

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(80) 286 final

Brussels, 22 May 1980

Proposal for a
COUNCIL DIRECTIVE

on the approximation of the laws of the Member
States relating to flavourings for use in food-
stuffs and to source materials for their production

(submitted to the Council by the Commission)

COM(80) 286 final

EXPLANATORY NOTE

1. INTRODUCTION

- 1.1 The attached proposal for Directive is intended to outline a scheme for Community legislation on flavourings used in food. The theme central to the proposal is that substances and materials should not be used as flavourings unless they appear on permitted lists (Article 5) and have been subjected to independent toxicological evaluation to assess their safety in use. The Directive is one of a series of "horizontal" directives on food additives.
- 1.2 Several Member States are drawing up, or have adopted differing legislations on the subject. The economic consequences of these differences cannot fully be analysed but they would inevitably create obstruction to Trade in flavoured foodstuffs (see paragraph 2.5).
- 1.3 The proposal describes means by which Directives on specific topics should be elaborated (Articles 5-9).
- 1.4 Definitions (Article 1), general purity criteria (Annex I), and minimum labelling requirements (Article 10) for flavourings in Trade are stipulated. These provisions are to be applied on the adoption of this Directive.
- 1.5 On the advice of the Scientific Committee for Food limits have been established for a number of components of natural flavourings in anticipation of the adoption of permitted lists of natural flavouring materials used for the production of flavourings (Article 4, Annex II).

2. DETAILED COMMENTS

2.1 Article 1

Article 1 defines the scope of application of the Directive and proposes a number of special terms for different kinds of flavourings. These terms have been devised for the purposes of the Directive and may not be exactly the same as those used by other organisations (e.g. FAO/WHO Codex Alimentarius) for other purposes. The list of definitions, existing in all the Community languages, provides a means of identification of flavourings in equivalent terms in the various Member States. The need for a list of comparable, defined terms became apparent during the Commissions preliminary discussions with non-government and government experts when it was found that similar terms were being used to denote materials whose composition was not necessarily equivalent.

The term "nature-identical" has been the source of considerable controversy. There are many who believe that it does not correctly describe a substance chemically identical to a substance occurring naturally in food or in a natural flavouring material, but which has been obtained either synthetically or extracted from these materials by chemical processes. However, the term is well known in international trade and is used by the FAO/WHO Codex Alimentarius. No more suitable alternative has been suggested for these isolated and chemically identified substances. Nevertheless although the term is considered adequate for these substances the Commission does not believe that it is appropriate for labelling of foodstuffs, where its use could be misleading. In practice few "nature-identical substances" are sold as such, since more usually they are part of flavouring mixtures. The labelling of these mixtures is provided for in Article 10.

The use of the term "artificial" for flavouring substances not identified in foods or natural flavouring materials has been criticised as being unnecessary, but the Commission believes that the user (food manufacturer, or consumer) has a right to know that such substances are present in order to make an informed choice.

The term "natural" has also been criticised for the same reason, and there is some value in the argument that natural flavouring materials, once subjected to extraction, distillation, high temperature and other processes are no longer "natural" and therefore that the use of the word "natural" is inappropriate for the flavouring thus produced. This question is relevant to use of the term "natural" for the labelling of foodstuffs in general and will be discussed in this context at a later date. In the meantime guidance has to be given on the use of this term for flavourings. The definitions referring to "natural" are included so that the purchaser of a flavouring preparation labelled as being natural can be assured that it does not differ significantly in composition from the naturally occurring source material.

2.2 Article 2

Article 2 defines groups of materials (e.g. foodstuffs, salt, sugar, hydrolysed vegetable protein) specifically excluded from the scope of the Directive.

Natural flavouring materials (e.g. spices, herbs, foodstuffs) are included in the Directive to the extent that they serve as source materials for flavourings (Article 5) and to the extent that they contribute to the residues in food of substances listed in Annex II. The proposal does not attempt to lay down rules on the quality of natural flavouring materials as such.

2.3 Article 3 is self explanatory.

2.4 Article 4

Paragraph 1(a) refers to general purity criteria listed in Annex I. Similar provisions have been included in Community provisions on colourings, preservatives, antioxidants, emulsifiers, etc..

The Commission has accepted the advice of the Scientific Committee for Food that a number of substances present in food as a result of the use of natural flavouring materials should be limited, both in quantity, and in the types of foodstuffs in which they might be allowed (Paragraph 1(b)). The Committee stressed that as these substances could be harmful the maximum levels it recommended should be regarded as "tolerable" - rather than "acceptable".

A number of organisations have demanded that the limits proposed should also apply to added sythetic equivalents, on the grounds that the substances are equally toxic whether synthetically derived or naturally occurring in the spices, herbs and foodstuffs used in food. Neither the Scientific Committee for Food nor the Commission accepts the argument that it should be permitted to add to a flavouring a substances known to be potentially harmful to the consumer on the grounds that the same substance is unavoidably present in a natural material (e.g. hydrocyanic acid in bitter almonds). Paragraph 1(b) reflects this principle by forbidding the direct addition to food of any substance listed in Annex II.

When a permitted list of source materials used for the production of natural flavourings is elaborated other substances may have to be included in Annex II. Paragraph 2 declares this intention. Annex II should therefore be regarded as a first list.

2.5 Article 5

The principle that only permitted food additives should be authorized in food, and the corollary that additives not so authorized are prohibited has been accepted in the Community by governmental and non-governmental organisations. The application of this principle to flavourings is complicated by the large numbers of materials and substances involved. The Advisory Committee for Foodstuffs has been informed by Industry that there are some 3 000 flavouring substances in natural flavouring materials and foodstuffs, of these about 650 have been synthesized or chemically extracted as "nature-identical flavouring substances" for the preparation of flavourings used in food. By reference to the Council of Europe's 1974 publication "Natural Flavouring Substances, their sources, and added artificial flavouring substances"¹ it can be estimated that there could also be 500 or so foodstuffs, herbs, spices and other vegetable and animal materials used to flavour foods themselves or as source materials for the production of extracts, oleoresins, distillates, essences, etc. These materials contain large numbers of components. (For instance more than 400 constituents of strawberry flavour have been identified). Thus enforcement of a total permitted list system would be complicated, and indeed the analysis of a particular flavouring substance in food would in many cases be impossible.

It has also been put to the Commission that the introduction of a permitted list system could arrest development of new flavourings. It has been argued that the immediate introduction on to a list of a new flavouring on which a great deal of research and expenditure has been devoted by a particular manufacturer would permit competitors to take advantage of the results at no great expense to themselves.

The flavouring producing industry has strongly maintained that such a list would neither be enforceable nor equitable in application and has proposed a mixed system by which any substance which occurs naturally in the diet may be used unless explicitly prohibited or restricted and by which substances not yet found to occur in the human diet may not be used unless explicitly permitted. This mixed system allows as a matter of principle both the natural flavouring substances and their nature-identical counterparts. The industry

¹Published in France by Maisonneuve, 1974

believes that in cases where for toxicological reasons a limitation is necessary and the risk of excessive use is unacceptable then the substance concerned can be included on a restricted list (i.e. restricted to a number of foods or at a maximum level) otherwise no permitted list of natural flavouring materials or nature-identical flavouring substances is envisaged.

In a few Member States legislation is being prepared or has been already adopted broadly similar to this mixed system. Other Member States are convinced that a full permitted list of authorized flavourings and their sources is the best means of regulating the use of these substances. Many processed foods contain flavourings, and to now no evidence has been submitted that major problems in relation to free movement of such foodstuffs exist. However, the Commission is aware that more restrictive and differing legislation is being developed or envisaged in many Member States. Such widely differing legislations would impede trade in foodstuffs containing flavourings. The economic consequences of these potential barriers to trade are difficult to evaluate. The Commission has decided that it should initiate, now, action to avoid the creation of these barriers.

The Commission has consulted widely with governments and non-government associations on the scheme for legislation most appropriate for the needs of the Community and has decided that while the mixed system proposed by the flavouring producing industry might have superficial advantages in the short term in contributing to the resolution of what are admittedly complex problems, the interests of the Community as a whole can best be served by the development of lists of authorized flavourings (whether natural or chemically derived), and notes that the majority of the food industry, consumers, agriculture and commerce represented on the Advisory Committee for Foodstuffs endorses this approach. Article 5 of the Directive lays down the procedure for the future development of these lists.

The Commission recognizes that a "positive list system" will place a constraint on the producing industry which searches to give to the consumer a wide variety of delicately flavoured foods. Its enforcement will be costly and controls on imported foods will be difficult to apply. The alternatives have been fully discussed by the Commission and its advisers but their purported advantages have not seemed such

as to be sufficiently convincing to persuade the Commission to deviate from the usual "positive list" approach to food additives.

The Commission is convinced that given the impetus of legislation, science will develop the more advanced and precise techniques necessary for its application and that consumers and users of flavourings, and indeed the producing industry, will benefit from the reassurance that these substances and materials, deliberately added to foods, will have had the benefit of an independent toxicological evaluation prior to their admission.

Article 5 paragraph 2 also prepares the way for the establishment of lists of products and materials that may be used in the production of flavourings as solvents, diluents, supports, etc.

- 2.6 Article 6 prescribes the procedures by which methods of analysis and sampling, and purity criteria shall be determined.
- 2.7 Article 7 prescribes conditions under which a new substance or material may be temporarily permitted by an individual Member State, and is comparable to the text adopted by the Council, (Directive 76/893/EEC) relating to materials and objects destined to come into contact with foodstuffs².
- 2.8 Article 8 prescribes a procedure for modifying the annexes to the Directive and subsequent separate Directives relating to flavourings, to take into account progress in scientific and technical knowledge.
- 2.9 Article 9 relates to the reassessment on health grounds of already admitted flavouring components.
- 2.10 Article 10
Article 10 stipulates the minimum labelling requirements for flavourings sold as such. It is to be noted that these requirements will not necessarily apply to the labelling of foodstuffs containing such flavourings. Separate Community provisions will be drawn up for

²OJ L 340, 9.2.1976, p. 19

the ingredient declaration for flavourings in foods in addition to those relating to mixtures of spices and herbs extant in Directive 79/112/EEC relating to the labelling presentation and advertising of foodstuffs for sale to the ultimate consumer³.

The minimum requirements included in Article 10 remain flexible given the enormous variety of mixture of flavourings commercialised - to other flavour blenders, to the ultimate consumer, to the food industry, - some with definite flavour (e.g. orange), some simply mixtures of no pronounced note (e.g. ice cream flavourings, soft drink flavourings). Nevertheless a certain amount of essential information about the flavouring is required for example:

- the word "artificial" or "reproduced" has to be used in the appropriate context;
- mixtures of flavourings must be indicated in decreasing order by weight of each category (e.g. natural flavouring preparation, nature-identical flavouring substances, artificial flavouring substances, etc.);
- the rules governing the use of "natural" are laid down;
- information must be provided about the quantities present of the substances listed in Annex II.

The Commission has considered whether it would not be appropriate to require a mention of the date of minimum durability for flavourings sold to the final consumer. It has been decided that such a provision would be best included at a later stage on completion of the current review of the labelling provisions relating to all food additives subject to Community legislation.

2.11 Articles 11-15 relate to the implementation of the Directive. Any flavouring moving in Trade has to comply with the present Directive although free movement of all flavourings cannot be achieved until the provisions of Article 5 are applied (Article 14).

³OJ L 33, 8.2.1979, p. 1

Proposal for a Council Directive on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production

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 Commission¹;

Having regard to the opinion of the European Parliament²;

Having regard to the opinion of the Economic and Social Committee³;

Whereas differences between national laws relating to flavourings hinder the free movement of foodstuffs and may create conditions of unequal competition, thereby affecting the establishment or functioning of the common market;

Whereas the approximation of those laws is necessary if the free movement of foodstuffs is to be achieved;

Whereas laws relating to flavourings for use in foodstuffs should take account primarily of human health requirements but also, within the limit required for the protection of health, of economic and technical needs;

Whereas the first step should be to lay down in a framework Directive provisions on general purity criteria, definitions, labelling, and the principles on the basis of which legal differences may subsequently be eliminated.

Whereas at a later stage specific Directives relating to individual categories of flavourings and source materials from which they are derived should be adopted, listing the flavourings which are to be authorized by the Member States for the treatment of foodstuffs and indicating any special conditions of manufacture or limitations on use that might be necessary;

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Whereas on the most recent scientific and technical advice certain components of natural flavouring materials and natural flavouring preparations ought to be limited in foodstuffs;

Whereas specific purity criteria for flavourings and substances and materials used in their production, and methods of analysis and sampling of flavourings in and on foodstuffs, should be established;

Whereas, in order to encourage technical progress, Member States should be allowed to permit provisionally in their territory, under official control, the use of flavourings not provided for in one of the specific Directives, pending a final decision at Community level;

Whereas, should the use in a flavouring of a substance or material provided for in one of the specific Directives or the presence of one of the substances listed in Annex II appear to constitute a health risk, Member States should be authorized to suspend or limit such use, or to reduce the limits provided, pending a decision at Community level;

Whereas the updating of the list of flavourings and substances and materials authorized in their manufacture and the establishment of sampling procedures and of the methods of analysis required for checking not only the substances listed, their purity standards and conditions of use but also the limits which have been laid down in Annex II constitute technical implementing measures; whereas in order to simplify and expedite the procedure, the adoption of such measures should be entrusted to the Commission;

Whereas, it is desirable that for all cases where the Council empowers the Commission to implement rules relating to flavourings for use in foodstuffs, 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 Council Decision 69/414/EEC⁴;

Whereas, without prejudice to the application of national provisions which in the absence of specific Directives on flavourings shall apply to certain groups of flavourings, the requirements laid down in the following provisions should be applied in such a way as to authorize, two years after notification of this Directive, trade in and use of flavourings complying with the provisions

⁴OJ N° L 291, 19.11.1969, p. 9

of this Directive and to prohibit, three years after the notification thereof, trade in and use of flavourings which do not comply therewith,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to flavouring agents, hereinafter called "flavourings" used or intended for use in or on foodstuffs to impart odour or taste, and to natural flavouring materials and other source materials used for the production of flavourings.
2. For the purposes of this Directive:
 - (a) "flavouring" means flavouring substance, flavouring preparation or their mixtures;
 - (b) "flavouring substance" means a defined chemical substance with flavouring properties and is:
 - "natural" when isolated from natural flavouring materials, natural flavouring preparations or foodstuffs by appropriate physical processes, (including distillation, solvent extraction),
 - "nature-identical" when obtained by chemical synthesis, or isolated by chemical processes and chemically identical to a substance occurring naturally in natural flavouring materials, natural flavouring preparations or foodstuffs,
 - "artificial" when not chemically identical to a substance occurring naturally in natural flavouring materials, natural flavouring preparations or foodstuffs;
 - (c) "flavouring preparation" means a product or mixture, concentrated or not, with flavouring properties and is:
 - "natural" when isolated by appropriate physical processes (including distillation, solvent extraction) or traditional food preparation processes (including drying, torrefaction and fermentation) from natural flavouring materials or foodstuffs and when the composition of the flavouring component of the preparation is substantially the same as in the natural flavouring material or foodstuff,
 - "artificial" when obtained by other than appropriate physical processes or other than traditional food preparation processes from natural flavouring materials or foodstuffs, or when not exclusively derived from natural flavouring materials or foodstuffs;
 - (d) "natural flavouring material" means material of vegetable or animal origin, inherently having flavouring properties and used for its flavouring properties either as such or processed for human consumption by traditional food preparation processes (including drying, torrefaction and fermentation).

Article 2

This Directive shall not apply to

- substances and products intended to be consumed as such, with or without reconstitution,
- natural flavouring materials, except as is provided for in Articles 4 and 5,
- substances and products which have exclusively a sweet, sour or salt taste,
- protein hydrolysates obtained by the autolysis or hydrolysis of protein rich foods, or food proteins, without the addition of other substances.

Article 3

Member States shall take all measures necessary to ensure that flavourings and, insofar as this Directive applies, natural flavouring materials may be marketed or used only if they comply with the rules laid down in this Directive.

Article 4

1. Member States shall take all measures necessary to ensure that
 - (a) flavourings satisfy the general purity criteria listed in Annex I,
 - (b) the use of natural flavouring materials and/or natural flavouring preparations may not result in the presence in food as consumed of any substance listed in Annex II in a quantity greater than therein specified. These substances must not be added as such, being present exclusively from the use of such natural flavouring materials or natural flavouring preparations.
2. Annex II shall be completed as soon as possible on the basis of the list drawn up under the provisions of Article 5 (1)(c).

Article 5

1. The Council shall, under the procedure provided for in Article 100 of the Treaty adopt by means of specific Directives special provisions applicable to groups of flavourings (e.g. special conditions governing their use which may be necessary and methods used in their production). These specific Directives shall include lists of substances or materials the use of which is authorized to the exclusion of all others of:
 - (a) artificial flavouring substances;
 - (b) nature-identical flavouring substances;

- (c) source materials for the production of natural flavouring preparations and natural flavouring substances;
- (d) source materials for the production of artificial flavouring preparations;

2. The Council, under the procedure provided for in Article 100 of the Treaty, shall:

- (a) adopt lists of substances or materials the use of which is authorized to the exclusion of all others of;
 - additives necessary for the production and storage of flavourings,
 - products used for dissolving and diluting flavourings,
 - processing aids (e.g. extraction solvents) necessary for the production of flavourings;
- (b) specify the conditions for the use of the substances and materials referred to in paragraph 2(a).

Article 6

The procedure laid down in Article 11 shall be used to determine:

- the methods of analysis needed to verify compliance with the general and specific purity criteria referred to in Article 4 (1)(a) and this Article;
- the methods of analysis needed to verify compliance with the limits referred to in Article 4(1)(b);
- the procedure for taking samples and the methods for qualitative and quantitative analysis of flavourings in or on foodstuffs;
- the specific criteria of purity for the substances and materials referred to in Article 5(1)(a) and (b), and where necessary Article 5 (1)(c) and (d) and 2(a).

Article 7

1. Notwithstanding Article 5, a Member State may, where a list of substances or materials has been drawn up in accordance with paragraph 1(a) to (d) of that Article, authorize the use within its territory of a substance or material not included in such list, subject to the following conditions:

- (a) the authorization must be limited to a maximum period of three years;
- (b) flavourings manufactured using the substance or material must bear a distinctive indication which will be defined on 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 entry into force.
3. Before the expiry of the three year period provided for in paragraph 1, the Member State may submit to the Commission a request to authorize the inclusion of the substance or material referred to in paragraph 1 in a list as referred to in Article 5(1)(a) to (d). At the same time, it shall supply supporting documents setting out the grounds on which it deems such authorization justified and shall indicate the uses for which such substance or material is intended.

Within 18 months of the submission of this request, a decision shall be taken on the basis of information relating to public health, and in accordance with the procedure laid down in Article 11 as to whether the substance or material in question may be included in the list as referred to in Article 5(1)(a) to (d) or whether the authorization should be revoked. If any special provisions prove necessary pursuant to the provisions of Article 5(1), these too shall be adopted under the same procedure. Notwithstanding paragraph 1(a), the national authorization shall remain in force until a decision is taken on the request.

Should the authorization be revoked by the Member State, this decision to revoke shall apply to any other temporary authorization granted in respect of the substance or material in question. Such decision may stipulate that the ban on the use of the substance or material in question shall extend to uses other than those referred to in the first sub-paragraph.

Article 8

Without prejudice to Article 7(3), amendments to the technical Annexes of the specific Directives referred to in Article 5(1), to the lists referred to in Article 5(2), and to the Annexes to this Directive, necessary to take account of progress in scientific and technical knowledge shall be adopted in accordance with the procedure provided for in Article 11.

Article 9

1. Where a Member State, as a result of new information or of a re-assessment of existing information made since this Directive or one of the specific Directives laid down in Article 5 was adopted has detailed grounds for establishing

- that the presence of one of the substances listed in the Annexes to this Directive or the maximum level which may be present, although it complies with the provisions of this Directive,
- that the use of a flavouring although it complies with the relevant specific Directive,

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 as soon as possible the grounds given by the Member State 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 or a specific 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 11, 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 10

1. Without prejudice to any exception provided for in the specific Directives, flavourings may be marketed only if their packagings or containers bear the following information:

- (a) the name or business name and address of the manufacturer or packager, or of a seller established within the Community;
- (b) either the word "flavouring" or a more specific name or description of the flavouring;
- (c) either the statement "for foodstuffs" or a more specific reference to its intended food use;

- (d) in the case of mixtures of flavourings a list of the categories of flavourings present in accordance with the definitions given in Article 1(2) in order of proportion by weight which each category bears to the total;
- (e) in the case of flavourings containing other substances or materials in accordance with the first and second indents of Article 5(2)
- the name of any such substances or material or where appropriate its "E" number,
 - the percentage of such substance or material, where this requirement is laid down in provisions relating to other categories of additives;
- (f) an indication of the maximum amount present of any substance listed in Annex II, and instructions for use where the absence of such instructions would make it impossible for the user to comply with the special conditions of use stipulated in Article 4 (1)(b);
- (g) in the case of pre-packaged flavourings, the net quantity; Article 8 of Council Directive 79/112/EEC of 19 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 consumer¹ shall apply by analogy.
2. The word "natural", or any word having substantially the same meaning, may only be used for flavourings, the flavouring component of which contains exclusively natural flavouring preparations.
3. Any reference to the type of flavour shall be accompanied by the word "reproduced" where the flavouring contains nature-identical flavouring substances, this indication being replaced by "artificial" if one or more artificial flavouring substances is present.
4. The details referred to in paragraph 1(b) and (c) and paragraph 3 shall appear on one of the main surfaces of the packaging or container and in the same field of vision.
5. By derogation from the provisions of this Article, where flavourings are not intended for retail sale, the information required in paragraph 1 (a), (d), (e), (f) and (g) may figure on the relevant trade documents.

¹OJ No L 33, 8.12.1979, p. 1

6. 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 for are to be shown.

The Member States shall, however, ensure that the sale of flavourings within their own territories is prohibited if the particulars provided 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 11

1. Where the procedure laid down in this Article is to be followed, the matter shall be referred to the Standing Committee for Feedstuffs set up by Decision 69/414/EEC (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 41 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 12

1. Without prejudice to Article 14, Member States shall adopt all the measures necessary to ensure that trade in flavourings referred to in Article 1 which comply with the definitions and rules laid down in this Directive or in the Directives referred to in Article 5(1) and (2) cannot be impeded by the application of non-harmonized national provisions governing the composition, manufacturing specifications, packaging or labelling of those products.
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 13

1. This Directive shall apply equally to flavourings 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 14

Within 18 months of the notification of this Directive, Member States shall take the measures necessary to comply with this Directive and shall forthwith inform the Commission thereof. The measures taken shall:

- authorize, two years after notification of this Directive, trade in and use of flavourings, complying with the provisions laid down in this Directive, without prejudice to the application of national provisions, which in the absence of the Directives referred to in Article 5(1) and (2) shall apply to certain groups of flavourings;
- prohibit, three years after notification of this Directive, trade in and use of flavourings which do not comply with the provisions laid down in this Directive.

Article 15

This Directive is addressed to the Member States.

Done at

For the Council

The President

ANNEX I

Flavourings shall not contain a toxicologically dangerous amount of any element.

Subject to any exception deriving from the criteria of purity referred to in Article 6:

- they shall not contain more than 0.5mg/kg cadmium, more than 0.5 mg/kg mercury, more than 2 mg/kg arsenic or more than 5 mg/kg lead;
- they shall not contain more than 50 mg/kg of copper and zinc taken together of which the zinc content must not exceed 25 mg/kg;

ANNEX II

Maximum limits for certain substances having biological activity present in food as consumed as a result of the use of natural flavouring materials and/or natural flavouring preparations

Substance	Food mg/kg	Beverages mg/kg	Exceptions
Beta asarone	0.1	0.1	1 mg/kg in alcoholic beverages and seasonings used in snack foods
Coumarin	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	1	1	25 mg/kg in confectionery 50 mg/kg in marzipan or its substitutes 1 mg/kg per 1% vol. alcohol in alcoholic beverages 5 mg/kg in stone fruit juices
Safrole and iso-safrole	1	1	2 mg/kg in alcoholic beverages less than 25% volume alcohol 5 mg/kg in alcoholic beverages above 25% volume alcohol 15 mg/kg in foods containing mace and nutmeg
Thujone (alpha and beta)	0.5	0.5	5 mg/kg in alcoholic beverages less than 25% volume alcohol 10 mg/kg in alcoholic beverages above 25% volume alcohol 50 mg/kg in foods containing sage 100 mg/kg in sage stuffings 35 mg/kg in bitters