

Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs

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THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the Proposal from the Commission,

In cooperation with the European Parliament (1),

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

Whereas Council Directive 76/893/EEC of 23 November 1976 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs (3), as last amended by the act of Accession of Spain and Portugal (4), has been substantially amended on a number of occasions; whereas on making the new amendments to the said Directive, the opportunity should be taken to consolidate the provisions of the existing relevant texts with a view to ensuring legal clarity;

Whereas Directive 76/893/EEC was adopted on the grounds that the differences that existed at that time between the national laws relating to the aforesaid materials and articles impeded the free movement thereof, could create unequal conditions of competition and could thereby directly affect the establishment or functioning of the common market;

Whereas those laws had to be approximated if free movement was to be achieved for the aforesaid materials and articles, taking account primarily of human health requirements but also, within the limits required for the protection of health, of economic and technological needs;

Whereas the chosen method was to lay down, in the first place, in a framework directive, general principles on the basis of which legal differences between certain groups of materials and articles had been and could subsequently be

eliminated by means of specific directives; whereas this method has proved itself and should therefore be retained;

Whereas covering or coating substances, all or part of which form part of foodstuffs, could not be considered to be simply in contact with these foodstuffs: whereas, in that case, account had to be taken of possible direct consumption by consumers; whereas the rules laid down in this Directive are therefore inappropriate in such circumstances;

Whereas the principle underlying this Directive should be that any material or article intended to come into contact or which is intentionally in contact either directly or indirectly with foodstuffs, must be sufficiently stable not to transfer substances to the foodstuffs in quantities which could endanger human health or bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic properties thereof;

Whereas, in order to achieve this objective, it may prove necessary to lay down various types of limitations, alone or in combination; whereas it is appropriate to retain in specific directives those limitations which are most appropriate to the desired objective, having regard to the technological characteristics peculiar to each group of materials and articles;

Whereas, in order to allow the informed use of the materials and articles, appropriate labelling should be provided for; whereas the methods used for such labelling may vary according to the user;

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

Whereas the drafting of specific directives implementing the basic principles and of amendments

thereto constitute technical implementing measures; whereas, in order to simplify and expedite the procedure, the adoption of these measures should be entrusted to the Commission; Whereas the Scientific Committee for Food, set up by Commission Decision 74/234/EEC (5), should be asked for its opinion before provisions liable to affect public health are adopted under specific directives;

Whereas it is desirable that in all cases where the Council empowers the Commission to implement rules relating to foodstuffs, provision should be made for a procedure establishing close cooperation between the Member States and the Commission within the Standing Committee on Foodstuffs set up by Council Decision 69/414/EEC (1)  
HAS ADOPTED THIS DIRECTIVE:

#### Article 1

1. This Directive shall apply to materials and articles which, in their finished state, are intended to be brought into contact with foodstuffs or which are brought into contact with foodstuffs and are intended for that purpose, hereinafter referred to as 'materials and articles'.

Covering or coating substances, such as the substances covering cheese rinds, prepared meat products or fruit, which form part of foodstuffs and may be consumed together with those foodstuffs, shall not be subject to this Directive

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

3. This Directive shall not apply to antiques.

#### Article 2

Materials and articles must be manufactured in compliance with good manufacturing practice so that, under their normal or foreseeable conditions of use, they do not transfer their constituents to foodstuffs in quantities which could:

- endanger human health,
- bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof.

#### Article 3

1. The groups of materials and articles listed in Annex I and, where appropriate, combinations of these materials and articles shall be subject to specific directives.

2. The specific directives, including amendments to existing specific directives, shall be adopted in accordance with the procedure laid down in Article 8.

3. The specific directives may include:

- (a) a list of the substances the use of which is authorized to the exclusion of all others (positive list);
- (b) purity standards for such substances;
- (c) special conditions of use for these substances and/or the materials and articles in which they are used;
- (d) specific limits on the migration of certain constituents or groups of constituents into or onto foodstuffs;
- (e) an overall limit on the migration of constituents into or out of foodstuffs;
- (f) if necessary, provisions aimed at protecting human health against any hazards which might arise through oral contact with materials and articles;
- (g) other rules to ensure compliance with Article 2;
- (h) the basic rules necessary for checking compliance with the provisions of points (d), (e), (f)

and (g);

(i) detailed rules concerning sample taking and the methods of analysis required to check compliance with the provisions of points (a) to (g).

provisions liable to affect public health shall be adopted after consulting the Scientific Committee for Food. They must fulfill the criteria set out in Annex II.

#### Article 4

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

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

(b) the Member State must carry out an official check on materials and articles manufactured from a substance of which it has authorized the use;

(c) materials and articles thus manufactured must bear a distinctive indication which will be defined in the authorization.

2. The Member State shall forward to the other Member States and to the Commission the text of any authorization drawn up pursuant to paragraph 1 within two months of the date of its taking effect.

3. Before the expiry of the two-year period provided for in paragraph 1 (a), the Member State may submit to the Commission a request for the inclusion in the list referred to.

in Article 3 (3) (a) of the substance given national authorization in accordance with paragraph 1 of this Article. At the same time, it shall supply supporting documents setting out the grounds on which it deems such inclusion justified and shall indicate the uses for which this substance is intended

Within 18 months of the submission of the request, a decision shall be taken on the basis of information relating to public health, after consulting the Scientific Committee for Food and in accordance with the procedure laid down in Article 9 as to whether the substance in question may be included in the list referred to in Article 3 (a) or whether the national authorization should be revoked. If provisions prove necessary pursuant to Article 3 (3) (b), (c) and (d), these shall be adopted in accordance with the same procedure. Notwithstanding paragraph 1 (a) of this Article, the national authorization shall remain in force until a decision is taken on the request for inclusion in the list.

Should it be decided pursuant to the preceding subparagraph that the national authorization should be revoked, this decision shall apply to any other national authorization in respect of the substance in question. The decision may stipulate that the ban on the use of this substance shall extend to uses other than those referred to in the request for inclusion in the list.

#### Article 5

1. Where a Member State, as a result of new information or of a reassessment of existing information made since one of the specific directives was adopted, has detailed grounds for establishing that the use of a material or article endangers human health although it complies with the relevant specific directive, that Member State may temporarily suspend or restrict application of the provisions in question within its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision

2. The Commission shall examine as soon as possible within the Standing Committee on Foodstuffs the grounds adduced by the Member State referred to in Paragraph 1 and shall deliver its opinion without delay and take the appropriate measures.

3. If the Commission considers that amendments to the specific directives in question are necessary in order to remedy the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure laid down in Article 9 with a view to adopting those amendments; the Member State which has adopted safeguard measures may in

that event retain them until the amendments have been adopted.

#### Article 6

1. Without prejudice to any exceptions provided for in the specific directives, materials and articles not already in contact with foodstuffs must, when placed on the market, be accompanied by:

(a) - the words 'for food use',

- or a specific indication as to their use, such as coffee-machine, wine bottle, soup spoon,
- or a symbol determined in accordance with the procedure laid down in Article 9;

(b) where appropriate, any special conditions to be observed when they are being used:

(c) - either the name or trade name and the address or registered office,

- or the registered trade mark,

of the manufacturer or processor, or of a seller established within the Community.

2. The particulars listed in paragraph 1 must be conspicuous, clearly legible and indelible:

(a) at the retail stage:

- on the materials and articles or on the packaging,
- or on labels affixed to the materials and articles or to their packaging,
- or on a notice in the immediate vicinity of the materials and articles and clearly visible to purchasers; in the case mentioned in paragraph 1 (e), however, the latter option shall only be open if these particulars or a label bearing them cannot, for technical reasons, be affixed to the said materials and articles at either the manufacturing or the marketing stage;

(b) at the marketing stages other than the retail stage:

- on the accompanying documents,
- on the labels or packaging,
- or on the materials and articles themselves.

3. However, the particulars provided for in paragraph 1 shall not be compulsory for materials and articles which by their nature are clearly intended to come into contact with foodstuffs.

4. The particulars provided for in paragraph 1 (a) and (b) shall be confined to materials and articles which comply:

(a) with the criteria laid down in Article 2;

(b) with the specific directives, in the absence of such directives, with any national provisions.

5. The specific directives shall require that such materials and articles be accompanied by a written declaration attesting that they comply with the rules applicable to them.

In the absence of specific directives, Member States may retain existing provisions or adopt provisions to this effect.

6. Member States shall ensure that retail trade in materials and articles is prohibited if the particulars required under paragraph 1 (a) and (b) are not given in a language easily understood by purchasers, unless the purchaser is informed by other means. This provision shall not preclude such particulars appearing in several languages.

#### Article 7

1. Member States shall not, for reasons relating to composition, behaviour in the presence of foodstuffs or labelling, prohibit or restrict either trade in or the use of materials and articles complying with this Directive or with the specific directives.

2. Paragraph 1 shall not affect national provisions which are applicable in the absence of the specific directives.

#### Article 8

Amendments made to existing specific directives in order to bring them into line with this Directive shall be adopted in accordance with the procedure laid down in Article 9.

## Article 9

1. Where the procedure laid down in this Article is to be followed, the chairman shall refer the matter to the Standing Committee on Foodstuffs either on his own initiative or at the request of the representative of a Member State.

2. The Commission representative shall submit to the committee a draft of measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the qualified majority laid down in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the intended measures when they are in accordance with the committee's opinion;

(b) where the intended measures are not in accordance with the opinion of the committee, or in the absence of any opinion, the Commission shall forthwith submit to the Council a proposal relating to the measures to be taken. The Council shall act on a qualified majority.

If, on the expiry of three months from the date on which the matter was referred to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures and apply them immediately.

## Article 10

1. Directive 76/893/EEC is hereby repealed

2. References to the Directive repealed under paragraph 1 shall be construed as references to this Directive.

References to the Articles of the repealed Directive should be read in accordance with the correlation table appearing in Annex III.

## Article 11

1. Member States shall take all measures necessary to comply with this Directive. They shall forthwith inform the Commission thereof. The measures taken shall:

- permit, not later than 18 months after notification (1), trade in and use of materials and articles complying with this Directive, without prejudice to the application of national provisions which, in the absence of specific directives, apply to certain groups of materials and articles;

- prohibit not later than 36 months after notification trade in and use of materials and articles which do not comply with this Directive.

2. Paragraph 1 shall not affect those national provisions which, in the absence of the specific directives, apply to certain groups of materials and articles intended to come into contact with foodstuffs.

## Article 12

This Directive shall not apply to materials and articles intended for export outside the Community.

## Article 13

This Directive is addressed to the Member States.

Done at Brussels, 21 December 1988.

For the Council The President

V. PAPANDREOU

(1) This Directive was notified to the Member States on 10 January 1989

## ANNEX I

List of groups of materials and articles covered by specific directives

Plastics, including varnish and coatings

Regenerated cellulose

Elastomers and rubber

Paper and board

Ceramics

Glass

Metals and alloys

Wood, including cork

Textile products

Paraffin waxes and micro-crystalline waxes

## ANNEX II

Health criteria to be applied in the drafting of specific directives

1. Where appropriate, Positive lists of substances shall be established for materials and articles intended to come into contact with foodstuffs. The acceptability of a substance for inclusion in a positive list shall be determined by considering both the quantity of the substance which is liable to migrate into foodstuffs and the toxicity of the substance

2. A substance shall only be included in a positive list where, under normal or foreseeable conditions of use of any material or article of which it forms a part, the substance is not liable to migrate into foodstuffs in a quantity likely to constitute a danger to human health

3. For certain materials it may be inappropriate to establish a positive list because such a list would offer no tangible benefit in terms of safeguarding human health. In such circumstances, any substances for which specific migration limits need to be established in order to prevent their being transferred to foodstuffs in quantities likely to constitute a danger to health shall be identified. The criteria set out in paragraphs 1 and 2 shall also apply to these substances

4. All substances shall be kept under review and reassessed whenever this is justified by fresh scientific data or a re-evaluation of existing scientific data

5. Where an acceptable daily intake or a tolerable daily intake is established for a particular substance, the need to establish a specific migration limit in order that this intake is not exceeded shall be considered. Where such a specific migration limit is established for a substance, due regard shall be paid to other possible sources of exposure to the substance

6. In certain circumstances, a specific migration limit on a substance may not be the most valid means of safeguarding human health. In such circumstances, the need to protect human health shall be the primary consideration in determining what action might be appropriate.

## ANNEX III missing