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## REPORT

drawn up on behalf of the Committee on the Environment,  
Public Health and Consumer Protection

on the proposal from the Commission of the European  
Communities to the Council for a directive 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  
(COM(84) 152 final - Doc. 1-197/84)

Rapporteur: Mrs V. SQUARCIALUPI

WG(2)/1820E

PE 97.257/fin.



By letter of 19 April 1984, the President of the Council of the European Communities requested the European Parliament to deliver an opinion on the proposal from the Commission of the European Communities to the Council for a directive 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.

On 22 May 1984, the President of the European Parliament referred this proposal to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible and to the Committee on Economic and Monetary Affairs and Industrial Policy for an opinion.

At its meeting of 25 September 1984, the Committee on the Environment, Public Health and Consumer Protection appointed Mrs Squarcialupi rapporteur.

The committee considered the Commission's proposal and the draft report at its meetings of 20 March 1985, 24 April 1985 and 21 May 1985.

At the last meeting the committee unanimously approved the Commission's proposal and unanimously adopted the motion for a resolution as a whole.

The following took part in the vote: Mrs Weber, chairman; Mrs Schleicher, Mrs Bloch von Blottnitz and Mr Collins, vice-chairmen; Mrs Squarcialupi, rapporteur; Mrs Banotti, Mr Elliott (deputizing for Mr Tognoli), Mr Hughes, Mr Iversen, Mrs Lentz-Cornette, Mr Mertens, Mr Pearce, Mrs Pens (deputizing for Mr Alber), Mr Ryan (deputizing for Mr Parodi), Mr Schmid, Mr Sherlock, Ms Tongue and Mr Vittinghoff.

The opinion of the Committee on Economic and Monetary Affairs and Industrial Policy is attached.

The report was tabled on 28 May 1985.

The deadline for the tabling of amendments to this report appears in the draft agenda for the part-session at which it will be debated.

CONTENTS

	<u>Page</u>
A. MOTION FOR A RESOLUTION .....	5
B. EXPLANATORY STATEMENT .....	7
1. General aspects of the problem of plastic packaging ...	7
2. Directive 82/711 of 18 October 1982 which the present proposal is designed to supplement .....	7
3. Remarks on the present proposal for a directive .....	9
4. Questions to the Commission of the European Communities	10
 Opinion of the Committee on Economic and Monetary Affairs and Industrial Policy .....	 11

The Committee on the Environment, Public Health and Consumer Protection hereby submits to the European Parliament the following motion for a resolution, together with explanatory statement:

A

DRAFT MOTION FOR A RESOLUTION

closing the procedure for consulting the European Parliament on the proposal from the Commission of the European Communities to the Council for a directive 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 (COM(84) 152 final - Doc. 1-197/84)

The European Parliament,

- having regard to the proposal from the Commission to the Council<sup>1</sup>,
  - having been consulted by the Council pursuant to Article 100 of the EEC Treaty (Doc. 1-197/84),
  - whereas one of the principles sanctioned by the European Community's consumer policy is the safeguarding of health and safety,
  - having regard to the third action programme for the protection of the environment, the conclusions of the committee of inquiry into the treatment of toxic and dangerous substances and the resolution of the European Parliament on waste (Doc. 1-1376/83),
  - having regard to Directive 82/711/EEC, which lays down the basic rules for testing migration of plastic materials and articles intended to come into contact with foodstuffs and specifies the simulants to be used,
  - having regard to the increasingly widespread use of plastic materials for the packaging of food products,
  - having regard to the report of the Committee on the Environment, Public Health and Consumer Protection and the opinion of the Committee on Economic and Monetary Affairs and Industrial Policy (Doc. A 2-52/85),
  - having regard to the result of the vote on the Commission's proposal,
- A. whereas only two countries - Belgium and Italy - have any legislation on this subject whilst others such as France, the Netherlands and the Federal Republic of Germany have already adopted a system similar to that outlined by the Commission;
- B. whereas there are still many gaps in scientific knowledge, which means that the legislation in various countries varies considerably;
- C. whereas only the governments of the Member States agree on the Commission's text, whilst the consumers do not;

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<sup>1</sup>OJ No. C 102 of 14.4.1984

1. Approves of the Commission's proposal for a directive to lay down a Community procedure on the subject, in view of the extensive market in plastic materials and the need to remove the numerous technical barriers which still exist in the sector because of the continuing differences in the legislation of different countries, but above all in order to ensure more effective safeguarding of public health;
2. Welcomes this proposal as an example of the preventive health policy consistently called for by the European Parliament, since damage to health in this context has not hitherto come to light;
3. Considers that, because of the contact time and/or the soluble properties of the plastic materials and the food products involved, the transfer of constituents of plastic materials and articles in contact with foodstuffs may be such as to affect human health;
4. Notes, however, that the harmonization measures proposed by the Commission are incomplete, in that they merely supplement the previous Directive 82/711/EEC, which specifies the simulants to be used, and that the entry into force of this directive depends on the prior adoption of proposals laying down not only the list of substances and plastic materials whose use is authorized (positive list) but also the admissible rates of transfer;
5. Therefore calls upon the Commission to submit as soon as possible further proposals needed for the implementation of the whole body of Community regulations in the sector and to see that more thorough research on toxicity and the risk of migration is carried out in order to remove any doubt on the subject;
6. Considers that until fuller scientific information is available every effort must be made to safeguard consumers more effectively;
7. Therefore calls for a larger number of simulants to be used in order to provide better guarantees for consumers and make it possible to reuse many packaging materials in the interests of preventing wastage of raw materials and protecting the environment;
8. Consequently finds the table attached to the directive unsatisfactory since the migration tests do not involve a sufficient number of simulants to give consumers the greatest possible guarantees and therefore calls upon the Commission to revise the table as soon as possible;
9. Also considers it essential that a European guarantee mark be devised for packaging made of plastic materials, with labelling giving information about possible reuse of the packaging;
10. Also calls on the Commission to consider as soon as possible the problem of packaging - whether of plastic or other materials exposed to high temperatures - and to submit proposals to ensure that they are safe;
11. Calls upon the Commission to draw up as soon as possible rules, at present lacking, for plastic materials composed of two or more layers, one or more of which consists of plastics, as also for elastomers and other materials which come into contact with foodstuffs;
12. Instructs its President to forward this resolution, as the opinion of the European Parliament, to the Council, the Commission and the Governments of the Member States.

EXPLANATORY STATEMENT1. GENERAL ASPECTS OF THE PROBLEM OF PLASTIC PACKAGING

1.1. Most foodstuffs, whether liquid or solid, are packaged in plastic materials, which are now becoming increasingly popular because of their low specific weight, their durability and their generally low cost. However, the unconditional use of this type of packaging can pose a serious threat to consumers since these containers may transfer to the product which they contain monomers, oligomers with a low molecular weight, additives used in the polymerization process and products caused by thermal decomposition during the manufacturing stage.

1.2. There are various factors which influence both the type and quantity of migration, but the main ones are the period of contact, the soluble properties of the chemical substances present in the plastic material and the solvent properties of the foodstuff concerned.

1.3. In general, the highest extractive capacity, and thus the greatest potential risk, is to be found in beverages and foodstuffs which are acid or alcoholic, or which have a high fat content, such as oils, animal and vegetable fats, milk, dairy products, cheese, yoghurt, aerated beverages, vinegar, wine and so on, many of which are consumed in large quantities by children.

1.4. It is therefore very important to determine cases in which migration of constituents from the packaging to the foodstuff is possible, and this depends on three basic factors:

- (a) the nature of the material which comes into contact with the foodstuff;
- (b) the nature of the foodstuff which comes into contact with the material;
- (c) the conditions under which the contact takes place (length of time, temperature, etc.).

1.5. It must be stressed, however, that in this complex field there is a lack of adequate scientific and technical information, while in addition the results are not yet available from the studies instigated by the Commission on the toxicity and risk of migration of constituents of plastic materials and on various controversial aspects of questions concerning fatty foodstuffs when they come into contact with plastic packaging materials. That is why particular caution must be exercised by the legislator in order to avoid damage to the health of consumers which could prove permanent.

2. DIRECTIVE 82/711 OF 18 OCTOBER 1982 WHICH THE PRESENT PROPOSAL IS DESIGNED TO SUPPLEMENT

2.1. The present proposal for a directive is intended to supplement 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, which in the opinion of your rapporteur has numerous shortcomings that need to be rectified. For example,

it refers to the danger to human health which could arise from the migration to foodstuffs of substances which could 'bring about an unacceptable change in the composition of the foodstuffs', but fails to mention that in many cases the packaging can also produce a change in the organoleptic characteristics of the foodstuffs. It also states that 'in the current state of analytical techniques, it is not possible to determine all the conditions under which conventional migration tests should be performed on materials and articles consisting of two or more layers, one or more of which does not consist entirely of plastics...'. This statement is questionable, however, since 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' (Article 1(4)).

2.2. Since Directive 82/711/EEC does not apply to 'elastomers and natural synthetic rubber (Art. 1, 2 (iii)) - even though these products are harmful to the health of consumers in more respects than are plastic materials - nor to "mixtures of ... waxes ... with each other and/or with plastics" (Art. 1.3(iv)), it would be desirable for the Commission to submit proposals concerning these materials after dealing with 'homogeneous' plastic materials and materials composed of two or more layers, one or more of which consists of plastics.

2.3. Directive 82/711 has already laid down the simulants to be generally used for testing plastic materials and articles intended to come into contact with foodstuffs, which are as follows:

- 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 (= simulant D),

2.4. It is important to stress the differences between Directive 82/711/EEC and the law of the Italian Republic, which apart from Belgium is the only country to have introduced regulations on this subject. Under the provisions of the Italian law, which are more restrictive, it is possible, for example, in addition to using the simulant acetic acid (3%), to use the same simulant in a higher concentration, corresponding to the concentration actually used. Similarly, the simulant ethanol (15% v/v) may be used in a higher concentration, corresponding to the concentration actually used, for tests involving beverages and products with an alcohol content greater than 15% v/v or, in the case of the former, a concentration in acetic acid greater than 3%. In Italy it is also permitted to use a simulant composed of ethanol in the concentration actually used with 3% acetic acid, a test offering even greater security for consumers.

The provisions of Italian law also differ on the temperatures to be used for certain of the migration tests (70°C in the EEC directive, 80°C under the Italian law).



### 3. REMARKS ON THE PRESENT PROPOSAL FOR A DIRECTIVE

3.1. The present proposal for a directive is intended to cover specific cases, i.e. plastic materials and articles intended to come into contact with a single foodstuff or a group of foodstuffs, classified in the conventional manner on the basis of their composition and the way in which they are preserved, by reproducing in the laboratory the various reactions which occur when they come into contact with plastic packaging materials. For these foodstuffs, simulants are used, in other words substances which simulate the chemical and physical reactions of the foodstuffs to determine the specific extraction capacity of each category of foodstuffs.

3.2. The proposal for a directive states that 'if no simulant is shown for a given foodstuff, the material in contact with this type of foodstuff does not need to be subjected to the migration test since it is considered that there is no risk of transfer of substances from the packaging to the foodstuff'.

It is necessary, however, to take account of the by no means negligible possibility that, even if there is no transfer of substances, there is always a risk of contamination of the volatile constituents produced in the normal conditions under which foodstuffs are preserved.

3.3. It is therefore important to take into consideration not only the nature of the foodstuff but also the actual conditions of contact with the packaging, which include:

- the period of conservation, i.e. the possibility of prolonged contact between the foodstuff and the plastic material, either at room temperature or refrigerated;
- the production process, i.e. the various temperatures prevailing during the different stages of production, where contact is usually of brief duration (pasturization, sterilization, packaging while hot, etc.).

3.4. Fatty or partially fatty foodstuffs are a particularly difficult case and the 'reduction factors' are useful only for the migration of polymers and offer no guarantee in respect of the migration of specific constituents with a low concentration.

3.5. There are also doubts about the possibility of regulating a labelling system which would be appropriate for the various types of packaging as required by Directive 76/893/EEC of 23 November 1976, which states that 'materials and articles not already in contact with foodstuffs must, when placed on the market, be accompanied by (...) any special conditions to be observed when they are being used'.

It would therefore be useful to provide a better definition of these special conditions to enable the final consumer to distinguish and recognize various types of packaging. The proposal for a directive under consideration, however, makes no provision whatsoever for this and would therefore be of little benefit to consumers in the European Community if it were to be applied in its present form.

3.6. In brief, the present proposal for a directive offers no improvements over Directive 82/711. It touches on specific sectors but retains the general character of the previous directive, providing little in the way of consumer guarantees. Particularly apparent are the limitations of the concept of 'global migration', the type of migration peculiar to medium-high boiling compounds, whereas it is well known that one of the most difficult and important problems to be dealt with is that of the 'specific migration' of constituents which are present in low concentrations in the plastic packaging material.

3.7. There is no doubt that the best way of ensuring adequate protection of consumer health is to carry out the migration tests on a sufficient number of simulants to guarantee consumers under all possible conditions. The present proposal for a directive, however, seeks to reduce the number of tests as far as possible, neglecting even those tests which are required by the actual composition of the foodstuff. With this in view, the table listing simulants should be completely revised in line with the indications given in Annex 1. For example, there is no provision for tests using simulant D on egg-based pasta products, bread containing oil or fat, or chocolate containing nuts or fillings made from butter or for tests using simulant C for liqueur chocolates.

3.8. With regard to the opinion drawn up by Mrs Van Hemeldonck on behalf of the Committee on Economic and Monetary Affairs and Industrial Policy, your rapporteur considers that its conclusions should be accepted in their entirety, except that the concept referred to in veiled terms as 'simplification' in paragraph 1 should in some cases be seen for what it is - negligence.

#### 4. QUESTIONS TO THE COMMISSION OF THE EUROPEAN COMMUNITIES

4.1. Can the Commission give details of how the field covered by the present directive is regulated in countries which have no legislation on the subject?

4.2. Can the Commission say on what date and from whom the studies on the toxicity and risk of migration of the constituents of plastic materials and on the specific problems connected with fatty foodstuffs were commissioned? When are these studies expected to be available to the Commission and the European Parliament?

4.3. What instruments do the Commission and Council have at their disposal to implement the present directive in the near future, given that, as is pointed out in paragraph 6 of the Commission's introduction, the 'wide divergence between the various standards applied' means that 'it is impossible to harmonize legislation in a short space of time'?

4.4. Since the adaptation of Directive 82/711 is contingent on the implementation of a specific directive fixing the permissible rate of migration of constituents of plastic materials and articles intended to come into contact with foodstuffs, can the Commission say when it expects a conclusion to be reached in the process begun in 1976 with Directive 76/893 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs?

OPINION

(Rule 101 of the Rules of Procedure)

of the Committee on Economic and Monetary Affairs and Industrial Policy

Draftsman: Mrs Van HEMELDONCK

On 16 October 1984, the Committee on Economic and Monetary Affairs and Industrial Policy appointed Mrs Van Hemeldonck draftsman.

The committee considered the draft opinion at its meeting of 21 November 1984 and unanimously adopted its conclusions.

The following took part in the vote: Mr SEAL, chairman, Mr BEAZLEY, vice-chairman, Mrs van HEMELDONCK, draftsman, Mr ABELIN, Mr BONACCINI, Mr CASSIDY, Mr CHANTERIE (deputizing for Mr I. FRIEDRICH), Mr CHRISTODOULOU (deputizing for Mr BEUMER), Mr GAUTIER, Mr GAWRONSKI (deputizing for Mr DE GUCHT), Mr METTEN, Mrs OPPENHEIM, Mr PATTERSON, Mr RAFTERY and Mr WEDEKIND.

## I. OBJECT OF THE PROPOSAL

The proposal under consideration constitutes a supplement to Council Directive 82/711/EEC of 18 October 1982. This directive lays down the basic rules needed for testing migration of constituents of plastic materials and articles intended to come into contact with all types of foodstuffs.

The new proposal sets out the methods to be used to ascertain the rate of migration only where there is contact with a single foodstuff or a specific group of foodstuffs and no longer in cases of contact with all types of foodstuffs. It is no longer necessary to submit the materials in question to all the tests.

The annex to the proposal therefore lists one or more of the four selected simulants to be used for each foodstuff or group of foodstuffs. Where no simulant is shown a migration test is not required. The use of simulant D (olive oil) includes a reduction factor to take account of the greater extractive capacity of this simulant for fatty foodstuffs compared with certain types of foodstuffs.

The Commission also states that in drafting this proposal it has borne in mind the legislation currently in force in Italy and Belgium and the work of the Council of Europe. It has also obtained the view of the Advisory Committee on Foodstuffs.

## II. OBSERVATIONS

The Committee on Economic and Monetary Affairs and Industrial Policy welcomes the Commission's proposal which aims to harmonize procedures for testing the level of transfer resulting from contact between plastic packaging materials and foodstuffs. More particularly it welcomes the simplification and harmonization of testing procedures for packaging in contact with a single foodstuff or group of foodstuffs. There are still wide divergences between the various legislations in the Community. A progressive reduction in these divergences will facilitate the free movement of packaged products. Plastics are of prime importance in the packaging sector and the elimination of these technical barriers to trade should be accomplished as early as possible.

Progress in this field has, however, been far too slow; the present proposal for a directive relates only to control procedures. Once it is adopted it will doubtless provide an implicit reference for producers but it is unlikely to come into force for some time, as the Member States are not required to comply with the provisions of this directive until they have taken the implementing measures of Directive 82/711/EEC Article 3. In other words the introduction of these testing procedures is contingent on the presentation of supplementary proposals establishing the lists of substances and plastic materials whose use is authorized and the rates of migration allowed.

The slow progress of the procedure followed is regrettable when one considers that the framework directive on the harmonization of legislation on packaging was adopted by the Council on 23 November 1976. It is also regrettable that the studies ordered by the Commission on the toxicity and the risk of migration of the constituent substances of plastic materials, and on a number of controversial aspects of questions concerning fatty foodstuffs in contact with plastic packaging are not yet available.

Even though constant advances are being made in the field of plastic materials the results of these studies could lead to a review of the testing procedures adopted.

As a general rule both the protection of consumers' health and the requirements of the free movement of goods call for Community regulations to be applied to this sector as soon as possible. The producers of plastic materials should also be informed in due time of the standards applicable to packaging made from these products.

In conclusion,

The Committee on Economic and Monetary Affairs and Industrial Policy:

1. Considers the Commission's proposal for a directive, which lays down a simplified Community procedure for testing the migration of constituents of plastic packaging intended to come into contact with a single foodstuff or group of foodstuffs, to be a useful measure;
2. Notes however that this harmonization measure is highly incomplete since it merely supplements the previous Directive 82/711/EEC, which specifies the simulants to be used in the case of plastic materials and articles intended to come into contact with all types of foodstuffs; the entry into force of the directive under consideration, as provided in its Article 3, is contingent on the prior adoption of proposals establishing both a list of substances and plastic materials whose use is authorized and the rates of migration permitted.
3. Stresses, in view of the growing use of plastic packaging, the importance for the Community of eliminating the numerous technical obstacles remaining in this sector, on account of the continuing divergences between national legislations;
4. Regrets deeply in this connection the slow progress of the work currently undertaken and calls therefore on the Commission to put forward rapidly the supplementary proposals necessary for the implementation of the whole body of Community regulations in this field and also to ensure that the results of the current studies on toxicity and the danger of migration are made available in good time;
5. Approves, subject to these reservations, the proposal for the directive and hopes that the Council will adopt it without delay.

