II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

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

(76/893/EEC)

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 (1),

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

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

Whereas the manufacture and sale of these materials and articles are of considerable importance in the common market;

Whereas the existing differences between the national laws relating to the aforesaid materials and articles impede the free movement thereof, may create unequal conditions of competition and may thereby directly affect the establishment or functioning of the common market;

Whereas these laws must be approximated if free movement is to be achieved for the aforesaid materials and articles;

Whereas the first step should be to lay down, in a framework Directive, general principles on the basis of which legal differences may subsequently be eliminated by means of specific Directives;

Whereas covering or coating substances, all or part of which form part of foodstuffs, cannot be considered as being simply in contact with these foodstuffs; whereas, in such a case, account should be taken of possible direct consumption by consumers; whereas the rules laid down in this Directive are therefore unsuitable in such circumstances;

Whereas pending a Community definition of foodstuffs this shall continue to come within the jurisdiction of national legislation; whereas, however, it appears necessary already to specify which materials and articles in contact with water intended for human consumption are subject to the provisions of this Directive;

Whereas this Directive applies only to the behaviour of materials and articles in the presence of foodstuffs with which they come into contact and does not affect the provisions concerning possible effects resulting from direct contact with the human body; whereas, however, it should be possible if necessary to adopt, in

(1) OJ No C 155, 9. 12. 1974, p. 10.
(2) OJ No C 108, 15. 5. 1975, p. 72.

specific Directives, provisions which apply to parts of certain articles which, when used, come into contact simultaneously with the mouth and with foodstuffs;

Whereas, therefore, the principle underlying this Directive should be that any material or article intended to come into 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 characteristics thereof;

Whereas, in order to achieve this objective, it may occasionally prove necessary to list those substances (indicating purity standards and conditions of use) which may be used in the manufacture of the materials and articles concerned and to lay down overall and/or specific migration or other limits;

Whereas specific Directives should indicate those provisions referred to in the framework Directive which are most suitable for achieving the objective laid down, having regard to the technological characteristics of each group of materials and articles;

Whereas, in order that consumers may be properly informed as to their correct use, arrangements should be made for materials and articles retailed in an empty state to bear *inter alia* the indication 'for food use' or more specific particulars regarding their use or an agreed symbol; whereas Member States should, however, be permitted not to require such indication in the case of materials and articles for which neither specific Community Directives nor national provisions exist;

Whereas this Directive does not apply to the labelling of products which, by reason of their behaviour in the presence of foodstuffs, may not come into contact with them;

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

Whereas, should the use in a material or article of a substance provided for in one of the specific Directives appear to constitute a health risk, Member States should be authorized to suspend or limit such use pending a decision at Community level;

Whereas the updating of the list of substances authorized in the manufacture of the materials and articles, 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 overall and specific migration limits which have been laid down, constitute technical implementing measures; whereas, in order to simplify and expedite the procedure, the adoption of these measures should be entrusted to the Commission as regards the said updating inasmuch as the specific Directives provide for this, and as regards the sampling procedures and the methods of analysis inasmuch as the said Directives do not provide otherwise; in the case of the updating procedure the Scientific Committee for Food, set up by Decision 74/234/EEC [1] should, where appropriate, be consulted;

Whereas, it is desirable that for all cases where the Council empowers the Commission to implement rules relating to materials and articles intended to come into contact with 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 Directive 69/414/EEC [2];

Whereas, to enable the processes used in the manufacture of the materials and articles concerned to be adapted to the new requirements laid down in the following provisions, the rules should be applied in such a way as to authorize, two years after notification of this Directive, trade in materials and articles complying with the provisions of this Directive and to prohibit, three years after the notification thereof, trade in and use of materials and articles which do not comply therewith,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to 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. They are herinafter referred to as 'materials and articles'.

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[1] OJ No L 136, 20. 5. 1974, p. 1.
[2] OJ No L 291, 19. 11. 1969, p. 9.

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 the food, shall not be subject to this Directive.

2. This Directive shall apply to materials and articles which are in contact with water intended for human consumption. It shall not, however, apply to fixed public or private water supply equipment.

3. Member States may derogate, wholly or partially, from this Directive as regards 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

The Council shall, under the procedure provided for in Article 100 of the Treaty, adopt by means of Directives special provisions applicable to certain groups of materials and articles (specific Directives).

Such specific Directives may include :

(a) if possible and if necessary, a list of the substances the use of which is authorized 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 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 these materials and articles ;

(g) other rules to ensure compliance with Article 2 ;

(h) the basic rules necessary for checking compliance with (d), (e), (f) and (g).

Article 4

1. Notwithstanding Article 3, a Member State may, where a list of substances has been drawn up in accordance with Article 3 (a), authorize the use within its territory of a substance not included in the list, subject to the following conditions :

(a) the authorization must be limited to a maximum period of three years ;

(b) the Member States must carry out an official check of 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 three-year period provided for in paragraph 1, the Member State may submit to the Commission a request for the inclusion in the list referred to in Article 3 (a) of the substance given national authorization in accordance with paragraph 1. 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 10 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 (b), (c) and (d), these shall be adopted in accordance with the same procedure. Notwithstanding paragraph 1 (a), 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.