REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 27 October 2004

on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [2],

Whereas:

(1) 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 [3] established general principles for eliminating the differences between the laws of the Member States as regards those materials and articles and provided for the adoption of implementing directives concerning specific groups of materials and articles (specific directives). This approach was successful and should be continued.

(2) The specific directives adopted under Directive 89/109/EEC in general contain provisions which leave little room for the exercise of discretion by the Member States in their transposition besides being subject to frequent amendments required to adapt them rapidly to technological progress. It should therefore be possible for such measures to take the form of regulations or decisions. At the same time it is appropriate to include a number of additional subjects. Directive 89/109/EEC should therefore be replaced.

(3) The principle underlying this Regulation is that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties.

(4) New types of materials and articles designed to actively maintain or improve the condition of the food (active food contact materials and articles) are not inert by their design, unlike traditional materials and articles intended to come into contact with food. Other types of new materials and articles are designed to monitor the condition of the food (intelligent food contact materials and articles). Both these types of materials and articles may be brought into contact with food. It is therefore necessary, for reasons of clarity and legal certainty, for active and intelligent food contact materials and articles to be included in the scope of this Regulation and the main requirements for their use to be established. Further requirements should be stated in specific measures, to include positive lists of authorised substances and/or materials and articles, which should be adopted as soon as possible.

(5) Active food contact materials and articles are designed to deliberately incorporate 'active' components intended to be released into the food or to absorb substances from the food. They should be distinguished from materials and articles which are traditionally used to release their natural ingredients into specific types of food during the process of their manufacture, such as wooden barrels.

(6) Active food contact materials and articles may change the composition or the organoleptic properties of the food only if the changes comply with the Community provisions applicable to food, such as the provisions of Directive 89/107/EEC [4] on food additives. In particular, substances such as food additives deliberately incorporated into certain active food contact materials and articles for release into packaged foods or the environment surrounding such foods, should be authorised under the relevant Community provisions applicable to food and also be subject to other rules which will be established in a specific measure.

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[1] OJ C 117, 30.4.2004, p. 1.

[2] Opinion of the European Parliament of 31 March 2004 (not yet published in the Official Journal) and Council Decision of 14 October 2004.

[3] OJ L 40, 11.2.1989, p. 38. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

[4] Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption (OJ L 40, 11.2.1989, p. 27). Directive as last amended by Regulation (EC) No 1882/2003.

In addition, adequate labelling or information should support users in the safe and correct use of active materials and articles in compliance with the food legislation, including the provisions on food labelling.

(7) Active and intelligent food contact materials and articles should not change the composition or the organoleptic properties of food or give information about the condition of the food that could mislead consumers. For example, active food contact materials and articles should not release or absorb substances such as aldehydes or amines in order to mask an incipient spoilage of the food. Such changes which could manipulate signs of spoilage could mislead the consumer and they should therefore not be allowed. Similarly, active food contact materials and articles which produce colour changes to the food that give the wrong information concerning the condition of the food could mislead the consumer and therefore should not be allowed either.

(8) Any material or article intended to come into contact with food which is placed on the market should comply with the requirements of this Regulation. Nevertheless, materials and articles supplied as antiques should be excluded as they are available in restricted quantities and their contact with food is therefore limited.

(9) Covering or coating materials forming part of the food and possibly being consumed with it should not fall within the scope of this Regulation. On the other hand, this Regulation should apply to covering or coating materials which cover cheese rinds, prepared meat products or fruit but which do not form part of food and are not intended to be consumed together with such food.

(10) It is necessary to lay down various types of restrictions and conditions for the use of the materials and articles covered by this Regulation and the substances used in their manufacture. It is appropriate to establish those restrictions and conditions in specific measures having regard to the technological characteristics specific to each group of materials and articles.

(11) Pursuant to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [1], the European Food Safety Authority (the Authority) should be consulted before provisions liable to affect public health are adopted under specific measures.

(12) When specific measures include a list of substances authorised within the Community for use in the manufacture of materials and articles intended to come into contact with food, those substances should undergo a safety assessment prior to their authorisation. The safety assessment and authorisation of those substances should be without prejudice to the relevant requirements of the Community legislation concerning the registration, evaluation, authorisation and restriction of chemicals.

(13) Differences between national laws, regulations and administrative provisions concerning the safety assessment and authorisation of substances used in the manufacture of materials and articles intended to come into contact with food may hinder the free movement of those materials and articles, creating conditions of unequal and unfair competition. An authorisation procedure should therefore be established at Community level. In order to ensure harmonised safety assessment of those substances, the Authority should carry out such assessments.

(14) The safety assessment of substances should be followed by a risk management decision as to whether those substances should be entered on a Community list of authorised substances.

(15) It is appropriate to provide for the possibility of an administrative review of specific acts or omissions on the part of the Authority under this Regulation. This review should be without prejudice to the role of the Authority as an independent scientific point of reference in risk assessment.

(16) Labelling supports users in the correct use of the materials and articles. Methods used for such labelling may vary according to the user.

(17) Commission Directive 80/590/EEC [2] introduced a symbol that may accompany materials and articles intended to come into contact with foodstuffs. This symbol should, for reasons of simplicity, be incorporated in this Regulation.

(18) The traceability of materials and articles intended to come into contact with food should be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility. Business operators should at least be able to identify the businesses from which, and to which, the materials and articles are supplied.

[1] OJ L 31, 1.2.2002, p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

[2] Commission Directive 80/590/EEC of 9 June 1980 determining the symbol that may accompany materials and articles intended to come into contact with foodstuffs (OJ L 151, 19.6.1980, p. 21). Directive as last amended by the 2003 Act of Accession

(19) In the control of the compliance of the materials and articles with this Regulation, it is appropriate to take into account the special needs of developing countries, and in particular of the least developed countries. The Commission has been committed by Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules [1] to support developing countries with regard to food safety, including the safety of the materials and articles in contact with food. Special provisions have therefore been established in that Regulation which should be applicable also to the food contact materials and articles.

(20) It is necessary to establish procedures for the adoption of safeguard measures in situations where a material or article is likely to constitute a serious risk to human health.

(21) Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents [2] applies to documents held by the Authority.

(22) It is appropriate to protect the investment made by innovators in gathering the information and data supporting an application made under this Regulation. In order to avoid unnecessary repetition of studies and in particular animal testing, however, sharing of data should be permitted provided there is agreement between the interested parties.

(23) Community and national reference laboratories should be designated to contribute to a high quality and uniformity of analytical results. This objective will be achieved within the framework of Regulation (EC) No 882/2004.

(24) The use of recycled materials and articles should be favoured in the Community for environmental reasons, provided that strict requirements are established to ensure food safety and consumer protection. Such requirements should be established taking also into account the technological characteristics of the different groups of materials and articles mentioned in Annex I. Priority should be given to the harmonisation of rules on recycled plastic material and articles as their use is increasing and national laws and provisions are lacking or are divergent. Therefore, a draft of a specific measure on recycled plastic materials and articles should be made available to the public as soon as possible in order to clarify the legal situation in the Community.

(25) The measures necessary for the implementation of this Regulation and amendments to Annexes I and II hereto should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [3].

(26) Member States should lay down rules on sanctions applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Such sanctions must be effective, proportionate and dissuasive.

(27) It is necessary for business operators to have sufficient time to adapt to some of the requirements established by this Regulation.

(28) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States because of the differences between the national laws and provisions and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(29) Directives 80/590/EEC and 89/109/EEC should therefore be repealed,

HAVE ADOPTED THIS REGULATION:

Article 1

Purpose and subject matter

1. The purpose of this Regulation is to ensure the effective functioning of the internal market in relation to the placing on the market in the Community of materials and articles intended to come into contact directly or indirectly with food, whilst providing the basis for securing a high level of protection of human health and the interests of consumers.

[1] OJ L 165, 30.4.2004, p. 1. Regulation as corrected in OJ L 191, 28.5.2004, p. 1.

[2] OJ L 145, 31.5.2001, p. 43.

[3] OJ L 184, 17.7.1999, p. 23

2. This Regulation shall apply to materials and articles, including active and intelligent food contact materials and articles, (hereinafter referred to as materials and articles) which in their finished state:

(a) are intended to be brought into contact with food;

or

(b) are already in contact with food and were intended for that purpose;

or

(c) can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.

3. This Regulation shall not apply to:

(a) materials and articles which are supplied as antiques;

(b) covering or coating materials, such as the materials covering cheese rinds, prepared meat products or fruits, which form part of the food and may be consumed together with this food;

(c) fixed public or private water supply equipment.

Article 2

Definitions

1. For the purposes of this Regulation, the relevant definitions laid down in Regulation (EC) No 178/2002 shall apply, with the exception of the definitions of 'traceability' and 'placing on the market', which shall have the following meanings:

(a) 'traceability': the ability to trace and follow a material or article through all stages of manufacture, processing and distribution;

(b) 'placing on the market': the holding of materials and articles for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves.

2. The following definitions shall also apply:

(a) 'active food contact materials and articles' (hereinafter referred to as active materials and articles) means materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food. They are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food;

(b) 'intelligent food contact materials and articles' (hereinafter referred to as intelligent materials and articles) means materials and articles which monitor the condition of packaged food or the environment surrounding the food;

(c) 'business' means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of manufacture, processing and distribution of materials and articles;

(d) 'business operator' means the natural or legal persons responsible for ensuring that the requirements of this Regulation are met within the business under their control.

Article 3

General requirements

1. Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

(a) endanger human health;

or

(b) bring about an unacceptable change in the composition of the food;

or

(c) bring about a deterioration in the organoleptic characteristics thereof.

2. The labelling, advertising and presentation of a material or article shall not mislead the consumers.

Article 4

Special requirements for active and intelligent materials and articles

1. In the application of Article 3(1)(b) and 3(1)(c), active materials and articles may bring about changes in the composition or organoleptic characteristics of food on condition that the changes comply with the Community provisions applicable to food, such as the provisions of Directive 89/107/EEC on food additives and related implementing measures, or, if no Community provisions exist, with the national provisions applicable to food.

2. Pending the adoption of additional rules in a specific measure on active and intelligent materials and articles, substances deliberately incorporated into active materials and articles to be released into the food or the environment surrounding the food shall be authorised and used in accordance with the relevant Community provisions applicable to food, and shall comply with the provisions of this Regulation and its implementing measures.

These substances shall be considered as ingredients within the meaning of Article 6(4)(a) of Directive 2000/13/EC [1].

3. Active materials and articles shall not bring about changes in the composition or organoleptic characteristics of food, for instance by masking the spoilage of food, which could mislead consumers.

4. Intelligent materials and articles shall not give information about the condition of the food which could mislead consumers.

5. Active and intelligent materials and articles already brought into contact with food shall be adequately labelled to allow identification by the consumer of non-edible parts.

6. Active and intelligent materials and articles shall be adequately labelled to indicate that the materials or articles are active and/or intelligent.

Article 5

Specific measures for groups of materials and articles

1. For the groups of materials and articles listed in Annex I and, where appropriate, combinations of those materials and articles or recycled materials and articles used in the manufacture of those materials and articles, specific measures may be adopted or amended in accordance with the procedure referred to in Article 23(2).

Those specific measures may include:

(a) a list of substances authorised for use in the manufacturing of materials and articles;

(b) list(s) of authorised substances incorporated in active or intelligent food contact materials and articles, or list(s) of active or intelligent materials and articles and, when necessary, special conditions of use for these substances and/or the materials and articles in which they are incorporated;

(c) purity standards for substances referred to in (a);

(d) special conditions of use for substances referred to in (a) and/or the materials and articles in which they are used;

(e) specific limits on the migration of certain constituents or groups of constituents into or on to food, taking due account of other possible sources of exposure to those constituents;

(f) an overall limit on the migration of constituents into or on to food;

(g) provisions aimed at protecting human health against hazards arising from oral contact with materials and articles;

(h) other rules to ensure compliance with Articles 3 and 4;

(i) basic rules for checking compliance with points (a) to (h);

(j) rules concerning the collection of samples and the methods of analysis to check compliance with points (a) to (h);

(k) specific provisions for ensuring the traceability of materials and articles including provisions regarding the duration for retention of records or provisions to allow, if necessary, for derogations from the requirements of Article 17;

(l) additional provisions of labelling for active and intelligent materials and articles;

(m) provisions requiring the Commission to establish and maintain a publicly available Community Register (Register) of authorised substances, processes, or materials or articles;

[1] Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29). Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

(n) specific procedural rules adapting, as necessary, the procedure referred to in Articles 8 to 12, or making it appropriate for the authorisation of certain types of materials and articles and/or processes used in their manufacture, including, where necessary, a procedure for an individual authorisation of a substance, process, or material or article through a decision addressed to an applicant.

2. Existing specific directives on materials and articles shall be amended in accordance with the procedure laid down in Article 23(2).

Article 6

National specific measures

In the absence of specific measures referred to in Article 5, this Regulation shall not prevent Member States from maintaining or adopting national provisions provided they comply with the rules of the Treaty.

Article 7

Role of the European Food Safety Authority

Provisions liable to affect public health shall be adopted after consulting the European Food Safety Authority, hereinafter referred to as 'the Authority'.

Article 8

General requirements for the authorisation of substances

1. When a list of substances as referred to in points (a) and (b) of the second subparagraph of Article 5(1) is adopted, anyone seeking an authorisation for a substance not yet included in that list shall submit an application in accordance with Article 9(1).

2. No substance shall be authorised unless it has been adequately and sufficiently demonstrated that, when used under the conditions to be set in the specific measures, the final material or article satisfies the requirements of Article 3 and, where they apply, Article 4.

Article 9

Application for authorisation of a new substance

1. To obtain the authorisation referred to in Article 8(1), the following procedure shall apply:

(a) an application shall be submitted to the competent authority of a Member State accompanied by the following:

(i) the name and address of the applicant;

(ii) a technical dossier containing the information specified in the guidelines for the safety assessment of a substance to be published by the Authority;

(iii) a summary of the technical dossier;

(b) the competent authority referred to in (a) shall:

(i) acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;

(ii) inform the Authority without delay;

and

(iii) make the application and any supplementary information supplied by the applicant available to the Authority;

(c) the Authority shall without delay inform the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them.

2. The Authority shall publish detailed guidelines concerning the preparation and the submission of the application [1].

Article 10

Opinion of the Authority

1. The Authority shall give an opinion within six months of the receipt of a valid application, as to whether, under the intended conditions of use of the material or article in which it is used, the substance complies with the safety criteria laid down in Article 3 and, where they apply, Article 4.

The Authority may extend the said period by a maximum period of a further six months. In such a case it shall provide an explanation for the delay to the applicant, the Commission and the Member States.

[1] Pending such publication, applicants may consult the 'Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation'. – http://europa.eu.int/comm/food/fs/sc/scf/out82_en.pdf.

2. The Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a time limit specified by the Authority. Where the Authority requests supplementary information, the time limit laid down in paragraph 1 shall be suspended until that information has been provided. Similarly, the time limit shall be suspended for the time allowed the applicant to prepare oral or written explanations.

3. In order to prepare its opinion, the Authority shall:

(a) verify that the information and documents submitted by the applicant are in accordance with Article 9(1)(a), in which case the application shall be regarded as valid, and examine whether the substance complies with the safety criteria laid down in Article 3 and, where they apply, Article 4;

(b) inform the applicant, the Commission and the Member States if an application is not valid.

4. In the event of an opinion in favour of authorising the evaluated substance, the opinion shall include:

(a) the designation of the substance including its specifications;

and

(b) where appropriate, recommendations for any conditions or restrictions of use for the evaluated substance and/or the material or article in which it is used;

and

(c) an assessment as to whether the analytical method proposed is appropriate for the intended control purposes.

5. The Authority shall forward its opinion to the Commission, the Member States and the applicant.

6. The Authority shall make its opinion public, after deletion of any information identified as confidential, in accordance with Article 20.

Article 11

Community authorisation

1. The Community authorisation of a substance or substances shall take place in the form of the adoption of a specific measure. The Commission shall, where appropriate, prepare a draft of a specific measure, as referred to in Article 5, to authorise the substance or substances evaluated by the Authority and specify or change the conditions of its or their use.

2. The draft specific measure shall take into account the opinion of the Authority, relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft specific measure is not in accordance with the opinion of the Authority, the Commission shall provide without delay an explanation for the reasons for the differences. If the Commission does not intend to prepare a draft specific measure after a favourable opinion by the Authority, it shall inform the applicant without delay and provide the applicant with an explanation.

3. Community authorisation in the form of a specific measure, as referred to in paragraph 1, shall be adopted in accordance with the procedure referred to in Article 23(2).

4. After the authorisation of a substance in accordance with this Regulation, any business operator using the authorised substance or materials or articles containing the authorised substance shall comply with any condition or restriction attached to such authorisation.

5. The applicant or any business operator using the authorised substance or materials or articles containing the authorised substance shall immediately inform the Commission of any new scientific or technical information, which might affect the safety assessment of the authorised substance in relation to human health. If necessary, the Authority shall then review the assessment.

6. The granting of an authorisation shall not affect the general civil and criminal liability of any business operator in respect of the authorised substance, the material or article containing the authorised substance, and the food that is in contact with such material or article.

Article 12

Modification, suspension and revocation of authorisation

1. The applicant or any business operator using the authorised substance or materials or articles containing the authorised substance may, in accordance with the procedure laid down in Article 9(1), apply for modification of the existing authorisation.

2. The application shall be accompanied by the following:

(a) a reference to the original application;

(b) a technical dossier containing the new information in accordance with the guidelines referred to in Article 9(2);

(c) a new complete summary of the technical dossier in a standardised form.

3. On its own initiative or following a request from a Member State or the Commission, the Authority shall evaluate whether the opinion or the authorisation is still in accordance with this Regulation, in accordance with the procedure laid down in Article 10, where applicable. The Authority may, where necessary, consult the applicant.

4. The Commission shall examine the opinion of the Authority without delay and prepare a draft specific measure to be taken.

5. A draft specific measure modifying an authorisation shall specify any necessary changes in the conditions of use and, if any, in the restrictions attached to that authorisation.

6. A final specific measure on the modification, suspension or revocation of the authorisation shall be adopted in accordance with the procedure referred to in Article 23(2).

Article 13

Competent authorities of Member States

Each Member State shall notify to the Commission and to the Authority the name and address, as well as a contact point, of the national competent authority or authorities designated to be responsible in its territory for receiving the application for authorisation referred to in Articles 9 to 12. The Commission shall publish the name and address of the national competent authorities as well as the contact points notified in accordance with this Article.

Article 14

Administrative review

Any act adopted under, or failure to exercise, the powers vested in the Authority by this Regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member State or from any person directly and individually concerned.

To this effect a request shall be submitted to the Commission within two months from the day on which the party concerned became aware of the act or omission in question.

The Commission shall take a decision within two months requiring, if appropriate, the Authority to undo its act or to remedy its failure to act.

Article 15

Labelling

1. Without prejudice to the specific measures referred to in Article 5, materials and articles, which are not yet in contact with food when placed on the market, shall be accompanied by:

(a) the words 'for food contact', or a specific indication as to their use, such as coffee machine, wine bottle, soup spoon, or the symbol reproduced in Annex II;

and

(b) if necessary, special instructions to be observed for safe and appropriate use;

and

(c) the name or trade name and, in either case, the address or registered office of the manufacturer, processor, or seller responsible for placing on the market established within the Community;

and

(d) adequate labelling or identification to ensure traceability of the material or article, as described in Article 17;

and

(e) in the case of active materials and articles, information on the permitted use or uses and other relevant information such as the name and quantity of the substances released by the active component so as to enable food business operators who use these materials and articles to comply with any other relevant Community provisions or, in their absence, national provisions applicable to food, including the provisions on food labelling.

2. The information referred to in paragraph 1(a) shall not, however, be obligatory for any articles which, because of their characteristics, are clearly intended to come into contact with food.

3. The information required by paragraph 1 shall be conspicuous, clearly legible and indelible.

4. Retail trade in materials and articles shall be prohibited if the information required under paragraph (1)(a), (b) and (e) is not given in a language easily understood by purchasers.

5. Within its own territory, the Member State in which the material or article is marketed may, in accordance with the rules of the Treaty, stipulate that those labelling particulars shall be given in one or more languages which it shall determine from among the official languages of the Community.

6. Paragraphs 4 and 5 shall not preclude the labelling particulars from being indicated in several languages.

7. At the retail stage, the information required under paragraph 1 shall be displayed on:

(a) the materials and articles or on their packaging;

or

(b) labels affixed to the materials and articles or to their packaging;

or

(c) a notice in the immediate vicinity of the materials and articles and clearly visible to purchasers; for the information referred to in paragraph 1(c), however, this option shall be open only if, for technical reasons, that information or a label bearing it cannot be affixed to the materials and articles at either the manufacturing or the marketing stage.

8. At the marketing stages other than the retail stage, the information required by paragraph 1 shall be displayed on:

(a) the accompanying documents;

or

(b) the labels or packaging;

or

(c) the materials and articles themselves.

9. The information provided for in paragraph 1(a), (b) and (e) shall be confined to materials and articles which comply with:

(a) the criteria laid down in Article 3 and, where they apply, Article 4;

and

(b) the specific measures referred to in Article 5 or, in their absence, with any national provisions applicable to these materials and articles.

Article 16

Declaration of compliance

1. The specific measures referred to in Article 5 shall require that materials and articles covered by those measures be accompanied by a written declaration stating that they comply with the rules applicable to them.

Appropriate documentation shall be available to demonstrate such compliance. That documentation shall be made available to the competent authorities on demand.

2. In the absence of specific measures, this Regulation shall not prevent Member States from retaining or adopting national provisions for declarations of compliance for materials and articles.

Article 17

Traceability

1. The traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.

2. With due regard to technological feasibility, business operators shall have in place systems and procedures to allow identification of the businesses from which and to which materials or articles and, where appropriate, substances or products covered by this Regulation and its implementing measures used in their manufacture are supplied. That information shall be made available to the competent authorities on demand.

3. The materials and articles which are placed on the market in the Community shall be identifiable by an appropriate system which allows their traceability by means of labelling or relevant documentation or information.

Article 18

Safeguard measures

1. When a Member State, as a result of new information or a reassessment of existing information has detailed grounds for concluding that the use of a material or article endangers human health, although it complies with the relevant specific measures, it 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 and give reasons for the suspension or restriction.

2. The Commission shall examine as soon as possible, where appropriate after obtaining an opinion from the Authority, within the Committee referred to in Article 23(1) the grounds adduced by the Member State referred to in paragraph 1 and shall deliver its opinion without delay and take appropriate measures.

3. If the Commission considers that amendments to the relevant specific measures are necessary in order to remedy the difficulties referred to in paragraph 1 and to ensure the protection of human health, those amendments shall be adopted in accordance with the procedure referred to in Article 23(2).

4. The Member State referred to in paragraph 1 may retain the suspension or restriction until the amendments referred to in paragraph 3 have been adopted or the Commission has declined to adopt such amendments.

Article 19

Public access

1. Applications for authorisation, supplementary information from applicants and opinions from the Authority, excluding confidential information, shall be made accessible to the public in accordance with Articles 38, 39 and 41 of Regulation (EC) No 178/2002.

2. Member States shall process applications for access to documents received under this Regulation in accordance with Article 5 of Regulation (EC) No 1049/2001.

Article 20

Confidentiality

1. The applicant may indicate which information submitted under Articles 9(1), 10(2) and 12(2) is to be treated as confidential on the ground that its disclosure might significantly harm its competitive position. Verifiable justification must be given in such cases.

2. Information relating to the following shall not be considered confidential:

(a) the name and address of the applicant and the chemical name of the substance;

(b) information of direct relevance to the assessment of the safety of the substance;

(c) the analytical method or methods.

3. The Commission shall determine, after consultation with the applicant, which information should be kept confidential and shall inform the applicant and the Authority of its decision.

4. The Authority shall supply the Commission and the Member States with all information in its possession on request.

5. The Commission, the Authority and the Member States shall take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation, except for information which must be made public if circumstances so require in order to protect human health.

6. If an applicant withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of commercial and industrial information provided, including research and development information as well as information on which the Commission and the applicant disagree as to its confidentiality.

Article 21

Sharing of existing data

Information given in an application submitted in accordance with Articles 9(1), 10(2) and 12(2) may be used for the benefit of another applicant, provided that the Authority considered that the substance is the same as the one for which the original application was submitted, including the degree of purity and the nature of impurities, and that the other applicant has agreed with the original applicant that such information may be used.

Article 22

Amendments to Annexes I and II

Amendments to Annexes I and II shall be adopted in accordance with the procedure referred to in Article 23(2).

Article 23

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58(1) of Regulation (EC) No 178/2002.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

Article 24

Inspection and control measures

1. Member States shall carry out official controls in order to enforce compliance with this Regulation in accordance with relevant provisions of Community law relating to official food and feed controls.

2. Where necessary and on the request of the Commission, the Authority shall assist in developing technical guidance on sampling and testing to facilitate a coordinated approach for the application of paragraph 1.

3. The Community reference laboratory for materials and articles intended to come into contact with food and national reference laboratories established as laid down in Regulation (EC) No 882/2004 shall assist Member States in the application of paragraph 1 by contributing to a high quality and uniformity of analytical results.

Article 25

Sanctions

Member States shall lay down the rules on sanctions applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive. Member States shall communicate the relevant provisions to the Commission by 13 May 2005 and shall communicate to it without delay any subsequent amendment affecting them.

Article 26

Repeals

Directives 80/590/EEC and 89/109/EEC are repealed.

References to the repealed Directives shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex III.

Article 27

Transitional arrangements

Materials and articles that have been lawfully placed on the market before 3 December 2004 may be marketed until the stocks are exhausted.

Article 28

Entry into force

This Regulation shall enter into force on the 20 th day following that of its publication in the *Official Journal of the European Union*.

Article 17 shall apply from 27 October 2006.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 27 October 2004.

For the European Parliament
J. BORRELL FONTELLES
For the Council
The President
A. NICOLAI
The President

ANNEX I

List of groups of materials and articles which may be covered by specific measures

1. Active and intelligent materials and articles
2. Adhesives
3. Ceramics
4. Cork
5. Rubbers
6. Glass
7. Ion-exchange resins
8. Metals and alloys
9. Paper and board
10. Plastics
11. Printing inks
12. Regenerated cellulose
13. Silicones
14. Textiles
15. Varnishes and coatings
16. Waxes
17. Wood

ANNEX II

Symbol

ANNEX III

Correlation table

Directive 89/109/EEC	This Regulation
Article 1	Article 1
—	Article 2
Article 2	Article 3
—	Article 4
Article 3	Article 5
—	Article 7
—	Article 8
—	Article 9
—	Article 10
—	Article 11
—	Article 12
—	Article 13
—	Article 14
Article 4	—
Article 6	Article 15
—	Article 16
—	Article 17
Article 5	Article 18
Article 7	Article 6
—	Article 19
—	Article 20
—	Article 21
—	Article 22
Article 8	—
Article 9	Article 23
—	Article 24
—	
—	Article 25
Article 10	Article 26
—	Article 27
Article 11	—
Article 12	—
Article 13	Article 28
Annex I	Annex I
Annex II	—
Annex III	Annex III
Directive 80/590/EEC	This Regulation
Annex	Annex II

CORRIGENDA

Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs

(Official Journal of the European Communities L 220 of 15 August 2002)

On page 18, the text of Commission Directive 2002/72/EC shall be replaced by the following:

'COMMISSION DIRECTIVE 2002/72/EC
of 6 August 2002
relating to plastic materials and articles intended to come into contact with foodstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 [1], and in particular Article 3 thereof,

After consulting the Scientific Committee on Food,

Whereas:

(1) Commission Directive 90/128/EEC of 23 February 1990 relating to plastic materials and articles intended to come into contact with foodstuffs [2], as last amended by Directive 2002/17/EC [3], has been frequently and substantially amended; for reasons of clarity and rationality, it should therefore be consolidated.

(2) Article 2 of Directive 89/109/EEC lays down that materials and articles, in their finished state, must not transfer their constituents to foodstuffs in quantities which could endanger human health or bring about an unacceptable change in the composition of the foodstuffs.

(3) In order to achieve this objective in the case of plastic materials and articles, a suitable instrument is a specific Directive within the meaning of Article 3 of Directive 89/109/EEC, the general provisions of which are also applicable to the case in question.

(4) The scope of this Directive must coincide with that of Council Directive 82/711/EEC [4].

(5) Since the rules established in this Directive are not suitable for ion-exchange resins, these materials and articles will be covered by a subsequent specific Directive.

(6) Silicones should be regarded as elastomeric materials rather than plastic materials and therefore should be excluded from the definition of plastic.

(7) The establishment of a list of approved substances accompanied by a limit on overall migration and, where necessary, by other specific restrictions will be sufficient to achieve the objective laid down in Article 2 of Directive 89/109/EEC.

(8) Besides the monomers and other starting substances fully evaluated and authorised at Community level, there are also monomers and starting substances evaluated and authorised in at least one Member State which may continue to be used pending their evaluation by the Scientific Committee on Food and the decision on their inclusion in the Community list; this Directive will accordingly be extended in due course to the substances and sectors provisionally excluded.

(9) The current list of additives is an incomplete list inasmuch as it does not contain all the substances which are currently accepted in one or more Member States; accordingly, these substances continue to be regulated by national laws pending a decision on inclusion in the Community list.

(10) This Directive establishes specifications for only a few substances. The other substances, which may require specifications, therefore remain regulated in this respect by national laws pending a decision at Community level.

(11) For certain additives the restrictions established in this Directive cannot yet be applied in all situations pending the collection and evaluation of all the data needed for a better estimation of the exposure of the consumer in some specific situations; therefore, these additives appear in a list other than that of the additives fully regulated at Community level.

(12) Directive 82/711/EEC lays down the basic rules necessary for testing migration of the constituents of plastic materials and articles and Council Directive 85/572/EEC [5] establishes the list of simulants to be used in the migration tests.

(13) The determination of a quantity of a substance in a finished material or article is simpler than the determination of its specific migration level. The verification of compliance through the determination of quantity rather than specific migration level should therefore be permitted under certain conditions.

(14) For certain types of plastics the availability of generally recognised diffusion models based on experimental data allows the estimation of the migration level of a substance under certain conditions, therefore avoiding complex, costly and time-consuming testing.

[1] OJ L 40, 11.2.1989, p. 38.
[2] OJ L 75, 21.3.1990, corrected by OJ L 349, 13.12.1990, p. 26.
[3] OJ L 58, 28.2.2002, p. 19.
[4] OJ L 297, 23.10.1982, p. 26. Directive as last amended by Directive 97/48/EC (OJ L 222, 12.8.1997, p. 10).
[5] OJ L 372, 31.12.1985, p. 14.

(15) The overall migration limit is a measure of the inertness of the material and prevents an unacceptable change in the composition of the foodstuffs, and, moreover, reduces the need for a large number of specific migration limits or other restrictions, thus giving effective control.

(16) Council Directive 78/142/EEC [1] lays down limits for the quantity of vinyl chloride present in plastic materials and articles prepared with this substance and for the quantity of vinyl chloride released by these materials and articles, and Commission Directives 80/766/EEC [2] and 81/432/EEC [3] establish the Community methods of analysis for controlling these limits.

(17) In view of potential liability, there is a need for the written declaration provided for in Article 6(5) of Directive 89/109/EEC whenever professional use is made of plastic materials and articles which are not by their nature clearly intended for food use.

(18) Commission Directive 80/590/EEC [4] determines the symbol that may accompany any material and article intended to come into contact with foodstuffs.

(19) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of ensuring the free movement of plastic materials and articles intended to come into contact with foodstuffs, to lay down rules on the definition of plastics and permitted substances. This Directive confines itself to what is necessary in order to achieve the objectives pursued in accordance with the third paragraph of Article 5 of the Treaty.

(20) In accordance with Article 3 of Directive 89/109/EEC, the Scientific Committee on Food has been consulted on the provisions liable to affect public health.

(21) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health.

(22) This Directive should be without prejudice to the deadlines set out in Annex VII, Part B within which the Member States are to comply with Directive 90/128/EEC, and the acts amending it,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific Directive within the meaning of Article 3 of Directive 89/109/EEC.

2. This Directive shall apply to plastic materials and articles and parts thereof:

(a) consisting exclusively of plastics; or

(b) composed of two or more layers of materials, each consisting exclusively of plastics, which are bound together by means of adhesives or by any other means,

which, in the finished product state, are intended to come into contact or are brought into contact with foodstuffs and are intended for that purpose.

3. For the purposes of this Directive, "plastics" shall mean the organic macromolecular compounds obtained by polymerisation, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromolecules. Other substances or matter may be added to such macromolecular compounds.

However, the following shall not be regarded as "plastics":

(a) varnished or unvarnished regenerated cellulose film, covered by Commission Directive 93/10/EEC [5];

(b) elastomers and natural and synthetic rubber;

(c) paper and paperboard, whether modified or not by the addition of plastics;

(d) surface coatings obtained from:

— paraffin waxes, including synthetic paraffin waxes, and/or micro-crystalline waxes,

— mixtures of the waxes listed in the first indent with each other and/or with plastics,

(e) ion-exchange resins;

(f) silicones.

4. This Directive shall not apply, until further action by the Commission, 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 2

Plastic materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams per square decimetre of surface area of material or article (mg/dm^2) (overall migration limit). However, this limit shall be 60 milligrams of the constituents released per kilogram of foodstuff (mg/kg) in the following cases:

(a) articles which are containers or are comparable to containers or which can be filled, with a capacity of not less than 500 millilitres (ml) and not more than 10 litres (l);

(b) articles which can be filled and for which it is impracticable to estimate the surface area in contact with foodstuffs;

(c) caps, gaskets, stoppers or similar devices for sealing.

[1] OJ L 44, 15.2.1978, p. 15.
[2] OJ L 213, 16.8.1980, p. 42.
[3] OJ L 167, 24.6.1981, p. 6.
[4] OJ L 151, 19.6.1980, p. 21.
[5] OJ L 93, 17.4.1993, p. 27. Directive amended by Directive 93/111/EC (OJ L 310, 14.12.1993, p. 41).

Article 3

1. Only those monomers and other starting substances listed in Annex II, Sections A and B, may be used for the manufacture of plastic materials and articles subject to the restrictions specified.

2. By way of derogation from the first paragraph the monomers and other starting substances listed in Annex II, Section B, may continue to be used until 31 December 2004 at latest, pending their evaluation by the Scientific Committee on Food.

3. The list in Annex II, Section A, may be amended:

— either by adding substances listed in Annex II, Section B, according to the criteria in Annex II of Directive 89/109/EEC, or

— by including "new substances", i.e. substances which are listed neither in Section A nor in Section B of Annex II, according to Article 3 of Directive 89/109/EEC.

4. No Member State shall authorise any new substance for use within its territory except under the procedure in Article 4 of Directive 89/109/EEC.

5. The lists appearing in Annex II, Sections A and B, do not yet include monomers and other starting substances used only in the manufacture of:

— surface coatings obtained from resinous or polymerised products in liquid, powder or dispersion form, such as varnishes, lacquers, paints, etc.,

— epoxy resins,

— adhesives and adhesion promoters,

— printing inks.

Article 4

An incomplete list of additives, which may be used for the manufacture of plastic materials and articles, together with the restrictions and/or specifications on their use, is set out in Annex III, Sections A and B.

For the substances in Annex III, Section B, the specific migration limits are applied as from 1 January 2004 when the verification of compliance is carried out in simulant D or in test media of substitute tests as laid down in Directives 82/711/EEC and 85/572/EEC.

Article 5

Only the products obtained by means of bacterial fermentation listed in Annex IV may be used in contact with foodstuffs.

Article 6

1. General specifications related to plastic materials and articles are laid down in Annex V, Part A. Other specifications related to some substances appearing in Annexes II, III and IV are laid down in Annex V, Part B.

2. The meaning of the numbers between brackets appearing in the column "Restrictions and/or specifications" is explained in Annex VI.

Article 7

The specific migration limits in the list set out in Annex II are expressed in mg/kg. However, such limits are expressed in mg/dm^2 in the following cases:

(a) articles which are containers or are comparable to containers or which can be filled, with a capacity of less than 500 ml or more than 10 l;

(b) sheet, film or other materials which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of such materials and the quantity of foodstuff in contact therewith.

In these cases, the limits set out in Annex II, expressed in mg/kg shall be divided by the conventional conversion factor of 6 in order to express them in mg/dm^2.

Article 8

1. Verification of compliance with the migration limits shall be carried out in accordance with the rules laid down in Directives 82/711/EEC and 85/572/EEC and the further provisions set out in Annex I.

2. The verification of compliance with the specific migration limits provided for in paragraph 1 shall not be compulsory, if it can be established that compliance with the overall migration limit laid down in Article 2 implies that the specific migration limits are not exceeded.

3. The verification of compliance with the specific migration limits provided for in paragraph 1 shall not be compulsory, if it can be established that, by assuming complete migration of the residual substance in the material or article, it cannot exceed the specific limit of migration.

4. The verification of compliance with the specific migration limits provided for in paragraph 1 may be ensured by the determination of the quantity of a substance in the finished material or article provided that a relationship between that quantity and the value of the specific migration of the substance has been established either by an adequate experimentation or by the application of generally recognised diffusion models based on scientific evidence. To demonstrate the non-compliance of a material or article, confirmation of the estimated migration value by experimental testing is obligatory.

Article 9

1. At the marketing stages other than the retail stages, the plastic materials and articles which are intended to be placed in contact with foodstuffs shall be accompanied by a written declaration in accordance with Article 6(5) of Directive 89/109/EEC.

2. Paragraph 1 does not apply to plastic materials and articles which by their nature are clearly intended to come into contact with foodstuffs.

Article 10

1. Directive 90/128/EEC, as amended by the Directives set out in Annex VII, Part A, is hereby repealed without prejudice to the obligations of the Member States in respect of the deadlines for transposition and application laid down in Annex VII, Part B.

2. References to the repealed Directives shall be construed as references to this Directive and be read in accordance with the correlation table set out in Annex VIII.

Article 11

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Communities*.

Article 12

This Directive is addressed to the Member States.

Done at Brussels, 6 August 2002.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

FURTHER PROVISIONS APPLICABLE WHEN CHECKING COMPLIANCE WITH THE MIGRATION LIMITS

General provisions

1. When comparing the results of the migration tests specified in the Annex to Directive 82/711/EEC, the specific gravity of all the simulants should conventionally be assumed to be 1. Milligrams of substance(s) released per litre of simulant (mg/l) will thus correspond numerically to milligrams of substance(s) released per kilogram of simulant and, taking into account the provisions laid down in Directive 85/572/EEC, to milligrams of substance(s) released per kilogram of foodstuff.

2. Where the migration tests are carried out on samples taken from the material or article or on samples manufactured for the purpose, and the quantities of foodstuff or simulant placed in contact with the sample differ from those employed in the actual conditions under which the material or article is used, the results obtained should be corrected by applying the following formula:

$$M = \frac{m \cdot a_2}{a_1 \cdot q} \cdot 1\,000$$

Where:

M is the migration in mg/kg;

m is the mass in mg of substance released by the sample as determined by the migration test;

a_1 is the surface area in dm^2 of the sample in contact with the foodstuff or simulant during the migration test;

a_2 is the surface area in dm^2 of the material or article in real conditions of use;

q is the quantity in grams of foodstuff in contact with the material or article in real conditions of use.

3. The determination of migration is carried out on the material or article or, if that is impracticable, using either specimens taken from the material or article or, where appropriate, specimens representative of this material or article.

The sample shall be placed in contact with the foodstuff or simulant in a manner representing the contact conditions in actual use. For this purpose, the test shall be performed in such a way that only those parts of the sample intended to come into contact with foodstuffs in actual use will be in contact with the foodstuff or simulant. This condition is particularly important in the case of materials and articles comprising several layers, for closures, etc.

The migration testing of caps, gaskets, stoppers or similar devices for sealing must be carried out on these articles by applying them to the containers for which they are intended in a manner which corresponds to the conditions of closing in normal or foreseeable use.

It shall in all cases be permissible to demonstrate compliance with migration limits by the use of a more severe test.

4. In accordance with the provisions set out in Article 8 of the present Directive, the sample of the material or article is placed in contact with the foodstuff or appropriate simulant for a period and at a temperature which are chosen by reference to the contact conditions in actual use, in accordance with the rules laid down in Directives 82/711/EEC and 85/572/EEC. At the end of the prescribed time, the analytical determination of the total quantity of substances (overall migration) and/or the specific quantity of one or more substances (specific migration) released by the sample is carried out on the foodstuff or simulant.

5. Where a material or article is intended to come into repeated contact with foodstuffs, the migration test(s) shall be carried out three times on a single sample in accordance with the conditions laid down in Directive 82/711/EEC using another sample of the food or simulant(s) on each occasion. Its compliance shall be checked on the basis of the level of the migration found in the third test. However, if there is conclusive proof that the level of the migration does not increase in the second and third tests and if the migration limit(s) is (are) not exceeded on the first test, no further test is necessary.

Special provisions relating to overall migration

6. If the aqueous simulants specified in Directives 82/711/EEC and 85/572/EEC are used, the analytical determination of the total quantity of substances released by the sample may be carried out by evaporation of the simulant and weighing of the residue.

If rectified olive oil or any of its substitutes is used, the procedure given below may be followed.

The sample of the material or article is weighed before and after contact with the simulant. The simulant absorbed by the sample is extracted and determined quantitatively. The quantity of simulant found is subtracted from the weight of the sample measured after contact with the simulant. The difference between the initial and corrected final weights represents the overall migration of the sample examined.

Where a material or article is intended to come into repeated contact with foodstuffs and it is technically impossible to carry out the test described in paragraph 5, modifications to that test are acceptable, provided that they enable the level of migration occurring during the third test to be determined. One of these possible modifications is described below.

The test is carried out on three identical samples of the material or article. One of these shall be subjected to the appropriate test and the overall migration determined (M_1). The second and third samples shall be subjected to the same conditions of temperature but the period of contact shall be two and three times that specified and overall migration determined in each case (M_2 and M_3, respectively).

The material or article shall be deemed to be in compliance provided that either M_1 or $M_3 - M_2$ does not exceed the overall migration limit.

7. A material or article that exceeds the overall migration limit by an amount not greater than the analytical tolerance mentioned below should therefore be deemed to be in compliance with this Directive.

   The following analytical tolerances have been observed:

   — 20 mg/kg or 3 mg/dm² in migration tests using rectified olive oil or substitutes,

   — 12 mg/kg or 2 mg/dm² in migration tests using the other simulants referred to in Directives 82/711/EEC and 85/572/EEC.

8. Without prejudice to the provisions of Article 3(2) of Directive 82/711/EEC, migration tests using rectified olive oil or substitutes shall not be carried out to check compliance with the overall migration limit in cases where there is conclusive proof that the specified analytical method is inadequate from a technical standpoint.

   In any such case, for substances exempt from specific migration limits or other restrictions in the list provided in Annex II, a generic specific migration limit of 60 mg/kg or 10 mg/dm², according to the case, is applied. However, the sum of all specific migrations determined shall not exceed the overall migration limit.

ANNEX II

LIST OF MONOMERS AND OTHER STARTING SUBSTANCES WHICH MAY BE USED IN THE MANUFACTURE OF PLASTIC MATERIALS AND ARTICLES

GENERAL INTRODUCTION

1. This Annex contains the list of monomers or other starting substances. The list includes:
   — substances undergoing polymerisation, which includes polycondensation, polyaddition or any other similar process, to manufacture macromolecules,
   — natural or synthetic macromolecular substances used in the manufacture of modified macromolecules, if the monomers or the other starting substances required to synthesise them are not included in the list,
   — substances used to modify existing natural or synthetic macromolecular substances.

2. The list does not include the salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc of the authorised acids, phenols or alcohols which are also authorised. However, names containing "… acid(s), salts" appear in the lists if the corresponding free acid(s) is (are) not mentioned. In each case the meaning of the term "salts" is "salts of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc".

3. The list also does not include the following substances although they may be present:
   (a) substances which could be present in the finished product as:
      — impurities in the substances used,
      — reaction intermediates,
      — decomposition products;
   (b) oligomers and natural or synthetic macromolecular substances as well as their mixtures, if the monomers or starting substances required to synthesise them are included in the list;
   (c) mixtures of the authorised substances.

   The materials and articles which contain the substances indicated under points (a), (b) and (c) shall comply with the requirements stated in Article 2 of Directive 89/109/EEC.

4. Substances shall be of good technical quality as regards the purity criteria.

5. The list contains the following information:
   — column 1 (Ref. No): the EEC packaging material reference number of the substances on the list,
   — column 2 (CAS No): the CAS (Chemical Abstracts Service) registry number,
   — column 3 (Name): the chemical name,
   — column 4 (Restrictions and/or specifications): These may include:
      — specific migration limit (SML),
      — maximum permitted quantity of the substance in the finished material or article (QM),
      — maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm^2 of the surface in contact with foodstuffs (QMA),
      — any other restriction specifically mentioned,
      — any type of specifications related to the substance or to the polymer.

6. If a substance appearing on the list as an individual compound is also covered by a generic term, the restrictions applying to this substance shall be those indicated for the individual compound.

7. Where there is any inconsistency between the CAS number and the chemical name, the chemical name shall take precedence over the CAS number. If there is an inconsistency between the CAS number reported in EINECS and the CAS Registry, the CAS number in the CAS Registry shall apply.

8. A number of abbreviations or expressions are used in column 4 of the table, the meanings of which are as follows:

   DL = Detection limit of the method of analysis;

   FP = Finished material or article;

   NCO = Isocyanate moiety;

   ND = not detectable. For the purpose of this Directive "not detectable" means that the substance should not be detected by a validated method of analysis which should detect it at the detection limit (DL) specified. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the detection limit may be used, pending the development of a validated method;

QM = Maximum permitted quantity of the "residual" substance in the material or article;

QM(T) = Maximum permitted quantity of the "residual" substance in the material or article expressed as total of moiety or substance(s) indicated. For the purpose of this Directive the quantity of the substance in the material or article should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;

QMA = Maximum permitted quantity of the "residual" substance in the finished material or article expressed as mg per 6 dm^2 of the surface in contact with foodstuffs. For the purpose of this Directive the quantity of the substance in the surface of the material or article should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;

QMA(T) = Maximum permitted quantity of the "residual" substance in the material or article expressed as mg of total of moiety or substance(s) indicated per 6 dm^2 of the surface in contact with foodstuffs. For the purpose of this Directive the quantity of the substance in the surface of the material or article should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;

SML = Specific migration limit in food or in food simulant, unless it is specified otherwise. For the purpose of this Directive the specific migration of the substance should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;

SML(T) = Specific migration limit in food or in food simulant expressed as total of moiety or substance(s) indicated. For the purpose of this Directive the specific migration of the substances should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method.

Section A

List of authorised monomers and other starting substances

Ref. No.	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
10030	000514-10-3	Abietic acid	
10060	000075-07-0	Acetaldehyde	SML(T) = 6 mg/kg ([2])
10090	000064-19-7	Acetic acid	
10120	000108-05-4	Acetic acid, vinyl ester	SML = 12 mg/kg
10150	000108-24-7	Acetic anhydride	
10210	000074-86-2	Acetylene	
10630	000079-06-1	Acrylamide	SML = ND (DL = 0,01 mg/kg)
10660	015214-89-8	2-Acrylamido-2-methylpropanesulphonic acid	SML = 0,05 mg/kg
10690	000079-10-7	Acrylic acid	
10750	002495-35-4	Acrylic acid, benzyl ester	
10780	000141-32-2	Acrylic acid, n-butyl ester	
10810	002998-08-5	Acrylic acid, sec-butyl ester	
10840	001663-39-4	Acrylic acid, tert-butyl ester	
11000	050976-02-8	Acrylic acid, dicyclopentadienyl ester	QMA = 0,05 mg/6 dm^2
11245	002156-97-0	Acrylic acid, dodecyl ester	SML = 0,05 mg/kg ([1])
11470	000140-88-5	Acrylic acid, ethyl ester	
11510	000818-61-1	Acrylic acid, hydroxyethyl ester	See "Acrylic acid, monoester with ethyleneglycol"
11530	000999-61-1	Acrylic acid, 2-hydroxypropyl ester	QMA = 0,05 mg/6 dm^2
11590	000106-63-8	Acrylic acid, isobutyl ester	
11680	000689-12-3	Acrylic acid, isopropyl ester	
11710	000096-33-3	Acrylic acid, methyl ester	
11830	000818-61-1	Acrylic acid, monoester with ethyleneglycol	
11890	002499-59-4	Acrylic acid, n-octyl ester	
11980	000925-60-0	Acrylic acid, propyl ester	
12100	000107-13-1	Acrylonitrile	SML = ND (DL= 0,020 mg/kg, analytical tolerance included)
12130	000124-04-9	Adipic acid	
12265	004074-90-2	Adipic acid, divinyl ester	QM = 5 mg/kg in FP. Or use only as comonomer
12280	002035-75-8	Adipic anhydride	
12310		Albumin	
12340		Albumin, coagulated by formaldehyde	
12375		Alcohols, aliphatic, monohydric, saturated, linear, primary (C_4-C_{22})	
12670	002855-13-2	1-Amino-3-aminomethyl-3,5,5-trimethylcyclohexane	SML = 6 mg/kg
12761	000693-57-2	12-Aminododecanoic acid	SML= 0,05 mg/kg
12763	000141-43-5	2-Aminoethanol	SML = 0,05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC and for indirect food contact only, behind the PET layer
12765	084434-12-8	N-(2-Aminoethyl)-beta-alanine, sodium salt	SML= 0,05 mg/kg
12788	002432-99-7	11-Aminoundecanoic acid	SML= 5 mg/kg
12789	007664-41-7	Ammonia	
12820	000123-99-9	Azelaic acid	

Ref. No.	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
12970	004196-95-6	Azelaic anhydride	
13000	001477-55-0	1,3-Benzenedimethanamine	SML= 0,05 mg/kg
13060	004422-95-1	1,3,5-Benzenetricarboxylic acid trichloride	QMA = 0,05 mg/6 dm^2 (measured as 1,3,5-Benzenetricarboxylic acid)
13075	000091-76-9	Benzoguanamine	See "2,4-Diamino-6-phenyl-1,3,5-triazine"
13090	000065-85-0	Benzoic acid	
13150	000100-51-6	Benzyl alcohol	
13180	000498-66-8	Bicyclo[2.2.1]hept-2-ene (=Norbornene)	SML= 0,05 mg/kg
13210	001761-71-3	Bis(4-aminocyclohexyl)methane	SML= 0,05 mg/kg
13326	000111-46-6	Bis(2-hydroxyethyl)ether	See "Diethyleneglycol"
13380	000077-99-6	2,2-Bis(hydroxymethyl)-1-butanol	See "1,1,1-Trimethylolpropane"
13390	000105-08-8	1,4-Bis(hydroxymethyl)cyclohexane	
13395	004767-03-7	2,2-Bis(hydroxymethyl)propionic acid	QMA = 0,05 mg/6 dm^2
13480	000080-05-7	2,2-Bis(4-hydroxyphenyl)propane	SML = 3 mg/kg
13510	001675-54-3	2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (=BADGE)	According to Commission Directive 2002/16/EC of 20 February 2002 on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs (OJ L 51, 22.2.2002, p. 27)
13530	038103-06-9	2,2-Bis(4-hydroxyphenyl)propane bis(phthalic anhydride)	SML = 0,05 mg/kg
13550	000110-98-5	Bis(hydroxypropyl) ether	See "Dipropyleneglycol"
13560	0005124-30-1	Bis(4-isocyanatocyclohexyl)methane	See "Dicyclohexylmethane-4,4′-diisocyanate"
13600	047465-97-4	3,3-Bis(3-methyl-4-hydroxyphenyl)2-indolinone	SML = 1,8 mg/kg
13607	000080-05-7	Bisphenol A	See "2,2-Bis(4-hydroxyphenyl)propane"
13610	001675-54-3	Bisphenol A bis(2,3-epoxypropyl) ether	See "2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether"
13614	038103-06-9	Bisphenol A bis(phthalic anhydride)	See "2,2-Bis(4-hydroxyphenyl)propane bis(phthalic anhydride)"
13617	000080-09-1	Bisphenol S	See "4,4′-Dihydroxydiphenyl sulphone"
13620	010043-35-3	Boric acid	SML(T) = 6 mg/kg ([23]) (expressed as Boron) without prejudice to the provisions of Directive 98/83/EC on water for human consumption (OJ L 330, 5.12.1998, p. 32).
13630	000106-99-0	Butadiene	QM = 1 mg/kg in FP or SML = not detectable (DL = 0,020 mg/kg, analytical tolerance included)
13690	000107-88-0	1,3-Butanediol	
13720	000110-63-4	1,4-Butanediol	SML(T) = 0,05 mg/kg ([24])
13780	002425-79-8	1,4-Butanediol bis(2,3-epoxypropyl)ether	QM = 1 mg/kg in FP (expressed as Epoxy group, Mw = 43)
13810	000505-65-7	1,4-Butanediol formal	QMA = 0,05 mg/6 dm^2
13840	000071-36-3	1-Butanol	
13870	000106-98-9	1-Butene	
13900	000107-01-7	2-Butene	

Ref. No.	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
13932	000598-32-3	3-Buten-2-ol	QMA = ND (DL = 0,02 mg/6 dm²) To be used only as a comonomer for the preparation of polymeric additive
14020	000098-54-4	4-tert-Butylphenol	SML = 0,05 mg/kg
14110	000123-72-8	Butyraldehyde	
14140	000107-92-6	Butyric acid	
14170	000106-31-0	Butyric anhydride	
14200	000105-60-2	Caprolactam	SML(T) = 15 mg/kg ([5])
14230	002123-24-2	Caprolactam, sodium salt	SML(T) = 15 mg/kg ([5]) (expressed as Caprolactam)
14320	000124-07-2	Caprylic acid	
14350	000630-08-0	Carbon monoxide	
14380	000075-44-5	Carbonyl chloride	QM = 1 mg/kg in FP
14411	008001-79-4	Castor oil	
14500	009004-34-6	Cellulose	
14530	007782-50-5	Chlorine	
14570	000106-89-8	1-Chloro-2,3-epoxypropane	See "Epichlorohydrin"
14650	000079-38-9	Chlorotrifluoroethylene	QMA = 0,5 mg/6 dm²
14680	000077-92-9	Citric acid	
14710	000108-39-4	*m*-Cresol	
14740	000095-48-7	*o*-Cresol	
14770	000106-44-5	*p*-Cresol	
14841	000599-64-4	4-Cumylphenol	SML = 0,05 mg/kg
14880	000105-08-8	1,4-Cyclohexanedimethanol	See "1,4-Bis(hydroxymethyl)cyclohexane"
14950	003173-53-3	Cyclohexyl isocyanate	QM(T) = 1 mg/kg (expressed as NCO) ([26])
15030	000931-88-4	Cyclooctene	SML = 0,05 mg/kg. For use only in polymers contacting foods for which simulant A is laid down in Directive 85/572/EEC
15070	001647-16-1	1,9-Decadiene	SML = 0,05 mg/kg
15095	000334-48-5	Decanoic acid	
15100	000112-30-1	1-Decanol	
15130	000872-05-9	1-Decene	SML = 0,05 mg/kg
15250	000110-60-1	1,4-Diaminobutane	
15272	000107-15-3	1,2-Diaminoethane	See "Ethylenediamine"
15274	000124-09-4	1,6-Diaminohexane	See "Hexamethylenediamine"
15310	000091-76-9	2,4-Diamino-6-phenyl-1,3,5-triazine	QMA = 5 mg/6 dm²
15370	003236-53-1	1,6-Diamino-2,2,4-trimethylhexane	QMA = 5 mg/6 dm²
15400	003236-54-2	1,6-Diamino-2,4,4-trimethylhexane	QMA = 5 mg/6 dm²
15565	000106-46-7	1,4-Dichlorobenzene	SML = 12 mg/kg
15610	000080-07-9	4,4′-Dichlorodiphenyl sulphone	SML = 0,05 mg/kg

Ref. No.	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
15700	005124-30-1	Dicyclohexylmethane-4,4′-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO ([26])
15760	000111-46-6	Diethyleneglycol	SML(T) = 30 mg/kg ([3])
15790	000111-40-0	Diethylenetriamine	SML = 5 mg/kg
15820	000345-92-6	4,4′-Difluorobenzophenone	SML = 0,05 mg/kg
15880	000120-80-9	1,2-Dihydroxybenzene	SML = 6 mg/kg
15910	000108-46-3	1,3-Dihydroxybenzene	SML = 2,4 mg/kg
15940	000123-31-9	1,4-Dihydroxybenzene	SML = 0,6 mg/kg
15970	000611-99-4	4,4′-Dihydroxybenzophenone	SML(T) = 6 mg/kg ([15])
16000	000092-88-6	4,4′-Dihydroxybiphenyl	SML = 6 mg/kg
16090	000080-09-1	4,4′-Dihydroxydiphenyl sulphone	SML = 0,05 mg/kg
16150	000108-01-0	Dimethylaminoethanol	SML = 18 mg/kg
16240	000091-97-4	3,3′-Dimethyl-4,4′-diisocyanatobiphenyl	QM(T) = 1 mg/kg (expressed as NCO) ([26])
16360	000576-26-1	2,6-Dimethylphenol	SML = 0,05 mg/kg
16390	000126-30-7	2,2-Dimethyl-1,3-propanediol	SML = 0,05 mg/kg
16450	000646-06-0	1,3-Dioxolane	SML = 0,05 mg/kg
16480	000126-58-9	Dipentaerythritol	
16570	004128-73-8	Diphenylether-4,4′-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) ([26])
16600	005873-54-1	Diphenylmethane-2,4′-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) ([26])
16630	000101-68-8	Diphenylmethane-4,4′-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) ([26])
16650	000127-63-9	Diphenyl sulphone	SML(T) = 3 mg/kg ([25])
16660	000110-98-5	Dipropyleneglycol	
16690	001321-74-0	Divinylbenzene	QMA = 0,01 mg/6 dm^2 or SML = ND (DL = 0,02 mg/kg, analytical tolerance included) for the sum of divinylbenzene and ethylvinylbenzene and in compliance with the specifications laid down in Annex V
16694	013811-50-2	N,N′-Divinyl-2-imidazolidinone	QM = 5 mg/kg in FP
16697	000693-23-2	n-Dodecanedioic acid	
16704	000112-41-4	1-Dodecene	SML = 0,05 mg/kg
16750	000106-89-8	Epichlorohydrin	QM = 1 mg/kg in FP
16780	000064-17-5	Ethanol	
16950	000074-85-1	Ethylene	
16960	000107-15-3	Ethylenediamine	SML = 12 mg/kg
16990	000107-21-1	Ethyleneglycol	SML(T) = 30 mg/kg ([3])
17005	000151-56-4	Ethyleneneimine	SML = ND (DL = 0,01 mg/kg)
17020	000075-21-8	Ethylene oxide	QM = 1 mg/kg in FP
17050	000104-76-7	2-Ethyl-1-hexanol	SML = 30 mg/kg

Ref. No.	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
17160	000097-53-0	Eugenol	SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
17170	061788-47-4	Fatty acids, coco	
17200	068308-53-2	Fatty acids, soya	
17230	061790-12-3	Fatty acids, tall oil	
17260	000050-00-0	Formaldehyde	SML(T) = 15 mg/kg ([22])
17290	000110-17-8	Fumaric acid	
17530	000050-99-7	Glucose	
18010	000110-94-1	Glutaric acid	
18070	000108-55-4	Glutaric anhydride	
18100	000056-81-5	Glycerol	
18220	068564-88-5	N-Heptylaminoundecanoic acid	SML = 0,05 mg/kg ([1])
18250	000115-28-6	Hexachloroendomethylenetetrahydrophthalic acid	SML = ND (DL = 0,01 mg/kg)
18280	000115-27-5	Hexachloroendomethylenetetrahydrophthalic anhydride	SML = ND (DL = 0,01 mg/kg)
18310	036653-82-4	1-Hexadecanol	
18430	000116-15-4	Hexafluoropropylene	SML = ND (DL = 0,01 mg/kg)
18460	000124-09-4	Hexamethylenediamine	SML = 2,4 mg/kg
18640	000822-06-0	Hexamethylene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) ([26])
18670	000100-97-0	Hexamethylenetetramine	SML(T) = 15 mg/kg ([22]) (expressed as Formaldehyde)
18820	000592-41-6	1-Hexene	SML = 3 mg/kg
18867	000123-31-9	Hydroquinone	See "1,4-Dihydroxybenzene"
18880	000099-96-7	p-Hydroxybenzoic acid	
18897	016712-64-4	6-Hydroxy-2-naphthalenecarboxylic acid	SML = 0,05 mg/kg
18898	000103-90-2	N-(4-Hydroxyphenyl) acetamide	Only to be used in liquid crystals and behind a barrier layer in multilayered plastics
19000	000115-11-7	Isobutene	
19060	000109-53-5	Isobutyl vinyl ether	QM = 5 mg/kg in FP
19110	004098-71-9	1-Isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	QM(T) = 1 mg/kg (expressed as NCO) ([26])
19150	000121-91-5	Isophthalic acid	SML = 5 mg/kg
19210	001459-93-4	Isophthalic acid, dimethyl ester	SML = 0,05 mg/kg
19243	000078-79-5	Isoprene	See "2-Methyl-1,3-butadiene"
19270	000097-65-4	Itaconic acid	
19460	000050-21-5	Lactic acid	
19470	000143-07-7	Lauric acid	
19480	002146-71-6	Lauric acid, vinyl ester	
19490	000947-04-6	Laurolactam	SML = 5 mg/kg
19510	011132-73-3	Lignocellulose	
19540	000110-16-7	Maleic acid	SML(T) = 30 mg/kg ([4])
19960	000108-31-6	Maleic anhydride	SML(T) = 30 mg/kg ([4]) (expressed as maleic acid)
19975	000108-78-1	Melamine	See "2,4,6-triamino-1,3,5-triazine"
19990	000079-39-0	Methacrylamide	SML = ND (DL = 0,02 mg/kg, analytical tolerance included)

Ref. No.	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
20020	000079-41-4	Methacrylic acid	
20050	000096-05-9	Methacrylic acid, allyl ester	SML = 0,05 mg/kg
20080	002495-37-6	Methacrylic acid, benzyl ester	
20110	000097-88-1	Methacrylic acid, butyl ester	
20140	002998-18-7	Methacrylic acid, sec-butyl ester	
20170	000585-07-9	Methacrylic acid, tert-butyl ester	
20260	000101-43-9	Methacrylic acid, cyclohexyl ester	SML = 0,05 mg/kg
20410	002082-81-7	Methacrylic acid, diester with 1,4-butanediol	SML = 0,05 mg/kg
20530	002867-47-2	Methacrylic acid, 2-(dimethylamino)-ethyl ester	SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
20590	000106-91-2	Methacrylic acid, 2,3-epoxypropyl ester	QMA = 0,02 mg/6 dm^2
20890	000097-63-2	Methacrylic acid, ethyl ester	
21010	000097-86-9	Methacrylic acid, isobutyl ester	
21100	004655-34-9	Methacrylic acid, isopropyl ester	
21130	000080-62-6	Methacrylic acid, methyl ester	
21190	000868-77-9	Methacrylic acid, monoester with ethyleneglycol	
21280	002177-70-0	Methacrylic acid, phenyl ester	
21340	002210-28-8	Methacrylic acid, propyl ester	
21460	000760-93-0	Methacrylic anhydride	
21490	000126-98-7	Methacrylonitrile	SML = ND (DL = 0,020 mg/kg, analytical tolerance included)
21520	001561-92-8	Methallylsulphonic acid, sodium salt	SML = 5 mg/kg
21550	000067-56-1	Methanol	
21640	000078-79-5	2-Methyl-1,3-butadiene	QM = 1 mg/kg in FP or SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
21730	000563-45-1	3-Methyl-1-butene	QMA = 0,006 mg/6 dm^2. For use only in Polypropylene
21765	106246-33-7	4,4′-Methylenebis(3-chloro-2,6-diethylaniline)	QMA = 0,05 mg/6 dm^2
21821	000505-65-7	1,4-(Methylenedioxy)butane	See "1,4-Butanediol formal"
21940	000924-42-5	N-Methylolacrylamide	SML = ND (DL = 0,01 mg/kg)
22150	000691-37-2	4-Methyl-1-pentene	SML = 0,02 mg/kg
22331	025513-64-8	Mixture of (40 % w/w) 1,6-diamino-2,2,4-trimethylhexane and (60 % w/w) 1,6-diamino-2,4,4-trimethylhexane	QMA = 5 mg/6 dm^2
22332	028679-16-5	Mixture of (40 % w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60 % w/w) 2,4,4-trimethylhexane-1,6-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) ([26])
22350	000544-63-8	Myristic acid	
22360	001141-38-4	2,6-Naphthalenedicarboxylic acid	SML = 5 mg/kg
22390	000840-65-3	2,6-Naphthalenedicarboxylic acid, dimethyl ester	SML = 0,05 mg/kg
22420	003173-72-6	1,5-Naphthalene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) ([26])
22437	000126-30-7	Neopentylglycol	See "2,2-Dimethyl-1,3-propanediol"
22450	009004-70-0	Nitrocellulose	
22480	000143-08-8	1-Nonanol	
22550	000498-66-8	Norbornene	See "Bicyclo[2.2.1]hept-2-ene"
22570	000112-96-9	Octadecyl isocyanate	QM(T) = 1 mg/kg (expressed as NCO) ([26])

Ref. No.	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
22600	000111-87-5	1-Octanol	
22660	000111-66-0	1-Octene	SML = 15 mg/kg
22763	000112-80-1	Oleic acid	
22778	007456-68-0	4,4′-Oxybis(benzenesulphonyl azide)	QMA = 0,05 mg/6 dm^2
22780	000057-10-3	Palmitic acid	
22840	000115-77-5	Pentaerythritol	
22870	000071-41-0	1-Pentanol	
22900	000109-67-1	1-Pentene	SML = 5 mg/kg
22937	001623-05-8	Perfluoropropylperfluorovinyl ether	SML = 0,05 mg/kg
22960	000108-95-2	Phenol	
23050	000108-45-2	1,3-Phenylenediamine	SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
23155	000075-44-5	Phosgene	See “Carbonyl chloride”
23170	007664-38-2	Phosphoric acid	
23175	000122-52-1	Phosphorous acid, triethyl ester	QM = ND (DL = 1 mg/kg in FP)
23187		Phthalic acid	See “Terephthalic acid”
23200	000088-99-3	o-Phthalic acid	
23230	000131-17-9	Phthalic acid, diallyl ester	SML = ND (DL = 0,01 mg/kg)
23380	000085-44-9	Phthalic anhydride	
23470	000080-56-8	alpha-Pinene	
23500	000127-91-3	beta-Pinene	
23547	009016-00-6 063148-62-9	Polydimethylsiloxane (Mw > 6 800)	In compliance with the specifications laid down in Annex V
23590	025322-68-3	Polyethyleneglycol	
23651	025322-69-4	Polypropyleneglycol	
23740	000057-55-6	1,2-Propanediol	
23770	000504-63-2	1,3-Propanediol	SML = 0,05 mg/kg
23800	000071-23-8	1-Propanol	
23830	000067-63-0	2-Propanol	
23860	000123-38-6	Propionaldehyde	
23890	000079-09-4	Propionic acid	
23920	000105-38-4	Propionic acid, vinyl ester	SML(T) = 6 mg/kg ([2]) (expressed as Acetaldehyde)
23950	000123-62-6	Propionic anhydride	
23980	000115-07-1	Propylene	
24010	000075-56-9	Propylene oxide	QM = 1 mg/kg in FP
24051	000120-80-9	Pyrocatechol	See “1,2-Dihydroxybenzene”
24057	000089-32-7	Pyromellitic anhydride	SML = 0,05 mg/kg (expressed as Pyromellitic acid)
24070	073138-82-6	Resin acids and Rosin acids	
24072	000108-46-3	Resorcinol	See “1,3-Dihydroxybenzene”
24073	000101-90-6	Resorcinol diglycidyl ether	QMA = 0,005 mg/6 dm^2. Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC and for indirect food contact only, behind the PET layer.

Ref. No.	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
24100	008050-09-7	Rosin	
24130	008050-09-7	Rosin gum	See "Rosin"
24160	008052-10-6	Rosin tall oil	
24190	009014-63-5	Rosin wood	
24250	009006-04-6	Rubber, natural	
24270	000069-72-7	Salicylic acid	
24280	000111-20-6	Sebacic acid	
24430	002561-88-8	Sebacic anhydride	
24475	001313-82-2	Sodium sulphide	
24490	000050-70-4	Sorbitol	
24520	008001-22-7	Soybean oil	
24540	009005-25-8	Starch, edible	
24550	000057-11-4	Stearic acid	
24610	000100-42-5	Styrene	
24760	026914-43-2	Styrenesuphonic acid	SML = 0,05 mg/kg
24820	000110-15-6	Succinic acid	
24850	000108-30-5	Succinic anhydride	
24880	000057-50-1	Sucrose	
24887	006362-79-4	5-Sulphoisophthalic acid, monosodium salt	SML = 5 mg/kg
24888	003965-55-7	5-Sulphoisophthalic acid, monosodium salt, dimethyl ester	SML = 0,05 mg/kg
24910	000100-21-0	Terephthalic acid	SML = 7,5 mg/kg
24940	000100-20-9	Terephthalic acid dichloride	SML(T) = 7,5 mg/kg (expressed as Terephthalic acid)
24970	000120-61-6	Terephthalic acid, dimethyl ester	
25080	001120-36-1	1-Tetradecene	SML = 0,05 mg/kg
25090	000112-60-7	Tetraethyleneglycol	
25120	000116-14-3	Tetrafluoroethylene	SML = 0,05 mg/kg
25150	000109-99-9	Tetrahydrofuran	SML = 0,6 mg/kg
25180	000102-60-3	N,N,N′,N′,-Tetrakis(2-hydroxypropyl)ethylenediamine	
25210	000584-84-9	2,4-Toluene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) ([26])
25240	000091-08-7	2,6-Toluene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) ([26])
25270	026747-90-0	2,4-Toluene diisocyanate dimer	QM(T) = 1 mg/kg (expressed as NCO) ([26])
25360		Trialkyl(C5-C15)acetic acid, 2,3-epoxypropyl ester	QM = 1 mg/kg in FP (expressed as Epoxy group, Mw = 43)
25380	—	Trialkyl acetic acid (C7-C17), vinyl esters (= Vinyl versatate)	QMA = 0,05 mg/6 dm^2
25385	000102-70-5	Triallyamine	In compliance with the specifications laid down in Annex V
25420	000108-78-1	2,4,6-Triamino-1,3,5-triazine	SML = 30 mg/kg
25450	026896-48-0	Tricyclodecanedimethanol	SML = 0,05 mg/kg
25510	000112-27-6	Triethyleneglycol	
25600	000077-99-6	1,1,1-Trimethylolpropane	SML = 6 mg/kg

Ref. No.	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
25840	003290-92-4	1,1,1-Trimethylolpropane trimethacrylate	SML = 0,05 mg/kg
25900	000110-88-3	Trioxane	SML = 0,05 mg/kg
25910	024800-44-0	Tripropyleneglycol	
25927	027955-94-8	1,1,1-Tris(4-hydroxyphenol)ethane	QM= 0,5 mg/kg in FP. For use only in polycarbonates
25960	000057-13-6	Urea	
26050	000075-01-4	Vinyl chloride	See Council Directive 78/142/EEC
26110	000075-35-4	Vinylidene chloride	QM = 5 mg/kg in FP or SML = ND (DL = 0,05 mg/kg)
26140	000075-38-7	Vinylidene fluoride	SML = 5 mg/kg
26155	001072-63-5	1-Vinylimidazole	QM = 5 mg/kg in FP
26170	003195-78-6	N-Vinyl-N-methylacetamide	QM = 2 mg/kg in FP
26320	002768-02-7	Vinyltrimethoxysilane	QM = 5 mg/kg in FP
26360	007732-18-5	Water	In compliance with Directive 98/83/EC

Section B

List of monomers and other starting substances which may continue to be used pending a decision on inclusion in Section A

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
10599/90A	061788-89-4	Acids, fatty, unsaturated (C_{18}), dimers, distilled	
10599/91	061788-89-4	Acids, fatty, unsaturated (C_{18}), dimers, non-distilled	
10599/92A	068783-41-5	Acids, fatty, unsaturated (C_{18}), dimers, hydrogenated, distilled	
10599/93	068783-41-5	Acids, fatty, unsaturated (C_{18}), dimers, hydrogenated, non-distilled	
11500	000103-11-7	Acrylic acid, 2-ethylhexyl ester	
13050	000528-44-9	1,2,4-Benzenetricarboxylic acid	See "Trimellitic acid"
14260	000502-44-3	Caprolactone	
14800	003724-65-0	Crotonic acid	
15730	000077-73-6	Dicyclopentadiene	
16210	006864-37-5	3,3′-Dimethyl-4,4′-diaminodicyclohexylmethane	
17110	016219-75-3	5-Ethylidenebicyclo[2.2.1]hept-2-ene	
18370	000592-45-0	1,4-Hexadiene	
18700	000629-11-8	1,6-Hexanediol	
21370	010595-80-9	Methacrylic acid, 2-sulphoethyl ester	
21400	054276-35-6	Methacrylic acid, sulphopropyl ester	
21970	000923-02-4	N-Methylolmethacrylamide	
22210	000098-83-9	alpha-Methylstyrene	
25540	000528-44-9	Trimellitic acid	QM(T) = 5 mg/kg in FP
25550	000552-30-7	Trimellitic anhydride	QM(T) = 5 mg/kg in FP (expressed as Trimellitic acid)
26230	000088-12-0	Vinylpyrrolidone	

ANNEX III

INCOMPLETE LIST OF ADDITIVES WHICH MAY BE USED IN THE MANUFACTURE OF PLASTIC MATERIALS AND ARTICLES

GENERAL INTRODUCTION

1. This Annex contains the list of:

   (a) substances which are incorporated into plastics to achieve a technical effect in the finished product. They are intended to be present in the finished articles;

   (b) substances used to provide a suitable medium in which polymerisation occurs (e.g. emulsifiers, surfactants, buffering agents etc.).

   The list does not include the substances which directly influence the formation of polymers (e.g. the catalytic system).

2. The list does not include the salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc of the authorised acids, phenols or alcohols which are also authorised. However, names containing "...acid(s), salts" appear in the lists if the corresponding free acid(s) is (are) not mentioned. In such cases the meaning of the term "salts" is "salts of aluminium ammonium, calcium, iron, magnesium, potassium, sodium and zinc".

3. The list does not include the following substances although they may be present:

   (a) substances which could be present in the finished product such as:
   — impurities in the substances used,
   — reaction intermediates,
   — decomposition products;

   (b) mixtures of the authorised substances.

   The materials and articles which contain the substances indicated in (a) and (b) shall comply with the requirements stated in article 2 of Directive 89/109/EEC.

4. Substances shall be of good technical quality as regards the purity criteria.

5. The list contains the following information:
   — column 1 (Ref. No): the EEC packaging material reference number of the substances on the list,
   — column 2 (CAS No): the CAS (Chemical Abstracts Service) registry number,
   — column 3 (Name): the chemical name,
   — column 4 (Restrictions and/or specifications). These may include:
   — specific migration limit (SML),
   — maximum permitted quantity of the substance in the finished material or article (QM),
   — maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm^2 of the surface in contact with foodstuffs (QMA),
   — any other restriction specifically laid down,
   — any type of specification related to the substance or polymer.

6. If a substance appearing on the list as an individual compound is also covered by a generic term, the restrictions applying to this substance shall be those indicated for the individual compound.

7. Where there is any inconsistency between the CAS number and the chemical name, the chemical name shall take precedence over the CAS number. If there is an inconsistency between the CAS number reported in EINECS and the CAS registry, the CAS number in the CAS registry shall apply.

Section A

Incomplete list of additives fully harmonised at Community level

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
30000	000064-19-7	Acetic acid	
30045	000123-86-4	Acetic acid, butyl ester	
30080	004180-12-5	Acetic acid, copper salt	SML(T) = 30 mg/kg (7) (expressed as Copper)
30140	000141-78-6	Acetic acid, ethyl ester	
30280	000108-24-7	Acetic anhydride	
30295	000067-64-1	Acetone	
30370	—	Acetylacetic acid, salts	
30400	—	Acetylated glycerides	
30610	—	Acids, C_2-C_{24}, aliphatic, linear, monocarboxylic from natural oils and fats, and their mono-, di- and triglycerol esters (branched fatty acids at naturally occuring levels are included)	
30612	—	Acids, C_2-C_{24}, aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters	
30960	—	Acids, aliph., monocarb. (C_6-C_{22}), esters with polyglycerol	
31328	—	Acids, fatty, from animal or vegetable food fats and oils	
31530	123968-25-2	Acrylic acid, 2,4-di-tert-pentyl-6-(1-(3,5-di-tert-pentyl-2-hydroxy-phenyl)ethyl)phenyl ester	SML = 5 mg/kg
31730	000124-04-9	Adipic acid	
33120	—	Alcohols, aliph, monoh., sat., linear, primary (C_4-C_{24})	
33350	009005-32-7	Alginic acid	
33801	—	n-Alkyl(C_{10}-C_{13})benzenesulphonic acid	SML = 30 mg/kg
34240	—	Alkyl(C_{10}-C_{20})sulphonic acid, esters with phenols	SML = 6 mg/kg. Authorised until 1 January 2002
34281	—	Alkyl(C_8-C_{22})sulphuric acids, linear, primary with an even number of carbon atoms	
34475	—	Aluminum calcium hydroxide phosphite, hydrate	
34480	—	Aluminium fibers, flakes and powders	
34560	021645-51-2	Aluminium hydroxide	
34690	011097-59-9	Aluminium magnesium carbonate hydroxide	
34720	001344-28-1	Aluminium oxide	
35120	013560-49-1	3-Aminocrotonic acid, diester with thiobis (2-hydroxyethyl) ether	
35160	006642-31-5	6-Amino-1,3-dimethyluracil	SML = 5 mg/kg
35170	000141-43-5	2-Aminoethanol	SML = 0,05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC and for indirect food contact only, behind the PET layer
35284	000111-41-1	N-(2-aminoethyl)ethanolamine	SML = 0,05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC and for indirect food contact only, behind the PET layer.

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
35320	007664-41-7	Ammonia	
35440	001214-97-9	Ammonium bromide	
35600	001336-21-6	Ammonium hydroxide	
35840	000506-30-9	Arachidic acid	
35845	007771-44-0	Arachidonic acid	
36000	000050-81-7	Ascorbic acid	
36080	000137-66-6	Ascorbyl palmitate	
36160	010605-09-1	Ascorbyl stearate	
36640	000123-77-3	Azodicarbonamide	For use only as a blowing agent
36840	012007-55-5	Barium tetraborate	SML(T) = 1 mg/kg expressed as Barium ([12]) and SML(T) = 6 mg/kg ([23]) expressed as Boron) without prejudice to the provisions of Directive 98/83/EC on water for human consumption (OJ L330, 5.12.1998, p. 32).
36880	008012-89-3	Beeswax	
36960	003061-75-4	Behenamide	
37040	000112-85-6	Behenic acid	
37280	001302-78-9	Bentonite	
37360	000100-52-7	Benzaldehyde	In compliance with note 9 in Annex VI
37600	000065-85-0	Benzoic acid	
37680	000136-60-7	Benzoic acid, butyl ester	
37840	000093-89-0	Benzoic acid, ethyl ester	
38080	000093-58-3	Benzoic acid, methyl ester	
38160	002315-68-6	Benzoic acid, propyl ester	
38320	005242-49-9	4-(2-Benzoxazolyl)-4'-(5-methyl-2-benzoxazolyl)stilbene	In compliance with the specifications laid down in Annex V
38510	136504-96-6	1,2-Bis(3-aminopropyl)ethylenediamine, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine	SML = 5 mg/kg
38515	001533-45-5	4,4'-Bis(2-benzoxazolyl)stilbene	SML = 0,05 mg/kg ([1])
38810	080693-00-1	Bis(2,6-di-tert-butyl-4-methylphenyl)pentaerythritol diphosphite	SML = 5 mg/kg (sum of phosphite and phosphate)
38840	154862-43-8	Bis(2,4-dicumylphenyl)pentaerythritol-diphosphite	SML = 5 mg/kg (as sum of the substance itself, its oxidised form bis(2,4-dicumylphenyl)pentaerythritol-phosphate and its hydrolysis product (2,4-dicumylphenol)).
38879	135861-56-2	Bis(3,4-dimethylbenzylidene)sorbitol	
38950	079072-96-1	Bis(4-ethylbenzylidene)sorbitol	
39200	006200-40-4	Bis(2-hydroxyethyl)-2-hydroxypropyl-3-(dodecyloxy)methylammonium chloride	SML = 1,8 mg/kg
39815	182121-12-6	9,9-Bis(methoxymethyl)fluorene	QMA = 0,05 mg/6 dm^2
39890	087826-41-3 069158-41-4 054686-97-4 081541-12-0	Bis(methylbenzylidene)sorbitol	
39925	129228-21-3	3,3-Bis(methoxymethyl)-2,5-dimethylhexane	SML = 0,05 mg/kg
40120	068951-50-8	Bis(polyethyleneglycol)hydroxymethylphosphonate	SML = 0,6 mg/kg

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
40320	010043-35-3	Boric acid	SML(T) = 6 mg/kg ([23]) (expressed as Boron) without prejudice to the provisions of Directive 98/83/EC on water for human consumption (OJ L 330, 5.12.1998, p.32).
40400	010043-11-5	Boron nitride	
40570	000106-97-8	Butane	
40580	000110-63-4	1,4-Butanediol	SML(T) = 0,05 mg/kg ([24])
41040	005743-36-2	Calcium butyrate	
41120	010043-52-4	Calcium chloride	
41280	001305-62-0	Calcium hydroxide	
41520	001305-78-8	Calcium oxide	
41600	012004-14-7 037293-22-4	Calcium sulphoaluminate	
41680	000076-22-2	Camphor	In compliance with note 9 in Annex VI
41760	008006-44-8	Candelilla wax	
41840	000105-60-2	Caprolactam	SML(T) = 15 mg/kg ([5])
41960	000124-07-2	Caprylic acid	
42160	000124-38-9	Carbon dioxide	
42320	007492-68-4	Carbonic acid, copper salt	SML(T) = 30 mg/kg ([7]) (expressed as Copper)
42500	—	Carbonic acid, salts	
42640	009000-11-7	Carboxymethylcellulose	
42720	008015-86-9	Carnauba wax	
42800	009000-71-9	Casein	
42960	064147-40-6	Castor oil, dehydrated	
43200	—	Castor oil, mono- and diglycerides	
43280	009004-34-6	Cellulose	
43300	009004-36-8	Cellulose acetate butyrate	
43360	068442-85-3	Cellulose, regenerated	
43440	008001-75-0	Ceresin	
43515	—	Chlorides of choline esters of coconut oil fatty acids	QMA = 0,9 mg/6 dm^2
44160	000077-92-9	Citric acid	
44640	000077-93-0	Citric acid, triethyl ester	
45195	007787-70-4	Copper bromide	SML(T) = 30 mg/kg ([7]) (expressed as Copper)
45200	001335-23-5	Copper iodide	SML(T) = 30 mg/kg ([7]) (expressed as Copper) and SML = 1 mg/kg ([11]) (expressed as Iodine)
45280	—	Cotton fibers	
45450	068610-51-5	p-Cresol-dicyclopentadiene - isobutylene, copolymer	SML = 0,05 mg/kg
45560	014464-46-1	Cristobalite	
45760	000108-91-8	Cyclohexylamine	
45920	009000-16-2	Dammar	
45940	000334-48-5	n-Decanoic acid	

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
46070	010016-20-3	alpha-Dextrin	
46080	007585-39-9	beta-Dextrin	
46375	061790-53-2	Diatomaceous earth	
46380	068855-54-9	Diatomaceous earth, soda ash flux-calcined	
46480	032647-67-9	Dibenzylidene sorbitol	
46790	004221-80-1	3,5-Di-tert-butyl-4-hydroxybenzoic acid, 2,4-di-tert-butylphenyl ester	
46800	067845-93-6	3,5-Di-tert-butyl-4-hydroxybenzoic acid, hexadecyl ester	
46870	003135-18-0	3,5-Di-tert-butyl-4-hydroxybenzylphosphonic acid, dioctadecyl ester	
46880	065140-91-2	3,5-Di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	SML = 6 mg/kg
47210	026427-07-6	Dibutylthiostannoic acid polymer [= Thiobis(butyl-tin sulphide), polymer]	In compliance with the specifications laid down in Annex V.
47440	000461-58-5	Dicyanodiamide	
47540	027458-90-8	Di-tert-dodecyl disulphide	SML = 0,05 mg/kg
47680	000111-46-6	Diethyleneglycol	SML(T) = 30 mg/kg ([3])
48460	000075-37-6	1,1-Difluoroethane	
48620	000123-31-9	1,4-Dihydroxybenzene	SML = 0,6 mg/kg
48720	000611-99-4	4,4'-Dihydroxybenzophenone	SML(T) = 6 mg/kg ([15])
49485	134701-20-5	2,4-Dimethyl-6-(1-methylpentadecyl)phenol	SML = 1 mg/kg
49540	000067-68-5	Dimethyl sulphoxide	
51200	000126-58-9	Dipentaerythritol	
51700	147315-50-2	2-(4,6-Diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol	SML = 0,05 mg/kg
51760	025265-71-8 000110-98-5	Dipropyleneglycol	
52640	016389-88-1	Dolomite	
52645	010436-08-5	cis-11-Eicosenamide	
52720	000112-84-5	Erucamide	
52730	000112-86-7	Erucic acid	
52800	000064-17-5	Ethanol	
53270	037205-99-5	Ethylcarboxymethylcellulose	
53280	009004-57-3	Ethylcellulose	
53360	000110-31-6	N,N'-Ethylenebisoleamide	
53440	005518-18-3	N,N'-Ethylenebispalmitamide	
53520	000110-30-5	N,N'-Ethylenebisstearamide	
53600	000060-00-4	Ethylenediaminetetraacetic acid	
53610	054453-03-1	Ethylenediaminetetraacetic acid, copper salt	SML(T) = 30 mg/kg ([7]) (expressed as Copper)
53650	000107-21-1	Ethyleneglycol	SML(T) = 30 mg/kg ([3])
54005	005136-44-7	Ethylene-N-palmitamide-N'-stearamide	
54260	009004-58-4	Ethylhydroxyethylcellulose	
54270	—	Ethylhydroxymethylcellulose	
54280	—	Ethylhydroxypropylcellulose	
54300	118337-09-0	2,2'-Ethylidenebis(4,6-di-tert-butylphenyl) fluorophosphonite	SML = 6 mg/kg
54450	—	Fats and oils, from animal or vegetable food sources	
54480	—	Fats and oils, hydrogenated, from animal or vegetable food sources	
54930	025359-91-5	Formaldehyde-1-naphthol, copolymer [=poly(1-hydroxynaphthylmethane)]	SML = 0,05 mg/kg
55040	000064-18-6	Formic acid	

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
55120	000110-17-8	Fumaric acid	
55190	029204-02-2	Gadoleic acid	
55440	009000-70-8	Gelatin	
55520	—	Glass fibers	
55600	—	Glass microballs	
55680	000110-94-1	Glutaric acid	
55920	000056-81-5	Glycerol	
56020	099880-64-5	Glycerol dibehenate	
56360	—	Glycerol, esters with acetic acid	
56486	—	Glycerol, esters with acids, aliph., sat., linear, with an even number of carbon atoms (C_{14}-C_{18}) and with acids, aliph., unsat., linear, with an even number of carbon atoms (C_{16}-C_{18})	
56487	—	Glycerol, esters with butyric acid	
56490	—	Glycerol, esters with erucic acid	
56495	—	Glycerol, esters with 12-hydroxystearic acid	
56500	—	Glycerol, esters with lauric acid	
56510	—	Glycerol, esters with linoleic acid	
56520	—	Glycerol, esters with myristic acid	
56540	—	Glycerol, esters with oleic acid	
56550	—	Glycerol, esters with palmitic acid	
56565	—	Glycerol, esters with nonanoic acid	
56570	—	Glycerol, esters with propionic acid	
56580	—	Glycerol, esters with ricinoleic acid	
56585	—	Glycerol, esters with stearic acid	
56610	030233-64-8	Glycerol monobehenate	
56720	026402-23-3	Glycerol monohexanoate	
56800	030899-62-8	Glycerol monolaurate diacetate	
56880	026402-26-6	Glycerol monooctanoate	
57040	—	Glycerol monooleate, ester with ascorbic acid	
57120	—	Glycerol monooleate, ester with citric acid	
57200	—	Glycerol monopalmitate, ester with ascorbic acid	
57280	—	Glycerol monopalmitate, ester with citric acid	
57600	—	Glycerol monostearate, ester with ascorbic acid	
57680	—	Glycerol monostearate, ester with citric acid	
57800	018641-57-1	Glycerol tribehenate	
57920	000620-67-7	Glycerol triheptanoate	
58300	—	Glycine, salts	
58320	007782-42-5	Graphite	
58400	009000-30-0	Guar gum	
58480	009000-01-5	Gum arabic	
58720	000111-14-8	Heptanoic acid	
59360	000142-62-1	Hexanoic acid	
59760	019569-21-2	Huntite	
59990	007647-01-0	Hydrochloric acid	
60030	012072-90-1	Hydromagnesite	

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
60080	012304-65-3	Hydrotalcite	
60160	000120-47-8	4-Hydroxybenzoic acid, ethyl ester	
60180	004191-73-5	4-Hydroxybenzoic acid, isopropyl ester	
60200	000099-76-3	4-Hydroxybenzoic acid, methyl ester	
60240	000094-13-3	4-Hydroxybenzoic acid, propyl ester	
60480	003864-99-1	2-(2'-Hydroxy-3,5'-di-tert-butylphenyl)-5-chlorobenzotriazole	SML(T) = 30 mg/kg ([19])
60560	009004-62-0	Hydroxyethylcellulose	
60880	009032-42-2	Hydroxyethylmethylcellulose	
61120	009005-27-0	Hydroxyethyl starch	
61390	037353-59-6	Hydroxymethylcellulose	
61680	009004-64-2	Hydroxypropylcellulose	
61800	009049-76-7	Hydroxypropyl starch	
61840	000106-14-9	12-Hydroxystearic acid	
62140	006303-21-5	Hypophosphorous acid	
62240	001332-37-2	Iron oxide	
62450	000078-78-4	Isopentane	
62640	008001-39-6	Japan wax	
62720	001332-58-7	Kaolin	
62800	—	Kaolin, calcined	
62960	000050-21-5	Lactic acid	
63040	000138-22-7	Lactic acid, butyl ester	
63280	000143-07-7	Lauric acid	
63760	008002-43-5	Lecithin	
63840	000123-76-2	Levulinic acid	
63920	000557-59-5	Lignoceric acid	
64015	000060-33-3	Linoleic acid	
64150	028290-79-1	Linolenic acid	
64500	—	Lysine, salts	
64640	001309-42-8	Magnesium hydroxide	
64720	001309-48-4	Magnesium oxide	
64800	00110-16-7	Maleic acid	SML(T) = 30 mg/kg ([4])
65020	006915-15-7	Malic acid	
65040	000141-82-2	Malonic acid	
65520	000087-78-5	Mannitol	
65920	066822-60-4	N-Methacryloyloxyethyl-N,N-dimethyl-N-carboxymethylammonium chloride, sodium salt -octadecyl methacrylate-ethyl methacrylate-cyclohexyl methacrylate-N-vinyl-2-pyrrolidone, copolymers	
66200	037206-01-2	Methylcarboxymethylcellulose	
66240	009004-67-5	Methylcellulose	
66560	004066-02-8	2,2'-Methylenebis(4-methyl-6-cyclohexylphenol)	SML(T) = 3 mg/kg ([6])
66580	000077-62-3	2,2'-Methylenebis(4-methyl-6-(1-methylcyclohexyl)phenol)	SML(T) = 3 mg/kg ([6])
66640	009004-59-5	Methylethylcellulose	

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
66695	—	Methylhydroxymethylcellulose	
66700	009004-65-3	Methylhydroxypropylcellulose	
66755	002682-20-4	2-Methyl-4-isothiazolin-3-one	SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
67120	012001-26-2	Mica	
67170	—	Mixture of (80 to 100 % w/w) 5,7-di-tert-butyl-3-(3,4-dimethylphenyl)-2(3H)-benzofuranone and (0 to 20 % w/w)5,7-di-tert-butyl-3-(2,3-dimethylphenyl)-2(3H)-benzofuranone	SML = 5 mg/kg
67180	—	Mixture of (50 % w/w) phthalic acid, n-decyl n-octyl ester, (25 % w/w) phthalic acid di-n-decyl ester, and (25 % w/w) phthalic acid di-n-decyl ester, and (25 % w/w) phthalic acid di-n-octyl ester	SML = 5 mg/kg ([1])
67200	001317-33-5	Molybdenum disulphide	
67840	—	Montanic acids and/or their esters with ethyleneglycol and/or with 1,3-butanediol and/or with glycerol	
67850	008002-53-7	Montan wax	
67891	000544-63-8	Myristic acid	
68040	003333-62-8	7-[2H-Naphtho-(1,2-D)triazol-2-yl]-3-phenylcoumarin	
68125	037244-96-5	Nepheline syenite	
68145	080410-33-9	2,2',2"-Nitrilo(triethyl tris(3,3',5,5'-tetra-tert-butyl-1,1'-bi-phenyl-2,2'-diyl)phosphite)	SML =5 mg/kg (sum of phosphite and phosphate)
68960	000301-02-0	Oleamide	
69040	000112-80-1	Oleic acid	
69760	000143-28-2	Oleyl alcohol	
70000	070331-94-1	2,2'-Oxamidobis[ethyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	
70240	012198-93-5	Ozokerite	
70400	000057-10-3	Palmitic acid	
71020	000373-49-9	Palmitoleic acid	
71440	009000-69-5	Pectin	
71600	000115-77-5	Pentaerythritol	
71635	025151-96-6	Pentaerythritol dioleate	SML = 0,05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC
71670	178671-58-4	Pentaerythritol tetrakis (2-cyano-3,3-diphenylacrylate)	SML = 0,05 mg/kg
71680	006683-19-8	Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	
71720	000109-66-0	Pentane	
72640	007664-38-2	Phosphoric acid	
73160	—	Phosphoric acid, mono- and di-n-alkyl (C_{16} and C_{18}) esters	SML = 0,05 mg/kg
73720	000115-96-8	Phosphoric acid, trichloroethyl ester	SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
74010	145650-60-8	Phosphorous acid, bis(2,4-di-tert-butyl-6-methylphenyl) ethyl ester	SML =5 mg/kg (sum of phosphite and phosphate)
74240	031570-04-4	Phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	
74480	000088-99-3	o-Phthalic acid	

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
76320	000085-44-9	Phthalic anhydride	
76721	009016-00-6 063148-62-9	Polydimethylsiloxane (Mw > 6800)	In compliance with the specifications laid down in Annex V
76730	—	Polydimethylsiloxane, gamma-hydroxypropylated	SML = 6 mg/kg
76865	—	Polyesters of 1,2-propanediol and/or 1,3- and/or 1,4-butanediol and/or polypropyleneglycol with adipic acid, also end-capped with acetic acid or fatty acids C_{10}-C_{18} or n-octanol and/or n-decanol	SML = 30 mg/kg
76960	025322-68-3	Polyethyleneglycol	
77600	061788-85-0	Polyethyleneglycol ester of hydrogenated castor oil	
77702	—	Polyethyleneglycol esters of aliph. monocarb. acids (C_6-C_{22}) and their ammonium and sodium sulphates	
77895	068439-49-6	Polyethyleneglycol(EO = 2-6) monoalkyl (C_{16}-C_{18}) ether	SML = 0,05 mg/kg
79040	009005-64-5	Polyethyleneglycol sorbitan monolaurate	
79120	009005-65-6	Polyethyleneglycol sorbitan monooleate	
79200	009005-66-7	Polyethyleneglycol sorbitan monopalmitate	
79280	009005-67-8	Polyethyleneglycol sorbitan monostearate	
79360	009005-70-3	Polyethyleneglycol sorbitan trioleate	
79440	009005-71-4	Polyethyleneglycol sorbitan tristearate	
80240	029894-35-7	Polyglycerol ricinoleate	
80640	—	Polyoxyalkyl (C_2-C_4) dimethylpolysiloxane	
80720	008017-16-1	Polyphosphoric acids	
80800	025322-69-4	Polypropyleneglycol	
81220	192268-64-7	Poly-[[6-[N-(2,2,6,6-tetramethyl-4-piperidinyl)-n-butylamino]-1,3,5-triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidinyl)imino]-1,6-hexanediyl-[(2,2,6,6-tetramethyl-4-piperidinyl)imino]]-alpha-[N,N,N',N'-tetrabutyl-N"-(2,2,6,6-tetramethyl-4-piperidinyl)-N"-[6-(2,2,6,6-tetramethyl-4-piperidinylamino)-hexyl]-[1,3,5-triazine-2,4,6-triamine]-omega-N,N,N',N'-tetrabutyl-1,3,5-triazine-2,4-diamine]	SML = 5 mg/kg
81515	087189-25-1	Poly(zinc glycerolate)	
81520	007758-02-3	Potassium bromide	
81600	001310-58-3	Potassium hydroxide	
81760	—	Powders, flakes and fibres of brass, bronze, copper, stainless steel, tin and alloys of copper, tin and iron	SML(T) = 30 mg/kg (7) (expressed as Copper); SML = 48 mg/kg (expressed as Iron)
81840	000057-55-6	1,2-Propanediol	
81882	000067-63-0	2-Propanol	
82000	000079-09-4	Propionic acid	
82080	009005-37-2	1,2-Propyleneglycol alginate	
82240	022788-19-8	1,2-Propyleneglycol dilaurate	
82400	000105-62-4	1,2-Propyleneglycol dioleate	
82560	033587-20-1	1,2-Propyleneglycol dipalmitate	
82720	006182-11-2	1,2-Propyleneglycol distearate	
82800	027194-74-7	1,2-Propyleneglycol monolaurate	

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
82960	001330-80-9	1,2-Propyleneglycol monooleate	
83120	029013-28-3	1,2-Propyleneglycol monopalmitate	
83300	001323-39-3	1,2-Propyleneglycol monostearate	
83320	—	Propylhydroxyethylcellulose	
83325	—	Propylhydroxymethylcellulose	
83330	—	Propylhydroxypropylcellulose	
83440	002466-09-3	Pyrophosphoric acid	
83455	013445-56-2	Pyrophosphorous acid	
83460	012269-78-2	Pyrophyllite	
83470	014808-60-7	Quartz	
83599	068442-12-6	Reaction products of oleic acid, 2-mercaptoethyl ester, with dichlorodimethyltin, sodium sulphide and trichloromethyltin	SML(T) = 0,18 mg/kg ([16]) (expressed as Tin)
83610	073138-82-6	Resin acids and Rosin acids	
83840	008050-09-7	Rosin	
84000	008050-31-5	Rosin, ester with glycerol	
84080	008050-26-8	Rosin, ester with pentaerythritol	
84210	065997-06-0	Rosin, hydrogenated	
84240	065997-13-9	Rosin, hydrogenated, ester with glycerol	
84320	008050-15-5	Rosin, hydrogenated, ester with methanol	
84400	064365-17-9	Rosin, hydrogenated, ester with pentaerythritol	
84560	009006-04-6	Rubber, natural	
84640	000069-72-7	Salicylic acid	
85360	000109-43-3	Sebacic acid, dibutyl ester	
85600	—	Silicates, natural	
85610	—	Silicates, natural, silanated (with the exception of asbestos)	
85680	001343-98-2	Silicic acid	
85840	053320-86-8	Silicic acid, lithium magnesium sodium salt	SML(T) = 0,6 mg/kg ([8]) (expressed as Lithium)
86000	—	Silicic acid, silylated	
86160	000409-21-2	Silicon carbide	
86240	007631-86-9	Silicon dioxide	
86285	—	Silicon dioxide, silanated	
86560	007647-15-6	Sodium bromide	
86720	001310-73-2	Sodium hydroxide	
87040	001330-43-4	Sodium tetraborate	SML(T) = 6 mg/kg ([23]) (expressed as Boron) without prejudice to the provisions of Directive 98/83/EC on water for human consumption (OJ L 330, 5.12.1998, p.32).
87200	000110-44-1	Sorbic acid	
87280	029116-98-1	Sorbitan dioleate	

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
87520	062568-11-0	Sorbitan monobehenate	
87600	001338-39-2	Sorbitan monolaurate	
87680	001338-43-8	Sorbitan monooleate	
87760	026266-57-9	Sorbitan monopalmitate	
87840	001338-41-6	Sorbitan monostearate	
87920	061752-68-9	Sorbitan tetrastearate	
88080	026266-58-0	Sorbitan trioleate	
88160	054140-20-4	Sorbitan tripalmitate	
88240	026658-19-5	Sorbitan tristearate	
88320	000050-70-4	Sorbitol	
88600	026836-47-5	Sorbitol monostearate	
88640	008013-07-8	Soybean oil, epoxidised	In compliance with the specifications laid down in Annex V
88800	009005-25-8	Starch, edible	
88880	068412-29-3	Starch, hydrolysed	
88960	000124-26-5	Stearamide	
89040	000057-11-4	Stearic acid	
89200	007617-31-4	Stearic acid, copper salt	SML(T) = 30 mg/kg ([7]) (expressed as Copper)
89440	—	Stearic acid, esters with ethyleneglycol	SML(T) = 30 mg/kg ([3])
90720	058446-52-9	Stearoylbenzoylmethane	
90800	005793-94-2	Stearoyl-2-lactylic acid, calcium salt	
90960	000110-15-6	Succinic acid	
91200	000126-13-6	Sucrose acetate isobutyrate	
91360	000126-14-7	Sucrose octaacetate	
91840	007704-34-9	Sulphur	
91920	007664-93-9	Sulphuric acid	
92030	010124-44-4	Sulphuric acid, copper salt	SML(T) = 30 mg/kg ([7]) (expressed as Copper)
92080	014807-96-6	Talc	
92150	001401-55-4	Tannic acids	According to the JECFA specifications
92160	000087-69-4	Tartaric acid	

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
92195	—	Taurine, salts	
92205	057569-40-1	Terephthalic acid, diester with 2,2'-methylenebis(4-methyl-6-tert-butylphenol)	
92350	000112-60-7	Tetraethyleneglycol	
92640	000102-60-3	N,N,N',N'-Tetrakis(2-hydroxypropyl)ethylenediamine	
92700	078301-43-6	2,2,4,4-Tetramethyl-20-(2,3-epoxypropyl)-7-oxa-3,20-diazadispiro-[5.1.11.2]-heneicosan-21-one, polymer	SML = 5 mg/kg
92930	120218-34-0	Thiodiethanolbis(5-methoxycarbonyl-2,6-dimethyl-1,4-dihydropyridine-3-carboxylate)	SML = 6 mg/kg
93440	013463-67-7	Titanium dioxide	
93520	000059-02-9 010191-41-0	alpha-Tocopherol	
93680	009000-65-1	Tragacanth gum	
93720	000108-78-1	2,4,6-Triamino-1,3,5-triazine	SML = 30 mg/kg
94320	000112-27-6	Triethyleneglycol	
94960	000077-99-6	1,1,1-Trimethylolpropane	SML = 6 mg/kg
95200	001709-70-2	1,3,5-Trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene	
95270	161717-32-4	2,4,6-Tris(tert-butyl)phenyl-2-butyl-2-ethyl-1,3-propanediol phosphite	SML = 2 mg/kg (as sum of phosphite, phosphate and the hydrolysis product = TTBP)
95725	110638-71-6	Vermiculite, reaction product with citric acid, lithium salt	SML(T) = 0,6 mg/kg [8] (expressed as Lithium)
95855	007732-18-5	Water	In compliance with Directive 98/83/EEC
95859	—	Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks	In compliance with the specifications laid down in Annex V
95883	—	White mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks	In compliance with the specifications laid down in Annex V
95905	013983-17-0	Wollastonite	
95920	—	Wood flour and fibers, untreated	
95935	011138-66-2	Xanthan gum	
96190	020427-58-1	Zinc hydroxide	
96240	001314-13-2	Zinc oxide	
96320	001314-98-3	Zinc sulphide	

Section B

Incomplete list of additives referred to in Article 4, second paragraph

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
30180	002180-18-9	Acetic acid, manganese salt	SML(T) = 0,6 mg/kg ([10]) (expressed as Manganese)
31520	061167-58-6	Acrylic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenyl ester	SML = 6 mg/kg
31920	000103-23-1	Adipic acid, bis(2-ethylhexyl) ester	SML = 18 mg/kg ([1])
34230	—	Alkyl(C_8-C_{22})sulphonic acids	SML = 6 mg/kg
35760	001309-64-4	Antimony trioxide	SML = 0,02 mg/kg (expressed as Antimony and analytical tolerance included)
36720	017194-00-2	Barium hydroxide	SML(T) = 1 mg/kg ([12]) (expressed as Barium)
36800	010022-31-8	Barium nitrate	SML(T) = 1 mg/kg ([12]) (expressed as Barium)
38240	000119-61-9	Benzophenone	SML = 0,6 mg/kg
38560	007128-64-5	2,5-Bis(5-tert-butyl-2-benzoxazolyl)thiophene	SML = 0,6 mg/kg
38700	063397-60-4	Bis(2-carbobutoxyethyl)tin-bis(isooctyl mercaptoacetate)	SML = 18 mg/kg
38800	032687-78-8	N,N'-Bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)hydrazide	SML = 15 mg/kg
38820	026741-53-7	Bis(2,4-di-tert-butylphenyl) pentaerythritol diphosphite	SML = 0,6 mg/kg
39060	035958-30-6	1,1-Bis(2-hydroxy-3,5-di-tert-butylphenyl)ethane	SML = 5 mg/kg
39090	—	N,N-Bis(2-hydroxyethyl)alkyl(C_8-C_{18})amine	SML(T) = 1,2 mg/kg ([13])
39120	—	N,N-Bis(2-hydroxyethyl)alkyl(C_8-C_{18})amine hydrochlorides	SML(T) = 1,2 mg/kg ([13]) expressed as Tertiary amine (expressed excluding HCl)
40000	000991-84-4	2,4-Bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	SML = 30 mg/kg
40020	110553-27-0	2,4-Bis(octylthiomethyl)-6-methylphenol	SML = 6 mg/kg
40160	061269-61-2	N,N'-Bis(2,2,6,6-tetramethyl-4-piperidyl)hexamethylenediamine-1,2-dibromoethane, copolymer	SML = 2,4 mg/kg
40800	013003-12-8	4,4'-Butylidene-bis(6-tert-butyl-3-methylphenyl-ditridecyl phosphite)	SML = 6 mg/kg
40980	019664-95-0	Butyric acid, manganese salt	SML(T) = 0,6 mg/kg ([10]) (expressed as Manganese)
42000	063438-80-2	(2-Carbobutoxyethyl)tin-tris(isooctyl mercaptoacetate)	SML = 30 mg/kg
42400	010377-37-4	Carbonic acid, lithium salt	SML(T) = 0,6 mg/kg ([8]) (expressed as Lithium)
42480	000584-09-8	Carbonic acid, rubidium salt	SML = 12 mg/kg
43600	004080-31-3	1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	SML = 0,3 mg/kg
43680	000075-45-6	Chlorodifluoromethane	SML = 6 mg/kg and in compliance with the specifications laid down in Annex V
44960	011104-61-3	Cobalt oxide	SML(T) = 0,05 mg/kg ([14]) (expressed as Cobalt)
45440	—	Cresols, butylated, styrenated	SML = 12 mg/kg
45650	006197-30-4	2-Cyano-3,3-diphenylacrylic acid, 2-ethylhexyl ester	SML = 0,05 mg/kg
46720	004130-42-1	2,6-Di-tert-butyl-4-ethylphenol	QMA = 4,8 mg/6 dm^2
47600	084030-61-5	Di-n-dodecyltin bis(isooctyl mercaptoacetate)	SML = 12 mg/kg
48640	000131-56-6	2,4-Dihydroxybenzophenone	SML(T) = 6 mg/kg ([15])

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
48800	000097-23-4	2,2'-Dihydroxy-5,5'-dichlorodiphenylmethane	SML = 12 mg/kg
48880	000131-53-3	2,2'-Dihydroxy-4-methoxybenzophenone	SML(T) = 6 mg/kg ([15])
49600	026636-01-1	Dimethyltin bis(isooctyl mercaptoacetate)	SML(T) = 0,18 mg/kg ([16]) (expressed as Tin)
49840	002500-88-1	Dioctadecyl disulphide	SML = 3 mg/kg
50160	—	Di-n-octyltin bis(n-alkyl(C_{10}-C_{16}) mercaptoacetate)	SML(T) = 0,04 mg/kg ([17]) (expressed as Tin)
50240	010039-33-5	Di-n-octyltin bis(2-ethylhexyl maleate)	SML(T) = 0,04 mg/kg ([17]) (expressed as Tin)
50320	015571-58-1	Di-n-octyltin bis(2-ethylhexyl mercaptoacetate)	SML(T) = 0,04 mg/kg ([17]) (expressed as Tin)
50360	—	Di-n-octyltin bis(ethyl maleate)	SML(T) = 0,04 mg/kg ([17]) (expressed as Tin)
50400	033568-99-9	Di-n-octyltin bis(isooctyl maleate)	SML(T) = 0,04 mg/kg ([17]) (expressed as Tin)
50480	026401-97-8	Di-n-octyltin bis(isooctyl mercaptoacetate)	SML(T) = 0,04 mg/kg ([17]) (expressed as Tin)
50560	—	Di-n-octyltin 1,4-butanediol bis(mercaptoacetate)	SML(T) = 0,04 mg/kg ([17]) (expressed as Tin)
50640	003648-18-8	Di-n-octyltin dilaurate	SML(T) = 0,04 mg/kg ([17]) (expressed as Tin)
50720	015571-60-5	Di-n-octyltin dimaleate	SML(T) = 0,04 mg/kg ([17]) (expressed as Tin)
50800	—	Di-n-octyltin dimaleate, esterified	SML(T) = 0,04 mg/kg ([17]) (expressed as Tin)
50880	—	Di-n-octyltin dimaleate, polymers (n = 2-4)	SML(T) = 0,04 mg/kg ([17]) (expressed as Tin)
50960	069226-44-4	Di-n-octyltin ethyleneglycol bis(mercaptoacetate)	SML(T) = 0,04 mg/kg ([17]) (expressed as Tin)
51040	015535-79-2	Di-n-octyltin mercaptoacetate	SML(T) = 0,04 mg/kg ([17]) (expressed as Tin)
51120	—	Di-n-octyltin thiobenzoate 2-ethylhexyl mercaptoacetate	SML(T) = 0,04 mg/kg ([17]) (expressed as Tin)
51570	000127-63-9	Diphenyl sulphone	SML(T) = 3 mg/kg ([25])
51680	000102-08-9	N,N'-diphenylthiourea	SML = 3 mg/kg
52000	027176-87-0	Dodecylbenzenesulphonic acid	SML = 30 mg/kg
52320	052047-59-3	2-(4-Dodecylphenyl)indole	SML = 0,06 mg/kg
52880	023676-09-7	4-Ethoxybenzoic acid, ethyl ester	SML = 3,6 mg/kg
53200	023949-66-8	2-Ethoxy-2'-ethyloxanilide	SML = 30 mg/kg
58960	000057-09-0	Hexadecyltrimethylammonium bromide	SML = 6 mg/kg
59120	023128-74-7	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide)	SML = 45 mg/kg
59200	035074-77-2	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)	SML = 6 mg/kg
60320	070321-86-7	2-[2-Hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl]benzotriazole	SML = 1,5 mg/kg
60400	003896-11-5	2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole	SML(T) = 30 mg/kg ([19])
60800	065447-77-0	1-(2-Hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethyl piperidine-succinic acid, dimethyl ester, copolymer	SML = 30 mg/kg
61280	003293-97-8	2-Hydroxy-4-n-hexyloxybenzophenone	SML(T) = 6 mg/kg ([15])
61360	000131-57-7	2-Hydroxy-4-methoxybenzophenone	SML(T) = 6 mg/kg ([15])

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
61440	002440-22-4	2-(2'-Hydroxy-5'-methylphenyl)benzotriazole	SML(T) = 30 mg/kg ([19])
61600	001843-05-6	2-Hydroxy-4-n-octyloxybenzophenone	SML(T) = 6 mg/kg ([15])
63200	051877-53-3	Lactic acid, manganese salt	SML(T) = 0,6 mg/kg ([10]) (expressed as Manganese)
64320	010377-51-2	Lithium iodide	SML(T) = 1 mg/kg ([11]) (expressed as Iodine) and SML(T) = 0,6 mg/kg ([8]) (expressed as Lithium)
65120	007773-01-5	Manganese chloride	SML(T) = 0,6 mg/kg ([10]) (expressed as Manganese)
65200	012626-88-9	Manganese hydroxide	SML(T) = 0,6 mg/kg ([10]) (expressed as Manganese)
65280	010043-84-2	Manganese hypophosphite	SML(T) = 0,6 mg/kg ([10]) (expressed as Manganese)
65360	011129-60-5	Manganese oxide	SML(T) = 0,6 mg/kg ([10]) (expressed as Manganese)
65440	—	Manganese pyrophosphite	SML(T) = 0,6 mg/kg ([10]) (expressed as Manganese)
66360	085209-91-2	2,2'-Methylene bis(4,6-di-tert-butylphenyl) sodium phosphate	SML = 5 mg/kg
66400	000088-24-4	2,2'-Methylene bis(4-ethyl-6-tert-butylphenol)	SML(T) = 1,5 mg/kg ([20])
66480	000119-47-1	2,2'-Methylene bis(4-methyl-6-tert-butylphenol)	SML(T) = 1,5 mg/kg ([20])
67360	067649-65-4	Mono-n-dodecyltin tris(isooctyl mercaptoacetate)	SML = 24 mg/kg
67520	054849-38-6	Monomethyltin tris(isooctyl mercaptoacetate)	SML(T) = 0,18 mg/kg ([16]) (expressed as Tin)
67600	—	Mono-n-octyltin tris(alkyl(C_{10}-C_{16}) mercaptoacetate)	SML(T) = 1,2 mg/kg ([18]) (expressed as Tin)
67680	027107-89-7	Mono-n-octyltin tris(2-ethylhexyl mercaptoacetate)	SML(T) = 1,2 mg/kg ([18]) (expressed as Tin)
67760	026401-86-5	Mono-n-octyltin tris(isooctyl mercaptoacetate)	SML(T) = 1,2 mg/kg ([18]) (expressed as Tin)
68078	027253-31-2	Neodecanoic acid, cobalt salt	SML(T) = 0,05 mg/kg (expressed as Neodecanoic acid) and SML(T) = 0,05 mg/kg ([14]) (expressed as Cobalt). Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC.
68320	002082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	SML = 6 mg/kg
68400	010094-45-8	Octadecylerucamide	SML = 5 mg/kg
68860	004724-48-5	n-Octylphosphonic acid	SML = 0,05 mg/kg
69840	016260-09-6	Oleylpalmitamide	SML = 5 mg/kg
72160	000948-65-2	2-Phenylindole	SML = 15 mg/kg
72800	001241-94-7	Phosphoric acid, diphenyl 2-ethylhexyl ester	SML = 2,4 mg/kg
73040	013763-32-1	Phosphoric acid, lithium salts	SML(T) = 0,6 mg/kg ([8]) (expressed as Lithium)
73120	010124-54-6	Phosphoric acid, manganese salt	SML(T) = 0,6 mg/kg ([10]) (expressed as Manganese)

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
74400	—	Phosphorous acid, tris(nonyl-and/or dinonylphenyl) ester	SML = 30 mg/kg
77440	—	Polyethyleneglycol diricinoleate	SML = 42 mg/kg
77520	061791-12-6	Polyethyleneglycol ester of castor oil	SML = 42 mg/kg
78320	009004-97-1	Polyethyleneglycol monoricinoleate	SML = 42 mg/kg
81200	071878-19-8	Poly[6-[(1,1,3,3-tetramethylbutyl)amino]-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-tetramethyl-4-piperidyl)-imino]hexamethylene[(2,2,6,6-tetramethyl-4-piperidyl) imino]	SML = 3 mg/kg
81680	007681-11-0	Potassium iodide	SML(T) = 1 mg/kg ([11]) (expressed as Iodium)
82020	019019-51-3	Propionic acid, cobalt salt	SML(T) = 0,05 mg/kg ([14]) (expressed as Cobalt)
83595	119345-01-6	Reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorous trichloride and biphenyl	SML = 18 mg/kg and in compliance with the specifications mentioned in Annex V.
83700	000141-22-0	Ricinoleic acid	SML = 42 mg/kg
84800	000087-18-3	Salicylic acid, 4-tert-butylphenyl ester	SML = 12 mg/kg
84880	000119-36-8	Salicylic acid, methyl ester	SML = 30 mg/kg
85760	012068-40-5	Silicic acid, lithium aluminium salt(2:1:1)	SML(T) = 0,6 mg/kg ([8]) (expressed as Lithium)
85920	012627-14-4	Silicic acid, lithium salt	SML(T) = 0,6 mg/kg ([8]) (expressed as Lithium)
86800	007681-82-5	Sodium iodide	SML(T) = 1 mg/kg ([11]) (expressed as Iodine)
86880	—	Sodium monoalkyl dialkylphenoxybenzenedisulphonate	SML = 9 mg/kg
89170	013586-84-0	Stearic acid, cobalt salt	SML(T) = 0,05 mg/kg ([14]) (expressed as Cobalt)
92000	007727-43-7	Sulphuric acid, barium salt	SML(T) = 1 mg/kg ([12]) (expressed as Barium)
92320	—	Tetradecyl-polyethyleneglycol(EO=3-8) ether of glycolic acid	SML = 15 mg/kg
92560	038613-77-3	Tetrakis(2,4-di-tert-butyl-phenyl)-4,4'-biphenylylene diphosphonite	SML = 18 mg/kg
92800	000096-69-5	4,4'-Thiobis(6-terc-butyl-3-methylphenol)	SML = 0,48 mg/kg
92880	041484-35-9	Thiodiethanol bis(3-(3,5-di-tert-butyl-4-hydroxy phenyl) propionate)	SML = 2,4 mg/kg
93120	000123-28-4	Thiodipropionic acid, didodecyl ester	SML(T) = 5 mg/kg ([21])
93280	000693-36-7	Thiodipropionic acid, dioctadecyl ester	SML(T) = 5 mg/kg ([21])
94560	000122-20-3	Triisopropanolamine	SML = 5 mg/kg
95000	028931-67-1	Trimethylolpropane trimethacrylate-methyl methacrylate copolymer	
95280	040601-76-1	1,3,5-Tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	SML = 6 mg/kg
95360	027676-62-6	1,3,5-Tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	SML = 5 mg/kg
95600	001843-03-4	1,1,3-Tris(2-methyl-4-hydroxy-5-tert-butylphenyl) butane	SML = 5 mg/kg

ANNEX IV

PRODUCTS OBTAINED BY MEANS OF BACTERIAL FERMENTATION

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
18888	080181-31-3	3-Hydroxybutanoic acid-3-hydroxy-pentanoic acid, copolymer	SML = 0,05 mg/kg for Crotonic acid (as impurity) and in compliance with the specifications laid down in Annex V

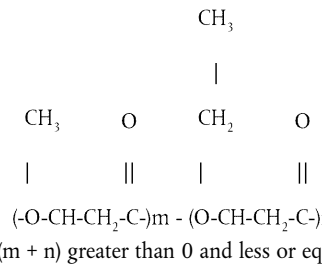
ANNEX V

SPECIFICATIONS

Part A: **General specifications**

The material and article manufactured by using aromatic isocyanates or colorants prepared by diazo-coupling, shall not release primary aromatic amines (expressed as aniline) in a detectable quantity (DL = 0,02 mg/kg of food or food simulant, analytical tolerance included). However, the migration value of the primary aromatic amines listed in this Directive are excluded from this restriction.

Part B: **Other specifications**

Ref. No	OTHER SPECIFICATIONS	
16690	Divinylbenzene It may contain up to 40 % of Ethylvinylbenzene.	
18888	3-Hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer	
	Definition	The copolymers are produced by the controlled fermentation of *Alcaligenes eutrophus* cepa using mixtures of glucose and propanoic acid as carbon sources. The organism used has not been genetically engineered and has been derived from a single wild-type organism *Alcaligenes eutrophus* strain HI6 NCIMB 10442. Master stocks of the organism are stored as freeze-dried ampoules. A submaster/working stock is prepared from the master stock and stored in liquid nitrogen and used to prepare inocula for the fermenter. Fermenter samples will be examined daily both microscopically and for any changes in colonial morphology on a variety of agars at different temperatures. The copolymers are isolated from heat treatment bacteria by controlled digestion of the other cellular components, washing and drying. These copolymers are normally offered as formulated, melt formed granules containing additives such as nucleating agents, plasticisers, fillers, stabilisers and pigments which all conform to the general and individual specifications.
	Chemical name	Poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate)
	CAS number	080181-31-3
	Structural formula	 where n/(m + n) greater than 0 and less or equal to 0,25
	Average molecular weight	Not less than 150 000 Daltons (measured by gel permeation chromotography).
	Assay	Not less than 98 % poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate) analysed after hydrolysis as a mixture of 3-D-hydroxybutanoic and 3-D-hydroxypentanoic acids.
	Description	White to off-white powder after isolation
	Characteristics	
	Identification tests:	
	Solubility	Soluble in chlorinated hydrocarbons such as chloroform or dichloromethane but practically insoluble in ethanol, aliphatic alkanes and water.
	Migration	The migration of crotonic acid should not exceed 0,05 mg/kg food.
	Purity	Prior to granulation the raw material copolymer powder must contain:
	— Nitrogen	Not more than 2 500 mg/kg of plastic
	— Zinc	Not more than 100 mg/kg of plastic
	— Copper	Not more than 5 mg/kg of plastic

Ref. No	OTHER SPECIFICATIONS
	— Lead Not more than 2 mg/kg of plastic — Arsenic Not more than 1 mg/kg of plastic — Chromium Not more than 1 mg/kg of plastic
23547	Polydimethylsiloxane (Mw > 6 800) Minimum viscosity 100×10^{-6} m²/s (= 100 centistokes) at 25 °C
25385	Triallylamine 40 mg/kg hydrogel at a ratio of 1 kg food to a maximum of 1,5 grams of hydrogel. For use only in hydrogels intended for non-direct food contact use.
38320	4-(2-Benzoxazolyl)-4′-(5-methyl-2-benzoxazolyl) stilbene Not more than 0,05 %w/w (quantity of substance used/quantity of the formulation)
43680	Chlorodifluoromethane Content of chlorofluoromethane less than 1 mg/kg of the substance
47210	Dibutylthiostannoic acid polymer Molecular unit = $(C_8H_{18}S_3Sn_2)n$ (n = 1,5-2)
76721	Polydimethylsiloxane (Mw > 6 800) Minimum viscosity 100×10^{-6} m²/s (= 100 centistokes) at 25 °C
83595	Reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorous trichloride and biphenyl **Composition:** — 4,4′-Biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS.No 38613-77-3) (36-46 % w/w (*)), — 4,3′-Biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS.No 118421-00-4 (17-23 % w/w (*)), — 3,3′-Biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS.No 118421-01-5) (1-5 % w/w (*)), — 4-Biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS.No 91362-37-7) (11-19 % w/w (*)), — Tris(2,4-di-tert-butylphenyl)phosphite (CAS.No 31570-04-4) (9-18 % w/w (*)), — 4,4′-Biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonate-0,0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS.No 112949-97-0) (< 5 % w/w (*)). **Other specifications:** — Phosphor content of min. 5,4 % to max. 5,9 % — Acid value of max. 10 mg KOH per gram — Melt range of 85-110 °C
88640	Soybean oil, epoxidized Oxirane < 8 %, iodine number < 6
95859	Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks The product should have the following specifications: — Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w) — Viscosity not less than 11×10^{-6} m²/s (= 11 centistokes) at 100 °C — Average molecular weight not less than 500.
95883	White mineral oils, paraffinic derived from petroleum based hydrocarbon feedstocks The product should have the following specifications: — Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w) — Viscosity not less than $8,5 \times 10^{-6}$ m²/s (= 8,5 centistokes) at 100 °C — Average molecular weight not less than 480

(*) Quantity of substance used /quantity of formulation

ANNEX VI

NOTES RELATED TO THE COLUMN "RESTRICTIONS AND/OR SPECIFICATIONS"

(1) Warning: there is a risk that the SML could be exceeded in fatty food simulants.

(2) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as Ref. Nos: 10060 and 23920.

(3) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as Ref. Nos: 15760, 16990, 47680, 53650 and 89440.

(4) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as Ref. Nos: 19540, 19960 and 64800.

(5) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as Ref. Nos: 14200, 14230 and 41840.

(6) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as Ref. Nos: 66560 and 66580.

(7) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref. Nos: 30080, 42320, 45195, 45200, 53610, 81760, 89200 and 92030.

(8) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref. Nos: 42400, 64320, 73040, 85760, 85840, 85920 and 95725.

(9) Warning: there is a risk that the migration of the substance deteriorates the organoleptic characteristics of the food in contact and then, that the finished product does not comply with the second indent of Article 2 of Directive 89/109/EEC.

(10) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref. Nos: 30180, 40980, 63200, 65120, 65200, 65280, 65360, 65440 and 73120.

(11) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref. Nos: 45200, 64320, 81680 and 86800.

(12) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref. Nos: 36720, 36800, 36840, and 92000.

(13) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref. Nos: 39090 and 39120.

(14) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref. Nos: 44960, 68078, 82020 and 89170.

(15) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref. Nos: 15970, 48640, 48720, 48880, 61280, 61360 and 61600.

(16) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref. Nos: 49600, 67520 and 83599.

(17) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref. Nos: 50160, 50240, 50320, 50360, 50400, 50480, 50560, 50640, 50720, 50800, 50880, 50960, 51040 and 51120.

(18) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref. Nos: 67600, 67680 and 67760.

(19) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref. Nos: 60400, 60480 and 61440.

(20) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref. Nos: 66400 and 66480.

(21) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref. Nos: 93120 and 93280.

(22) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref. Nos: 17260 and 18670.

(23) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref. Nos: 13620, 36840, 40320 and 87040.

(24) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref. Nos: 13720 and 40580.

([25]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref. Nos: 16650 and 51570.

([26]) QM(T) in this specific case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances mentioned as Ref. Nos: 14950, 15700, 16240, 16570, 16600, 16630, 18640, 19110, 22332, 22420, 22570, 25210, 25240 and 25270.

ANNEX VII

Part A

REPEALED DIRECTIVE AND ITS AMENDMENTS

(Referred to by Article 10(1))

Commission Directive 90/128/EEC (OJ L 349, 13.12.1990, p. 26)

Commission Directive 92/39/EEC (OJ L 168, 23.6.1992, p. 21)

Commission Directive 93/9/EEC (OJ L 90, 14.4.1993, p. 26)

Commission Directive 95/3/EC (OJ L 41, 23.2.1995, p. 44)

Commission Directive 96/11/EC (OJ L 61, 12.3.1996, p. 26)

Commission Directive 1999/91/EC (OJ L 310, 4.12.1999, p. 41)

Commission Directive 2001/62/EC (OJ L 221, 17.8.2001, p. 18)

Commission Directive 2002/17/EC (OJ L 58, 28.2.2002, p. 19)

Part B

DEADLINES FOR TRANSPOSITION INTO NATIONAL LAW

(Referred to by Article 10(1))

Directive	Deadlines		
	For transposition	To permit trade in those products which comply with this Directive	To prohibit trade in those products which do not comply with this Directive
90/128/EEC (OJ L 349, 13.12.1990, p. 26)	31 December 1990	1 January 1991	1 January 1993
92/39/EEC (OJ L 168, 23.6.1992, p. 21)	31 December 1992	31 March 1994	1 April 1995
93/9/EEC (OJ L 90, 14.4.1993, p. 26)	1 April 1994	1 April 1994	1 April 1996
95/3/EC (OJ L 41, 23.2.1995, p. 44)	1 April 1996	1 April 1996	1 April 1998
96/11/EC (OJ L 61, 12.3.1996, p. 26)	1 January 1997	1 January 1997	1 January 1999
1999/91/EC (OJ L 310, 4.12.1999, p. 41)	31 December 2000	1 January 2002	1 January 2003
2001/62/EC (OJ L 221, 17.8.2001, p. 18)	30 November 2002	1 December 2002	1 December 2002
2002/17/EC (OJ L 58, 28.2.2002, p. 19)	28 February 2003	1 March 2003	1 March 2004 1 March 2003 for materials and articles which contain Divinylbenzene

ANNEX VIII

CORRELATION TABLE

Directive 90/128/EEC	This Directive
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3
Article 3a	Article 4
Article 3b	Article 5
Article 3c	Article 6
Article 4	Article 7
Article 5	Article 8
Article 6	Article 9
-	Article 10
-	Article 11
-	Article 12
ANNEX I	ANNEX I
ANNEX II	ANNEX II
ANNEX III	ANNEX III
ANNEX IV	ANNEX IV
ANNEX V	ANNEX V
ANNEX VI	ANNEX VI
-	ANNEX VII
-	ANNEX VIII'

31982L0711

Council 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

Official Journal L 297 , 23/10/1982 P. 0026 - 0030
Finnish special edition: Chapter 13 Volume 12 P. 0132
Spanish special edition: Chapter 13 Volume 12 P. 0278
Swedish special edition: Chapter 13 Volume 12 P. 0132
Portuguese special edition Chapter 13 Volume 12 P. 0278

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COUNCIL DIRECTIVE

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

(82/711/EEC)

THE COUNCIL OF THE EUROPEAN

COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to 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 (1), and in particular Article 3 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas Article 2 of Directive 76/893/EEC laid down inter alia that materials and articles must not transfer their constituents to foodstuffs in quantities which could endanger human health or bring about an unacceptable change in the composition of the foodstuffs;

Whereas in order to achieve this objective in the case of plastic materials the suitable instrument is a specific directive within the meaning of Article 3 of Directive 76/893/EEC, the general rules of which shall also be applicable to the case in question;

Whereas, given the complexity of the problem, the Directive should initially be limited to fixing the basic rules for verification of constituent migration; whereas further directives, to be adopted in accordance with the procedure laid down in Article 10 of Directive 76/893/EEC, will establish the methods of analysis necessary for the verification of such migration;

Whereas this Directive does not affect all aspects of plastic materials and articles; whereas it is therefore necessary to authorize the Member States, on the one hand, not to impose the labelling particulars laid down in Article 7 of Directive 76/893/EEC in accordance with paragraphs 4 and 5 of that Article and, on the other hand, to prohibit the marketing of materials and articles which, although conforming with the standards laid down by that Directive, do not comply with national provisions regarding other possible standards referred to in Article 3 or in the absence of these, with Article 2 of the Directive in question;

Whereas, in view of the analytical difficulties connected with the determination of the migration levels in food products, conventional tests should be chosen (liquids capable of simulating the

attack on foodstuffs and standard test conditions) in order to reproduce, as far as possible, the migration phenomena which may occur in contact between the article and the foodstuff;

Whereas if such tests subsequently prove not to reflect reality Member States should be authorized to amend them provisionally, pending a Community decision;

Whereas, 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; whereas a decision on the application of this Directive to such materials and articles should therefore be taken at a later date;

Whereas the adaptation of this Directive to technical progress is an implementing measure; whereas, in order to simplify and accelerate the procedure, this should be the responsibility of the Commission;

Whereas in all cases in which the Council confers on the Commission authority to implement the provisions relating to plastic materials and articles intended to come into contact with foodstuffs, a procedure should be laid down establishing close cooperation between Member States and the Commission within the Standing Committee for Foodstuffs set up under Decision 69/414/EEC (1),

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific Directive within the meaning of Article 3 of Directive 76/893/EEC.

2. This Directive shall apply to plastic materials and articles, that is to say to materials and articles and parts thereof:

(a) consisting exclusively of plastics, or

(b) composed of two or more layers of materials, each consisting exclusively of plastics, which are bound together by means of adhesives or by any other means,

which, in the finished product state, are intended to come into contact or are brought into contact with foodstuffs and are intended for that purpose.

3. For the purposes of this Directive, 'plastics' shall mean the organic macromolecular compounds obtained by polymerization, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromolecules. Silicones and other similar macromolecular compounds shall also be regarded as plastics. Other substances or matter may be added to such macromolecular compounds.

However, the following shall not be regarded as 'plastics':

(i) varnished or unvarnished regenerated cellulose film;

(ii) elastomers and natural and synthetic rubber;

(iii) paper and paperboard, whether modified or not by the addition of plastics;

(iv) surface coatings obtained from:

- paraffin waxes, including synthetic paraffin waxes, and/or micro-crystalline waxes,

- mixtures of the waxes listed in the first indent with each other and/or with plastics.

4. This Directive shall not apply to materials and articles composed or 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.

A decision on the application of this Directive to the materials and articles referred to in the first subparagraph and on any adaptations to the Directive that may become necessary shall be taken at a later date.

Article 2

1. The migration level of the constituents of the materials and articles referred to in Article 1 into or onto foodstuffs must not exceed the limits laid down in the lists of substances whose use is authorized to the exclusion of any others.

2. In the absence of methods of analysis determined in accordance with Article 9 of Directive 76/893/EEC which make it possible to determine the level of migration into foodstuffs, that level shall be determined in the simulants listed in Chapter I of the Annex.

3. The Council, acting in accordance with the procedure laid down in Article 100 of the Treaty and on a proposal from the Commission, shall draw up a list of substances or matter whose use is authorized to the exclusion of any others and a list of simulants to be used for each foodstuff or group of foodstuffs and shall determine the concentration thereof.

Article 3

1. Verification of a migration in the simulants shall be carried out using conventional migration tests, the basic rules for which are laid down in the Annex to this Directive.

2. (a) However, where a Member State, as a result of new information or of a reassessment of existing information made since this Directive was adopted, has detailed grounds for establishing that for a given plastic material or article the basic rules laid down in the Annex for migration tests are technically unsuitable or because the actual conditions of use are basically different from the test conditions specified in the table in the Annex, that Member State may,

within its territory and only for the particular case, temporarily suspend application of the basic rules referred to in the Annex and permit the use of more appropriate basic rules. It shall immediately inform the other Member States and the Commission thereof and give the reasons for its decision.

(b) The Commission shall examine, as soon as possible, the reasons given by the Member State concerned and shall consult the Member States within the Standing Committee for Foodstuffs and shall then deliver its opinion forthwith and take the appropriate measures.

(c) If the Commission considers that amendments to this Directive are necessary in order to alleviate the difficulties mentioned in subparagraph (a), it shall initiate the procedure laid down in Article 10 of Directive 76/893/EEC; in that case, the Member State which has adopted the more appropriate basic rules may retain them until the said amendments enter into force.

Article 4

Adaptations to be made to Chapter II of the Annex to this Directive in the light of progress in scientific and technical knowledge shall be adopted in accordance with the procedure laid down in Article 10 of Directive 76/893/EEC.

Article 5

This Directive shall not affect national provisions relating to the other rules provided for in Article 3 of Directive 76/893/EEC nor the options open to Member States under Article 7 (4) and (5) of that Directive.

Article 6

Member States shall comply with this Directive not later than such time as a specific directive laying down the limits referred to in Article 2 (1) is implemented.

Article 7

This Directive is addressed to the Member States.

Done at Luxembourg, 18 October 1982.

For the Council

The President

N. A. KOFOED

(1) OJ No L 340, 9. 12. 1976, p. 19.

(2) OJ No C 140, 5. 6. 1979, p. 173.

(3) OJ No C 227, 10. 9. 1979, p. 31.

(1) OJ No L 291, 19. 11. 1969, p. 9.

ANNEX

BASIC RULES NECESSARY FOR TESTING MIGRATION IN SIMULANTS

The determination of migration in simulants is to be carried out using the simulants laid down in Chapter I of this Annex and under the test conditions specified in Chapter II of the Annex.

CHAPTER I

Simulants

1. General case: plastic materials and articles intended to come into contact with foodstuffs of all types

The tests are to be carried out using all the simulants mentioned below, taking a fresh sample of the plastic material or article for each simulant:

- 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 (1); if for technical reasons connected with the method of analysis it is necessary to use different simulants, olive oil must be replaced by a mixture of synthetic triglycerides (2) or by sunflower oil (= simulant D).

2. Special case: plastic materials and articles intended to come into contact with a single foodstuff or a specific group of foodstuffs

The tests are to be carried out:

- using only the simulants specified as appropriate for the foodstuff or group of foodstuffs in the list referred to in Article 2 (3),

- where the foodstuff or group of foodstuffs is not included in the list referred to in the first indent, selecting the simulant or simulants prescribed in Section 1 which correspond most closely to the extractive capacity of the foodstuff or group of foodstuffs.

CHAPTER II

Test conditions (times and temperatures)

1. The migration tests are to be carried out, selecting from the times and temperatures specified in the table those which correspond most closely to the normal or foreseeable conditions of contact for the plastic materials or articles being studied.

2. If a plastic material or article is intended to be used successively at short intervals in several of the conditions of contact referred to in column 1 of the table, migration will be determined by subjecting that material or article successively to all the corresponding test conditions specified in column 2, using the same simulant.

3. For a given test time, where a plastic material or article passes the test at the higher temperature, the test need not be repeated at the lower temperature.

For a given test temperature, where a plastic material or article passes the test over the longer time, the test need not be repeated over the shorter time.

(1) Characteristics of rectified olive oil:

- iodine index (Wijs) = 80 to 88,

- refraction index at 25 °C = 1;4665 to 1;4679,

- acidity (expressed in % of oleic acid = 0;5 % maximum,

- peroxide index (expressed in milli-equivalents of oxygen per kg of oil) = 10 maximum.

(2) Characteristics of the standard synthetic triglycerides mixture as described in K. Figge's article, 'Food cosmet. Toxicol' 10 (1972) 815.

TABLE

Test conditions (times (t) and temperatures (T)) to be chosen according to conditions of contact in actual use

1.2 // // // Conditions of contact in actual use // Test conditions // // // 1 // 2 // // // 1. Contact time: t > 24 hours // // 1.1. T µ 5 °C // 10 days at 5 °C // 1.2. 5 °C < T µ 40 °C (1) // 10 days at 40 °C // 2. Contact time: two hours µ t µ 24 hours // // 2.1. T µ 5 °C // 24 hours at 5 °C // 2.2. 5 °C < T µ 40 °C // 24 hours at 40 °C // 2.3. T > 40 °C // In accordance with national laws // 3. Contact time: t < two hours // // 3.1. T µ 5 °C // Two hours at 5 °C // 3.2. 5 °C < T µ 40 °C // Two hours at 40 °C // 3.3. 40 °C < T µ 70 °C // Two hours at 70 °C // 3.4. 70 °C < T µ 100 °C // One hour at 100 °C // 3.5. 100 °C < T µ 121 °C // 30 min at 121 °C // 3.6. T > 121 °C // In accordance with national laws // //

(1) For plastic materials and articles in contact with foodstuffs for which a preservation temperature of less than 20 °C is specified on the labelling or by law, the test conditions will be 10 days at 20 °C.

4. Where the plastic material or article may in actual use be employed under any conditions of contact time or temperature, only the 10-day tests at 40 °C and the two-hour tests at 70 °C are to be carried out, these being conventionally regarded as the most stringent.

If simulant D is used (rectified olive oil or substitutes for it), only the 10-day test at 40 °C is to be carried out.

5. If it is found that carrying out the tests under the conditions specified in the table causes physical or other changes in the plastic material or article which do not occur under normal or foreseeable conditions of use of that material or article, the migration tests should be carried out under conditions more appropriate to the specific case.

31993L0008

Commission Directive 93/8/EEC of 15 March 1993 amending Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs

Official Journal L 090 , 14/04/1993 P. 0022 - 0025
Finnish special edition: Chapter 13 Volume 24 P. 0016
Swedish special edition: Chapter 13 Volume 24 P. 0016

COMMISSION DIRECTIVE 93/8/EEC of 15 March 1993 amending Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to 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 (1), and in particular Article 3 thereof,

Whereas the Community measures envisaged by this Directive are not only necessary but also indispensable for the attainment of the objectives of the internal market; whereas these objectives cannot be achieved by Member States individually, and whereas furthermore their attainment at Community level is already provided for by Directive 89/109/EEC;

Whereas Commission Directive 90/128/EEC of 23 February 1990 relating to plastic materials and articles intended to come into contact with foodstuffs (2), as amended by Directive 92/39/EEC (3), provides the possibility of carrying out the migration tests either on foodstuffs or on food simulants, whilst Council Directive 82/711/EEC (4) requires the migration tests to be carried out only on food simulants unless the method of analysis which enables migration into foodstuffs to be established has been adopted officially; whereas this discrepancy is capable of affecting the proper application of the Directives and whereas it is therefore necessary to eliminate it;

Whereas the increasing use of microwave ovens makes it necessary to establish new specific test conditions;

Whereas it is necessary to remove the possibility given to the Member States to adopt national rules for high-temperature testing in order to eliminate the existing discrepancies;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 82/711/EEC is amended as follows:

1. Articles 2 and 3 are replaced by the following:

'Article 2

The overall and specific migration levels of constituents of the materials and articles referred to in Article 1 into or onto foodstuffs or food simulants must not exceed the limits laid down in Commission Directive 90/128/EEC (*) or in any other relevant specific directive.

Article 3

1. Verification of compliance of migration into foodstuffs with the migration limits shall be carried out under the most extreme conditions of time and temperature foreseeable in actual use.

Verification of compliance of migration into food simulants with the migration limits shall be carried out using conventional migration tests, the basic rules for which are laid down in the Annex to this Directive.

2. (a) However, where a Member State, as a result of new information or of a reassessment of existing information made since this Directive was adopted, has detailed grounds for establishing that for a given plastic material or article the basic rules laid down in the Annex for migration tests are technically unsuitable or because the actual conditions of use are basically different from the test conditions specified in the table in the Annex, that Member State may, within its territory and only for the particular case, temporarily suspend application of the basic rules referred to in the Annex and permit the use of more appropriate basic rules. It shall immediately inform the other Member States and the Commission thereof and give the reasons for its decision.

(b) The Commission shall examine, as soon as possible, the reasons given by the Member States concerned and shall consult the Member States within the Standing Committee for Foodstuffs and shall then deliver its opinion forthwith and amend this Directive, if necessary. In that case, the Member State which has adopted the more appropriate basic rules may retain them until the said amendments enter into force.

(*) OJ No L 75, 21. 3. 1990, p. 19, amended by OJ No L 349, 13. 12. 1990, p. 26.'

2. The Annex is replaced by the Annex hereto.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive as from 1 April 1994. They shall immediately inform the Commission thereof.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 15 March 1993.

For the Commission

Martin BANGEMANN

Member of the Commission

(1) OJ No L 40, 11. 2. 1989, p. 38.

(2) OJ No L 75, 21. 3. 1990, p. 19, rectified by OJ No L 349, 13. 12. 1990, p. 26.

(3) OJ No L 168, 23. 6. 1992, p. 21.

(4) OJ No L 297, 23. 10. 1982, p. 26.

ANNEX

'ANNEX

BASIC RULES FOR TESTING MIGRATION IN FOOD SIMULANTS

The determination of migration in food simulants shall be carried out using the food simulants laid down in Chapter I of Annex and under the test conditions specified in Chapter II of Annex. However the determination of migration shall be restricted to the food simulant(s) and to the

condition(s) of test which, in the specific case under examination, may be considered to be the most severe on the basis of experience.

CHAPTER I

Food simulants

1. General case: plastic materials and articles intended to come into contact with foodstuffs of all types

The tests shall be carried out using the food simulants mentioned below, taking a fresh sample of the plastic material or article for each simulant:

- 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 (1) (= simulant D); if for technical reasons connected with the method of analysis it is necessary to use different food simulants, olive oil shall be replaced by a mixture of synthetic triglycerides (2) or by sunflower oil. If all the food simulants provided in this indent are inappropriate, other food simulants and conditions of time and temperature may be used.

However, the simulant A shall be used only in the cases mentioned specifically in the Table of this Annex.

2. Special case: plastic materials and articles intended to come into contact with a single foodstuff or a specific group of foodstuffs

The tests shall be carried out:

- using only the food simulant(s) specified as appropriate for the foodstuff or group of foodstuffs in the Directive 85/572/EEC (3),

- where the foodstuff or group of foodstuffs is not included in the list referred to in the first indent, selecting the food simulant(s) prescribed in Section 1 which correspond most closely to the extractive capacity of the foodstuff or group of foodstuffs.

CHAPTER II

Test conditions (times and temperatures)

1. The migration tests are to be carried out, selecting from the times and temperatures specified in the table those which correspond most closely to, but are not less than, the normal or foreseeable conditions of contact for the plastic materials or articles being studied.

2. Where a material or article passes a test at a given time and temperature, it need not to be tested for a shorter time at the same temperature, nor for the same time at a lower temperature.

3. However if a plastic material or article is intended for a food contact application covered by two or more combinations of time and temperature taken from the Table, migration will be determined by subjecting that material or article successively to all the applicable test conditions, using the same aliquot of food simulant.

4. If a plastic material or article is intended to come into contact with foodstuffs at any condition of time, the conditions for testing will be the following:

(a) where the plastic material or article may in actual use be employed at any temperature up to and including 70 °C and that is indicated by an appropriate labelling or instructions, only the 10 day test(s) at 40 °C shall be carried out;

(b) where a plastic material or article may in actual use be employed at a temperature above 70° C:

(i) where no labelling or instructions are given to indicate temperature expected in real use, simulants B and C shall be used at reflux temperature, if possible, or at two-hour test(s) at 100° C and simulant D shall be used for two hours at 175° C;

(ii) where labelling or instructions are given to indicate conditions expected in real use, time and temperatures from the Table shall be selected.

5. By derogation from the conditions provided in the table and in paragraph 2, if the plastic material or article may in actual use be employed for periods of less than 15 minutes at temperatures between 70° C and 100° C and that is indicated by an appropriate labelling or instructions, only the two-hour test at 70° C and the 10-day test at 40° C shall be carried out. These tests shall be carried out separately taking different samples. For each of these two types of test, use a new sample of the same material or article to be examined.

6. If it is found that carrying out the tests under the conditions specified in the table causes physical or other changes in the plastic material or article which do not occur under normal of foreseeable conditions of use of that material or article, the migration tests shall be carried out under conditions more appropriate to the specific case.

7. For materials and articles intended for use in microwave ovens, migration testing shall use a conventional oven and appropriate time and temperature conditions selected from the Table.

Table

/* Tables: see OJ */

(1) Characteristics of rectified olive oil: - iodine index (Wijs) = 80 to 88, - refraction index at 25 °C = 1,4665 to 1,4679, - acidity (expressed in % of oleic acid) = 0,5 % maximum, - peroxide index (expressed in milli-equivalents of oxygen per kg of oil) = 10 maximum.

(2) Characteristics of the standard synthetic triglycerides mixture as described in K. Figge's article, 'Food Cosmet. Toxicol' 10 (1972) 81.5.

(3) OJ No L 372, 31. 12. 1985, p. 14.

31997L0048

Commission Directive 97/48/EC of 29 July 1997 amending for the second time Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs (Text with EEA relevance)

Official Journal L 222 , 12/08/1997 P. 0010 - 0015

COMMISSION DIRECTIVE 97/48/EC of 29 July 1997 amending for the second time Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs (Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 (1), and in particular Article 3 thereof,

Whereas Council 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 (2), as amended by Directive 93/8/EEC (3), does not specify the migration tests to be carried out in cases where the fatty food simulants are inappropriate;

Whereas the application of the test using the fatty food simulants is time consuming and difficult to conduct and therefore alternative tests in some specified conditions should be permitted;

Whereas it is not clear whether Directive 82/711/EEC authorizes the use of plastic materials and articles which are not intended to come into contact with foodstuffs of all types but which are intended to come into contact with more than one single foodstuff or more than one specific group of foodstuffs; whereas this use may be authorized without posing any problem to health provided an appropriate indication informs the consumer or the retailer of the type(s) of foodstuff(s) with which it may or may not come into contact;

Whereas the indication of an excessive number of foodstuffs types which could be in contact with some plastic materials and articles may not be easy to understand and therefore these materials and articles should be submitted to all the food simulants or test media provided by this Directive to protect the consumer;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Annex to Directive 82/711/EEC is replaced by the Annex hereto.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive as from 1 July 1998. They shall immediately inform the Commission thereof.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 3

This Directive shall enter into force on the 20th day following that of its publication in the Official Journal of the European Communities.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 29 July 1997.

For the Commission

Martin BANGEMANN

Member of the Commission

(1) OJ No L 40, 11. 2. 1989, p. 38.

(2) OJ No L 297, 23. 10. 1982, p. 26.

(3) OJ No L 90, 14. 4. 1993, p. 22.

ANNEX

'ANNEX

BASIC RULES FOR OVERALL AND SPECIFIC MIGRATION TESTING

1. "Migration tests" for the determination of specific and overall migration shall be carried out using the "food simulants" laid down in Chapter I of this Annex and under "conventional migration test conditions" specified in Chapter II of this Annex.

2. "Substitute tests" which use the "test media" under the "conventional substitute test conditions" as set out in Chapter III shall be carried out if the migration test using the fatty food simulants (see Chapter I) is not feasible for technical reasons connected with the method of analysis.

3. "Alternative tests" indicated in Chapter IV are permissible instead of migration tests with fatty food simulant when the conditions specified in Chapter IV are fulfilled.

4. In all three cases it is permissible:

(a) to reduce the number of tests to be carried out to that or those which, in the specific case under examination, is (are) generally recognized to be the most severe on the basis of scientific evidence;

(b) to omit the migration or the substitute or the alternative tests where there is conclusive proof that the migration limits cannot be exceeded in any foreseeable conditions of use of the material or article.

CHAPTER I

Food simulants

1. Introduction

As it is not possible always to use foodstuffs for testing food contact materials, food simulants are introduced. They are classified by convention as having the character of one or more food types. The food types and the food simulants to be used are indicated in Table 1. In practice various mixtures of food types are possible, for instance fatty and aqueous foods. They are described in Table 2 accompanied by the indication of the food simulant(s) to be selected in carrying out the migration tests.

>TABLE>

2. Selection of food simulants

2.1. Materials and articles intended for contact with all food types

The tests shall be carried out using the food simulants mentioned below, which are considered the more severe, at the test conditions specified in Chapter II, taking a new test specimen of the plastic material or article for each simulant:

- 3 % acetic acid (w/v) in aqueous solution,

- 10 % ethanol (v/v) in aqueous solution,

- rectified olive oil ("reference simulant D").

However this reference simulant D may be replaced by a synthetic mixture of triglycerides or sunflower oil or corn oil with standardized specifications ("Other fatty food simulants", called "simulants D"). If, when using any of these other fatty food simulants, the migration limits are exceeded, for the judgement of non compliance a confirmation of the result by using olive oil is obligatory, when technically feasible. If this information is not technically feasible and the material or article exceeds the migration limits it shall be deemed not in compliance with the Directive 90/128/EEC.

2.2. Materials and articles intended for contact with specific food types

This case refers only to the following situations:

(a) when the material or article is already in contact with a known foodstuff;

(b) when the material or article is accompanied, according to the rules of Article 6 of Directive 89/109/EEC, by a specific indication stating with which food types described in Table 1 it may or may not be used, for example "only for aqueous foods";

(c) when the material or article is accompanied, according to the rules of Article 6 of Directive 89/109/EEC, by a specific indication stating with which foodstuff(s) or group(s) of foodstuffs mentioned in Directive 85/572/EEC they may or may not be used. This indication shall be expressed:

(i) at the marketing stages other than retail stage, by using the "reference number" or "description of foodstuffs" provided in the Table of Directive 85/572/EEC;

(ii) at the retail stage using an indication which shall refer to only a few foods or groups of food, preferably with examples which are easy to understand.

In these situations the tests shall be carried out using for the case under (b) the food simulant(s) indicated as examples in Table 2 and for the case under (a) and (c) the food(s) simulant(s) mentioned in Directive 85/572/EEC. Where the foodstuff(s) or group(s) of foodstuffs is (are) not included in the list specified in Directive 85/572/EEC, select the item from Table 2 which corresponds most closely to the foodstuff(s) or group(s) of foodstuffs under examination.

If the material or article is intended to come into contact with more than one foodstuff or group(s) of foodstuffs having different reduction factors, for each foodstuff apply the appropriate reduction factors to the test result. If one or more results of such calculation exceed the restriction, then the material is not suitable for that particular foodstuff or group(s) of foodstuff.

The tests shall be carried out at the test conditions specified in Chapter II, taking a new test specimen for each simulant.

>TABLE>

CHAPTER II

Migration test conditions (times and temperatures)

1. The migration tests are to be carried out, selecting from the times and temperatures specified in Table 3 those which correspond to the worst foreseeable conditions of contact for the plastic material or article being studied and to any labelling information on maximum temperature for use. Therefore if the plastic material or article is intended for a food contact application covered

by a combination of two or more times and temperatures taken from the table, the migration test shall be carried out subjecting the test specimen successively to all the applicable worst foreseeable conditions appropriate to the sample, using the same portion of food simulant.

2. Contact conditions generally recognized as more severe

In application of the general criteria that the determination of migration should be restricted to the test conditions which, in the specific case under examination, are recognized to be the most severe on the basis of scientific evidence, some specific examples for the test contact conditions are given below.

2.1. Plastic materials and articles intended to come into contact with foodstuffs at any condition of time and temperature

Where no labelling or instructions are given to indicate contact temperature and time expected in actual use, depending on food type(s), simulant(s) A and/or B and/or C shall be used for 4 hours at 100 °C or for 4 hours at reflux temperature and/or simulant D shall be used only for 2 hours at 175 °C. These conditions of time and temperature are conventionally considered to be the more severe.

2.2. Plastic materials and articles intended to come into contact with foodstuffs at room temperature or below for an unspecified period

Where the materials and articles are labelled for use at room temperature or below or where the materials and articles by their nature are clearly intended for use at room temperature and below, the test shall be carried out at 40 °C for 10 days. These conditions of time and temperature are conventionally considered to be the more severe.

3. Volatile migrants

When testing for the specific migration of volatile substances, the test(s) with simulant(s) shall be performed in a manner which recognizes the loss of volatile migrants which may occur in the worst foreseeable conditions of use.

4. Special cases

4.1. For materials and articles intended for use in microwave ovens, migration testing may use either a conventional or a microwave oven provided the appropriate time and temperature conditions are selected from Table 3.

4.2. If it is found that carrying out the tests under the contact conditions specified in Table 3 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.

4.3. By derogation from the test conditions provided in Table 3 and in paragraph 2, if the plastic material or article may in actual use be employed for periods of less than 15 minutes at temperatures between 70 °C and 100 °C (e.g. "hot fill") and is so indicated by appropriate labelling or instructions, only the 2 hours test at 70 °C shall be carried out. However if the material or article is intended to be used also for storage at room temperature, the above-mentioned test is replaced by a test at 40 °C for 10 days conventionally considered more severe.

4.4. In those instances where the conventional conditions for migration testing are not adequately covered by the test contact conditions of Table 3 (for instance contact temperatures greater than 175 °C or contact time less than 5 minutes), other contact conditions may be used which are more appropriate to the case under examination, provided that the selected conditions may represent the worst foreseeable conditions of contact for the plastic materials or articles being studied.

>TABLE>

CHAPTER III

Substitute fat test for overall and specific migration

1. If the use of the fatty food simulants is not feasible for technical reasons connected with the method of analysis, use instead all test media prescribed in Table 4 under the test conditions corresponding to the test conditions for simulant D.

This table gives some examples of the most important conventional migration test conditions and their corresponding conventional conditions of the substitute tests. For other test conditions not stated in Table 4, take into account these examples as well as the existing experience for the type of polymer under examination.

Use for each test a new test specimen. Apply for each test medium the same rules prescribed in Chapters I and II for simulant D. Use, where appropriate, the reduction factors established in Directive 85/572/EEC. To ascertain compliance with any migration limit, select the highest value obtained using all the test media.

However if it is found that carrying out these tests causes physical or other changes in the test specimen which do not occur under the worst foreseeable conditions of use of the material or article under examination, the result for this test media shall be discarded and the highest of the remaining values shall be chosen.

2. By derogation of point 1, it may be possible to omit one or two of the substitute tests provided in Table 4, if these tests are generally recognized as not appropriate for the sample under consideration on the basis of scientific evidence.

>TABLE>

CHAPTER IV

Alternative fat tests for overall and specific migration

1. It is permissible to use the result of alternative tests as specified in this Chapter provided that both the following conditions are fulfilled:

(a) the results obtained in a "comparison test" show that the values are equal to or greater than those obtained in the test with simulant D;

(b) the migration in alternative test does not exceed the migration limits, after application of appropriate reduction factors provided in Directive 85/572/EEC.

If either or both conditions are not fulfilled, then the migration tests must be performed.

2. By derogation of the condition previously mentioned in paragraph 1 (a), it is possible to omit the comparison test if there is other conclusive proof based on scientific experimental results that the values obtained in the alternative test are equal to or greater than those obtained in the migration test.

3. Alternative tests

3.1. Alternative tests with volatile media

These tests use volatile media such as isooctane or ethanol 95 % or other volatile solvents or mixture of solvents. They shall be carried out at the contact conditions such that the condition under 1 (a) is fulfilled.

3.2. "Extraction tests"

Other tests, which use media having a very strong extraction power under very severe test conditions, may be used if it is generally recognized, on the basis of scientific evidence, that the results obtained using these tests ("extraction tests") are equal to or higher than those obtained in the test with simulant D.`

COMMISSION DIRECTIVE 2004/1/EC

of 6 January 2004

amending Directive 2002/72/EC as regards the suspension of the use of azodicarbonamide as blowing agent

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 [1], and in particular Article 3 thereof,

Whereas:

(1) Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs [2] authorises the use of azodicarbonamide as a blowing agent in plastic materials and articles intended to come into contact with foodstuffs in accordance with the opinion of the Scientific Committee on Food (SCF).

(2) Azodicarbonamide is used as blowing agent in the manufacture of plastic gaskets in metal lids used for the closure of glass jars. New findings have shown that azodicarbonamide decomposes into semicarbazide (SEM) when heated during production of the foamed gasket and during sterilisation of the sealed glass jar.

(3) On 8 July 2003 the European Food Safety Authority (hereinafter called 'the Authority') was informed by industry that SEM had been found in a number of foods contained in glass jars. The levels of SEM in these foods were variable (up to 25 µg/kg), with the highest concentrations found in baby foods.

(4) Based on the existing scientific data, including recent research commissioned by the Authority, the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (hereinafter called 'the Panel') concluded, in its statement of 1 October 2003, that SEM has a weak carcinogenic activity in laboratory animals and weak genotoxicity *in vitro* but that it was not possible according to the current scientific knowledge to conclude whether SEM poses a carcinogenic risk to humans.

(5) An ad hoc expert group was specifically commissioned by the Authority to advise further on possible risks to infants, the consumer group for which potential exposure to SEM per body weight is likely to be the highest. In evaluating the possible consequences of SEM in baby foods, the expert group reviewed toxicological aspects alongside microbiological and nutritional considerations.

(6) On 9 October 2003 they advised that, taking into account the current available information on the levels of SEM in food, intake and toxicology, the risk to both infants and adults eating foods containing SEM was probably very small. However, the Panel stated that the presence of SEM in baby food was undesirable and recommended that it would be prudent to reduce exposure to SEM as swiftly as technological progress safely allows.

(7) Considering the conclusions of the Panel and the ad hoc expert group and the remaining scientific uncertainties it is appropriate, in order to achieve the high level of health protection chosen in the Community, to suspend the use of azodicarbonamide in accordance with the precautionary principle referred to in Article 7 of Regulation (EC) No 178/2002 of the European Parliament and of the Council [3] (Food law). The suspension of azodicarbonamide from the incomplete list of additives fully harmonised at Community level should apply while the Community seeks more complete information from any source, which could clarify the gaps in the present state of knowledge of SEM.

(8) The Commission has been informed that alternatives for azodicarbonamide will become available in the near future. With respect to the possible replacement of azodicarbonamide in packaging materials for baby foods, it is critical that careful consideration and evaluation of seal integrity be carried out prior to their introduction in order not to compromise the microbiological safety of the food. It is therefore necessary to provide for a transitional period of 18 months to allow such evaluation to be carried out over a time period, which takes account of the minimum shelf-life for such packaged foods.

(9) A transitional period should also be provided for in respect of materials and articles which are brought into contact with foodstuffs before the deadline for implementation of this Directive.

[1] OJ L 40, 11.2.1989, p. 38. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

[2] OJ L 220, 15.8.2002, p. 18.

[3] OJ L 31, 1.2.2002, p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

(10) This transitional period should also take into account the requirements of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs [1].

(11) Directive 2002/72/EC should therefore be amended accordingly.

(12) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

As regards the additive azodicarbonamide with reference number 36640 the text in column 4 of Section A of Annex III to Directive 2002/72/EC is replaced by the following:

'For use only as blowing agent. Use prohibited as from 2 August 2005.'

Article 2

1. Member States shall adopt and publish, by 2 August 2005 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

2. Member States shall apply the provisions referred to in paragraph 1 from 2 August 2005 in such a way as to prohibit the placing on the market and importation into the Community of plastic materials and articles intended to come into contact with foodstuffs and which do not comply with this Directive.

However, materials and articles filled before 2 August 2005 may continue to be placed on the market provided that the date of filling appears on the materials and articles. The date of filling may be replaced by another indication, provided that that indication permits the identification of the date of filling. Upon request the date of filling shall be made available to the competent authorities and any person enforcing the requirements of this Directive.

The first and second subparagraphs shall apply without prejudice to the requirements of Directive 2000/13/EC.

When Member States adopt the provisions referred to in paragraph 1, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

3. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 6 January 2004.

For the Commission

David BYRNE

Member of the Commission

[1] OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15.)

COMMISSION DIRECTIVE 2004/19/EC

of 1 March 2004

amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 [1], and in particular Article 3 thereof,

After consulting the European Food Safety Authority,

Whereas:

(1) Commission Directive 2002/72/EC [2] sets out rules for plastic materials and articles which are intended to come into contact with foodstuffs.

(2) Directive 2002/72/EC establishes a list of monomers and other starting substances, which may be used for the manufacture of plastic materials and articles. On the basis of new information, certain monomers provisionally admitted at national level as well as new monomers should be included in the Community list of permitted substances in that Directive.

(3) Directive 2002/72/EC also contains an incomplete list of additives which may be used in the manufacture of plastic materials and articles. That list should be amended so as to include other additives evaluated by the European Food Safety Authority (the Authority).

(4) For certain substances, the restrictions already established at Community level should be amended on the basis of the new information available.

(5) The current list of additives is incomplete inasmuch as it does not contain all substances currently accepted in one or more Member States. Those additives continue to be regulated by national laws pending a decision on inclusion into the Community list.

(6) The current list of additives should become a positive list in order to harmonise the use of these additives in the Community. For additives which are already placed on the market in one or more of the Member States, sufficient time should be allowed for the submission of the data necessary for the Authority to carry out an evaluation of their safety. Therefore, the deadline for the submission of the data should be set as 31 December 2006.

(7) If the data are in compliance with the Authority requirements, it should be possible to continue to use those additives in accordance with national law until their evaluation is completed. If the data are not in compliance with the Authority requirements or are submitted later than 31 December 2006 those additives should not be included in the first positive list.

(8) The date when the list of additives is to become a positive list should be established no later than 31 December 2007 as it is impossible to know the number of additives for which the data required by the Authority will be supplied. That date should be fixed taking into account the time needed for the Authority to evaluate all the applications supplied on time.

(9) Some substances used to manufacture plastic materials and articles intended to come into contact with food are also added directly to foodstuffs. These substances should not migrate from the materials or articles into the foodstuffs in quantities that could exceed the limits set in the relevant food legislation or in this Directive whichever provides the lower restriction. In any case, these substances should not migrate from the materials or articles into the foodstuffs in quantities having a technological function in the final food. The users of materials and articles which may release these substances into foodstuffs should be appropriately informed in order to be able to comply with other relevant food legislation.

(10) Member States should retain the right to lay down rules concerning substances used as active components in active food contact materials and articles until Community provisions are adopted.

(11) Directive 2002/72/EC should therefore be amended accordingly.

[1] OJ L 40, 11.2.1989, p. 38. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

[2] OJ L 220, 15.8.2002, p. 18. Directive as amended by Directive 2004/1/EC (OJ L 7, 13.1.2004, p. 45).

(12) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 2002/72/EC is amended as follows:

1. In Article 3, paragraphs 1 and 2 are replaced by the following:

'1. Only those monomers and other starting substances listed in Annex II, section A may be used for the manufacture of plastic materials and articles subject to the restrictions set out therein.

2. By way of derogation from paragraph 1, the monomers and other starting substances listed in Annex II, section B may continue to be used until 31 December 2004 at the latest, pending their evaluation by the European Food Safety Authority (hereinafter referred to as the Authority).'

2. Article 4 is replaced by the following:

'*Article 4*

1. A list of additives which may be used for the manufacture of plastic materials and articles, together with the restrictions and/or specifications on their use, is set out in Annex III.

That list of additives shall be considered to be an incomplete list until the Commission decides, in accordance with Article 4a, that it shall become a positive Community list of authorised additives, to the exclusion of all others.

The Commission shall establish, by 31 December 2007 at the latest, the date when that list shall become a positive list.

2. For the additives listed in Annex III, section B, the verification of compliance with the specific migration limits in simulant D or in test media of substitute tests as laid down in Article 3(1), second subparagraph of Directive 82/711/EEC and Article 1 of Directive 85/572/EEC shall apply from 1 July 2006.

3. The lists in Annex III, sections A and B do not yet include the following additives:

(a) additives used only in the manufacture of:

— surface coatings obtained from resinous or polymerised products in liquid, powder or dispersion form, such as varnishes, lacquers, paints,

— epoxy resins,

— adhesives and adhesion promoters,

— printing inks;

(b) colorants;

(c) solvents.'

3. The following Articles 4a and 4b are inserted:

'*Article 4a*

1. A new additive may always be added to the list of substances referred to in Article 4(1) following an evaluation of its safety by the Authority.

2. Member States shall provide that any person interested in the inclusion in the list referred to in Article 4(1) of an additive, which is already placed on the market in one or more of the Member States, shall submit data for the evaluation of its safety by the Authority by 31 December 2006 at the latest.

For the submission of the required data, the applicant shall consult the "Guidelines of the European Food Safety Authority for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation".

3. If during the examination of the data referred to in paragraph 2, the Authority calls for supplementary information, the additive may continue to be used subject to national law until the Authority has issued an opinion, provided that the information is submitted within the time limits specified by the Authority.

4. The Commission shall establish, by 31 December 2007 at the latest, a provisional list of additives which may continue to be used after 31 December 2007 subject to national law until the Authority has evaluated them.

5. The inclusion of an additive in the provisional list is subject to the following conditions:

(a) the additive must be permitted in one or more of the Member States no later than 31 December 2006;

(b) the data referred to in paragraph 2 concerning that additive must have been supplied in accordance with the Authority requirements no later than 31 December 2006.

Article 4b

Without prejudice to Article 4 of Directive 89/109/EEC, Member States may not authorise after 31 December 2006 additives referred to in Article 4(1) which were never evaluated by the Scientific Committee on Food or the Authority.'

4. The following Article 5a is inserted:

'*Article 5a*

5. Additives referred to in Article 4, which are authorised as food additives by Council Directive 89/107/EEC (*) or flavourings by Council Directive 88/388/EEC (**) shall not migrate into:

(a) foodstuffs in quantities having a technological function in the final foodstuffs;

(b) foodstuffs for which their use is authorised as food additives or flavourings, in quantities exceeding the restrictions provided for in Directive 89/107/EEC or in Directive 88/388/EEC or in Article 4 of this Directive, whichever is the lower;

(c) foodstuffs for which their use is not authorised as food additives or flavourings, in quantities exceeding the restrictions set out in Article 4 of this Directive.

2. At the marketing stages other than the retail stages, plastic materials and articles which are intended to be placed in contact with foodstuffs and which contain additives referred to in paragraph 1 shall be accompanied by a written declaration containing the information referred to in Article 9(1)(b).

3. By way of derogation from paragraph 1, when the substances referred to in point (a) of paragraph 1 are used as active components of active food contact materials and articles, they may be subject to national provisions pending the adoption of Community provisions.

(*) OJ L 40, 11.2.1989, p. 27.
(**) OJ L 184, 15.7.1988, p. 61.'

5. Article 7 is replaced by the following:

'*Article 7*

The specific migration limits in the list set out in Annexes II and III are expressed in mg/kg. However, such limits are expressed in mg/dm^2 in the following cases:

(a) articles which are containers or are comparable to containers or which can be filled, with a capacity of less than 500 ml or more than 10 l;

(b) sheet, film or other material or articles which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of such material or article and the quantity of food in contact therewith.

In those cases, the limits set out in Annexes II and III, expressed in mg/kg shall be divided by the conventional conversion factor of 6 in order to express them in mg/dm^2.'

6. In Article 8, paragraph 2 is replaced by the following:

'2. The verification of compliance with the specific migration limits provided for in paragraph 1 shall not be compulsory, if the value of overall migration determination implies that the specific migration limits referred to in that paragraph are not exceeded.'

7. Article 9 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. At the marketing stages other than the retail stages, plastic materials and articles which are intended to be placed in contact with foodstuffs shall be accompanied by a written declaration, which shall:

(a) be in accordance with Article 6(5) of Directive 89/109/EEC;

(b) provide, for substances which are subject to a restriction in food, adequate information obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Commission Directives 95/31/EC (*), 95/45/EC (**) and 2002/82/EC (***) to enable the user of these materials and articles to comply with the relevant Community provisions or, in their absence, with national provisions applicable to food.

(*) OJ L 178, 28.7.1995, p. 1.
(**) OJ L 226, 22.9.1995, p. 1.
(***) OJ L 292, 28.10.2002, p. 1.';

(b) paragraph 2 is deleted.

8. Annexes II to VI are amended in accordance with Annexes I to V to this Directive.

Article 2

1. Member States shall adopt and publish, by 1 September 2005 at the latest, the provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions in such a way as to:

(a) permit the trade in and use of plastic materials and articles intended to come into contact with foodstuffs and complying with this Directive, from 1 September 2005;

(b) prohibit the manufacture and importation into the Community of plastic materials and articles intended to come into contact with foodstuffs and which do not comply with this Directive, from 1 March 2006.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 1 March 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX I

Annex II to Directive 2002/72/EC is amended as follows:

1. in point 8, the definition of QM is replaced by the following:

'QM = Maximum permitted quantity of the "residual" substance in the material or article. For the purpose of this Directive the quantity of the substance in the material or article shall be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;';

2. the following monomers and other starting substances are inserted, in the appropriate numerical order, in the table in section A:

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'13323	000102-40-9	1,3-Bis(2-hydroxyethoxy)benzene	SML = 0,05 mg/kg
16540	000102-09-0	Diphenyl carbonate	SML = 0,05 mg/kg
18896	001679-51-2	4-(Hydroxymethyl)-1-cyclohexene	SML = 0,05 mg/kg
20440	000097-90-5	Methacrylic acid, diester with ethyleneglycol	SML = 0,05 mg/kg
22775	000144-62-7	Oxalic acid	SML(T) = 6 mg/kg ([29])
23070	000102-39-6	(1,3-Phenylenedioxy)diacetic acid	QMA = 0,05 mg/6 dm^2'

3. for the following monomers and other starting substances listed in the table in section A, the content of the columns 'Name' or 'CAS No' or 'Restrictions and/or specifications' is replaced by the following:

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'11530	00999-61-1	Acrylic acid, 2-hydroxypropyl ester	QMA = 0,05 mg/6 dm^2 for the sum of acrylic acid, 2-hydroxypropyl ester and acrylic acid, 2-hydroxyisopropyl ester and in compliance with the specifications laid down in Annex V
13480	000080-05-7	2,2-Bis(4-hydroxyphenyl)propane	SML(T) = 0,6 mg/kg ([28])
14950	003173-53-3	Cyclohexyl isocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO) ([26])
18898	000103-90-2	N-(4-Hydroxyphenyl) acetamide	SML = 0,05 mg/kg
22150	000691-37-2	4-Methyl-1-pentene	SML = 0,05 mg/kg
22331	025513-64-8	Mixture of (35-45 % w/w) 1,6-diamino-2,2,4-trimethylhexane and (55-65 % w/w)1,6-diamino-2,4,4-trimethylhexane	QMA = 5 mg/6 dm^2
22332	—	Mixture of (40 % w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60 % w/w) 2,4,4-trimethylhexane-1,6-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) ([26])
24190	065997-05-9	Rosin wood'	

4. the following monomers and other starting substances are deleted from the table in section B and inserted, in the appropriate numerical order, in the table in section A:

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'10599/90A	061788-89-4	Acids, fatty, unsaturated (C_{18}), dimers, distilled	QMA(T) = 0,05 mg/6 dm² ([27])
10599/91	061788-89-4	Acids, fatty, unsaturated (C_{18}), dimers, non distilled	QMA(T) = 0,05 mg/6 dm² ([27])
10599/92A	068783-41-5	Acids, fatty, unsaturated (C_{18}), dimers, hydrogenated, distilled	QMA(T) = 0,05 mg/6 dm² ([27])
10599/93	068783-41-5	Acids, fatty, unsaturated (C_{18}), dimers, hydrogenated, non distilled	QMA(T) = 0,05 mg/6 dm² ([27])
14800	003724-65-0	Crotonic acid	QMA(T) = 0,05 mg/6 dm² ([33])
16210	006864-37-5	3,3'-Dimethyl-4,4'-diaminodicyclohexylmethane	SML = 0,05 mg/kg ([32]). To be used only in polyamides.
17110	016219-75-3	5-Ethylidenebicyclo[2,2,1]hept-2-ene	QMA = 0,05 mg/6 dm². The ratio surface/quantity of food shall be lower than 2 dm²/kg
18700	000629-11-8	1,6-Hexanediol	SML = 0,05 mg/kg
21400	054276-35-6	Methacrylic acid, sulphopropyl ester	QMA = 0,05 mg/6 dm²'

5. The following monomers and other starting substances are deleted from the table in Section A:

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'15370	003236-53-1	1,6-Diamino-2,2,4-trimethylhexane	QMA = 5 mg/6 dm²
15400	003236-54-2	1,6-Diamino-2,4,4-trimethylhexane	QMA = 5 mg/6 dm²'

ANNEX II

Annex III is amended as follows:

1. point 1 is replaced by the following:

'1. This Annex contains the list of:

(a) substances which are incorporated into plastics to achieve a technical effect in the finished product, including "polymeric additives". They are intended to be present in the finished articles;

(b) substances used to provide a suitable medium in which polymerisation occurs.

For the purposes of this Annex, the substances referred to in (a) and (b) are hereinafter referred to as "additives".

For the purpose of this Annex, "Polymeric additives" means any polymer and/or prepolymer and/or oligomer which may be added to plastics in order to achieve a technical effect but which cannot be used in absence of other polymers as the main structural component of finished materials and articles. It includes also substances which may be added to the medium in which polymerisation occurs.

The list does not include:

(a) the substances which directly influence the formation of polymers;

(b) colorants;

(c) solvents.';

2. section A is amended as follows:

(a) the following additives are inserted, in the appropriate numerical order, in the table in section A:

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'34850	143925-92-2	Amines, bis(hydrogenated tallow alkyl) oxidised	QM = For use only: (a) in polyolefines at 0,1 % (w/w) but not in LDPE when it is in contact with foods for which the Directive 85/572/EEC establishes a reduction factor less than 3; (b) in PETat 0,25 % (w/w) in contact with foods other of those for which the simulant D is laid down in Directive 85/572/EEC 85/572/EEC
34895	000088-68-6	2-Aminobenzamide	SML = 0,05 mg/kg. To be used only for PET for water and beverages
39680	000080-05-7	2,2-Bis(4-hydroxyphenyl)propane	SML(T) = 0,6 mg/kg ([28])
42880	008001-79-4	Castor oil	
45600	003724-65-0	Crotonic acid	QMA(T) = 0,05 mg/6 dm^2 ([33])
45640	005232-99-5	2-Cyano-3,3-diphenylacrylic acid, ethyl ester	SML = 0,05 mg/kg
46700	—	5,7-di-tert-Butyl-3-(3,4- and 2,3-dimethylphenyl)-3H-benzofuran-2-one containing: a) 5,7-di-tert-butyl-3-(3,4-dimethylphenyl)-3H-benzofuran-2-one (80 to 100 % w/w) and b) 5,7-di-tert-butyl-3-(2,3-dimethylphenyl)-3H-benzofuran-2-one (0 to 20 % w/w)	SML = 5 mg/kg

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
46720	004130-42-1	2,6-Di-tert-butyl-4-ethylphenol	QMA = 4,8 mg/6 dm^2
56535	—	Glycerol, esters with nonanoic acid	
59280	000100-97-0	Hexamethylenetetramine	SML(T) = 15 mg/kg ([22]) (expressed as Formaldehyde)
68078	027253-31-2	Neodecanoic acid, cobalt salt	SML(T) = 0,05 mg/kg (expressed as Neodecanoic acid) and SML(T) = 0,05 mg/kg ([14]) (expressed as Cobalt). Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC.
69920	000144-62-7	Oxalic acid	SML(T) = 6 mg/kg ([29])
76866	—	Polyesters of 1,2-propanediol and/or 1,3- and/or 1,4-butanediol and/or polypropyleneglycol with adipic acid, which may be end-capped with acetic acid or fatty acids C_{12}-C_{18} or n-octanol and/or n-decanol	SML = 30 mg/kg
85601	—	Silicates, natural (with the exception of asbestos)	
95000	028931-67-1	Trimethylolpropane trimethacrylate-methyl methacrylate copolymer'	

(b) for the following additives of section A, the content of the column 'Restrictions and/or specifications' of the table is replaced by the following:

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'45450	068610-51-5	p-Cresol-dicyclopentadiene-isobutylene, copolymer	SML = 5 mg/kg
77895	068439-49-6	Polyethyleneglycol (EO = 2-6) monoalkyl (C_{16}-C_{18}) ether	SML = 0,05 mg/kg and in compliance with the specifications laid down in Annex V'

(c) the following additives are deleted from the table in section A:

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'56565	—	Glycerol, esters with nonanoic acid	
67170	—	Mixture of (80 to 100 % w/w) 5,7-di-tert-butyl-3-(3,4-dimethylphenyl)-2(3H)-benzofuranone and (0 to 20 % w/w)5,7-di-tert-butyl-3-(2,3-dimethylphenyl)-2(3H)-benzofuranone	SML = 5 mg/kg
76865	—	Polyesters of 1,2-propanediol and/or 1,3- and/or 1,4-butanediol and/or polypropyleneglycol with adipic acid, also end-capped with acetic acid or fatty acids C_{10}-C_{18} or n-octanol and/or n-decanol	SML = 30 mg/kg
85600	—	Silicates, natural'	

3. section B is amended as follows:

(a) the following additives are inserted, in the appropriate numerical order, in the table in section B:

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
‘34650	151841-65-5	Aluminium hydroxybis [2,2'-methylenebis (4,6-di-tert.butylphenyl) phosphate	SML = 5 mg/kg
38000	000553-54-8	Benzoic acid, lithium salt	SML(T) = 0,6 mg/kg ([8]) (expressed as Lithium)
40720	025013-16-5	tert-Butyl-4-hydroxyanisole (= BHA)	SML = 30 mg/kg
46640	000128-37-0	2,6-Di-tert-butyl-p-cresol (= BHT)	SML = 3,0 mg/kg
54880	000050-00-0	Formaldehyde	SML(T) = 15 mg/kg ([22])
55200	001166-52-5	Gallic acid, dodecyl ester	SML(T) = 30 mg/kg ([34])
55280	001034-01-1	Gallic acid, octyl ester	SML(T) = 30 mg/kg ([34])
55360	000121-79-9	Gallic acid, propyl ester	SML(T) = 30 mg/kg ([34])
67896	020336-96-3	Myristic acid, lithium salt	SML(T) = 0,6 mg/kg ([8]) (expressed as Lithium)
71935	007601-89-0	Perchloric acid, sodium salt monohydrate	SML = 0,05 mg/kg ([31])
76680	068132-00-3	Polycyclopentadiene, hydrogenated	SML = 5 mg/kg ([1])
86480	007631-90-5	Sodium bisulphite	SML(T) = 10 mg/kg ([30]) (expressed as SO_2)
86920	007632-00-0	Sodium nitrite	SML = 0,6 mg/kg
86960	007757-83-7	Sodium sulphite	SML(T) = 10 mg/kg ([30]) (expressed as SO_2)
87120	007772-98-7	Sodium thiosulphate	SML(T) = 10 mg/kg ([30]) (expressed as SO_2)
94400	036443-68-2	Triethyleneglycol bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl) propionate]	SML = 9 mg/kg’

(b) the following additives are deleted from the table in section B:

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
‘46720	004130-42-1	2,6-Di-tert-butyl-4-ethylphenol	QMA = 4,8 mg/6 dm^2
68078	027253-31-2	Neodecanoic acid, cobalt salt	SML(T) = 0,05 mg/kg (expressed as Neodecanoic acid) and SML(T) = 0,05 mg/kg ([14]) (expressed as Cobalt). Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC
95000	028931-67-1	Trimethylolpropane trimethacrylate-methyl methacrylate copolymer’	

ANNEX III

Annex IV is replaced by the following:

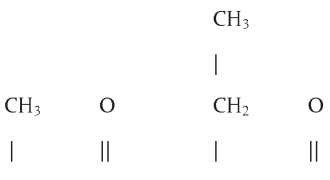
'ANNEX IV

PRODUCTS OBTAINED BY MEANS OF BACTERIAL FERMENTATION

Reference No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
18888	080181-31-3	3-Hydroxybutanoic acid-3-hydroxy-pentanoic acid, copolymer	In compliance with specifications included in Annex V'

ANNEX IV

In Annex V the previous specifications in part B for reference No 16690 and 18888 are replaced by the following and new specifications are added for reference No 11530 and 77895

'Reference No	OTHER SPECIFICATIONS	
11530	Acrylic acid, 2-hydroxypropyl ester. It may contain up to 25 % (m/m) of acrylic acid, 2-hydroxyisopropyl ester (CAS No 002918-23-2)	
16690	Divinylbenzene It may contain up to 45 % (m/m) of Ethylvinylbenzene	
18888	3-Hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer	
	Definition	The copolymers are produced by the controlled fermentation of Alcaligenes eutrophus using mixtures of glucose and propanoic acid as carbon sources. The organism used has not been genetically engineered and has been derived from a single wild-type organism Alcaligenes eutrophus strain HI6 NCIMB 10442. Master stocks of the organism are stored as freeze-dried ampoules. A submaster/working stock is prepared from the master stock and stored in liquid nitrogen and used to prepare inocula for the fermenter. Fermenter samples will be examined daily both microscopically and for any changes in colonial morphology on a variety of agars at different temperatures. The copolymers are isolated from heat treatment bacteria by controlled digestion of the other cellular components, washing and drying. These copolymers are normally offered as formulated, melt formed granules containing additives such as nucleating agents, plasticisers, fillers, stabilisers and pigments which all conform to the general and individual specifications
	Chemical name	Poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate)
	CAS number	080181-31-3
	Structural formula	 where n/(m + n) greater than 0 and less or equal to 0,25
	Average molecular weight	Not less than 150 000 Daltons (measured by gel permeation chromatography)
	Assay	Not less than 98 % poly(3-D-hydroxybutanoate-co-3-D-hydoxypentanoate) analysed after hydrolysis as a mixture of 3-D-hydroxybutanoic and 3-D-hydroxypentanoic acids
	Description	White to off-white powder after isolation
	Characteristics	
	Identification tests:	
	Solubility	Soluble in chlorinated hydrocarbons such as chloroform or dichloromethane but practically insoluble in ethanol, aliphatic alkanes and water
	Restriction	QMA for crotonic acid is 0.05 mg/6 dm^2
	Purity	Prior to granulation the raw material copolymer powder must contain:
	— nitrogen	Not more than 2 500 mg/kg of plastic
	— zinc	Not more than 100 mg/kg of plastic
	— copper	Not more than 5 mg/kg of plastic
	— lead	Not more than 2 mg/kg of plastic
	— arsenic	Not more than 1 mg/kg of plastic
	— chromium	Not more than 1 mg/kg of plastic

Reference No	OTHER SPECIFICATIONS
77895	Polyethyleneglycol (E0 = 2-6) monoalkyl (C_{16}-C_{18}) ether The composition of this mixture is as follows: — polyethyleneglycol (E0 = 2-6)monoalkyl (C_{16}-C_{18}) ether (approximately 28 %) — fatty alcohols (C_{16}-C_{18}) (approximately 48 %) — ethyleneglycol monoalkyl (C_{16}-C_{18}) ether (approximately 24 %)'

ANNEX V

Annex VI is replaced by the following:

'ANNEX VI

NOTES RELATED TO THE COLUMN "RESTRICTIONS AND/OR SPECIFICATIONS"

(1) Warning: there is a risk that the SML could be exceeded in fatty food simulants.

(2) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as reference Nos: 10060 and 23920.

(3) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as reference Nos: 15760, 16990, 47680, 53650 and 89440.

(4) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as reference Nos: 19540, 19960 and 64800.

(5) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as reference Nos: 14200, 14230 and 41840.

(6) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as reference Nos: 66560 and 66580.

(7) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 30080, 42320, 45195, 45200, 53610, 81760, 89200 and 92030.

(8) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 38000, 42400, 64320, 67896, 73040, 85760, 85840, 85920 and 95725.

(9) Warning: there is a risk that the migration of the substance deteriorates the organoleptic characteristics of the food in contact and then, that the finished product does not comply with the second indent of Article 2 of Directive 89/109/EEC.

(10) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 30180, 40980, 63200, 65120, 65200, 65280, 65360, 65440 and 73120.

(11) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels (expressed as Iodine) of the following substances mentioned as reference Nos: 45200, 64320, 81680 and 86800.

(12) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 36720, 36800, 36840 and 92000.

(13) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 39090 and 39120.

(14) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 44960, 68078, 82020 and 89170.

(15) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 15970, 48640, 48720, 48880, 61280, 61360 and 61600.

(16) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 49600, 67520 and 83599.

(17) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 50160, 50240, 50320, 50360, 50400, 50480, 50560, 50640, 50720, 50800, 50880, 50960, 51040 and 51120.

(18) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 67600, 67680 and 67760.

(19) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 60400, 60480 and 61440.

(20) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 66400 and 66480.

(21) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 93120 and 93280.

([22]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 17260, 18670, 54880 and 59280.

([23]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 13620, 36840, 40320 and 87040.

([24]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 13720 and 40580.

([25]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 16650 and 51570.

([26]) QM(T) in this specific case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances mentioned as reference Nos: 14950, 15700, 16240, 16570, 16600, 16630, 18640, 19110, 22332, 22420, 22570, 25210, 25240 and 25270.

([27]) QMA(T) in this specific case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances mentioned as reference Nos: 10599/90A, 10599/91, 10599/92A and 10599/93.

([28]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 13480 and 39680.

([29]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 22775 and 69920.

([30]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 86480, 86960 and 87120

([31]) Compliance testing when there is a fat contact should be performed using saturated fatty food simulants as simulant D.

([32]) Compliance testing when there is a fat contact should be performed using isoctane as substitute of simulant D (unstable).

([33]) QMA(T) in this specific case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances mentioned as reference Nos: 14800 and 45600.

([34]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as reference Nos: 55200, 55280 and 55360.'

31984L0500

Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs

Official Journal L 277 , 20/10/1984 P. 0012 - 0016
Finnish special edition: Chapter 13 Volume 13 P. 0207
Spanish special edition: Chapter 13 Volume 18 P. 0006
Swedish special edition: Chapter 13 Volume 13 P. 0207
Portuguese special edition Chapter 13 Volume 18 P. 0006

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COUNCIL DIRECTIVE

of 15 October 1984

on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs

(84/500/EEC)

THE COUNCIL OF THE EUROPEAN

COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to 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 (1), and in particular Article 3 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas Article 2 of Directive 76/893/EEC provides that materials and articles must not transfer their constituents to foodstuffs in quantities which could endanger human health;

Whereas Article 3 of the same Directive provides that the Council, under the procedure provided for in Article 100 of the Treaty, shall adopt by means of Directives special provisions applicable to certain groups of materials and articles (specific Directives);

Whereas in most of the Member States ceramic articles intended to come into contact with foodstuffs are subject to mandatory provisions for protecting human health which lay down limits for the extractable quantities of lead and cadmium;

Whereas these provisions vary from one Member State to another, thus creating obstacles to the establishment and functioning of the common market;

Whereas these obstacles may be eliminated if the placing of ceramic articles on the Community market is made subject to uniform rules; whereas it is therefore necessary to harmonize the limit values and the test and analysis methods for such articles;

Whereas the appropriate instrument for attaining this objective is a specific Directive within the meaning of Article 3 of Directive 76/893/EEC the general provisions of which also become applicable in this particular case;

Whereas the adaptation to technical progress of certain checking and analysis measures provided for in the Directive is an implementing measure the adoption of which should be entrusted to the Commission in order to simplify and expedite the procedure;

Whereas, in all cases where the Council grants the Commission powers to implement provisions concerning materials and articles intended to come into

contact with foodstuffs, a procedure should be established to ensure close cooperation between the Member States and the Commission in the Standing Committee for Foodstuffs set up by the Council Decision of 13 November 1969,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific Directive within the meaning of Article 3 of Directive 76/893/EEC.

2. This Directive concerns the possible migration of lead and cadmium from ceramic 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.

3. 'Ceramic articles' means articles manufactured from a mixture of inorganic materials with a generally high argillaceous or silicate content to which small quantities of organic materials may have been added. These articles are first shaped and the shape thus obtained is permanently fixed by firing. They may be glazed, enamelled and/or decorated.

Article 2

1. The quantities of lead and cadmium transferred from ceramic articles shall not exceed the limits laid down below.

2. The quantities of lead and cadmium transferred from ceramic articles shall be determined by means of a test, the conditions of which are specified in Annex I, using the method of analysis described in Annex II.

3. Where a ceramic article consists of a vessel fitted with a ceramic lid, the lead and/or cadmium limit which may not be exceeded (mg/dm2 or mg/litre) shall be that which applies to the vessel alone.

The vessel alone and the inner surface of the lid shall be tested separately and under the same conditions.

The sum of the two lead and/or cadmium extraction levels thus obtained shall be related as appropriate to the surface area or the volume of the vessel alone.

4. A ceramic article shall be recognized as satisfying the requirements of this Directive if the quantities of lead and/or cadmium extracted during the test carried out under the conditions laid down in Annexes I and II do not exceed the following limits:

1.2.3 // // Pb // Cd // - Category 1: // // // Articles which cannot be filled and articles which can be filled, the internal depth of which, measured from the lowest point to the horizontal plane passing through the upper rim, does not exceed 25 mm // 0,8 mg/dm2 // 0,07 mg/dm2 // - Category 2: // // // All other articles which can be filled // 4,0 mg/l // 0,3 mg/l // - Category 3: // // // Cooking ware; packaging and storage vessels having a capacity of more than three litres // 1,5 mg/l // 0,1 mg/l

5. However, where a ceramic article does not exceed the above quantities by more than 50 %, that article shall nevertheless be recognized as satisfying the requirements of this Directive if at least three other articles with the same shape, dimensions, decoration and glaze are subjected to a test carried out under the conditions laid down in Annexes I and II and the average quantities of lead and/or cadmium extracted from those articles do not exceed the limits set, with none of those articles exceeding those limits by more than 50 %.

Article 3

The amendments to be made to the Annexes in the light of developments in scientific and technical knowledge, with the exception of sections 1 and 2 of Annex I, shall be adopted in accordance with the procedure laid down in Article 10 of Directive 76/893/EEC.

Article 4

1. Within three years of notification (1) of this Directive, the Council shall determine in accordance with the procedure laid down in Article 100 of the Treaty:

(a) the limitations to be imposed on those areas of ceramic articles with which the mouth is intended to come into contact;

(b) the methods for checking that the limitations provided for in (a) are complied with.

2. Within the same period, the Commission shall, on the basis of toxicological and technological data, re-examine the limits laid down in Article 2, with a view to reducing them, and the lighting conditions for the test specified in Annex I, and shall, if appropriate, submit to the Council proposals for amendments to the Directive.

Article 5

1. The Member States shall, if necessary, amend their national laws to comply with this Directive so that:

- three years after the notification of this Directive, trade in ceramic articles which comply with its provisions is permitted,

- five years after the notification of this Directive, the placing on the market of ceramic articles which do not comply with its provisions is prohibited.

They shall forthwith inform the Commission of any such amendment.

2. Without prejudice to paragraph 1, Member States may prohibit or continue to prohibit the manufacture of ceramic articles which do not comply with this Directive.

Article 6

This Directive is addressed to the Member States.

Done at Luxembourg, 15 October 1984.

For the Council

The President

J. BRUTON

(1) OJ No L 340, 9. 12. 1976, p. 19.

(2) OJ No C 95, 28. 4. 1975, p. 41.

(3) OJ No C 263, 17. 11. 1975, p. 66.

(1) This Directive was notified to the Member States on 17 October 1984.

ANNEX I

BASIC RULES FOR DETERMINING THE MIGRATION OF LEAD AND CADMIUM

1. Test liquid ('simulant')

4 % (v/v) acetic acid, in a freshly prepared aqueous solution.

2. Test conditions

2.1. Carry out the test at a temperature of 22 ± 2 °C for a duration of 24 ± 0,5 hours.

2.2. When the migration of lead is to be determined, cover the sample by an appropriate means of protection and expose it to the usual lighting conditions in a laboratory.

When the migration of cadmium or of lead and cadmium is to be determined, cover the sample so as to ensure that the surface to be tested is kept in total darkness.

3. Filling

3.1. Samples which can be filled

Fill the article with a 4 % (v/v) acetic acid solution to a level no more than 1 mm from the overflow point; the distance is measured from the upper rim of the sample.

Samples with a flat or slightly sloping rim should be filled so that the distance between the surface of the liquid and the overflow point is no more than 6 mm measured along the sloping rim.

3.2. Samples which cannot be filled

The surface of the sample which is not intended to come into contact with foodstuffs is first covered with a suitable protective layer able to resist the action of the 4 % (v/v) acetic acid solution. The sample is then immersed in a recipient containing a known volume of acetic acid solution in such a way that the surface intended to come into contact with foodstuffs is completely covered by the test liquid.

4. Determination of the surface area

The surface area of the articles in category 1 is equal to the surface area of the meniscus formed by the free liquid surface obtained by complying with the filling requirements set out in section 3 above.

ANNEX II

METHODS OF ANALYSIS FOR DETERMINING THE MIGRATION OF LEAD AND CADMIUM

1. Object and field of application

The method allows the specific migration of lead and/or cadmium to be determined.

2. Principle

The determination of the specific migration of lead and/or cadmium is carried out by atomic absorption spectrophotometry.

3. Reagents

- All reagents must be of analytical quality, unless otherwise specified.

- Where reference is made to water, this always means distilled water or water of equivalent quality.

3.1. 4 % (v/v) acetic acid, in aqueous solution

Add 40 ml of glacial acetic acid to water and make up to 1 000 ml.

3.2. Stock solutions

Prepare stock solutions containing 1 000 mg/litre of lead and at least 500 mg/litre of cadmium respectively in a 4 % acetic acid solution (3.1).

4. Instruments

4.1. Atomic absorption spectrophotometer

The instrument's detection limit for lead and cadmium must be equal to or lower than:

- 0,1 mg/litre for lead,

- 0,01 mg/litre for cadmium.

The detection limit is defined as the concentration of the element in 4 % acetic acid (3.1) which gives a signal equal to twice the background noise of the instrument.

5. Method

5.1. Preparation of the sample

The sample must be clean and free from grease or other matter likely to affect the test.

Wash the sample in a solution containing a household liquid detergent at a temperature of approximately 40 °C. Rinse the sample first in tapwater and then in distilled water or water of equivalent quality. Drain and dry so as to avoid any stain. The surface to be tested should not be handled after it has been cleaned.

5.2. Determination of lead and/or cadmium

- The sample thus prepared is tested under the conditions laid down in Annex I.

- Before taking the test solution for determining lead and/or cadmium, homogenize the content of the sample by an appropriate method which avoids any loss of solution or abrasion of the surface being tested.

- Carry out a blank test on the reagent used for each series of determinations.

- Carry out determinations for lead and/or cadmium under appropriate conditions by atomic absorption spectrophotometry.

COMMISSION DIRECTIVE 2005/31/EC

of 29 April 2005

amending Council Directive 84/500/EEC as regards a declaration of compliance and performance criteria of the analytical method for ceramic articles intended to come into contact with foodstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC [1], and in particular Article 5(2) thereof,

Whereas:

(1) Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs [2] is a specific measure within the meaning of Article 5 of Regulation (EC) No 1935/2004. It concerns the possible migration of lead and cadmium from ceramic 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.

(2) Article 16 of Regulation (EC) No 1935/2004 provides that the specific measures are to require that materials and articles covered by those measures are accompanied by a written declaration stating that they comply with the rules applicable to them.

(3) That requirement has not yet been set out in Directive 84/500/EEC. There is a need to lay down that obligation for all ceramic articles which are not yet in contact with foodstuffs to clearly distinguish them from decorative articles.

(4) The national competent authorities should have access to documents demonstrating that the ceramic articles comply with the migration limits for lead and cadmium. Therefore, the manufacturer or importer into the Community should make information concerning analysis carried out available to them on request.

(5) Directive 84/500/EEC lays down a method for the analysis of lead and cadmium. Technological progress has been made in that area and the analytical method set out in that Directive is only one amongst several possible methods. This Directive should take technological progress into account and establish a set of performance criteria that the analytical method must comply with having regard to Commission Directive 2001/22/EC of 8 March 2001 laying down the sampling methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs [3].

(6) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of ensuring the free movement of ceramic articles intended to come into contact with foodstuffs to lay down rules for a correct enforcement of Directive 84/500/EEC. This Directive does not go beyond what is necessary in order to achieve the objectives pursued, in accordance with the third paragraph of Article 5 of the Treaty.

(7) Directive 84/500/EEC should therefore be amended accordingly.

(8) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 84/500/EEC is amended as follows:

1. The following Article 2a is inserted:

'*Article 2a*

1. At the marketing stages up to and including the retail stage, ceramic articles which are not yet in contact with foodstuffs shall be accompanied by a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004 of the European Parliament and of the Council (*).

That declaration shall be issued by the manufacturer or by a seller established within the Community and shall contain the information laid down in Annex III to this Directive.

[1] OJ L 338, 13.11.2004, p. 4.
[2] OJ L 277, 20.10.1984, p. 12.
[3] OJ L 77, 16.3.2001, p. 14. Directive as last amended by Directive 2005/4/EC (OJ L 19, 21.1.2005, p. 50).

2. Appropriate documentation to demonstrate that the ceramic articles comply with the migration limits for lead and cadmium set out in Article 2 shall be made available by the manufacturer or the importer into the Community to the national competent authorities on request. That documentation shall contain the results of the analysis carried out, the test conditions and the name and the address of the laboratory that performed the testing.

(*) OJ L 338, 13.11.2004, p. 4.'

2. Annex II is replaced by the text in Annex I to this Directive.

3. A new Annex III, the text of which is set out in Annex II to this Directive, is added.

Article 2

1. Member States shall adopt and publish, by 20 May 2006 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions in such a way as to:

(a) permit the trade in and use of ceramic articles complying with this Directive, from 20 May 2006;

(b) prohibit the manufacture and importation into the Community of ceramic articles which do not comply with this Directive, from 20 May 2007.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 29 April 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX I

'ANNEX II

METHODS OF ANALYSIS FOR DETERMINATION OF THE MIGRATION OF LEAD AND CADMIUM

1. **Object and field of application**

The method allows the specific migration of lead and/or cadmium to be determined.

2. **Principle**

The determination of the specific migration of lead and/or cadmium is carried out by an instrumental method of analysis that fulfils the performance criteria of point 4.

3. **Reagents**

— All reagents must be of analytical quality, unless otherwise specified.

— Where reference is made to water, it shall always mean distilled water or water of equivalent quality.

3.1. *4 % (v/v) acetic acid, in aqueous solution*

Add 40 ml of glacial acetic acid to water and make up to 1 000 ml.

3.2. *Stock solutions*

Prepare stock solutions containing 1 000 mg/litre of lead and at least 500 mg/litre of cadmium respectively in a 4 % acetic acid solution, as referred to in point 3.1.

4. **Performance criteria of the instrumental method of analysis**

4.1. The detection limit for lead and cadmium must be equal to or lower than:

— 0,1 mg/litre for lead,

— 0,01 mg/litre for cadmium.

The detection limit is defined as the concentration of the element in the 4 % acetic acid solution, as referred to in point 3.1, which gives a signal equal to twice the background noise of the instrument.

4.2. The limit of quantification for lead and cadmium must be equal to or lower than:

— 0,2 mg/litre for lead,

— 0,02 mg/litre for cadmium.

4.3. *Recovery*. The recovery of lead and cadmium added to the 4 % acetic acid solution, as referred to in point 3.1, must lie within 80-120 % of the added amount.

4.4. *Specificity*. The instrumental method of analysis used must be free from matrix and spectral interferences.

5. **Method**

5.1. *Preparation of the sample*

The sample must be clean and free from grease or other matter likely to affect the test.

Wash the sample in a solution containing a household liquid detergent at a temperature of approximately 40 °C. Rinse the sample first in tap-water and then in distilled water or water of equivalent quality. Drain and dry so as to avoid any stain. The surface to be tested is not to be handled after it has been cleaned.

5.2. *Determination of lead and/or cadmium*

— The sample thus prepared is tested under the conditions laid down in Annex I.

— Before taking the test solution for determining lead and/or cadmium, homogenise the content of the sample by an appropriate method, which avoids any loss of solution or abrasion of the surface being tested.

— Carry out a blank test on the reagent used for each series of determinations.

— Carry out determinations for lead and/or cadmium under appropriate conditions.'

ANNEX II

'*ANNEX III*

DECLARATION OF COMPLIANCE

The written declaration referred to in Article 2a(1) shall contain the following information:

1. the identity and address of the company which manufactures the finished ceramic article and of the importer who imports it into the Community;
2. the identity of the ceramic article;
3. the date of the declaration;
4. the confirmation that the ceramic article meets relevant requirements in this Directive and Regulation (EC) No 1935/2004.

The written declaration shall permit an easy identification of the goods for which it is issued and shall be renewed when substantial changes in the production bring about changes in the migration of lead and cadmium.'

31993L0010

Commission Directive 93/10/EEC of 15 March 1993 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs

Official Journal L 093 , 17/04/1993 P. 0027 - 0036
Finnish special edition: Chapter 13 Volume 24 P. 0027
Swedish special edition: Chapter 13 Volume 24 P. 0027

COMMISSION DIRECTIVE 93/10/EEC of 15 March 1993 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to 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 (1), and in particular Article 3 thereof,

After consulting the Scientific Committee for Food,

Whereas the number and nature of the changes that have had to be made and should now be made to Council Directive 83/229/EEC of 25 April 1993 on the approximation of the laws of the Member States relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs (2), as last amended by Commission Directive 92/15/EEC (3), indicate the need for the said Directive to be replaced;

Whereas the Community measures envisaged by this Directive are not only necessary but also indispensable for the attainment of the objectives of the internal market; whereas these objectives cannot be achieved by Member States individually; whereas, furthermore, their attainment at Community level is already provided for by Directive 89/109/EEC;

Whereas Article 2 of Directive 89/109/EEC lays down that materials and articles, in their finished state, must not transfer their constituents to foodstuffs in quantities which could endanger human health or bring about an unacceptable change in the composition of the foodstuffs;

Whereas, in order to achieve this objective in the case of regenerated cellulose film, the suitable instrument is a specific directive within the meaning of Article 3 of Directive 89/109/EEC;

Whereas synthetic casings of regenerated cellulose should be the subject of specific provisions;

Whereas the method for determining the absence of migration of colouring matters should be established at a later stage;

Whereas, until criteria of purity and methods of analysis have been drawn up, national provisions should remain in force;

Whereas the establishment of a list of approved substances, accompanied by limits to the quantities to be used, is sufficient in principle in this specific case to achieve the objective laid down in Article 2 of Directive 89/109/EEC;

Whereas, however, the bis(2-hydroxyethyl)ether (= diethyleneglycol) and ethanediol (= monoethyleneglycol), can migrate extensively to certain foodstuffs and therefore in order to avoid this possibility, as a preventive measure, it is more appropriate to lay down definitively the maximum authorized quantity of such substances in foodstuffs which have been in contact with regenerated cellulose film;

Whereas, to protect the health of the consumer, direct contact between foodstuffs and the printed surfaces of regenerated cellulose film should be avoided;

Whereas the written declaration referred to in Article 6 (5) of Directive 89/109/EEC should be provided for in the event of professional use of regenerated cellulose film for materials and articles intended to come into contact with foodstuffs, except those which are, by their nature, intended for this use;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific directive within the meaning of Article 3 of Directive 89/109/EEC.

2. This Directive shall apply to regenerated cellulose film within the meaning of the description given in Annex I which either:

(a) constitutes a finished product in itself; or (b) forms part of a finished product containing other materials,

and which is intended to come into contact with foodstuffs or which, by virtue of its purpose, does come into such contact.

3. This Directive does not apply to:

(a) regenerated cellulose film which, on the side intended to come into contact with foodstuffs or which, by virtue of its purpose does come into such contact, has a coating exceeding 50 mg/dm2;

(b) synthetic casings of regenerated cellulose.

Article 2

1. Only those substances or groups of substances listed in Annex II may be used for the manufacture of regenerated cellulose film and only under the conditions laid down therein.

2. By way of derogation from paragraph 1, substances other than those listed in Annex II may be used when these substances are employed as colouring matter (dyes and pigments) or as adhesives, provided that there is no trace of migration of the substances into or onto foodstuffs, detectable by a validated method.

Article 3

Printed surfaces of regenerated cellulose film shall not come into contact with the foodstuffs.

Article 4

1. At the marketing stages other than the retail stages, materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs shall be accompanied by a written declaration in accordance with Article 6 (5) of Directive 89/109/EEC.

2. Paragraph 1 does not apply to materials and articles made of regenerated cellulose film which by their nature are clearly intended to come into contact with foodstuffs.

3. Where special conditions of use are indicated, the material or article made of regenerated cellulose film shall be labelled accordingly.

Article 5

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive as from 1 January 1994. They shall immediately inform the Commission thereof.

Member States shall:

- permit, as from 1 January 1994, the trade in and use of regenerated cellulose film which is intended to come into contact with foodstuffs complying with this Directive,

- prohibit, as from 1 January 1994, the trade in and use of regenerated cellulose film which is intended to come into contact with foodstuffs and which complies with neither this Directive nor Directive 83/229/EEC,

- prohibit, as from 1 January 1995, the trade in and use of regenerated cellulose film which is intended to come into contact with foodstuffs and which does not comply with this Directive but did comply with Directive 83/229/EEC.

2. When Member States adopt the measures referred to in paragraph 1, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 6

1. Directive 83/229/EEC is hereby repealed as from 1 January 1994.

2. References to Directive 83/229/EEC shall be construed as references to this Directive and should be read in accordance with the correlation table appearing in Annex III.

Article 7

This Directive is addressed to the Member States.

Done at Brussels, 15 March 1993.

For the Commission Martin BANGEMANN Member of the Commission

ANNEX I

DESCRIPTION OF REGENERATED CELLULOSE FILM

Regenerated cellulose film is a thin sheet material obtained from a refined cellulose derived from unrecycled wood or cotton. To meet technical requirements, suitable substances may be added either in the mass or on the surface. Regenerated cellulose film may be coated on one or both sides.

ANNEX II

LIST OF SUBSTANCES AUTHORIZED IN THE MANUFACTURE OF REGENERATED CELLULOSE FILM

NB - The percentages in this Annex, first and second parts, are expressed in weight/weight (w/w) and are calculated in relation to the quantity of anhydrous uncoated regenerated cellulose film.

- The usual technical denominations are given in square brackets.

- The substances used shall be of good technical quality as regards the purity criteria.

FIRST PART

UNCOATED REGENERATED CELLULOSE FILM

>TABLE>

SECOND PART

COATED REGENERATED CELLULOSE FILM

>TABLE>

ANNEX III

CORRELATION TABLE

>TABLE>

31993L0111

Commission Directive 93/111/EC of 10 December 1993 amending Directive 93/10/EEC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs

Official Journal L 310 , 14/12/1993 P. 0041 - 0041
Finnish special edition: Chapter 13 Volume 25 P. 0092
Swedish special edition: Chapter 13 Volume 25 P. 0092

COMMISSION DIRECTIVE 93/111/EC of 10 December 1993 amending Directive 93/10/EEC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 (1), and in particular Article 3 thereof,

Whereas Article 2 of Commission Directive 92/15/EEC (2) prohibits, as from 1 July 1994, the trade in and use of regenerated cellulose film which is intended to come into contact with foodstuffs and which does not comply with Council Directive 83/229/EEC (3);

Whereas Article 5 of Commission Directive 93/10/EEC (4) prohibits, as from 1 January 1994, the trade in and use of the same products which comply neither with this Directive nor with Directive 83/229/EEC;

Whereas Article 5 of Directive 93/10/EEC should therefore be amended to eliminate the inconsistency between the dates specified in Directives 92/15/EEC and 93/10/EEC;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The second indent of Article 5 (1) of Directive 93/10/EEC is replaced by the following:

'- prohibit, as from 1 January 1994, the trade in and use of regenerated cellulose film which is intended to come into contact with foodstuffs and which complies with neither this Directive nor Directive 83/229/EEC, other than film which Directive 92/15/EEC prohibits as from 1 July 1994.'

Article 2

This Regulation shall enter into force on the third day following its publication in the Official Journal of the European Communities.

Done at Brussels, 10 December 1993.

For the Commission

Martin BANGEMANN

Member of the Commission

(1) OJ No L 40, 11. 2. 1989, p. 38.

(2) OJ No L 102, 16. 4. 1992, p. 44.

(3) OJ No L 123, 11. 5. 1983, p. 31.

(4) OJ No L 93, 17. 4. 1993, p. 27.

COMMISSION DIRECTIVE 2004/14/EC

of 29 January 2004

amending Directive 93/10/EEC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 [1], as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council [2], and in particular Article 3 thereof,

After consulting the Scientific Committee on Food,

Whereas:

(1) Commission Directive 93/10/EEC of 15 March 1993 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs [3], as amended by Directive 93/111/EC [4], applies to regenerated cellulose film and establishes a list of authorised substances together with restrictions on their use. That Directive covers regenerated cellulose films uncoated or coated with coatings manufactured only with substances listed therein.

(2) Further to technological developments, it is necessary to authorise a new type of regenerated cellulose film with a coating consisting of plastics, which is compostable and biodegradable. This new type of regenerated cellulose film is consistent with the environmental requirements of Directive 94/62/EC of the European Parliament and of the Council of 20 December 1994 on packaging and packaging waste [5], as amended by Regulation (EC) No 1882/2003. Accordingly, such authorisation is in the interest of consistency of Community legislation.

(3) The rules to be applied to the regenerated cellulose films should be specific to the nature of the layer in contact with the foodstuff. Accordingly, the requirements for regenerated cellulose films coated with coatings consisting of plastics should be different from those provided for regenerated cellulose films uncoated or coated with coatings derived from cellulose.

(4) Only authorised substances should be used in the manufacture of all the types of regenerated cellulose films, including regenerated cellulose films coated with plastics.

(5) In the case of regenerated cellulose films coated with coatings consisting of plastics, the layer in contact with foodstuffs consists of a material similar to plastic materials and articles intended to come into contact with foodstuffs. Therefore it is appropriate that the rules provided for in Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs [6] should be applicable also to such films.

(6) In the interest of consistency of Community legislation, the verification of compliance of plastic-coated regenerated cellulose films with the migration limits set by Directive 2002/72/EC should be carried out according to the rules laid down in Council 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 [7], as last amended by Commission Directive 97/48/EC [8], and Council Directive 85/572/EEC of 19 December 1985 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 [9].

(7) A number of polymers used as coatings should be deleted from the list of authorised substances set out in Directive 93/10/EEC as they are covered by the rules set out in Directive 2002/72/EC which apply to plastic-coated regenerated cellulose films.

(8) Four solvents should also be deleted from the list of authorised substances set out in Directive 93/10/EEC as new data are available showing a risk for reproduction and because they are no longer used in the manufacture of regenerated cellulose films. In addition, some plasticisers, which are no longer used, should also be deleted from that list.

[1] OJ L 40, 11.2.1989, p. 38.
[2] OJ L 284, 31.10.2003, p. 1.
[3] OJ L 93, 17.4.1993, p. 27.
[4] OJ L 310, 14.12.1993, p. 41.
[5] OJ L 365, 31.12.1994, p. 10.
[6] OJ L 220, 15.8.2002, p. 18.
[7] OJ L 297, 23.10.1982, p. 26.
[8] OJ L 222, 12.8.1997, p. 10.
[9] OJ L 372, 31.12.1985, p. 14.

(9) In addition, the restriction on the use of 2-ethylhexyl diphenyl phosphate (synonym: phosphoric acid diphenyl 2-ethylhexyl ester) set out in Directive 93/10/EEC should be amended to take into account the opinion of the Scientific Committee on Food of 19 March 1998.

(10) Directive 93/10/EEC should therefore be amended accordingly.

(11) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 93/10/EEC is amended as follows:

1. In Article 1(3), point (a) is deleted.

2. The following Article 1a is inserted:

'*Article 1a*

The regenerated cellulose films referred to in Article 1(2) shall belong to one of the following types:

(a) uncoated regenerated cellulose film;

(b) coated regenerated cellulose film with coating derived from cellulose;

or

(c) coated regenerated cellulose film with coating consisting of plastics.'

3. Article 2(1) is replaced by the following:

'1. Regenerated cellulose films referred to in points (a) and (b) of Article 1a shall be manufactured using only substances or groups of substances listed in Annex II subject to the restrictions set out therein.'

4. The following Article 2a is inserted:

'*Article 2a*

1. Regenerated cellulose film referred to in Article 1a(c) shall be manufactured, prior to coating, using only substances or groups of substances listed in the first part of Annex II, subject to the restrictions set out therein.

2. The coating to be applied to the regenerated cellulose film referred to in paragraph 1 shall be manufactured using only substances or groups of substances listed in Annexes II to VI to Directive 2002/72/EC, subject to the restrictions set out therein.

3. Without prejudice to paragraph 1, materials and articles made of regenerated cellulose film referred to in Article 1a(c) shall comply with Articles 2, 7 and 8 of Directive 2002/72/EC.'

5. Annex II is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 29 July 2005 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

Member States shall apply those provisions in such a way as to:

(a) permit the trade in and use of regenerated cellulose film which is intended to come into contact with foodstuffs complying with this Directive, from 29 July 2005;

(b) prohibit the manufacture and importation into the Community of regenerated cellulose film which is intended to come into contact with foodstuffs and which does not comply with the provisions of this Directive as from 29 January 2006. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 29 January 2004.

For the Commission

David BYRNE

Member of the Commission

ANNEX

The second part of Annex II to Directive 93/10/EEC is amended as follows:

1. In the third line (C. Coating) of the second column (Restrictions) of the table: 'Not more than 50 mg of coating/dm^2 of film on the side in contact with foodstuffs' is deleted.

2. The following polymers and their restrictions are deleted from the table:

Denominations	Restrictions
'— Polymers, copolymers and their mixtures made with the following monomers: vinyl acetals derived from saturated aldehydes (C_1 to C_6) vinyl acetate alkyl (C_1 to C_4) vinyl ethers acrylic, crotonic, itaconic, maleic, methacrylic acids and their esters butadiene styrene methylstyrene vinylidene chloride acrylonitrile methacrylonitrile ethylene, propylene, 1- and 2-butylene	In accordance with Community directives, and, in their absence, with national legislation pending the adoption of Community directives
vinyl chloride	According to Directive 78/142/EEC (OJ L 44, 15.2.1978, p. 15)'

3. For resins, the content of the column 'Restrictions' of the table is replaced by the following:

'2. *Resins*	The total quantity of substances may not exceed 12,5 mg/dm^2 of the coating on the side in contact with foodstuffs and solely for the preparation of regenerated cellulose films with cellulose nitrate based coatings'

4. The following plasticisers and their restrictions are deleted from the table:

Denominations	Restrictions
'— Butylbenzylphthalate	Not more than 2,0 mg/dm^2 of the coating on the side in contact with foodstuffs
— Di-n-butyl phthalate	Not more than 3,0 mg/dm^2 of the coating on the side in contact with foodstuffs
— Di(2-ethylhexyl) sebacate [= dioctylsebacate]'	

5. For the following plasticiser, the content of the column 'Restrictions' of the table is replaced by the following:

Denominations	Restrictions
'— 2-ethylhexyl diphenyl phosphate (synonym: phosphoric acid diphenyl 2-ethylhexyl ester)	The amount of 2-ethylhexyl diphenyl phosphate shall not exceed: (a) 2,4 mg/kg of the foodstuff in contact with this type of film, or (b) 0.4 mg/dm^2 in the coating on the side in contact with foodstuffs'

6. The following solvents are deleted from the table:

Denominations	Restrictions
'— Ethyleneglycol monoethyl ether — Ethyleneglycol monoethyl ether acetate — Ethyleneglycol monomethyl ether — Ethyleneglycol monomethyl ether acetate'	

31978L0142

Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs

Official Journal L 044 , 15/02/1978 P. 0015 - 0017
Finnish special edition: Chapter 13 Volume 8 P. 0044
Greek special edition: Chapter 03 Volume 20 P. 0087
Swedish special edition: Chapter 13 Volume 8 P. 0044
Spanish special edition: Chapter 13 Volume 8 P. 0091
Portuguese special edition Chapter 13 Volume 8 P. 0091

COUNCIL DIRECTIVE of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs (78/142/EEC)

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 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 (1), and in particular Article 3 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas Article 2 of Directive 76/893/EEC provides that materials and articles must not transfer any constituents to foodstuffs in quantities which could endanger human health;

Whereas Article 3 of the same Directive provides that the Council, under the procedure provided for in Article 100 of the Treaty, shall adopt by means of Directives special provisions applicable to certain groups of materials and articles (specific Directives) ; whereas these provisions may include specific limits on the migration of certain constituents into or onto foodstuffs as well as other rules to ensure compliance with Article 2 of the said Directive;

Whereas the administration of large doses of vinyl chloride monomer to experimental animals has been shown to produce harmful effects ; whereas such effects could also occur in man;

Whereas the Scientific Committee for Food has given the opinion that the levels of vinyl chloride monomer in polyvinyl chloride and related polymers should be reduced as far as possible and at the same time recommended that no trace of vinyl chloride should be detectable in food or potable water by a method which can be generally applied to the majority of foodstuffs by most laboratories;

Whereas further research is at present being conducted on vinyl chloride monomer, but as a precaution the ingestion of vinyl chloride monomer should be restricted until the results are known;

Whereas the appropriate instrument for attaining this objective is a specific Directive within the meaning of Article 3 of Directive 76/893/EEC, the general provisions of which also become applicable in this particular case;

Whereas, however, this Directive does not concern all aspects of materials and articles prepared from vinyl chloride polymers or copolymers and the Member States should therefore be

authorized not to require that labels carry the particulars laid down in Article 7 of Directive 76/893/EEC, in accordance with the opinions provided for in paragraphs 4 and 5 of that Article,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific Directive within the meaning of Article 3 of Directive 76/893/EEC.

2. This Directive concerns the presence of vinyl chloride monomer in, and possible migration from, materials and articles prepared with vinyl chloride polymers or copolymers, hereinafter called "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.

Article 2

1. Materials and articles must not contain vinyl chloride monomer in a quantity exceeding that laid down in Annex I.

2. Materials and articles must not pass on to foodstuffs which are in or have been brought into contact with such materials and articles any vinyl chloride detectable by the method which complies with the criteria laid down in Annex II. (1)OJ No L 340, 9.12.1976, p. 19. (2)OJ No C 118, 16.5.1977, p. 70. (3)OJ No C 114, 11.5.1977, p. 13.

Article 3

The method of analysis necessary for checking compliance with Article 2 shall be adopted in accordance with the procedure laid down in Article 10 of Directive 76/893/EEC and shall comply with the criteria laid down in Annex II.

Article 4

The Council shall review this Directive on the basis of reports from the Commission drawn up in the light of scientific and technical knowledge becoming available after adoption of the Directive and accompanied, where appropriate, by suitable proposals. The first report from the Commission shall be forwarded to the Council not later than 1 January 1979.

Article 5

This Directive shall not affect national provisions relating to other possible rules provided for in Article 3 of Directive 76/893/EEC or the options afforded to Member States under Article 7 (4) and (5) of that Directive.

Article 6

1. Member States shall bring into force the laws, regulations and administrative provisions needed in order to comply with this Directive not later than 26 November 1979. They shall forthwith inform the Commission thereof.

2. Member States may defer the introduction of Article 2 (2) and Annex II until such time as a Community method of analysis, as required by Article 3, has been adopted.

Article 7

This Directive is addressed to the Member States.

Done at Brussels, 30 January 1978.

For the Council

The President

P. DALSAGER

ANNEX I Maximum vinyl chloride monomer level in materials and articles

One milligram per kilogram in the final product.

ANNEX II Criteria applicable to the method of determining the level of vinyl chloride in materials and articles and of determining vinyl chloride released by materials and articles

1. The level of vinyl chloride in materials and articles and the level of vinyl chloride released by materials and articles to foodstuffs are determined by means of gas-phase chromatography using the "headspace" method.

2. For the purposes of determining vinyl chloride released by materials and articles to foodstuffs, the detection limit shall be 0 701 mg/kg.

3. Vinyl chloride released by materials and articles to foodstuffs is in principle determined in the foodstuffs. When the determination in certain foodstuffs is shown to be impossible for technical reasons, Member States may permit determination by simulants for these particular foodstuffs.

31980L0766

Commission Directive 80/766/EEC of 8 July 1980 laying down the Community method of analysis for the official control of the vinyl chloride monomer level in materials and articles which are intended to come into contact with foodstuffs

Official Journal L 213 , 16/08/1980 P. 0042 - 0046
Finnish special edition: Chapter 13 Volume 10 P. 0221
Greek special edition: Chapter 15 Volume 1 P. 0250
Swedish special edition: Chapter 13 Volume 10 P. 0221
Spanish special edition: Chapter 13 Volume 11 P. 0042
Portuguese special edition Chapter 13 Volume 11 P. 0042

COMMISSION DIRECTIVE of 8 July 1980 laying down the Community method of analysis for the official control of the vinyl chloride monomer level in materials and articles which are intended to come into contact with foodstuffs (80/766/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Communities,

Having regard to Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs (1), and in particular Article 3 thereof,

Whereas Article 2 of Directive 78/142/EEC lays down that such materials and articles must not contain vinyl chloride monomer in a quantity exceeding 1 milligram per kilogram in the final product and Article 3 that this limit must be controlled by a Community analysis method;

Whereas, on the basis of a series of inter-laboratory collaborative trials, the method described in the Annex has proved to be sufficiently accurate and reproducible to be adopted as a Community method;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Member States shall require that the analysis necessary for official control of the vinyl chloride monomer level in materials and articles intended to come into contact with foodstuffs, referred to in the Annex as "materials and articles", shall be performed according to the method described in the Annex.

Article 2

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 18 months following its notification. They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 8 July 1980.

For the Commission

Etienne DAVIGNON

Member of the Commission (1)OJ No L 44, 15.2.1978, p. 15.

ANNEX DETERMINATION OF THE VINYL CHLORIDE MONOMER LEVEL IN MATERIALS AND ARTICLES

1. SCOPE AND FIELD OF APPLICATION

The method determines the vinyl chloride monomer level in materials and articles.

2. PRINCIPLE

The level of vinyl chloride monomer level (VC) in materials or articles is determined by means of gas-chromatography using the "headspace" method after dissolution or suspension of the sample in N, N-dimethylacetamide.

3. REAGENTS 3.1. Vinyl chloride (VC), of purity greater than 99 75 % (v/v).

3.2. N, N-dimethylacetamide (DMA), free from any impurity with the same retention time as VC or as the internal standard (3.3) under the conditions of the test.

3.3. Diethyl ether or cis-2-butene, in DMA (3.2) as the internal standard solution. These internal standards must not contain any impurity with the same retention time as VC, under the conditions of the test.

4. APPARATUS

N.B.

An instrument or piece of apparatus is mentioned only if it is special or made to particular specifications. Usual laboratory apparatus is assumed to be available. 4.1. Gas-chromatograph fitted with automatic head-space sampler or with facilities for manual sample injection.

4.2. Flame ionization detector or other detectors mentioned in point 7.

4.3. Gas-chromatographic column.

The column must permit the separation of the peaks of air, of VC and of the internal standard, if used.

Furthermore, the combined 4.2 and 4.3 system must allow the signal obtained with a solution containing 0 702 mg VC/litre DMA or 0 702 mg VC/kg DMA to be equal to at least five times the background noise.

4.4. Sample phials or flasks fitted with silicon or butyl rubber septa.

When using manual sampling techniques the taking of a sample from the headspace with a syringe may cause a partial vacuum to form inside the phial or flask. Hence, for manual techniques where the phials are not pressurized before the sample is taken, the use of large phials is recommended.

4.5. Micro-syringes.

4.6. Gas-tight syringes for manual headspace sampling.

4.7. Analytical balance accurate to 0 71 mg.

5. PROCEDURE

CAUTION : VC is a hazardous substance and a gas at ambient temperature, therefore the preparation of solutions should be carried out in a well-ventilated fume cupboard.

N.B. - Take all the necessary precautions to ensure that no VC or DMA is lost;

- When employing manual sampling techniques an internal standard (3.3) should be used;

- When using an internal standard, the same solution must be utilized throughout the procedure.

5.1. Preparation of concentrated standard VC solution at approximately 2 000 mg/kg

Accurately weigh to the nearest 0 71 mg a suitable glass vessel and place in it a quantity (e.g. 50 ml) of DMA (3.2). Re-weigh. Add to the DMA a quantity (e.g. 0 71 g) of VC (3.1) in liquid or gas form, injecting it slowly on to the DMA. The VC may also be added by bubbling it into the DMA, provided that a device is used which will prevent loss of DMA. Re-weigh to the nearest 0 71 mg. Wait two hours to allow equilibrium to be attained. Keep the standard solution in a refrigerator.

5.2. Preparation of dilute standard VC solution

Take a weighed amount of concentrated standard solution of VC (5.1) and dilute, to a known volume or a known weight, with DMA (3.2) or with internal standard solution (3.3). The concentration of the resultant dilute standard solution is expressed as mg/l or mg/kg respectively.

5.3. Preparation of the calibration curve

N.B. - the curve must comprise at least seven pairs of points, - the repeatability of the responses (1) must be lower than 0 702 mg VC/l or kg of DMA,

- the curve must be calculated from these points by the least squares technique, i.e. the regression line must be calculated using the following equation >PIC FILE= "T0013583"> (1)See recommendation ISO DIS 5725 : 1977.

Prepare two series of at least seven phials (4.4). Add to each phial volumes of dilute standard VC solution (5.2) and DMA (3.2) or internal standard solution in DMA (3.3) such that the final VC concentration of the duplicate solutions will be approximately equal to 0 ; 0 7050 ; 0 7075 ; 0 7100 ; 0 7125 ; 0 7150 ; 0 7200, etc. mg/l or mg/kg of DMA and that all the phials contain the same quantity of DMA that is to be used under point 5.5. Seal the phials and proceed as described under point 5.6. Construct a graph in which the ordinate values show the areas (or heights) of the VC peaks of the duplicate solutions or the ratio of these areas (or heights) to those of the relevant internal standard peaks and the abscissa values show the VC concentrations of the duplicate solutions.

5.4. Validation of preparation of standard solutions obtained in points 5.1 and 5.2

Repeat the procedure described under points 5.1 and 5.2 to obtain a second diluted standard solution with a concentration equal to 0 71 mg VC/l or 0 71 mg/kg of DMA or internal standard solution. The average of two gas-chromatographic determinations of this solution must not differ by more than 5 % from the corresponding point of the calibration curve. If the difference is greater than 5 %, reject all the solutions obtained in points 5.1, 5.2, 5.3 and 5.4 and repeat the procedure from the beginning.

5.5. Preparation of the samples of materials or articles

Prepare two phials (4.4). Weigh into each phial not less than 200 mg, to the nearest 0 71 mg, of the sample obtained from a single material or article under investigation which has been reduced to small pieces. Try to ensure that an equal quantity is weighed into each phial. Close the phial immediately. Add to each phial for each gram of the sample 10 ml or 10 g of DMA (3.2) or 10 ml or 10 g of internal standard solution (3.3). Seal the phials and proceed as described under point 5.6.

5.6. Gas-chromatographic determinations 5.6.1. Agitate the phials avoiding contact between the contained liquid and the septum (4.4) to obtain a solution or suspension of the samples of material or article (5.5) as homogeneous as possible.

5.6.2. Put all the sealed phials (5.3, 5.4 and 5.5) in a waterbath for two hours at 60º + 1 ºC to allow equilibrium to be attained. Agitate again, if necessary.

5.6.3. Take a sample from the headspace in the phial. When utilizing manual sampling techniques care must be exercised in obtaining a reproducible sample (see point 4.4), in particular the syringe must be pre-warmed to the temperature of the sample. Measure the area (or height) of the peaks relating to the VC and to the internal standard if used.

5.6.4. Remove from the column (4.3) excess DMA using an appropriate method as soon as peaks of DMA appear on the chromatogram.

6. CALCULATION OF THE RESULTS 6.1. Find by interpolation on the curve, the unknown concentration of each of the two solutions of the sample taking account of the internal standard solution if used. Calculate the amount of VC in each of the two samples of material or article under investigation by applying the following formula: >PIC FILE= "T0013585">

where:

X = concentration of VC in the sample of the material or article expressed in mg/kg.

C = concentration of VC in the phial containing the sample of material or article (see under point 5.5) expressed in mg/l or mg/kg.

V = volume or mass of DMA in the phial containing the sample of material or article (see under point 5.5) expressed in litres or kg.

M = amount of the sample of the material or article, expressed in grams.

6.2. The concentration of VC in the material and article under investigation expressed in mg/kg shall be the average of the two concentrations of VC (mg/kg) determined in point 6.1 provided that the repeatability criterion in point 8 is satisfied.

7. CONFIRMATION OF THE VC LEVEL

In cases where the content of VC in materials and articles as calculated under point 6.2 exceeds the maximum permissible amount the results obtained by the analysis of each of the two samples (5.6 and 6.1) must be confirmed in one of three ways: - by using at least one other column (4.3) having a stationary phase with a different polarity. This procedure should continue until a chromatogram is obtained with no evidence of overlap of the VC and/or internal standard peaks with constituents of the sample of the material or article,

- by using other detectors, e.g. the micro-electrolytic conductivity detector (1),

- by using mass-spectrometry. In this case, if molecular ions with parent masses (m/e) of 62 and 64 are found in the ratio of 3 : 1, it may be regarded with high probability as confirming the presence of VC. In case of doubt the total mass spectrum must be checked.

8. REPEATABILITY

The difference between the results of two determinations (6.1) carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, must not exceed 0 72 mg VC/kg of material or article. (1)See Journal of Chromatographic Science, Vol. 12, March 1974, p. 152.

31981L0432

Commission Directive 81/432/EEC of 29 April 1981 laying down the Community method of analysis for the official control of vinyl chloride released by materials and articles into foodstuffs

Official Journal L 167 , 24/06/1981 P. 0006 - 0011
Finnish special edition: Chapter 13 Volume 11 P. 0140
Spanish special edition: Chapter 13 Volume 11 P. 0203
Swedish special edition: Chapter 13 Volume 11 P. 0140
Portuguese special edition Chapter 13 Volume 11 P. 0203

COMMISSION DIRECTIVE of 29 April 1981 laying down the Community method of analysis for the official control of vinyl chloride released by materials and articles into foodstuffs (81/432/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs (1), and in particular Article 3 thereof,

Whereas Article 2 of Directive 78/142/EEC lays down that materials and articles must not pass on to the foodstuffs which are in, or have been brought into, contact with such materials and articles any vinyl chloride detectable by a method having a limit of detection of 0 701 mg/kg, and Article 3 that this limit must be controlled by a Community method of analysis;

Whereas, on the basis of a series of inter-laboratory collaborative trials, the method described in the Annex has proved to be sufficiently accurate and reproducible to be adopted as a Community method;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The analysis necessary for official control of vinyl chloride released by materials and articles into foodstuffs shall be performed according to the method described in the Annex hereto.

Article 2

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 October 1982. They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 29 April 1981.

For the Commission

Karl-Heinz NARJES

Member of the Commission

(1) OJ No L 44, 15.2.1978, p. 15.

ANNEX DETERMINATION OF VINYL CHLORIDE RELEASED BY MATERIALS AND ARTICLES INTO FOODSTUFFS

1. SCOPE AND FIELD OF APPLICATION

The method determines the level of vinyl chloride in foodstuffs.

2. PRINCIPLE

The level of vinyl chloride (VC) in foodstuffs is determined by means of gas-chromatography using the "headspace" method.

3. REAGENTS 3.1. Vinyl chloride (VC), of purity greater than 99 75 % (v/v).

3.2. N, N-dimethylacetamide (DMA), free from any impurity with the same retention time as VC or as the internal standard (3.3) under the conditions of the test.

3.3. Diethyl ether or cis-2-butene, in DMA (3.2) as the internal standard solution. These internal standards must not contain any impurity with the same retention time as VC, under the conditions of the test.

3.4. Distilled water or demineralized water of equivalent purity.

4. APPARATUS

NB:

An instrument or piece of apparatus is mentioned only if it is special, or made to particular specifications. Usual laboratory apparatus is assumed to be available. 4.1. Gas-chromatograph fitted with automatic headspace sampler or with facilities for manual sample injection.

4.2. Flame ionization detector or other detectors mentioned in point 7.

4.3. Gas-chromatographic column

The column must permit the separation of the peaks of air, of VC and of the internal standard, if used.

Furthermore, the combined 4.2 and 4.3 system must allow the signal obtained with a solution containing 0 7005 mg VC/litre DMA or 0 7005 mg VC/kg DMA to be equal to at least five times the background noise.

4.4. Sample phials or flasks fitted with silicon or butyl rubber septa

When using manual sampling techniques, the taking of a sample from the headspace with a syringe may cause a partial vacuum to form inside the phial or flask. Hence, for manual techniques where the phials are not pressurized before the sample is taken, the use of large phials is recommended.

4.5. Micro-syringes.

4.6. Gas-tight syringes for manual headspace sampling.

4.7. Analytical balance accurate to 0 71 mg.

5. PROCEDURE

CAUTION : VC is a hazardous substance and a gas at ambient temperature therefore, the preparation of solutions should be carried out in a well-ventilated fume cupboard.

NB:

Take all the necessary precautions to ensure that no VC or DMA is lost.

When employing manual sampling techniques, an internal standard (3.3) should be used.

When using an internal standard, the same solution must be utilized throughout the procedure. 5.1. Preparation of standard VC solution (solution A) 5.1.1. Concentrated standard VC solution at approximately 2 000 mg/kg

Accurately weigh to the nearest 0 71 mg a suitable glass vessel and place in it a quantity (e.g. 50 ml) of DMA (3.2). Re-weigh. Add to the DMA a quantity (e.g. 0 71 g) of VC (3.1) in liquid or gas form, injecting it slowly onto the DMA. The VC may also be added by bubbling it into the DMA, provided that a device is used which will prevent loss of DMA. Reweigh to the nearest 0 71 mg. Wait two hours to allow equilibrium to be attained. If an internal standard is to be employed, add internal standard so that the concentration of the internal standard in the concentrated standard VC solution is the same as in the internal standard solution prepared under point 3.3. Keep the standard solution in a refrigerator.

5.1.2. Preparation of dilute standard VC solution

Take a weighed amount of concentrated standard solution of VC (5.1.1) and dilute, to a known volume or a known weight, with DMA (3.2) or with internal standard solution (3.3). The concentration of the resultant dilute standard solution (solution A) is expressed as mg/litre or mg/kg respectively.

5.1.3. Preparation of the response curve with solution A

NB:

The curve must comprise at least seven pairs of points.

The repeatability of the responses (1) must be lower than 0 7002 mg VC/litre or kg of DMA.

The curve must be calculated from these points by the least squares technique, i.e., the regression line must be calculated using the following equation: >PIC FILE= "T0019847">

(1) See recommendation ISO DIS 5725 : 1977. >PIC FILE= "T0019848">

Prepare two series of at least seven phials (4.4). Add to each phial volumes of dilute standard VC solution (5.1.2) and DMA (3.2) or internal standard solution in DMA (3.3) such that the final VC concentration of the duplicate solutions will be approximately equal to 0, 0 7005, 0 7010, 0 7020, 0 7030, 0 7040, 0 7050, etc., mg/litre or mg/kg of DMA and that each phial contains the same total volume of solution. The quantity of dilute standard VC solution (5.1.2) must be such that the ratio between the total volume (¶l) of added VC solution and quantity (g or ml) of DMA, or internal standard solution (3.3) does not exceed five. Seal the phials and proceed as described under points 5.4.2, 5.4.3 and 5.4.5. Construct a graph in which the ordinate values show the areas (or heights) of the VC peaks of the duplicate solutions, or the ratio of these areas (or heights) to those of the relevant internal standard peaks, and the abscissa values show the VC concentrations of the duplicate solutions.

5.2. Validation of preparation of standard solutions obtained in point 5.1 5.2.1. Preparation of a second standard VC solution (solution B)

Repeat the procedure described under points 5.1.1 and 5.1.2 to obtain a second dilute standard solution with, in this case, a concentration approximately equal to 0 702 mg VC : 1, or 0 702 mg VC/kg of DMA or internal standard solution. Add this solution to two phials (4.4). Seal the phials and proceed as described under points 5.4.2, 5.4.3 and 5.4.5.

5.2.2. Validation of solution A

If the average of two gas-chromatographic determinations relating to the solution B (5.2.1) does not differ by more than 5 % from the corresponding point of the response curve obtained in point 5.1.3, the solution A is validated. If the difference is greater than 5 %, reject all the solutions obtained in points 5.1 and 5.2 and repeat the procedure from the beginning.

5.3. Preparation of the "addition" curve

NB:

The curve must comprise at least seven pairs of points.

The curve must be calculated from these points by the least squares technique (5.1.3, third indent). >PIC FILE= "T0019849"> 5.3.1. Preparation of sample

The sample of foodstuff to be analyzed must be representative of the foodstuff presented for analysis. The foodstuff must, therefore, be mixed or reduced to small pieces and mixed before the sample is taken.

5.3.2. Procedure

Prepare two series of at least seven phials (4.4). Add to each phial a quantity, not less than 5 g, of sample obtained from the foodstuff under investigation (5.3.1). Ensure that an equal quantity is added to each phial. Close the phial immediately. Add to each phial for each gram of sample 1 ml, preferably of distilled water, or demineralized water of at least equivalent purity, or an appropriate solvent if necessary. (Note : for homogeneous foodstuffs, addition of distilled of demineralized water is not necessary.) Add to each phial volumes of dilute standard VC solution (5.1.2), containing the internal standard (3.3), if considered useful, such that concentrations of VC added to the phials equal to 0, 0 7005, 0 7010, 0 7020, 0 7030, 0 7040 and 0 7050, etc., mg/kg of foodstuffs. Ensure that the total volume of DMA or DMA containing internal standard (3.3) in each phial is the same. The quantity of dilute standard VC solution (5.1.2) and additional DMA where used, must be such that the ratio between the total volume (¶l) of these solutions and the quantity (g) of foodstuff contained in the phial is as low as possible but not more than five and is the same in all phials. Seal the phials and proceed as described under point 5.4.

5.4. Gas-chromatographic determinations 5.4.1. Agitate the phials avoiding contact between the contained liquid and the septum (4.4) to obtain a solution or a suspension of the samples of foodstuff as homogeneous as possible.

5.4.2. Put all the sealed phials (5.2 and 5.3) in a waterbath for two hours at 60 ± 1 ºC to allow equilibrium to be attained. Agitate again, if necessary.

5.4.3. Take a sample from the headspace in the phial. When utilizing manual sampling techniques care must be exercized in obtaining a reproducible sample (4.4) in particular the syringe must be pre-warmed to the temperature of the sample. Measure the area (or height) of the peaks relating to the VC and internal standard, if used.

5.4.4. Construct a graph in which the ordinate value shows the areas (or heights) of the VC peaks or the ratio of the areas (or heights) of VC peaks to the areas (or heights) of the internal standard peaks and the abscissa values show the quantities of VC added (mg) relating to the quantities of the sample of foodstuff weighed in each phial (kg). Measure the abscissa intercept from the graph. The value so obtained is the concentration of VC in the sample of the foodstuff under investigation.

5.4.5. Remove from the column (4.3) excess DMA using an appropriate method as soon as peaks of DMA appear on the chromatogram.

6. RESULTS

The VC released by materials and articles into the foodstuff under investigation expressed in mg/kg shall be defined as the average of the two determinations (5.4) provided that the repeatability criterion in point 8 is satisfied.

7. CONFIRMATION OF THE VC

In cases where the VC released by materials and articles into the foodstuffs as calculated under point 6, exceeds the criterion in Article 2 (2) of Council Directive 78/142/EEC of 30 January 1978, the values obtained in each of the two determinations (5.4) must be confirmed in one of three ways: (i) by using at least one other column (4.3) having a stationary phase of different polarity. This procedure should continue until a chromatogram is obtained with no evidence of overlap of the VC and/or internal standard peaks with constituents of the sample of foodstuff,

(ii) by using other detectors, e.g. the micro-electrolytic conductivity detector (1),

(iii) by using mass spectrometry ; in this case, if molecular ions with parent masses (m/e) of 62 and 64 are found in the ratio of 3 : 1 it may be regarded with high probability as (1) See Journal of Chromatographic Science (volume 12), March 1974, page 152. confirming the presence of VC. In case of doubt the total mass spectrum must be checked.

8. REPEATABILITY

The difference between the results of two determinations (5.4) carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, must not exceed 0 7003 mg VC/kg of foodstuff.

31993L0011

Commission Directive 93/11/EEC of 15 March 1993 concerning the release of the N-nitrosamines and N- nitrosatable substances from elastomer or rubber teats and soothers

Official Journal L 093 , 17/04/1993 P. 0037 - 0038
Finnish special edition: Chapter 15 Volume 12 P. 0167
Swedish special edition: Chapter 15 Volume 12 P. 0167

COMMISSION DIRECTIVE 93/11/EEC of 15 March 1993 concerning the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to 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 (1), and in particular Article 3 thereof,

Whereas the Community measures envisaged by this Directive are not only necessary but also indispensable for the attainment of the objectives of the internal market; whereas these objectives cannot be achieved by Member States individually; whereas furthermore their attainment at Community level is already provided for by Directive 89/109/EEC;

Whereas it has been shown that teats and soothers, made of elastomer or rubber, may release N-nitrosamines and substances capable of being converted into N-nitrosamines (N-nitrosatable substances);

Whereas the Scientific Committee for Food has given the opinion that N-nitrosamines and N-nitrosatable substances may endanger human health owing to their toxicity and has therefore recommended that migration of these substances from the abovementioned articles be kept below the detection limit of an appropriate sensitive method;

Whereas Article 2 of Directive 89/109/EEC lays down that materials and articles, in their finished state, must not transfer their constituents to foodstuffs in quantities which could endanger human health;

Whereas, in order to achieve this objective, the suitable instrument for teats is a specific directive within the meaning of Article 3 of Directive 89/109/EEC;

Whereas the use of soothers may produce the same type of risk and therefore it is convenient to adopt the same provisions for these articles too;

Whereas it is necessary to act immediately and therefore this Directive is limited to establishing specific rules regarding the release of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers, postponing to a more general directive regarding elastomers and rubber the solution of other problems concerning teats and soothers;

Whereas this Directive establishes the basic rules and general criteria for determining the release of N-nitrosamines and N-nitrosatable substances and postpones the definition of a detailed method of analysis;

Whereas the outline method of analysis given in the Annexes is adopted as a temporary measure until more results are available on the performance of this method and possible alternative methods;

Whereas the Commission has undertaken to promote further research on methods of analysis, to review the proposed methodology and to consider establishing analytical tolerances in the light of that research;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive is a specific directive within the meaning of Article 3 of Directive 89/109/EEC.

It concerns the release of N-nitrosamines and of substances capable of being converted into N-nitrosamines, hereinafter called 'N-nitrosatable substances`, from teats and soothers, made of elastomer or rubber.

Article 2

The teats and soothers referred to in Article 1 must not pass on to release-test liquid (saliva test solution) under the conditions specified in Annex I any N-nitrosamine and N-nitrosatable substance detectable by a validated method which complies with the criteria laid down in Annex II and which can detect the following quantities:

- 0,01 mg in total of N-nitrosamines released/kg (of the parts of teat or soother made of elastomer or rubber),

- 0,1 mg in total of N-nitrosatable substances/kg (of the parts of teat or soother made of elastomer or rubber).

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive as from 1 April 1994. They shall immediately inform the Commission thereof.

Member States shall:

- permit, as from 1 April 1994, the trade in and use of teats and soothers complying with this Directive,

- prohibit, as from 1 April 1995, the trade in and use of teats and soothers which do not comply with this Directive.

2. When Member States adopt the measures referred to in paragraph 1, these shall contain a reference to this Directive or shall be accompanied by such reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 15 March 1993.

For the Commission Martin BANGEMANN Member of the Commission

ANNEX I

BASIC RULES FOR DETERMINING THE RELEASE OF N-NITROSAMINES AND N-NITROSATABLE SUBSTANCES

1. Release-test liquid (saliva test solution) To obtain the release-test liquid, dissolve 4,2 g of sodium bicarbonate ($NaHCO_3$), 0,5 g of sodium chloride (NaCl), 0,2 g of potassium carbonate (K_2CO_3) and 30,0 mg of sodium nitrite ($NaNO_2$) in one litre of distilled water or water of equivalent quality. The solution must have a pH value of 9.

2. Test conditions Samples of material obtained from an appropriate number of teats or soothers are immersed in the test-release liquid for 24 hours at a temperature of 40 ± 2 °C.

ANNEX II

CRITERIA APPLICABLE TO THE METHOD FOR DETERMINING THE RELEASE OF N-NITROSAMINES AND N-NITROSATABLE SUBSTANCES

1. The release of N-nitrosamines is determined in one aliquot of each solution obtained according to Annex I. The N-nitrosamines are extracted from the aliquot with nitrosamine-free dichloromethane (DCM) and determined by gas chromatography.

2. The release of N-nitrosatable substances is determined in another aliquot of each solution obtained according to Annex I. The nitrosatable substances are converted into nitrosamines by acidification of the aliquot with hydrochloric acid. Subsequently the nitrosamines are extracted from the solution with DCM and determined by gas chromatography.

COMMISSION DIRECTIVE 2002/16/EC

of 20 February 2002

on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 [1], and in particular Article 3 thereof,

After consulting the Scientific Committee on Food,

Whereas:

(1) The use and/or presence of 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether ('BADGE'), bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers ('BFDGE') and novolac glycidyl ethers ('NOGE') in materials and articles intended to come into contact with foodstuffs has led to questions about their safety, mainly when they are used as an additive.

(2) Test results have shown significant levels of these substances and certain derivatives thereof in some foodstuffs.

(3) The Scientific Committee on Food has given an opinion that the specific migration limit for BADGE and some of its derivatives can be extended for another three years pending the submission of further toxicological data for evaluation.

(4) Acceptance of the use and/or presence of BADGE may therefore be provisionally extended.

(5) The Scientific Committee on Food has examined the data available on BFDGE, which are very similar to the corresponding data obtained for BADGE.

(6) Acceptance of the use and/or presence of BFDGE and some of its derivatives may therefore also be continued pending the submission and evaluation of further toxicological data, under certain conditions.

(7) The Scientific Committee on Food has stated that, in the absence of information about the potential exposure and toxicological profile of NOGE components with more than two aromatic rings and their derivatives, it is not in a position to evaluate the safety of use and/or the presence of corresponding products. The Committee is therefore of the opinion that at present, it is not appropriate to use NOGE as an additive in materials and articles intended to come into contact with foodstuffs due to its tendency to migrate in this application.

(8) The use and/or presence of NOGE components with more than two aromatic rings and their derivatives in plastic materials and articles, surface coatings and adhesives intended to come into contact with foodstuffs should be regulated through the establishment of a strict limit, which should, in practice, provisionally rule out their use as additives. This provisional limit should apply pending the submission of adequate data for a more complete scientific risk assessment, in accordance with Article 5(7) of the World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures, and the development of adequate methods for the determination of their levels in foodstuffs.

(9) The use and/or presence of NOGE and BFDGE as starting substances for the preparation of special coatings used to cover the surfaces of very big containers should provisionally be allowed to continue, pending the submission of further technical data. The large volume/surface area ratio of these containers, their repeated use over their long lifetime which reduces migration, and their contact with foodstuffs at ambient temperature in the majority of the applications suggest that it is not necessary to set a migration limit for NOGE and BFDGE in such containers.

[1] OJ L 40, 11.2.1989, p. 38.

(10) Member States which have not yet authorised the use and/or the presence of BADGE and/or BFDGE and/or NOGE in materials and articles intended to come into contact with foodstuffs should be able to maintain their prohibition.

(11) The use and/or presence of BADGE, BFDGE and NOGE in plastic materials and articles, surface coatings such as varnishes, lacquers and paints, as well as adhesives, should be regulated at Community level to avoid risks to human health and barriers to the free movement of goods.

(12) Errors due to the presence of other chemical substances may occur during analysis. Validated methods of analysis are, therefore, necessary for correct verification of compliance with the restrictions set out in the Directive.

(13) A transitional period should be provided for in respect of materials and articles which are brought into contact with foodstuffs before the deadline for implementation of this Directive.

(14) This transitional period should also take into account the requirements of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs [1], as amended by Commission Directive 2001/101/EC [2].

(15) In view of the new technical requirements, Commission Directive 2001/61/EC of 8 August 2001 on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs [3] should be repealed for reasons of clarity.

(16) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to materials and articles which, in the finished product state, are intended to come into contact or are brought into contact with foodstuffs and are intended for that purpose and which are manufactured with or contain one or more of the following substances:

(a) 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (hereinafter 'BADGE'), and some of its derivatives;

(b) bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers (hereinafter 'BFDGE'), and some of their derivatives;

(c) other novolac glycidyl ethers (hereinafter 'NOGE'), and some of their derivatives.

For the purposes of this Directive, 'materials and articles' are:

(a) materials and articles made of any type of plastics;

(b) materials and articles covered by surface coatings;

(c) adhesives.

2. This Directive shall not apply to containers or storage tanks having a capacity greater than 10 000 litres or to pipelines belonging to or connected with them, covered by special coatings called 'heavy-duty coatings'.

Article 2

The materials and articles referred to in Article 1(1) shall not release the substances listed in Annex I in a quantity exceeding the limit laid down in that Annex.

The use and/or presence of BADGE in the manufacture of those materials and articles may only be continued until 31 December 2004.

[1] OJ L 109, 6.5.2000, p. 29.
[2] OJ L 310, 28.11.2001, p. 19.
[3] OJ L 215, 9.8.2001, p. 26.

Article 3

The materials and articles referred to in Article 1(1) shall not release the substances listed in Annex II in a quantity which, when added, to the sum of BADGE and its derivatives listed in Annex I, exceeds the limit laid down in Annex II.

The use and/or presence of BFDGE in the manufacture of those materials and articles may only be continued until 31 December 2004.

Article 4

As from 1 March 2003, the quantity of NOGE components with more than two aromatic rings and at least one epoxy group as well as their derivatives containing chlorohydrin functions and having a molecular mass less than 1 000 daltons shall not be detectable in the materials and articles referred to in Article 1(1) at the detection limit of 0,2 mg/6 dm^2, including analytical tolerance.

For the purpose of this Directive, the detection limit specified in the first paragraph should be verified by a validated method of analysis. If such a method does not exist, an analytical method with appropriate performance characteristics may be used, pending the development of a validated method.

The use and/or presence of NOGE in the manufacture of those materials and articles may only be continued until 31 December 2004.

Article 5

The requirements of this Directive shall not apply to materials and articles covered by surface coatings, and adhesives, referred to in points (b) and (c) of the second subparagraph of Article 1(1), which are brought into contact with foodstuffs before 1 March 2003. These materials and articles may continue to be placed on the market provided that the date of filling appears on the materials and articles, taking into account the requirements of Directive 2000/13/EC.

Article 6

Directive 2001/61/EC is hereby repealed.

References to the repealed Directive shall be construed as references to this Directive and be read in accordance with the correlation table set out in Annex III.

Article 7

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 28 February 2003 at latest. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 8

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Communities*.

Article 9

This Directive is addressed to the Member States.

Done at Brussels, 20 February 2002.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

Specific migration limit for BADGE and certain of its derivatives

1. The sum of the migration levels of the following substances:

   (a) BADGE (= 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether;

   (b) BADGE.H_2O;

   (c) BADGE.HCl;

   (d) BADGE.2HCl;

   (e) BADGE.H_2O.HCl

   shall not exceed the following limits:

   — 1 mg/kg in foodstuffs or in food simulants (analytical tolerance excluded), or

   — 1 mg/6 dm² in accordance with the cases provided by Article 4 of Commission Directive 90/128/EEC [1].

2. The migration testing shall be carried out in accordance to the rules established in Council Directive 82/711/EEC [2], as well as in Directive 90/128/EEC. However in aqueous food simulants, this value should also include BADGE.$2H_2O$ unless the material or article is labelled for use in contact only with those foods and/or beverages for which it has been demonstrated that the sum of the migration levels of the five substances listed in paragraph 1(a), (b), (c), (d) and (e) cannot exceed the limits provided in paragraph 1.

3. For the purpose of this Directive, the specific migration of the substances listed in paragraph 1(a), (b), (c), (d) and (e) should be determined by a validated method of analysis. If such a method does not exist, an analytical method with appropriate performance characteristics may be used, pending the development of a validated method.

[1] OJ L 75, 21.3.1990, p. 19.
[2] OJ L 297, 23.10.1982, p. 26.

ANNEX II

Specific migration limit for BFDGE and certain of its derivatives

1. The sum of the migration levels of the following substances:

   (a) BFDGE (= bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers);

   (b) BFDGE.H_2O;

   (c) BFDGE.HCl;

   (d) BFDGE.2HCl;

   (e) BFDGE.H_2O.HCl

   added to the sum of those listed in Annex I, shall not exceed the following limits:

   — 1 mg/kg in foodstuffs or in food simulants (analytical tolerance excluded), or

   — 1 mg/6 dm² in accordance with the cases provided by Article 4 of Directive 90/128/EEC.

2. The migration testing shall be carried out in accordance to the rules established in Directive 82/711/EEC, as well as in Directive 90/128/EEC. However in aqueous food simulants, this value should also include BFDGE.$2H_2O$ unless the material or article is labelled for use in contact only with those foods and/or beverages for which it has been demonstrated that the sum of the migration levels of the five substances listed in paragraph 1(a), (b), (c), (d) and (e), added to those listed in Annex I, cannot exceed the limits provided in paragraph 1.

3. For the purpose of this Directive, the specific migration of the substances listed in paragraph 1(a), (b), (c), (d) and (e) should be determined by a validated method of analysis. If such a method does not exist, an analytical method with appropriate performance characteristics may be used, pending the development of a validated method.

ANNEX III

Correlation table

Directive 2001/61/EC	This Directive
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3
Article 4	Article 4
Article 5	Article 5
—	Article 6
Article 6	Article 7
Article 7	Article 8
Article 8	Article 9
Annex I	Annex I
Annex II	Annex II
—	Annex III

COMMISSION DIRECTIVE 2004/13/EC

of 29 January 2004

amending Directive 2002/16/EC on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 [1], and in particular Article 3 thereof,

After consulting the European Food Safety Authority,

Whereas:

(1) Commission Directive 2002/16/EC of 20 February 2002 on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs [2] lays down certain rules applicable to the use/presence of 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether ('BADGE'), bis(hydroxyphenyl) methane bis(2,3-epoxypropyl) ethers ('BFDGE'), novolac glycidyl ethers ('NOGE'), and some of their derivatives, in materials and articles intended to come into contact with foodstuffs.

(2) That Directive provides that the use and/or presence of BADGE in the manufacture of those materials and articles may only be continued until 31 December 2004.

(3) The Scientific Committee on Food (SCF) requested toxicological data to permit the evaluation of BADGE within certain deadlines. The SCF also requested that new toxicological data be supplied to evaluate the potential carcinogenicity of chlorinated derivatives which were included in the quantitative restriction to be applied to the migration of BADGE provided for in Annex I to Directive 2002/16/EC.

(4) On 4 December 2002, the SCF noted the negative results on the potential carcinogenicity of the chlorinated derivatives of BADGE and the low exposure of the European consumer to BADGE as a consequence of the considerable reduction of the content of BADGE found in canned food in the recent enquiries carried out by the Member States and by the Joint Research Centre of the European Commission. Therefore, it is considered admissible to extend the provisional authorisation of BADGE for one year, pending the submission of the new toxicological data and their evaluation by the European Food Safety Authority.

(5) Directive 2002/16/EC provides that the requirements of that Directive concerning BADGE, BFDGE and NOGE do not apply to materials and articles covered by surface coatings, and adhesives, which are brought into contact with foodstuffs before 1 March 2003. Those materials and articles may continue to be placed on the market provided that the date of filling appears on the materials and articles. In the interest of an unequivocal interpretation of how the date of filling should be applied on materials and articles, it is appropriate to provide that this date may be replaced by the 'best before' date as provided for by Directive 2000/13/EC of the European Parliament and of the Council [3], or another indication such as the lot number required by Council Directive 89/396/EEC [4] for the foodstuffs packed in such materials and articles. It is, though, necessary that a link is established between such indication and the date of filling so that the latter can be always identified.

(6) Directive 2002/16/EC should therefore be amended accordingly.

(7) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 2002/16/EC is amended as follows:

1. in Article 2, second paragraph, the date '31 December 2004' is replaced by the date '31 December 2005';

2. Article 5 is replaced by the following:

'*Article 5*

1. Articles 2, 3 and 4 shall not apply to the materials and articles referred to in points (b) and (c) of the second subparagraph of Article 1(1) which are brought into contact with foodstuffs before 1 March 2003.

[1] OJ L 40, 11.2.1989, p. 38.
[2] OJ L 51, 22.2.2002, p. 27.
[3] OJ L 109, 6.5.2000, p. 29.
[4] OJ L 186, 30.6.1989, p. 21.

Those materials and articles may be placed on the market provided that the date of filling appears on the materials and articles. However, the date of filling may be replaced by another indication, provided that this indication permits the identification of the date of filling. Upon request, the date of filling shall be made available to the competent authorities and any person enforcing the requirements of this Directive.

2. Paragraph 1 shall apply without prejudice to the requirements of Directive 2000/13/EC.'.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 29 January 2005 at latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 29 January 2004.

For the Commission

David BYRNE

Member of the Commission

COMMISSION REGULATION (EC) No 1895/2005

of 18 November 2005

on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC [1], and in particular Article 5(1) thereof,

After consulting the European Food Safety Authority,

Whereas:

(1) To avoid risks to human health and barriers to the free movement of goods, Commission Directive 2002/16/EC of 20 February 2002 on the use of certain epoxy derivatives in materials and articles intended to come into contact with food [2], lays down specific migration limits for 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether ('BADGE' i.e. Bisphenol-A DiGlycidyl Ether), bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers ('BFDGE' i.e. Bisphenol-F DiGlycidyl Ether) and novolac glycidyl ethers (NOGE) and some of their derivatives.

(2) Directive 2002/16/EC provides that the use and/or the presence of BFDGE and NOGE may only be continued until 31 December 2004. For BADGE the transitional period was extended until 31 December 2005 pending the expected submission of new toxicological data and their evaluation by the European Food Safety Authority (the Authority).

(3) The toxicological data required for BADGE have been transmitted. The Authority concluded that BADGE, BADGE.H_2O and BADGE.$2H_2O$ do not raise concern about carcinogenicity and genotoxicity *in vivo* and that a Tolerable Daily Intake of 0,15 mg/kg body weight can be established for BADGE, BADGE.H_2O and BADGE.$2H_2O$. Therefore a higher specific migration limit SML(T) can be established for BADGE BADGE.H_2O and BADGE.$2H_2O$. As regards the BADGE chlorohydrins, in view of the lack of data on genotoxicity *in vivo*, the Authority considers that the current specific migration limit of 1 mg/kg of food or food simulants remains appropriate.

(4) Trade in and use of materials and articles containing BADGE in accordance with this Regulation shall therefore be permitted throughout the Community as from 1 January 2006.

(5) The toxicological data required for NOGE and BFDGE have not been transmitted on time to permit their evaluation by the Authority and to continue their use. Therefore the use and/or presence BFDGE and NOGE is no longer permitted as from 1 January 2005 in accordance with Directive 2002/16/EC. However the exhaustion of existing stocks should be permitted.

(6) For large containers, the use and/or presence of BADGE, NOGE and BFDGE are permitted. The high volume/surface area ratio, the repeated use over their long lifetime which reduces migration and the fact that contact with food usually occurs at ambient temperature suggests that it is not necessary to set a migration limit for BADGE, NOGE and BFDGE used in such containers.

(7) Pursuant to Article 16 of Regulation (EC) No 1935/2004 materials and articles covered by specific measures are to be accompanied by a written declaration stating that they comply with the rules applicable to them. That requirement has not yet been included in Directive 2002/16/EC. Therefore it is necessary to introduce this obligation and to provide for a transitional period.

(8) Having regard to the amendments required and in the interest of clarity, Directive 2002/16/EC should be replaced by a new Regulation.

[1] OJ L 338, 13.11.2004, p. 4.
[2] OJ L 51 of 22.2.2002, p. 27. Regulation as amended by Directive 2004/13/EC (OJ L 27, 30.1.2004, p. 46).

(9) Directive 2002/16/EC provides that its requirements concerning BADGE, BFDGE and NOGE do not apply to materials and articles brought into contact with food before 1 March 2003. Those materials and articles may continue to be placed on the market provided that the date of filling appears on them. This date may be replaced by the 'best before' date as provided for by Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of food [1] or another indication, such as the lot number required by Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs [2] for the food packed in such materials and articles, provided a link is established between this indication and the date of filling so that the latter can always be identified.

(10) Directive 2002/16/EC should therefore be repealed.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Scope

1. This Regulation shall apply to materials and articles, including active and intelligent food contact materials and articles, as referred to in Article 1(2) of Regulation (EC) No 1935/2004, which are manufactured with or contain one or more of the following substances:

(a) 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether, hereinafter referred to as 'BADGE' (CAS No 001675-54-3), and some of its derivatives;

(b) bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers, hereinafter referred to as 'BFDGE' (CAS No 039817-09-9);

(c) other novolac glycidyl ethers, hereinafter referred to as 'NOGE'.

2. For the purposes of this Regulation, 'materials and articles' are:

(a) materials and articles made of any type of plastics;

(b) materials and articles covered by surface coatings; and

(c) adhesives.

3. This Regulation shall not apply to containers or storage tanks having a capacity greater than 10 000 litres or to pipelines belonging to or connected with them, covered by special coatings called 'heavy-duty coatings'.

Article 2

BADGE

Materials and articles shall not release the substances listed in Annex I in a quantity exceeding the limits laid down in that Annex.

Article 3

BFDGE

The use and/or presence of BFDGE in the manufacture of materials and articles are prohibited.

Article 4

NOGE

The use and/or presence of NOGE in the manufacture of materials and articles are prohibited.

Article 5

Written declaration

At the marketing stages other than the retail stages, materials and articles containing BADGE and its derivatives shall be accompanied by a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004.

Appropriate documentation shall be available to demonstrate such compliance. That documentation shall be made available to the competent authorities on demand.

Article 6

Transitional provisions

1. Articles 2, 3 and 4 shall not apply to materials and articles referred to in Article 1(2)(b) and (c) which are brought into contact with food before 1 March 2003.

2. Articles 3 and 4 shall not apply to materials and articles which are in compliance with Directive 2002/16/EC and which are brought into contact with food before 1 January 2005.

[1] OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).
[2] OJ L 186, 30.6.1989, p. 21. Directive as last amended by Directive 91/11/EEC (OJ L 65, 11.3.1992, p. 32).

3. Article 5 shall not apply to materials and articles referred to Article 1(2)(a)(b) and (c) which are brought into contact with food before 1 January 2007.

4. The materials and articles referred to in paragraphs 1, 2 and 3 may be placed on the market provided the date of filling appears on the materials and articles. The date of filling may be replaced by another indication, provided it permits the identification of the date of filling. Upon request the date of filling shall be made available to the competent authorities and any person enforcing the requirements of this Regulation.

5. Paragraphs 1 to 4 shall apply without prejudice to the requirements of Directive 2000/13/EC.

Article 7

Repeal

Directive 2002/16/EC is repealed.

References to the repealed Directive shall be construed as references to this Regulation and be read in accordance with the correlation table set out in Annex II.

Article 8

Entry into force

This Regulation shall enter into force on the twentieth day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2006.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 November 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX I

Specific migration limit for BADGE and certain of its derivatives

1. The sum of the migrations of the following substances:

   (a) BADGE [= 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether] (CAS No = 001675-54-3)

   (b) BADGE.H_2O (CAS No = 076002-91-0)

   (c) BADGE.$2H_2O$ (CAS No = 005581-32-8)

   shall not exceed the following limits:

   — 9 mg/kg in food or food simulants, or

   — 9 mg/6 dm^2 in accordance with the cases provided by Article 7 of Commission Directive 2002/72/EC ([1]).

2. The sum of the migrations of the following substances:

   (a) BADGE.HCl (CAS No = 013836-48-1)

   (b) BADGE.2HCl (CAS No = 004809-35-2)

   (c) BADGE.H_2O.HCl (CAS No = 227947-06-0)

   shall not exceed the following limits:

   — 1 mg/kg in food or in food simulants, or

   — 1 mg/6 dm^2 in accordance with the cases provided by Article 7 of Directive 2002/72/EC.

3. The migration testing shall be carried out in accordance to the rules established in Council Directive 82/711/EEC ([2]) and Directive 2002/72/EC.

([1]) OJ L 39, 13.2.2003, p. 1.
([2]) OJ L 297, 23.10.1982, p. 26.

ANNEX II

Correlation table

Directive 2002/16/EC as amended by Directive 2004/13/EC	This Regulation
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3
Article 4	Article 4
—	Article 5
Article 5	Article 6
Article 6	Article 7
Article 7	Article 8
Article 8	Article 8
Article 9	—
Annex I	Annex I
Annex II	—
Annex III	Annex II