 (1).

ARTICLE 11

THIS DIRECTIVE SHALL NOT APPLY TO PRODUCTS INTENDED FOR EXPORT OUTSIDE THE COMMUNITY.

ARTICLE 12

1. MEMBER STATES SHALL, WITHIN A PERIOD OF ONE YEAR FOLLOWING NOTIFICATION OF THIS DIRECTIVE, AMEND THEIR LAWS IN ACCORDANCE WITH THIS DIRECTIVE AND SHALL IMMEDIATELY INFORM THE COMMISSION THEREOF. THE LAWS THUS AMENDED SHALL BE APPLIED IN SUCH A WAY AS TO:

- PERMIT TRADE IN THOSE PRODUCTS WHICH COMPLY WITH THIS DIRECTIVE, TWO YEARS AFTER NOTIFICATION,
- PROHIBIT TRADE IN THOSE PRODUCTS WHICH DO NOT COMPLY WITH THIS DIRECTIVE, THREE YEARS AFTER NOTIFICATION; THIS PERIOD SHALL BE EXTENDED, FOR IRELAND AND THE UNITED KINGDOM, AS REGARDS ARTICLE 4, UNTIL THE EXPIRY OF THE TRANSITIONAL PERIOD DURING WHICH THE USE OF THE IMPERIAL UNITS OF MEASUREMENT LISTED IN CHAPTER D OF THE ANNEX TO DIRECTIVE 71/354/EEC (3), IS AUTHORIZED IN THE COMMUNITY.

2. PARAGRAPH 1 SHALL NOT PREVENT MEMBER STATES FROM PROHIBITING THE MANUFACTURE OF PRODUCTS WHICH DO NOT COMPLY WITH THIS DIRECTIVE, TWO YEARS AFTER NOTIFICATION.

ARTICLE 13

THIS DIRECTIVE IS ADDRESSED TO THE MEMBER STATES.

" ANNEX

DESCRIPTIONS AND DEFINITIONS OF THE PRODUCTS

1. Coffee extracts to which this Directive applies

(a) "Soluble coffee", "instant coffee", "dried coffee extract" or "dried extract of coffee"

means coffee extract in powder, granular, flake, cube or other solid form, of which the coffee-based dry matter content is not less than 95% by weight.
This product may not contain any substances other than those derived from its extraction.

(b) "Coffee extract paste"

means coffee extract, in paste form, of which the coffee-based dry matter content is not more than 85% and not less than 70% by weight.

This product may not contain substances other than those derived from its extraction.

(c) "Liquid coffee extract"

means coffee extract in liquid form, of which the coffee-based dry matter content is not more than 55% but greater than 15% by weight.
This product may not contain any substances other than those derived from its extraction. However, it may contain edible sugars, whether or not roasted, in a proportion not exceeding 12% by weight.

2. Chicory extracts to which this Directive applies

(a) "Dried chicory extract" or "soluble chicory" or "instant chicory"

means chicory extract in powder, granular, flake, cube or other solid form, the chicory-based dry matter content of which is not less than 95% by weight.
This product may not contain any substances other than those derived from its extraction. Substances which are not derived from chicory may not exceed 1%.

(b) "Chicory extract paste"

means chicory extract in paste form, of which the chicory-based dry matter content is not more than 85% and not less than 70% by weight.
This product may not contain any substances other than those derived from its extraction. Substances which are not derived from chicory may not exceed 1%.

(c) "Liquid chicory extract"

means chicory extract in liquid form, of which the chicory-based dry matter content is less than 55% but greater than 25% by weight.
This product may not contain any substances other than those derived from its extraction. It may, however, contain sugars in a proportion not exceeding 35% by weight. " **[4]**

(1) OJ No L 33, 08/02/1979, p. 1.
(2) OJ No L 291, 19/11/1969, p. 9.
(3) OJ No L 243, 29/10/1971, p. 29.

COMMISSION

FIRST COMMISSION DIRECTIVE

of 13 November 1979

laying down Community methods of analysis for testing coffee extracts and chicory extracts

(79/1066/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 77/436/EEC of 27 June 1977 on the approximation of the laws of the Member States relating to coffee extracts and chicory extracts [1], and in particular Article 8 thereof,

Whereas under Article 8 of Directive 77/436/EEC, the composition and characteristics of coffee extracts and chicory extract are required to be checked according to Community methods of analysis;

Whereas a first series of methods for which studies are completed should now be adopted;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Member States shall take all measures necessary to ensure that the analyses necessary for the verification of the criteria set out in Annex I are carried out in accordance with the methods described in Annex II.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive within 18 months of its notification. They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 13 November 1979.

For the Commission

Étienne DAVIGNON

Member of the Commission

[1] OJ No L 172, 12. 7. 1977, p. 20.

ANNEX I

SCOPE OF THE FIRST COMMUNITY METHODS OF ANALYSIS DIRECTIVE FOR COFFEE EXTRACTS AND CHICORY EXTRACTS

I. General provisions.

II. Determination of the caffeine content in decaffeinated coffee extracts using Annex II, method 1.

III. Determination of the dry matter content in dried coffee extract and dried chicory extract, soluble coffee and chicory, and instant coffee and chicory, using Annex II, method 2.

IV. Determination of the dry matter content in liquid coffee extract, liquid chicory extract, coffee extract paste and chicory extract paste using Annex II, method 3.

ANNEX II

METHODS OF ANALYSIS RELATING TO THE COMPOSITION OF COFFEE EXTRACTS AND CHICORY EXTRACTS

GENERAL PROVISIONS

1. PREPARATION OF THE ANALYSIS SAMPLE

1.1. **General**

The mass of the sample presented to the laboratory for analysis shall be at least 50 g.

1.2. **Preparation of the sample for analysis in the laboratory**

1.2.1. *Mixing*

The sample for analysis shall always be mixed thoroughly before any test portion is weighed out.

1.2.1.1. Samples in powder or paste form shall be removed from the container, any lumps broken down, the sample mixed in an appropriate manner and placed in a suitable container.

1.2.1.2. Samples in liquid form shall be mixed by stirring.

1.3. **Containers**

The sample shall always be kept in an airtight and moisture-tight container.

2. REAGENTS

2.1. **Water**

2.1.1. Wherever mention is made to water for solution, dilution or washing purposes, distilled water, or demineralized water of at least equivalent purity, shall be used.

2.1.2. Wherever reference is made to 'solution' or 'dilution' without further indication, 'solution in water' or 'dilution with water' is meant.

2.2. **Chemicals**

All chemicals used shall be of recognized analytical reagent quality except where otherwise specified.

3. EQUIPMENT

3.1. **Lists of equipment**

The lists of equipment contain only those items with a specialized use and items with a particular specification.

3.2. **Analytical balance**

Analytical balance means a balance capable of weighing to at least 0.1 mg.

4. EXPRESSION OF RESULTS

4.1. **Results**

The result stated in the analytical report is the mean value obtained from at least two determinations, the repeatability of which is satisfactory.

4.2. **Calculation of percentage**

Except where otherwise specified, the result shall be calculated as a percentage by mass of the sample.

4.3. **Number of significant figures**

The result shall not contain more significant figures than are justified by the precision of the method of analysis used.

5. TEST REPORT

The test report shall identify the method of analysis used as well as the results obtained. In addition, it shall mention all details of procedure, not specified in the method of analysis, or which are optional, as well as any circumstances that may have influenced the results obtained. The test report shall give all the information necessary for the complete identification of the sample.

METHOD 1: DETERMINATION OF CAFFEINE CONTENT

1. SCOPE AND FIELD OF APPLICATION

This method determines the caffeine content of decaffeinated coffee extracts.

2. DEFINITION

Caffeine content: the content of caffeine as determined by the method specified.

3. PRINCIPLE

Caffeine is extracted from a test portion of the sample in an ammoniacal medium. It is then successively purified with diethyl ether on two chromatographic columns, the first in an alkaline medium and the second in an acid medium. The caffeine is then eluted from the column by chloroform and determined spectrophotometrically.

4. REAGENTS

4.1. Sulphuric acid, 2 M solution.

4.2. Sodium hydroxide, 2 M solution.

4.3. Celite 545 or equivalent.

4.4. Ammonia solution, approximately 4 M (prepare by adding 1 volume of concentrated ammonia solution, ρ_{20} ca. 0.9 g/ml to 2 volumes of water).

4.5. Diethyl ether, pure or repurified by chromatography on a column of basic aluminium oxide of activity grade 1.

Pass 800 ml of diethyl ether through a column filled with 100 g of aluminium oxide. The diethyl ether thus purified, shall be kept in dark bottles until used.

(Diethyl ether, recently distilled and free of peroxides, can be used instead of diethyl ether purified by chromatography.) Saturate the diethyl ether with water.

4.6. Caffeine (1,3,7-trimethyl-2,6-dihydroxypurine), pure, anhydrous ($C_8H_{10}N_4O_2$).

4.7. Chloroform, pure or repurified by chromatography according to the method specified in 4.5 and saturated with water.

5. APPARATUS

5.1. Chromatographic columns (see figure 1), approximately 250 mm long, 21 mm internal diameter (column I) and 17 mm internal diameter (column II), fitted with stopcocks.

5.2. Ultra-violet spectrophotometer: The spectrophotometer shall be accurate to within 0.004 absorbance unit within the range used.

5.3. Silica cells with 10 mm optical path length.

5.4. Usual laboratory equipment, including

5.4.1. Water bath, boiling.

5.4.2. One-mark volumetric flasks, 50 ml, 100 ml and 1 000 ml, complying with ISO 1042.

5.4.3. One-mark pipettes, 2 ml and 5 ml; complying with ISO 648.

5.4.4. Analytical balance.

6. PROCEDURE

6.1. Preparation of the test portion

Weigh, to the nearest 0.1 mg, about 0.5 g of dried coffee extract sample, between 0.5 and 0.7 g of coffee extract paste sample or between 0.8 and 3.2 g of liquid coffee extract sample. (These last two weights should be chosen to give test portions containing approximately 0.5 g of dried coffee extract.) Transfer sample to a 100 ml beaker add 5 ml of ammonia solution (4.4) and warm for two minutes on the boiling water bath (5.4.1). Add 6 g of Celite (4.3) and mix carefully.

6.2. Filling of the columns

6.2.1. *Column I* (alkaline column)

Layer A. Mix carefully, by kneading with a flexible spatula blade, 3 g of Celite (4.3) and 2 ml of the sodium hydroxide solution (4.2), until homogeneous (see note below). A slightly wet powder will be obtained. Transfer this powder, in small portions (of approximately 2 g), into a chromatographic column (5.1), the lower part of which is packed with a wad of cotton wool or glass wool. Tamp down the mixture after each addition, without excessive force, using a glass rod, one end of which is flattened to the internal diameter of the column, until a perfectly homogeneous and compact layer is obtained. A small wad of cotton wool or glass wool may be placed on the top of layer A.

Note: Column packing material may be prepared in bulk quantities in advance and stored in closed containers.

Layer B. Transfer the Celite-sample mixture (6.1) into the column upon layer A. Dry the sample beaker twice with portions of about 1 g of Celite (4.3) transferring this Celite into the column. Tamp down to obtain a homogeneous layer and place a wad of cotton wool or glass wool on the top of layer B.

6.2.2. *Column II* (acid column)

Place in a second column, the lower part of which is packed with a wad of cotton wool or glass wool, 3 g of Celite (4.3) and 3 ml of the sulphuric acid solution (4.1), carefully mixed as directed for layer A in 6.2.1 (see the note in that sub-clause). Place a wad of cotton wool or glass wool on the top of the layer to prevent damage to the top of the column packing.

6.3. Chromatography

Mount the columns one above the other so that the effluent from column I can drip directly into column II. Pass 150 ml of diethyl ether (4.5) through the two columns. Keep open the stopcock in column I. Adjust the stopcock of column II so that a quantity of supernatant liquid remains above the column packing. Remove column I. Pass 50 ml of diethyl ether (4.5) through column II, using the initial portion to wash the tip of column I and passing this portion also into column II. Discard the effluent from column II.

Note: Used diethyl ether may be recovered by shaking it with iron (II) sulphate.

Pass a stream of air through column II with the stopcock open (for example by using an inflated rubber blower), until no more diethyl ether drips from the column and the air flow from the stopcock carries only a faint smell of diethyl ether (see note below). Elute column II with 45 to 50 ml of chloroform (4.7). Collect the eluate in a 50 ml volumetric flask (5.4.2), make up to volume with chloroform (4.7) and mix carefully.

The flow rate of the diethyl ether and the chloroform under conditions of natural flow should be between 1.5 and 3 ml/min. If this rate is exceeded, channelling through the packing should be suspected.

Note: This step should be carried out in a well-ventilated fume-cupboard to prevent both the possibility of inhalation of solvent vapours and the possibility of an explosion.

6.4. Spectrophotometric measurement (see figure 2)

6.4.1. *Measurement of the test solution*

Avoiding error from chloroform evaporation, measure the absorbance of the solution of caffeine in chloroform (6.3) using silica cells (5.3), against chloroform (4.7) at 276 nm (absorption maximum). Measure also the absorbance at 246 nm (absorption minimum) and at 306 nm in order to verify the purity of the caffeine obtained.

If the absorbance at 276 nm exceeds 1.3, repeat the measurement on a diluted portion of the test solution. In this case, take into account the dilution factor; the appropriate factors of the formulae in 7.1 will have to be adjusted accordingly. If the absorbance measured at 276 nm is lower than 0.2, repeat the determination using a larger test portion.

6.4.2. *Preparation and measurement of a reference solution*

Prepare a reference solution of caffeine in the following manner:

Weigh, to the nearest 0.1 mg; 100 ± 20 mg of pure anhydrous caffeine (4.6). Place in a 1 000 ml volumetric flask (5.4.2), dissolve in chloroform, and make up to volume. With a volumetric pipette (5.4.3), take 5 ml of this solution and make up the volume to 50 ml with chloroform.

Measure the absorbance of this solution as described in 6.4.1. The corrected absorbance of the reference solution should be in the region of 0.4.

6.5. Number of determinations

Carry out at least two determinations on the same test sample.

6.6. Blank test

Carry out a blank test on the reagents following the procedure described above but omitting the test portion. Before using recovered reagents (see 4.5 and 4.7), repeat the blank test to verify their purity.

7. EXPRESSION OF RESULTS

7.1. Formulae and method of calculation

The caffeine content, in percent by mass of dry matter on the sample, is equal to:

$$\frac{5 \times 10^{1} \times C \times A_1}{A_2 \times m \times p}$$

where:

C is the concentration of caffeine in the reference solution (6.4.2) in g/ml;

A_1 is the corrected absorbance of the purified extract (6.4.1) [i.e. absorbance at 276 nm − 0.5x (absorbance at 246 nm + absorbance at 306 nm)];

A_2 is the corrected absorbance of the caffeine reference solution (6.4.2) [i.e. absorbance at 276 nm − 0.5x (absorbance at 246 nm + absorbance at 306 nm)];

m is the mass in g of the test portion;

p is the dry matter content, expressed as a percentage by mass, of the sample, as determined by methods 2 or 3, Annex II.

7.2. Repeatability

The difference between the results of two determinations carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 0.01 g caffeine per 100 g sample on a dry matter basis.

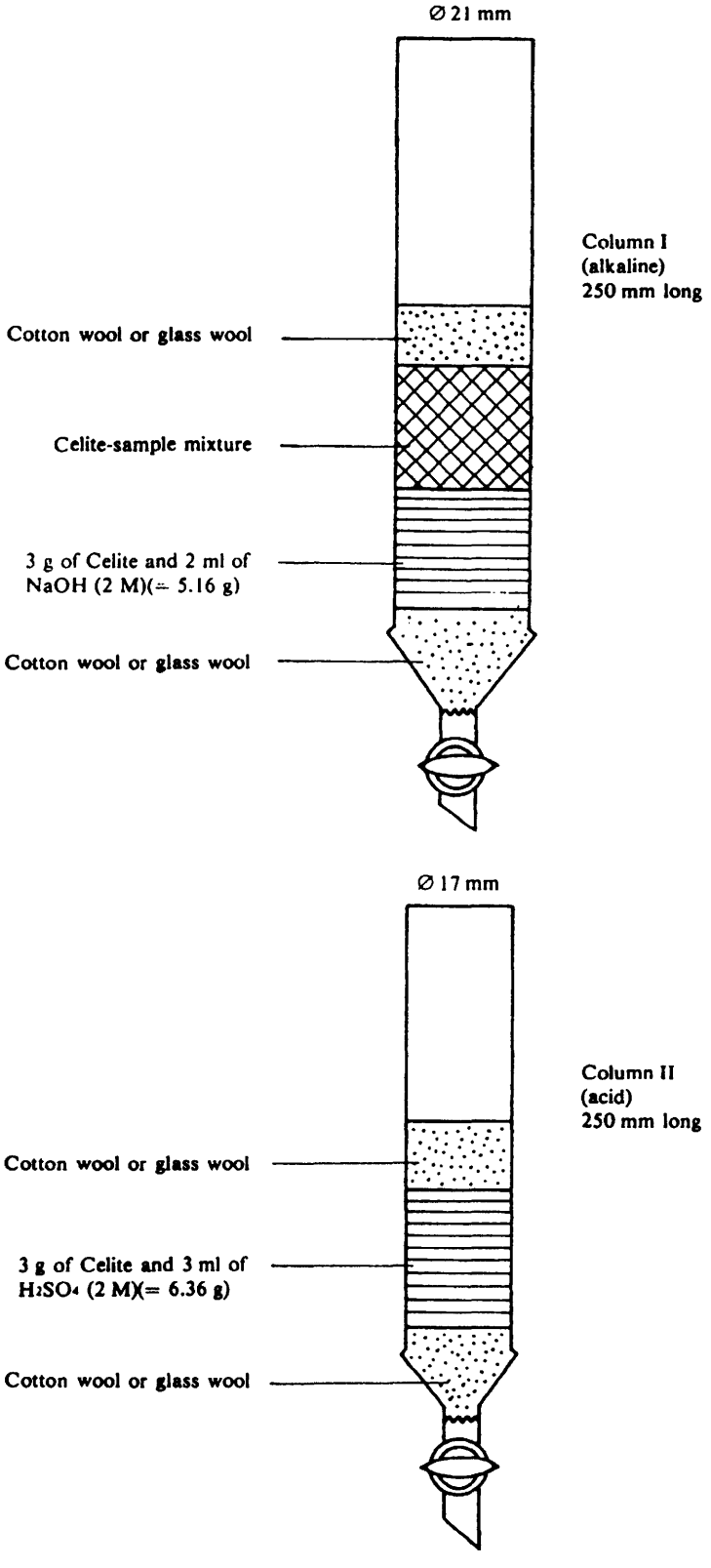


Figure 1

Chromatographic columns

Cells: silica with 10 mm optical path length
Solvent: chloroform
Blank: chloroform

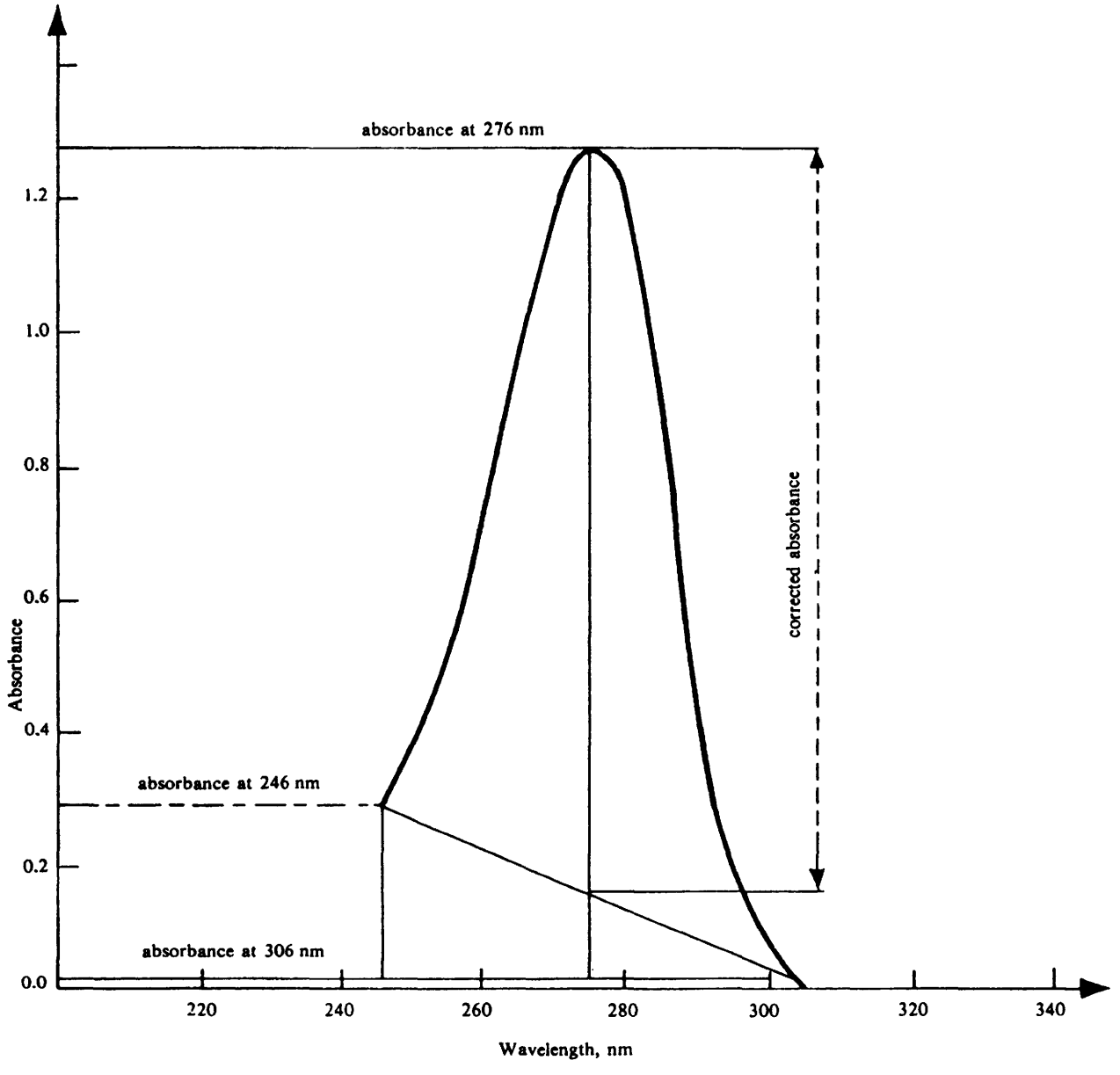


Figure 2

Spectrophotometric measurement

METHOD 2: DETERMINATION OF DRY MATTER CONTENT

1. SCOPE AND FIELD OF APPLICATION

This method determines the dry matter content of:

— dried coffee extract, soluble coffee, instant coffee,
— dried chicory extract, soluble chicory, instant chicory.

2. DEFINITION

Dry matter content: the content of dry matter as determined by the method specified.

3. PRINCIPLE

The residual mass of a test portion is determined after drying for 16 hours in a vacuum oven at a temperature of 70 °C and a pressure of 5.0 kPa and calculated as a percentage by mass of the sample.

4. APPARATUS

4.1. Weighing dishes, flat bottomed, resistant to attack by the sample and condition of the test, approximate dimensions 50 mm diameter by 30 mm height with closely fitting lids. Aluminium and stainless steel dishes are suitable.

4.2. Vacuum oven, electrically heated, temperature controlled by thermostat at 70 °C ± 1 °C throughout the volume of the oven equipped with a thermometer with a certificate of accuracy at 70 °C, indicating the temperature in the immediate vicinity of the shelf and a gauge indicating the internal pressure in kPa above zero pressure. This oven should have a uniform internal temperature distribution. The shelves shall be constructed and fitted so as to ensure good heat transfer to the dishes (4.1).

4.3. Drying oven, electrically heated, temperature controlled by thermostat at 102 °C ± 2 °C throughout the volume of the oven.

4.4. Vacuum pump capable of evacuating the vacuum oven (4.2) to an internal pressure of 5.0 kPa or less.

4.5. Air drying train, consisting of two glass washing bottles filled with glycerol to form a bubble train and two glass drying towers filled with freshly activated silica gel with a moisture content indicator. The bubble train and drying trains are connected in series with the vacuum oven (4.2) with the drying towers between the oven and the bubble train.

4.6. Desiccator, containing freshly activated silica gel (or an equivalent desiccant) with a moisture content indicator.

4.7. Analytical balance.

5. PROCEDURE

5.1. **Preparation of the dishes**

Place the clean dry empty dishes and lids (4.1) in a drying oven (4.3) set at 102 °C ± 2 °C for one hour. Covers should be placed beside dishes in order to expose all surfaces for drying.

Remove dishes and lids from the oven and place in a desiccator (4.6). Allow to cool and weigh dish and matching lid to the nearest 0.1 mg (M_0).

5.2. **Test portion**

Remove the lid from the prepared dish (5.1). As rapidly as possible place approximately 3 g of sample in dish and spread uniformly over the bottom of the dish. Cover dish with its matching lid and weigh with its contents to the nearest 0.1 mg (M_2). If more than one weighing is to be made place covered dishes in desiccator until all samples have been weighed and are ready to be placed in oven.

5.3. Place the dish and its lid separately in the vacuum oven (4.2).

5.4. Close the oven and reduce the pressure slowly (at least 2 to 2.5 minutes), to 5.0 ± 0.1 kPa.

5.5. Allow dry air to enter the oven slowly through the drying towers and bubble train (4.5) at about one bubble per second as observed in the liquid in the bubble train.

5.6. Dry in the vacuum oven at 70 °C ± 1 °C for 16 ± 0.5 hours maintaining the air stream.

5.7. At the end of the drying period allow the air to enter the oven slowly (two to three minutes) to prevent air turbulence that might cause some sample to be lost from dish.

Replace lid on matching dish and place covered dish in desiccator (4.6) and allow to cool to ambient temperature.

5.8. Weigh, to 0.1 mg, covered dish and contents (M_1).

6. EXPRESSION OF RESULTS

6.1. **Formula and method of calculation**

The content of dry matter calculated as a percentage by mass of the prepared sample, as given by:

$$\frac{M_1 - M_0}{M_2 - M_0} \times 100$$

where:

M_0 = mass of the dry prepared dish and lid;

M_1 = mass of the dish lid and test portion after drying;

M_2 = mass of the dish, lid and test portion before drying.

Take as the result the arithmetic mean of the results of two determinations provided that the evaluation concerning repeatability (6.2) is satisfied.

6.2. **Repeatability**

The difference between the results of two determinations carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 0.06 g dry matter per 100 g of sample.

METHOD 3: DETERMINATION OF DRY MATTER CONTENT

1. SCOPE AND FIELD OF APPLICATION

This method determines the dry matter content of:

— liquid coffee extract,
— liquid chicory extract,
— coffee extract paste,
— chicory extract paste.

2. DEFINITION

Dry matter content: the content of dry matter as determined by the method specified.

3. PRINCIPLE

Test portions of the samples are mixed with sea sand and then dried for 16 hours in a vacuum oven at a temperature of 70 °C and a pressure of 5 kPa. The residual mass is calculated as a percentage by mass of the sample.

4. REAGENTS

Sea sand, washed in acid and then water till acid free and then ignited.

5. APPARATUS

5.1. Weighing dishes, flat bottomed, resistant to attack by the sample and condition of the test, approximately 80 mm in diameter and with closely fitting lids.

5.2. Glass rods of such a length that they lie wholly in the weighing dishes (5.1) for example 50 to 75 mm long.

5.3. Vacuum oven, electrically heated, temperature controlled by thermostat at 70 °C ± 1 °C throughout the volume of the oven, equipped with a thermometer with a certificate of accuracy at 70 °C, indicating the temperature in the immediate vicinity of the shelf and a gauge indicating the internal pressure in kPa above zero pressure.

This oven shall have a uniform internal temperature distribution. The shelves shall be constructed and fitted so as to ensure good heat transfer to the dishes (5.1).

5.4. Vacuum pump capable of evacuating the vacuum oven (5.3) to an internal pressure of 5.0 kPa or less.

5.5. Air drying train consisting of two glass washing bottles filled with glycerol to form a bubble train and two glass drying tubes filled with freshly activated silica gel with a moisture content indicator. The bubble train towers are connected in series with the vacuum oven (5.3) with the drying towers between the oven and the bubble train.

5.6. Desiccator containing freshly activated silica gel (or an equivalent desiccant) with a moisture content indicator.

5.7. Analytical balance.

5.8. Water bath boiling.

6. PROCEDURE

6.1. **Preparation of weighing dish**

Place 25 to 35 g of sea sand (4) in a weighing dish (5.1) together with a glass rod (5.2) and weigh. Place the dish with sea sand lid and rod in the vacuum oven (5.3).

The lid should be placed beside the dish in order to expose all surfaces for drying.

Remove the dish, with contents, and its lid from the oven and place in a desiccator (5.6).

Allow to cool and weigh, to the nearest 0.1 mg, dish, contents and matching lid.

Repeat till constant weight is obtained (M_0).

6.2. **Test portion**

Remove the lid from the prepared dish (6.1). Add (as rapidly as possible) a portion of the sample with a dry matter content which should correspond to 0.1 to 1 g.

Weigh, to 0.1 mg, dish, contents, including test portion, and lid (M_2).

6.3. Carefully mix the sea sand and the sample with the glass rod (5.2). If mixing is not carried out satisfactorily add a little water to aid the mixing. Re-heat on a water bath (5.8) stirring occasionally until a completely homogeneous sandy mixture is obtained. Should the mixture tend to become lumpy or crusty, stir or pound continuously so as to prevent any lumpiness.

6.4. Place the dish and its lid separately in the vacuum oven (5.3).

6.5. Close the oven and reduce the pressure slowly (at least 2 to 2.5 minutes) to 5.0 ± 0.1 kPa.

6.6. Allow dry air to enter the oven slowly through the drying towers and bubble train (5.5) at about one bubble per second as observed in the liquid of the bubble train.

6.7. Dry in the vacuum oven at 70 °C ± 1 °C for 16 ± 0.5 hours maintaining the air stream.

6.8. At the end of the drying period allow the air to enter the oven slowly (two to three minutes) to prevent air turbulence that might cause some sample to be lost from the dish.

Replace lid on matching dish and place covered dish in desiccator (5.6) and allow to cool to ambient temperature.

6.9. Weigh, to 0.1 mg, covered dish and contents (M_1).

7. EXPRESSION OF RESULTS

7.1. Formula and method of calculation

The content of dry matter, calculated as a percentage by mass of the prepared sample, is given by:

$$\frac{M_1 - M_0}{M_2 - M_0} \times 100$$

where:

M_0 = the mass of the prepared dish, and lid;

M_1 = the mass of the dish, lid and test portion after drying;

M_2 = the mass of the dish, lid and test portion before drying.

Take as a result the arithmetic mean of the results of two determinations provided that the evaluation concerning repeatability (7.2) is satisfied.

7.2. Repeatability

The difference between the results of two determinations when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 0.06 g dry matter per 100 g of sample.

European Commission

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