

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(74) 1168 final

Brussels, 23 July 1974

Proposal for a
Council Directive on the approximation of the laws of the
Member States relating to materials and articles intended to come
into contact with foodstuffs

(submitted to the Council by the Commission)

COM(74) 1168 final

EXPLANATORY MEMORANDUM

1. INTRODUCTION

1. It is clear from a comparative study of the provisions laid down by law, regulation or administrative action in force in the Member States concerning materials and articles intended to come into contact with foodstuffs that considerable differences exist as to the composition of the said materials and articles, the limits imposed on the migration of certain constituents, the methods of analysis for the purpose of official controls and the rules on labelling. This gives rise to a situation where on the one hand producers of such materials and articles are compelled to adapt production to the different rules in the various countries of destination while on the other, food products, which themselves comply with Community or national standards are prevented from circulating by the provisions relating to the materials or articles in which they are contained. Approximation of the said laws would therefore seem to be the most suitable method of eliminating the disadvantages caused by their disparities, and hence materials and articles intended to come into contact with foodstuffs are included in the Council Resolution of 17 December 1973 on industrial policy (OJ No C 117, 31 December 1973). By this resolution it was provided that an outline Directive must be adopted before 1 January 1975. It will be followed by implementing Directives as work proceeds in the specific fields. The Council has moreover agreed to give priority to the study of these questions. The object of this Directive is to eliminate the abovementioned differences by approximating the relevant laws. Its legal basis is Article 100 of the Treaty of Rome.

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For the purposes of technical consultation the Commission has set up a subgroup (1) under the auspices of the Working Party on Foodstuffs Legislation consisting of specialised government experts in this field. Professional and trade associations and representatives of consumers in the European Economic Community (2) have also been officially consulted.

II. COMMENTARY ON THE PROPOSAL FOR A DIRECTIVE

1. This Directive is in the form of an outline Directive defining certain general principles on the basis of which it should be possible, by means of subsequent implementing Directives, to eliminate legal differences in the rules now in force in the Member States.

The scope of the Directive is extremely wide, applying to all materials and articles coming into contact or intended to come into contact with foodstuffs (Article 1 (1)). The only material excluded is piping for the public supply of drinking water, since there are special provisions in force in the Member States and these may more simply be approximated by means of a specific Directive on the subject.

The aim of the outline Directive, as with the present national legislation is to protect the consumer not only with regard to health (Article 3) but also as regards information (Article 6)... This is laid down :

- a. the principle of the "stability" of the material or article and the "purity" of the foodstuff (Article 3).
Under this principle not only must the materials and articles be stable on contact with food and not transfer to it any substance which might be dangerous to human health but, health reasons apart, they must not adversely affect the food in any way

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- (1) Member States' experts were consulted at a number of meetings and were most recently asked for their opinions at a meeting of the Working Party on Foodstuffs Legislation" (31 January 1974).
 - (2) Professional and trade associations and representatives of consumers in the EEC were consulted at the following meetings: 16 February 1973 and 20 February 1974.

or bring about undesirable changes in its composition or alter its organoleptic characteristics;

(b) the principle of positive labelling (Article 6),

Under this principle, all materials and articles intended to come into contact with foodstuffs and sold empty by retail must bear the words "for food use" a conventional symbol or, where there is a limitation on use, some indication limiting use as regards certain foodstuffs or types of foodstuffs so that the consumer may be adequately informed and assured that what has been purchased is suitable for domestic use. Provision has also been made to require the name (or business name) and address (or registered office) of the manufacturer or processor or of a retailer established within the Community to be shown on the label, so that in cases where the materials or articles concerned fail to comply with the prescribed standards the party responsible may be identified. It should also be pointed out that, in the interests of consumers, Member States retain the right to require that information concerning labelling be provided in their respective languages.

2. These basic principles will be put into effect by means of a number of specific Directives for the various types of material (for example plastics, pottery, paper and cardboard, etc.), containing from among the various provisions envisaged in Article 4 those best calculated, having regard to the special technological features of each type of material, to ensure that the principles contained in the outline Directive will be observed.

Attention is drawn to the rule provided for in Article 4 (1) (a), which establishes the principle of the "positive list", where this rule is incorporated in a specific Directive, then only duly authorised substances which comply with the conditions and limitations prescribed (Article 4 (1) (b) (c) and (d)) may be used in the manufacture of the materials and articles concerned. In such cases the admissibility of a new substance and the conditions and

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limitations governing it will be decided in accordance with the procedure laid down in Article 9.

By way of derogation from this rule, the Directive provides that a Member State may grant a temporary authorisation valid at national level until a valid final decision applicable at Community level has been taken.

Attention is also drawn to Article (4) (1) (e), which establishes the principle of "overall migration limit". This provision imposes limits on the transfer of "extraneous" substances from the material or article to the food with which it comes into contact. Serious contamination of food is thus avoided, and the consumer is assured of the purity of the product he has purchased, while at the same time there is a reduction in the number of specific migration limits needing to be fixed and enforced for substances of toxicological significance.

3. The outline Directive contains, moreover, in addition to the usual provisions concerning marketing contained in all Directives concerning harmonisation of laws in the foodstuffs sector, (Articles 2 and 7) the so-called "safeguard clause" (Article 5). Under this provision a Member State may prohibit or limit the use of a substance in a material or article even though this is permitted under the rules laid down in the relevant specific Directive, if such substances may be injurious to human health. In this case the measures adopted by the Member State remain in force until a Decision is taken at Community level.

The methods of sampling and analysis required for the purpose of checking compliance with the provisions laid down in the specific Directives are also to be adopted by Committee procedure (Article 8).

Member States have the customary period of one year in which to incorporate the provisions of the Directive into their national laws. Finally, in order to facilitate the adaptations to the new requirements laid down in this Directive of the processes used in the manufacture of the materials and articles concerned, it is provided that the rules will apply only to materials and articles manufactured in or imported into the Community two years after the notification of the Directive (Article 11).

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III. CONSULTATIONS WITH THE EUROPEAN PARLIAMENT AND THE
ECONOMIC AND SOCIAL COMMITTEE

Under the second paragraph of Article 100 of the EEC Treaty, consultation is required since the Directive involves amendments to the laws of all the Member States.

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THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 100 and 227 thereof;

Having regard to the proposal from the Commission;

Having regard to the Opinion of the European Parliament;

Having regard to the Opinion of the Economic and Social Committee;

Whereas laws relating to materials and articles intended to come in their finished state into contact with products intended for human consumption should take account primarily of human health requirements but also, within the limits laid down for the protection of health, of economic and technological requirements;

Whereas the manufacture and sale both of foodstuffs packaged in the said materials and articles and of the materials and articles themselves is of considerable importance in the common market;

Whereas the existing differences between the national laws relating to the said materials and articles hinder the free movement of foodstuffs packaged therein and of the materials and articles themselves and may create unequal conditions of competition, thereby directly affecting the establishment or functioning of the common market;

Whereas, if free movement is to be achieved in respect of foodstuffs packaged in the aforesaid materials and articles and of the materials and articles themselves, it is necessary that such laws be approximated;

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Whereas the first step should be to lay down, in an outline Directive, general principles on the basis of which differences in the relevant laws may subsequently be eliminated by means of implementing Directives;

Whereas the principle underlying the present Directive should be that any material or article intended to come into contact with foodstuffs must be sufficiently stable not to transfer substances to the foodstuffs in quantities which might prove dangerous to human health or bring about an undesirable change in the composition or in the organoleptic characteristics of the said foodstuffs;

Whereas, in order to achieve this object, it may prove necessary to establish a list of substances (with purity standards and conditions of use) in respect of the substances whose use is authorised in the manufacture of the materials and articles concerned and to lay down overall and/or specific migration and other limits;

Whereas specific Directives should be drawn up to deal with the different types of material, and whereas each should contain those of the provisions indicated in the outline Directive which are best calculated, having regard to the particular technical characteristics of the type of material concerned, to achieve the objectives laid down in that outline Directive;

Whereas, in order that consumers may be properly informed as to their correct use, it should be provided that all such materials and articles sold empty by retail are to bear the words "for food use" or a conventional symbol;

Whereas in order to encourage technical development, Member States should be allowed to permit temporarily in their own territory and under official control the use pending a final decision at Community level of substances not covered by the relevant specific Directives;

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Whereas, should it appear subsequently that the use of a substance in a material or article may be a health risk, Member States must be able to suspend or limit such use until a decision at Community level is taken;

Whereas the updating of the list of substances which may be used in the manufacture of the relevant materials and articles and the laying down of detailed rules relating to the methods of sampling and analysis required for the purpose of checking compliance with such list, of purity standards, of conditions of use in respect of the constituent substances, and of the prescribed overall and specific migration limits are implementing measures of a technical nature; and whereas, in order to simplify and speed up procedure, the task of adopting such measures should be entrusted to the Commission;

Whereas it is desirable that for all cases where the Council empowers the Commission to implement the rules laid down in respect of materials and articles intended to come into contact with foodstuffs provision should be made for a procedure establishing close co-operation between the Member States and the Commission within the Standing Committee for Foodstuffs set up by the Council Decision of 13 November 1969 (1);

Whereas, in order to facilitate the adaptation to the new requirements laid down herein of the processes used in the manufacture of the materials and articles concerned, it should be provided that the rules are to apply only to materials and objects manufactured in or imported into the Community two years after the notification of this Directive:

HAS ADOPTED THIS DIRECTIVE :

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(1) OJ No L 291, 19.11.1969, p.9

Article 1

1. This Directive applies to materials and articles which come or are intended to come in their finished state into contact with foodstuffs. Such materials and articles are hereinafter called "materials and articles".
2. For the purposes of this Directive,
 - a) chewing gum and drinking water, including "beverage waters", shall be regarded as foodstuffs;
 - b) tobacco and products with a tobacco base shall not be regarded as foodstuffs.

However, this Directive shall not apply to piping for the public supply of drinking water.

Article 2

The Member States shall take all provisions necessary to ensure that foodstuffs may be marketed only if the materials and articles with which they are in contact comply with the rules laid down in this Directive.

They shall also see to it that the said materials and articles themselves may be marketed, or used only if they comply with the said rules.

Article 3

Materials and articles must not, under their normal or foreseeable conditions of use, transfer their constituents to foodstuffs in a quantity liable either to endanger human health or to entail an undesirable change in the composition of, or a deterioration in the organoleptic characteristics of the said foodstuffs.

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Article 4

1. The Council shall adopt, under the procedure provided for in Article 100 and by means of Directives, special provisions applicable to particular groups of materials and articles (specific Directives). Such Directives may include in particular:

- a) a list of substances the use of which is authorised, to the exclusion of all others;
- b) purity standards for such substances;
- c) special conditions of use for these substances and/or the materials and articles in which they have been used;
- d) specific limits on the migration of certain specified constituents or groups of constituents into or onto foodstuffs;
- e) an overall limit on the migration of constituents into or onto foodstuffs;
- f) other rules designed to ensure that the provisions of Article 3 are complied with;
- g) the basic rules necessary for the purpose of checking compliance with the provisions referred to in d), e) and f).

2. Amendments on account of the growth of scientific and technical knowledge shall be made as follows:

- in respect of the provisions referred to in paragraph 1 a), b), c) and d) under the procedure provided for in Article 9;
- in respect of the provisions referred to in paragraph 1 e), f), g), under the procedure provided for in the relevant specific Directives.

3. By way of derogation from Article 2, any Member State may, where pursuant to paragraph 1 a) a list of substances has been established, authorise the use within its territory and under its official control of a substance not included in that list.

Each Member State shall within two months inform the other Member States and the Commission of every authorisation under the preceding subparagraph and shall furnish evidence in support of such authorisation.

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Within a reasonable period following authorisation of a substance by a Member State, a decision shall be taken under the procedure provided for in Article 9 to determine whether the substance may be included in the list as referred to in paragraph 1 a) or whether authorisation should be revoked.

Article 5

1. Where a Member State considers that the use of a material or article complying with the special provisions referred to in Article 4 (1) might endanger human health, that Member State may temporarily suspend or restrict the application of the provisions in question. It shall forthwith inform the other Member States and the Commission of the measures taken and of the reasons for such measures.
2. A decision shall be taken forthwith under the procedure laid down in Article 9 in order to determine whether amendments should be adopted or whether the measures taken by the Member States should be revoked. Until a decision has been so taken, the measures taken by the Member State may remain operative.

Article 6

1. Without prejudice to the rules contained in the specific Directives, all materials and articles marketed as such must be accompanied by the following:
 - a) one or more of the following indications as appropriate :
 - "for food use"
 - "pour contact alimentaire"
 - "til levnedsmidler"
 - "für Lebensmittel"
 - "per alimenti"
 - "voor levensmiddelen";
 - or a symbol to be determined in accordance with the procedure laid down in article 9;
 - b) particulars of any special conditions of use fixed pursuant to Article 4 paragraph 1 c); or
 - c) particulars either,
 - of the name or corporate name and address or registered office, or
 - of the registered trade mark of the manufacturer or processor, or of a seller established within the Community.

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2. The items specified in the preceding paragraph must be indicated, in indelible characters and in such manner as to be clearly visible and easily legible:

- either on the materials or articles themselves; or
- on labels affixed to the said materials or articles or to their packaging.

However, in the case of transactions prior to the retail stage such items may be indicated on the accompanying documents.

3. However, any Member State may prohibit retail trade in materials and articles on its territory if the items specified in paragraph 1 a) and b) are not shown in its national language or languages on the labels or packaging.

Article 7

1. Member States shall take all necessary measures to ensure that the marketing

- of foodstuffs which are in contact with materials or articles complying with the rules laid down in this Directive; or
- of the said materials and articles themselves

cannot be hindered by the application of non-harmonised national provisions governing the composition, behaviour in the presence of foodstuffs or labelling of such materials and articles.

2. Paragraph 1 shall not apply in respect of non-harmonised provisions justified on grounds of:

- protection of public health;
- suppression of fraud, unless such provisions are liable to impede the application of the rules laid down by this Directive;
- protection of industrial and commercial property, indications of source or prevention of unfair competition.

Article 8

The sampling procedures and methods of analysis required in order to check compliance with provisions laid down pursuant to Article 4 paragraph 1 a), b), c), d), e) or f) shall be determined in accordance with the procedure laid down in Article 9.

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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 the Council Decision of 13 November 1969 (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 Committee shall submit to the Commission 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 10

This Directive does not apply to materials and articles or foodstuffs intended to be exported outside the Community.

Article 11

1. Member States shall within one year following notification of this Directive make such amendments to their laws as may be necessary in order to comply with its provisions and shall forthwith inform the Commission thereof. The laws so amended shall apply to materials and articles and foodstuffs manufactured in or imported into the Community on or after a date two years from the notification of this Directive.

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However, Article 7 shall become applicable only as and when the relevant special provisions adopted pursuant to Article 4 (1) come into force.

- 2. Following notification of this Directive, Member States shall further see to it that the Commission is informed, before their adoption and in good time to enable it to submit its comments, of any major provisions by way of law, regulation or administrative action subsequently proposed by them in the field governed by this Directive.

Article 12

~~This Directive shall apply also to the French overseas departments.~~

Article 13

~~This Directive is addressed to the Member States.~~