EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate D – Food Safety: production and distribution chain
D3 - Chemical and physical risks; surveillance

Brussels, 02.03.2003
DG SANCO/D3/LR

EMB/993-Rev. 5-1

THIS WORKING DOCUMENT DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION SERVICES

Draft

COMMISSION DIRECTIVE ……..

of……..

relating to plastic materials and articles intended to come into contact with foodstuffs

(EN)

(Text with EEA relevance)

WARNING

The introduction and the whereas have not be amended in accordance with the new version and not all the amendments of 2nd amendment of 2002/72 have been introduced

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NOTE FOR THE READER

- The driving idea in writing this text is to collect in one text the rules set out in all the Directives related only to plastic materials and articles i.e.:
  - Commission Directive 2002/72/EC and its 1st amendment under approval
  - Consolidation of 82/711/EEC and its two amendments, 93/8/EEC and 97/48/EC;
  - 85/572/EEC; and
  - The three vinyl chloride monomer directives, 78/142/EEC, 80/766/EEC and 81/432/EEC.

- For brevity reasons and better clarity only the main changes to the existing Directives on plastics are written in blue colour and in italics (to be recognised in the printed uncoloured version). ***Non editorial changes of the previous version (EMB/933-Rev. 2, updated to 23.09.2003) are written in bold, italics and red colour. New articles i.e. articles not appearing in the repealed Directives above mentioned*** are indicated by "NEW". To compare the new Directive with the existing Directives it is necessary to consult the other document called "Consolidated EC Directives on food contact plastics" (EMB/933) as well as the correlation table set out in Annex X.

- Notes appearing in the text explain the reasoning or raise problems to be solved in future versions, as this text is only a second attempt to prepare a new proposal of Directive.

- This new version takes into account the majority of the remarks sent to the Commission services until ***27 February 2004*** as well as the result of the discussions held in the "Task force"(TF)[1]. Some remarks on the technical part of the Directives have not yet been taken into account as they should be analysed by TF.

Any person can send remarks, suggestions on this document to the following address (please: mention the references of this document as well the line number)

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[1] The Task force is a little group of technical experts (not representing the body in which they work) which assist the Commission services in drafting the technical part of this new plastic Directive. It is indicated in the document as TF

EXPLANATORY NOTE

1. *This version should be considered as an attempt to prepare in future a proposal of Commission Directive on all types of plastics. As usual, the Directive contains only general principles of the technical rules such as modelling, functional barrier etc. Details and guidance will be introduced at CEN level or in the Practical Guide.*

2. *This draft was prepared by taking into account the discussions held during 2003* **and 2004 (until 27 February)** *with all the stakeholders (governments, professional and consumer organisation, task forces etc.) which have been consulted by the Commission services to prepare this and the previous drafts. At this stage the draft should be considered preliminary not yet necessarily representing the point of view of the Commission services because:*

   (a) some parts needed to be deeply revised by the services in collaboration with the legal services;

   (b) some parts should take into account the advice of the Authority (EFSA);

   (c) all the document should be subject to the usual internal procedure necessary to prepare a formal proposal of Commission Directive.

3. *The document does not take into account the ongoing Framework Regulation on Food Contact Materials and, therefore, some parts of the Directive may need to be revised to take into account the content of the new Framework Directive.*

4. *The main points of the draft are:*

   a) a better format of all plastic rules, now dispersed in several texts;

   b) the extension of the rules to multi-layers composed of different materials, provided the material in contact with food is plastic (see art.13);

   c) the introduction of the new concept of the "functional barrier" (art. 13(3)). It should be noted that the layer acting as "functional barrier" may be

      - *either authorised by the Directive and listed together with the conditions of its validity (see Annex VII);*
      - *or used by the manufacturer without an authorisation, provided the written declaration of compliance mentions the substances not subject to an authorisation procedure;*

   d) the introduction of the fat (consumption) reduction factor for the lipophilic substances to take into account that the European consumer daily ingests not more than 200 grams of fat, not 1000 grams as assumed until today;

   e) the clarification of the manufacturer obligation to prepare the supporting document mentioned in Article 14(3) for those substances present in the finished material or article and migrating into food which are neither listed nor evaluated by the SCF or EFSA;

f) the transformation of all QM and QMA into SML to permit the verification of compliance in the foods or food simulants, which is more in line with the SCF opinion. Article 11(3) still allows industry and enforcement laboratories to verify the compliance through the determination of the QMA. The relationship between the two restrictions is QMA = SML/6 dm² and is based on the assumption that the whole amount of the substance contained in the material or article migrates into the foodstuff or food simulant. This last rule is particularly important if the substance reacts with the simulant or no method is available for the analysis in foods;

g) some changes in the list of simulants of Directive 85/572/EEC and, mainly, the introduction of special simulants for volatile substances in contact with dry foods;

h) the definition of new conditions for microwave (not yet inserted by the task force).

5. An amendment to the current Practical Guide is under preparation to clarify some issues of the Practical Guide such as:

a) Explanatory note on the field of application of the Super-directive;

b) List of substances which decomposes in aqueous simulants and for which it is recommended the verification of the compliance with QMA;

c) Explanatory note on the format of declaration of conformity and supporting documents;

d) Methodology to determine the existence of a functional barrier;

e) Methodology to determine the lag time (see Annex IX, Section 2, point 2.2)

Draft

COMMISSION DIRECTIVE ……..

Of……..

relating to 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 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 foods[2], and in particular Article 3 thereof,

After consulting the European Food Safety Authority ("the Authority"),

Whereas:

(1) Council Directive 76/893/EEC of 23 November 1976 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs[3], 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 through Council Directives.

(2) Council Directive 82/711/EEC of 18 October 1982 laid down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs[4] and Council Directive 85/572/EEC of 19 December 1985 laid 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[5].

(3) Council Directive 89/109/EEC, replacing Council Directive 76/893/EEC, empowered the Commission to adopt specific directives, including amendments to existing specific directives in accordance with the regulatory procedure set out in Article 9.

(4) A Commission Directive 2002/72/EC of 6 August 2002 relating to plastics materials and articles intended to come into contact with foodstuffs[6], which codified[7] the Commission Directive 90/128/EEC and its seven amendments, laid down the basic rules for plastics and including the lists of substances authorised in their manufacture.

(5) The introduction of new rules for plastics as well as the need to amend and improve the consistency of these rules compels the Commission to amend Council Directives 82/711/EEC and 85/572/EEC as well as Commission Directive 2002/72/EC. For reasons of clarity, simplicity and efficiency, the mentioned Directives on plastics should be combined into a single Directive. This enables achieving the necessary changes at the same time and in a single text;

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2 OJ L 40, 11.2.1989, p. 38

3 O.J. L 340, 9.12.1976, p.134

4 O.J. L 297, 23.10.1982, p. 26. Directive as last amended by Directive 97/48/EC, O.J. L 222, 12.08.97, p 10

5 O.J. L 372, 31.12.1985, p. 14

6 O.J. L 220, 15.8.2002, p. 18 as rectified by OJ 39, 13.2.2003, p. 1.

7 According to Vints « codify » should be chenged into « consolidate »

(6) **The main objectives of the Community legislation for materials and articles intended to come in contact with foodstuffs are the effective functioning of the internal market and the protection of the human health and the interest of consumers. The basic requirement aimed at protecting human health has been laid down in Article 2 of the framework Directive 89/109/EEC. It states that materials and articles, in their finished state *i.e. ready to be put in contact with foodstuffs*, 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 or deterioration in the organoleptic characteristics of the foodstuffs.**

(7) **In order to achieve these objectives, Directive 89/109/EEC provided for the adoption of implementing directives for those specific groups of materials and articles therein specified in Annex I (specific directives).**

(8) **This new Directive establishes the rules applicable to the plastics. It confirms the rules laid down in Directives 82/711/EEC, 85/572/EEC and 2002/72/EC, adjusts their format, extends the scope to other types of plastic articles and to new substances used in their manufacture, and inserts additional provisions.**

(9) **The scope is extended to multilayer materials and articles made of materials other than plastics, such as metals, paper etc., provided the food contact layer or part of the food contact layer consists of plastic.**

(10) **Waxes other than those used as additive for plastics, silicones and ion-exchange resins, even if they consist of plastics, are excluded from the scope of this Directive, since these materials could be subject to separate Directives taking into account their particular use and technological properties.**

(11) **The objectives laid down in Article 2 of Directive 89/109/EEC are achieved through a list of approved substances, accompanied by a limit on overall migration and, where necessary, specific restrictions. Additional provisions are necessary to rule out that reaction products, impurities or other migrating substances may be a risk for human health.**

(12) **The lists of authorised substances must regularly be updated by adding new substances or changing the restrictions applicable to them.**

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

(14) **The current list of additives should become a positive list in order to harmonise the use of these substances in the Community. For additives which are not listed yet, but marketed in one or more Member States, sufficient time should be allowed for the submission of the data necessary for their safety evaluation by the Authority. The deadline for the submission of the data is set on 31 December 2006. If the data are in compliance with the Authority requirements, these additives may continue to be used in accordance with national law until their evaluation is completed and a decision is taken as regards their addition to the Community lists or deletion from the national lists. If the data are not in compliance with the Authority requirements or have been submitted later than 31 December 2006 these additives will not be necessarily included in the first positive list and they are withdrawn from the national lists when the Community positive list is applied.**

(15) **The date when the list of additives will become a positive list will be fixed not later than 31 December 2007. This date will be determined when the time needed for the Authority to evaluate all the applications submitted by the deadline is known.**

(16) **Impurities in the authorised and permitted substances or reaction intermediates formed during the polymerisation process, decomposition or reaction products which may migrate into food are not authorized starting materials and therefore are not listed in the Directive. Their compliance with Article 2 of Directive 89/109/EEC must be therefore assessed by the producer in accordance with the international risk assessment procedures. This assessment shall be documented in the safety declaration ("supporting documents") which should be made available for each finished material or article.**

(17) **Some substances used to manufacture food contact materials may occur in food in other ways, e.g. as food additives, or they may not be permitted in a given food by other legislation. To avoid conflicts, the migration from the materials or articles into the food must not cause the limits set in the relevant food legislation to be exceeded (i.e. the sum of the contributions must remain within the limit). When substances used in food contact materials are not permitted as an additive in a given food, they should not migrate in quantities having a technical effect on this food (e.g. the effect of the additive). The users of the materials and articles (e.g. food packers) must be informed about migration of substances from food contact materials into foods in order to enable him to comply with the relevant food legislation.**

(18) **Active and intelligent food contact material should be regulated by a specific Directive which will take into account the specific nature of the materials applications; therefore they are excluded from this Directive.**

(19) **Several substances in the lists are subject to a specific migration limit in accordance with the evaluation of their toxicity by the Scientific Committee on Food (SCF) or the Authority. Further, the overall migration should not exceed a certain fixed value to avoid an unacceptable change in the composition of the foodstuffs as prescribed by Article 2 of Directive 89/109/EEC. Basic rules must be laid down on testing such migration.**

(20) **Other substances present in food contact plastic materials but not yet listed in the Community list of authorised substances or not covered by this Directive such as solvents or components of printing inks or *adhesives or colorants or the catalysts may contribute* to the total quantity of substance(s) released by a plastic material or article and, therefore, their *contribution to the migration level* shall be taken into account even if these substances or materials may be later regulated by a specific measure.**

(21) **Since the determination of migration into foods is difficult or even impossible, Directives 82/711/EEC and 85/572/EEC established tests simulating the worst case migration under simplified conditions. For instance, foods are substituted by food simulants having an extraction power at least equal to the food and contact is shortened by increased temperatures.**

(22) **The determination of the content of a substance in a finished material or article is easier than the determination of its migration. The verification of compliance through the determination of the content rather than specific migration should therefore be permitted under certain conditions.**

(23) **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.**

(24) **This Directive introduces the concept of the functional barrier, which permits the use of non-authorised substances in the layers behind this barrier, provided they do not migrate in detectable quantities and are not classified as carcinogenic or suspec*ted* carcinogenic*, mutagenic or toxic to reproduction.***

(25) **The extension of the scope of this Directive to multilayers composed of various types of materials calls for a clarification of the rules applicable to the materials not yet regulated at Community level.**

(26) **Directive 89/109/EEC, article 6(5) laid down that the materials and articles shall be accompanied by a written declaration attesting that they comply with the rules applicable to them. *In order to ensure the rules are respected, it is necessary to strengthen the co-ordination and responsibility of the persons involved in the various stages of manufacture of the finished material or article ("responsible persons"). Therefore it is provided that at each stage of manufacture of a material or article including the supply of the substances to be used in the manufacture of materials and articles, the responsible person shall document the conditions under which their stage in the manufacture complies with the relevant rules and shall provide to the enforcement authorities the documentation which demonstrates its compliance with the law ("Supporting documents").***

(27) **Council Directive 78/142/EEC[8] lays down limits for vinyl chloride as content and amount released from plastic materials and articles. This Directive was prepared as an urgent measure to protect the consumers before the Directives on plastics were established. For consistency and better clarity, these limits should now be inserted as restrictions in the Community lists of authorised substances in accordance with the usual restrictions applied to the substances classified in the same category by the SCF or the Authority.. Commission Directives 80/766/EEC[9] and 81/432/EEC[10], which established the Community methods of analysis for vinyl chloride, are repealed, since they are not longer in accordance with the modern analytical procedures.**

(28) **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.**

(29) **In accordance with Article 3 of Directive 89/109/EEC, the SCF and the Authority have been consulted on the provisions liable to affect public health.**

(30) **[This Directive should be without prejudice to the deadlines set out in Annex X, Part B within which the Member States are to comply with Directive 2002/72/EC, and the acts amending it;][11]**

(31) **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[12]:

CHAPTER I

AIM, SCOPE AND DEFINITIONS

Article 1
Subject matter and scope

1. This Directive seeks to ensure the effective functioning of the internal market in relation to plastic materials and articles intended to come into contact with foodstuffs, whilst providing the basis for securing a high level of protection of human health and the interests of consumers.

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

3. (a) The Directive applies to plastic materials and articles as well as parts thereof, which in their finished state:

– are intended to be brought into contact with foodstuffs or

8 OJ L 44, 15.2.1978, p.15
9 OJ L 213, 16.8.1980, p.42
10 OJ L 167, 24.6.1981, p.6
11 See the footnote in Annex X.
12 The term "Directive" will be replaced by the term "Regulation" if this text is adopted after the adoption of the new framework Directive, which replaces the Directive 89/109/EEC.

– are already brought into contact with foodstuffs and are intended for that purpose[13].

These materials are referred to as "plastic materials and articles"[14].

(b) Plastic materials and articles may be composed of one or more layer(s) or part(s) made of plastics or other materials provided the one intended to come into direct contact with foods consists of plastics as defined in Art. 2. These materials are referred to as "multilayer plastic materials".[15,16]

4. The Directive does not apply to the layers or parts of layers made of the following materials when these are intended to come into direct contact with foods:

(a) Regenerated cellulose film, covered by Commission Directive 93/10/EEC[17], amended by Directive 93/111/EC[18] [19];

(b) Rubber, including elastomers;

(c) Paper and paperboard modified or not by the addition of plastics[20];

(d) Coatings;

(e) Silicones.[21],

(f) Waxes other than those used as additive for materials and articles[22];

(g) Ion-exchange resins[23].

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13 The second part of the sentence intends to not include in the field of application the "misuse".

14 The field of application will be consistent with the final version of Framework Regulation under discussion at Council and EP level. It is not correct to insert the new field of application at this stage of the discussion.

15 In Practical Guide will be inserted an explanation.

16 French delegation proposed to extend the definition in order to include all the laminates having a layer of plastics in direct or indirect contact with foodstuffs. DK in favour of this inclusion.

17 OJ L 93, 17.4.1993, p. 27

18 OJ L 310, 14.12.1993, p. 41

19 Text to be revised to take into account the new proposal of Directive on regenerated cellulose films

20 A Resolution of the Council of Europe was adopted. Various Technical Documents also have been adopted. See CoE website in note 8.

21 A Resolution was adopted by the Council of Europe. See the CoE website: http://www.coe.int For further information on the draft Resolution, please contact directly peter.baum@coe.int

22 European Wax Federation ("EWF") has sent a document dated 10.2.2003 where clarified that the waxes are used to the following types of applications:

(a) coating in their own right (to be changed) with or without the addition of polymers and other additives (the wax content ranges from 100 to 70%) (e.g. peelable coating of the cheese rindt)

(b) coating (surface and pre-coatings) for food packaging materials such as paper and board, textiles, cork and wood (the wax content ranges from 100 to 30%)

(c) as additives in plastics, paper and board, in cork (the wax content is below 5%).

The EC services are collecting the needed information to find a solution to these materials.

23 A Resolution was adopted by the Council of Europe. See the CoE website: http://www.coe.int For further information on the Resolution, please contact directly peter.baum@coe.int

Article 2 (NEW)
Definitions

For the purposes of this Directive, the definitions laid down in Regulation (EC) No 178/2002 and in Directive 89/109/EEC shall apply.

The following definitions shall also apply:

1. *"Additives" are substances* ***including oligomeric and polymeric substances (see polymeric additives below)*** *which are incorporated into plastics to achieve a technical effect in the finished product. They are intended to be present in the finished materials or articles;*

2. ***"Authorised substances" are substances appearing in a Community or national list, including the German Rcommendations.***

3. *"Authority" means European Food Safety Authority, as set by Regulation (EC) No 178/2002 of the European Parliament and Council;*

4. *"Coating" means a product mainly prepared from* ***one or more*** *organic substances, which in its finished state does not form a self-supporting layer or film, but when it is applied onto a substrate (plastic, wood, metal, paper etc.) forms an integral layer or film which has certain intended technological effects in the material or article. Organic coatings are typically applied in a liquid state (solution, dispersion or melt) and need to dry, cure or solidify to reach their finished state. This definition includes also varnishes referred to in Annex I of Directive 89/109/EEC. Inorganic coatings largely based on inorganic materials including metals and oxides are excluded from this definition.*

5. *"Fat (consumption) Reduction Factor" (FRF): factor between >1 and 5 by which measured migration of lipophilic substances into food or simulant D and its substitutes shall be divided before comparison with the specific migration limits*[24]*;*

6. *"Food simulants" are test media simulating foods in their behaviour of extracting substances from food contact materials;*

7. *"Functional Barrier"* ***is a barrier consisting of one or more layers which shall (a) ensure that the migration of the authorised and permitted substances does not exceed their SML; (b) prevent the migration of the substances referred to in paragraph 2, their reaction products and their impurities into food or food simulants.***

8. ***"Lag time" for a substance is the time necessary for a substance contained in an inner layer of a multilayer material or article to reach the interface between the material or article and the food or food simulant.***

9. *"Migration test" means the determination of specific migration of a substance or the overall migration of substances either into food or into a food simulant;*

[24] This factor takes into account that a person cannot ingest more than 200 grams of fat per day as an average over lifetime (explanation to be inserted in the Practical Guide");

10. "Monomer and starting substance" means any starting substance such as compound, mixture, monomer, oligomer, pre-polymer natural or synthetic macromolecules etc. intentionally used as reagents in any type of polymerisation reaction including the modification of natural or synthetic macromolecular substances.

11. "Multilayer plastic material" means a material composed of one or more layer(s) or part(s) made of same or different types of materials provided the one intended to come into direct contact with foods consists of plastics;

12. "Overall migration" means the sum of the migrations of substances transferred from a material or article into food or a food simulant;

13. "Permitted substances" are substances intentionally added or present in the finished material or article which comply with Article 2 of Council Directive 89/109/EEC

14. "Plastics" are the organic macromolecular materials obtained by polymerisation, polycondensation, polyaddition, biological fermentation or similar processes 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. Plastics are converted using standard technologies, such as extrusion, moulding, calendering etc.;

15. "Plastic materials and articles" means objects covered by the definition mentioned in Article 1(3);

16. "Polymeric additive" means a polymer and/or oligomer which may be added to plastics in order to achieve a technical effect, but which cannot be used in the absence of another polymer as principal structural component;

17. "Polymerisation production aids" means substances used to provide a suitable medium in which polymerisation occurs (e.g. emulsifiers, surfactants, buffering agents etc.). They are not intended to be present in the finished materials or articles;

18. "Printing inks" means any ink applied to any substrate in a material or article intended to come into contact with foods[25];

19. "QMA" means maximal quantity of the substance contained in a material or article expressed as mg (of substance) per 6 dm^2 of the surface in contact with foods;

20. "QM" means maximal concentration of the substance in the material or article;

21. "Reference food simulants" are distilled water or water of equivalent quality (simulant A), 3% acetic acid (w/v, simulant B), 10% ethanol in aqueous solution (v/v, simulant C), rectified olive oil (simulant D)

22. "Regenerated cellulose film" means a thin sheet material obtained from a refined cellulose derived from un-recycled wood or cotton. Substances may be added either in

[25] This definition appears in the last draft Resolution of the Council of Europe (RD 8-1-42 RES Inks version N. 4, March 2003)

the mass or on the surface. Regenerated cellulose film may be coated on one or both sides;

23. *"Regulated simulant D substitutes" are isooctane, ethanol 95% and modified polyphenylene oxide, used to substitute simulant D under specified conditions;*

24. "Rubber"[26] means a family of materials showing property of high elasticity. In an unaged state, rubber can be substantially deformed under stress, but recovers nearly to its original stage when the stress is removed. Rubber is usually made from a mixture of (solid and/or liquid) materials and can be subjected to a curing process, which changes its nature[27].

25. "Silicones" are a group of polymeric chemical substances and preparations, all containing polysiloxanes;

26. "Simulant D oil substitutes" are synthetic triglycerides or other edible oils ***with standardised specifications*** *substituting the reference food simulant D under the same testing conditions;*

27. "Simulant D Reduction Factor" (DRF): factor ranging between 2 and 5 by which a measured migration into simulant D (overall or specific) can be divided before comparison with the legal limits. It takes into account the stronger extraction of simulant D compared to a given food;

28. "Specific migration" means the concentration of a specific substance in a foodstuff or food simulant which migrated from a material or article;

29. "Specific Migration Limit" (SML) means the maximum concentration of a given substance into food or food simulants from a material or article;

30. "Substitute test" means the determination of a specific migration or overall migration into a regulated or a non regulated simulant substitutes;

31. "Total Reduction Factor" (TRF) is the factor, by which a measured overall or specific migration into simulant D or a substitute can be divided before it is compared with the legal limit. It is obtained by multiplying DRF with FRF; its value is limited to a maximum of 5;

[26] Memo for Commission services: DK wishes to introduce a definition of “elastomers”. But this term does not exist in the CoE Resolution on rubber.

[27] This is the current proposal of definition at ISO level which should replace ISO 1382-1996

CHAPTER II

REQUIREMENTS

Article 3 (NEW)
Lists of substances authorised

Only the substances referred to in Articles 4, 5 and 6 may be used in the manufacture of plastic materials and articles subject to the conditions and restrictions specified therein. Annex I sets out the common requirements of these lists.

Article 4
Community list of monomers and other starting substances

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

2. The list in Annex II may be amended by adding *or deleting* substances or changing the *content of the columns in the Table* following the safety evaluation by the Authority.[28]

3. 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.[29]

[30]

Article 5[31]
Community list of additives and polymerisation production aids **[32]**

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[28] To be revised to be in line with the procedures establis hed in the new ongoing Framework Regulation on food contact materials

[29] To be maintained if the directive is adopted before the adoption of the new Framework Directive.

[30] This paragraph is withdrawn because it could be misinterpreted. The whereas n. 20 clarifies the situation of those substances and materials.

[31] Articles 5 to 7 have been modified in accordance with the 2nd amendment of Directive 2002/72/EC. Only the paragraph 3 of Article 5 was modified to avoid any confusion.

[32] The professional organisations (all the relevant organisations, see ref.n 18 and 21 of "Compilation of remarks on Superdirective Rev. 5") proposed the following approach:

Annex III should contain all the authorised additives as well as the PPA used also as additive and now appearing in Annex III. In practice Annex III remains unchanged. For clarity this Annex will be called **Annex IIIA**.

Another Annex - for clarity called **Annex IIIB** to be differentiate from the current Annex IV (related to "Products obtained by means of bacterial fermentation) - will contain an incomplete list of PPA used **only as PPA** and authorised at least by one Member State and affected by national restriction If the exposure to these PPA will be higher than 1.5 µg/kg/person/day these substances should be evaluated by EFSA in accordance with the international criteria for risk assessment. If the exposure is lower than 1.5 µg/kg/person/day these substances will not be listed.

COMMISSION REMARKS ON THE PROPOSAL FROM INDUSTRY ABOVE DESCRIBED.

1. **Without prejudice to Article 13(2) and 13(3) 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 4*a*, 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 include the following additives[33]:

(a) colorants;

(b) solvents.

Article 6

1. A new additive may always be added to the list of substances referred to in Article 5(1) following an evaluation of its safety by the Authority.

The following issues should be clarified by the professional organisations:

a) which restrictions, if any, should be applied to the AAP for which different limitations exist at national level?

b) how the exposure can be estimated and by who and through which mechanism? What about the new PPA used only as PPA?

Likely the proposal from industry for the AAP used only as PPA may be the following:

Annex III B will contain an incomplete list of PPA already authorised at Community level. These substances will be withdrawn by the current Annex III and will updated with the AAP evaluated by EFSA and classified into lists 0-4.

Annex III C will contain a list of PPA authorised at least by one Member State. These substances will be affected by the more severe restriction existing at national level and will be regulated taking into account ex artt. 30 and 36 of Treaty

Annex III D will contain other PPA not authorised at national level but now used. The exposure of these PPA will be evaluated by EFSA and, if the migration is not detectable at the level of 10 ppb or the exposure, if available, will be lower than than 1.5 µg/kg they will be transferred into Annex IIIA with the restriction "not detectable" having a DL = 10 ppb. If the migration will be higher than 10 ppb or exposure, if available, will be higher than 1.5 µg/kg, they will be not longer used unless a petition in accordance to SCF/EFSA guidelines is supplied before a certain deadline to be fixed.

[33] This paragraph is withdrawn because it could be misinterpreted. The whereas n. 20 clarifies the situation of those substances and materials.

2. Any person interested in the authorisation of an additive, which is already placed on the market in one or more of the Member States, shall submit data to a Member States for its safety evaluation by the Authority by 31 December 2006 at the latest.

Until the Authority provides its guidance for the submission of the required data, the applicant shall consult the "Guidelines of the Scientific Committee on Food 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 6b

Without prejudice to Article 4 of Directive 89/109/EEC, Member States may not authorise after 31 December 2006 additives referred to in Article 5(1) which were never evaluated by the Scientific Committee on Food or the Authority. "

Article 7[34]

1. Additives referred to in Article 5, which are authorised as food additives by Council Directive 89/107/EEC[35] or flavourings by Council Directive 88/388/EEC[36] shall not migrate:

(a) into foodstuffs in quantities having a technological function in the final foodstuffs,

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[34] This issue should be re-discussed as Sweden and Italy found that the compromise reached during the discussion on 2nd Amendment of Directive 2002/72 was not satisfactory. Sweden requested that (a) the migrating substances shall not have an effect also on the surface of the food (b) that these additives can not be used in plastics which are in contact with food for which the direct additive is not authorised. Italy wishes to rediscuss deeply the problem of those additives for which the restrictions as direct and indirect additives are very low.

[35] OJ L 40, 11.2.1989, p. 27.

[36] OJ L 184, 15.7.1988, p. 61

(b) into 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) into 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 14(2)(f).

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.

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Article 8
Community list of polymers produced by fermentation

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

Article 9
Specifications of materials and articles and substances

1. General specifications related to plastic materials and articles are laid down in Annex V, part A.

2. Specifications related to some substances appearing in Annexes II, III and IV are laid down in Annex V, part B.

Article 10 (NEW)
Use of the substances

Where no other quantitative restriction is applicable, the quantity of a substance used in the manufacture of materials and articles shall not exceed the amount required to accomplish the intended technical effect.

Article 11
Specific restrictions of substances

1. Plastic materials and articles shall not transfer their constituents to the foods or food simulants set out respectively in Annexes VIII and IX in quantities exceeding the restrictions established in Annexes II, III, IV and V. Where no SML appears in the column restriction an SML = 60 mg/kg shall be applied. The results of the migration testing into foods shall prevail over tests into food simulants.

2. The SML in the list set out in Annexes II, III, IV and V are expressed in mg (of substance)/kg (of food or food simulant). However, such limits are expressed in mg/dm² (of surface area of material or article) 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 *100 ml or grams*[37] or more than 10 l [38];

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

In those cases, the limits set out in Annexes II, III, IV and V expressed in mg/kg shall be divided by the conventional conversion factor of 6 in order to express them in mg/dm².

3 It is assumed that 1 kg of food is in contact with 6 dm². Therefore in Annexes II, III, IV and V the SML can be replaced by the corresponding QMA = SML/6 dm².

Article 12
*Overall migration limit (OML***)**

1. Plastic materials and articles shall not transfer their constituents to foods or the food simulants set out respectively in Annexes VIII and IX in quantities exceeding 60 milligrams (of the constituents released)/kilogram (of food or food simulant).

2. This limit shall be 10 milligrams per square decimetre of surface area of material or article in the following cases:

(a) articles which are containers or are comparable to containers or which can be filled, with a capacity less than *100*[39,40] *ml or grams* or more than 10 l[41];

(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 materials or article and the quantity of food in contact;

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[37] The insertion of grams is justified as in some cases the 100 ml of volume may be filled with a little quantity of food e.g. for chips and, then the rule is too severe (proposal from Vints). Professional organisation asked to justify the change (see ref. n. 18, 21)

[38] In the BADGE Directive the problem of the big container was raised. This issue should be re-discussed in TF.

[39] Mr Vints proposes: articles which are filled with less than 100 ml of food product (for solid or mixed food types the average density to calculate the volume is considered to be 1 g/cm³, unless a more precise value is known).

[40] Grob proposed that for OM only the limit of 60 ppm applies otherwise for small articles the OM expressed as ppm could be very high.

[41] See notes relates to specific migration, also applicable here.

Article 13 (NEW)

Rules for multilayer plastic materials

1. *A multilayer plastic material referred to in Article 1(3), second subparagraph shall comply with the following rules:*

*(a) any layer shall be manufactured from substances complying with the Community list subject to their restrictions. ("**authorised Community substances")**. In absence of a Community list, the substances shall comply with the specific national **lists ("authorised national substances")**. In absence of specific national **lists,** only substances in amounts which, in the practical use of the final materials or articles, can be proved to comply with article 2 of Directive 89/109/EEC may be used **("permitted substances").***

(b) the finished article shall comply with the OML, the SML and the other specific restrictions of the substances contained in the different layers[42];

(c) each layer shall comply with any additional restriction or requirement applicable to it by virtue of other Community or national legislation. In case of conflict with paragraph 1(b) the more stringent restriction prevails.

2. By derogation to paragraph 1(a), a layer, not in direct contact with food, may be manufactured with substances other than those referred to in paragraph 1(a) provided it is separated from the food by a functional barrier[43,44].

3. A "Functional Barrier" is a barrier consisting of one or more layers which shall:

*a) ensure that the migration of the authorised **and permitted** substances does not exceed **the OML or** their SML **or the restrictions applicable to them**;*

*b) prevent the migration of the substances referred to in paragraph 2, their reaction products and their impurities into food or food simulants. For the purpose of control, this means that they shall not be detectable at lowest concentration at which a substance can be measured with statistical certainty by a validated method of analysis in accordance with [new Regulation on control of feed and food].The "lowest concentration" shall not exceed **X** mg/kg[45]. It shall apply to the sum of migration of a group of compounds, if they are structurally and toxicologically related, e.g. isomers.]*

A list of recognised functional barriers and their conditions of use are described in Annex VII. However other barriers can be considered functional barrier if there is

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42 The professional organisation CIIA and EUPC-FCLC (see reff. n. 18 and 21 of the "Compilation of remarks on Superdirective rev. 5) proposed to change "*and the other specific restrictions of the substances contained in the different layers" into "and the other specific restrictions of the substances contained in the* **plastic** *layers"* . Justifications for this change are given the above mentioned references.

43 See ref. 11 of Compilation of remarks (2004.02.22)

44 The AFSSA asked to limit the use of the substances referred to in art. 13(2) only when there is a a recognised functional barrier '(see ref.n. 38 of "First compilation of all remarks")

45 Norway suggested 0.015 mg/kg (ref. n. 2)

scientific evidence that the requirements under a) and b) are fulfilled. This scientific evidence shall be included in the supporting documents referred to in Article 14(3)[46]

4. The substances referred to in paragraph 2 shall not belong to the following categories[47]*:*

(a) classified as "carcinogenic", "mutagenic" or "toxic to reproduction" in Annex I of Directive 67/548/EEC on dangerous substances[48,49]*or*

(b) classified under the self responsibility criteria as "carcinogenic", "mutagenic" or "toxic to reproduction" according to the rules of Article 6 of Directive 67/548/EEC and its amendments.

Article 14

Labelling requirements, declaration of compliance and supporting documents

1. The labelling requirements in Article 6 of Directive 89/109/EEC shall be applied. The written compliance declaration referred to in Article 6(5) of the cited Directive shall be kept by the food industry **and by the manufacturers of the material and article** , when the material and article is already in contact with foods, or by the manufacturers of the material or article, when this contact is established only by the final consumers **or *in both cases* where materials and articles are brought in from third countries, the importer into the Community.**

2. The written compliance declaration **shall *provide adequate and relevant information at each stage of the supply chain to help ensure the suitable use and safety of the materials and articles subject to the declaration and their compliance with relevant regulation. The declaration of compliance shall contain the following information, as can be adapted to take due account of the position of the issuing party in the supply chain.*[50] *The written declaration shall be reviewed as soon as it is necessary*.** *It shall contain the following information:*

(a) Identity and address of the company in the European Union which manufactures or imports the finished material or article;

(b) *Identity of the* ***substances used, under appropriate confidentiality agreements between the suppliers of them, the users and enforcement authorities,***

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[46] It is possible to include the description of a "Functional barrier" (FB) if there is a conclusive proof (experimental or by modelling) that a layer complies with the requirements of the paragraphs 2 and 3. The FB may be described by the type of the materials and by the conditions under which the layer can be used as functional barrier i.e. conditions of contact, characters of the substances for which the FB is ensured. For these FB there is no longer the need of an experimental test. If a layer is not included in the Annex 7, the user of the layer shall describe the FB in the "Supporting documents" referred to in Article 14.

[47] Spain requested t add another category (see ref. n.37 of "First Compilation of remarks)

[48] OJ 196, 16.8.1967, p. 1. as last amended ……..(to be filled)

[49] The professional organisations i.e. CIIA and EUPC-FCLC (see reff. n. 18 and 21 of the "Compilation of remarks on Superdirective rev. 5) required the deletion of cat. III of Directive 67/548/EEC

[50] Amendment proposed by CIIA and EUPC-FCLC (see reff. n. 18 and 21 of the "Compilation of remarks on Superdirective rev. 5)

)

(c) Identity of material or article and its range of application;

(d) Date of the declaration;

(e) The confirmation that the material or article complies with the requirements of this Directive and, when appropriate, of national law;

(f) When a functional barrier is used in a multilayer material, the following additional information shall be provided:

(i) the identity of the substances referred to in Article 13(2) ***in accordance with EFSA guidelines mentioned in Article 6(2);***

(ii) the date by which the material or article must be used and the maximum temperature at which it should be used and maximum time for which it should be exposed to that temperature to be and to remain effective[51]*;*

(iii) the type of foodstuffs with which the material or article will work as a functional barrier.

(g) For substances which are subject to a restriction in food, the level of their specific migration obtained by experimental data or theoretical calculation and, where appropriate, purity criteria in accordance with Commission Directives 95/31/EC[52], 95/45/EC[53], 2000/13/EC[54], 2002/82/EC[55], 2003/89/EC[56] 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[57]

Commission text in paragraph 3 of Article 14

(a) [*3.* ***An appropriate technical documentation, hereinafter "Supporting documents", shall consist of the experimental data or scientific evidence that demonstrates compliance article with the provisions of the Council Directive 89/109/EEC and this Directive of the substances used in the manufacture of the material or article or present in them as well as the finished material. Each provider of a supporting document shall specify their contribution to the manufacture of the material and article and, if necessary, indicate under which conditions compliance with the rules has been certified.***

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51 UK amendment. DK wishes to add « (iii) the maximum shelf life for the final food packaging after contact with the food occurs. Specify area of use with respect to temperature, time and food type.

52 OJ L 178, 28.7.1995, p.1

53 OJ L 226, 22.9.1995, p.1

54 OJ……. ? (to be checked)

55 OJ……. ? (to be checked)

56 OJ L 292, 28.10.2002, p.1

57 EUPC asked for a threshold below which this obligation does not apply.

(3) *The supporting documents will be kept by each provider of these declarations but shall be made available to the enforcement authorities* **on demand**[58]*.]*

Alternative Industrial Text for paragraph 3 of Article 14 (text to be put in anew article 14a

Article 14a (new)

Record-keeping obligation (idem ciia with some exception here indicated)

1. Manufacturers and processors of food contact materials and articles shall keep appropriate technical information necessary to suitably demonstrate that the products they certified comply with the rules applicable to them.

2. This information shall include, as is relevant for the products at stake and their place in the supply chain, the written declarations and other information received from suppliers, the results of testing, calculations, and other analysis, using internationally recognised scientific principles, including exposure assessments, carried out to demonstrate compliance, and any other pertinent legal, regulatory and scientific rationale.

3. ***This information is [without delay][59] at disposal of the enforcement Authorities on request [and food manufacturers, when specifically required, under appropriate agreements with their suppliers][60,61]***

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58 Norway requests that the documentation, at least as regards the empty articles, is available to the public (on request)

59 addition of the Commission services

60 The text between parenthesys is proposed by CIIA (= food manufacturers representative)

61 The professional organisation requested the inclusion of the following revision clause as Article 14''

"*Pending the adoption of more realistic exposure concepts and derived tools, such as Threshold Of Regulatory Conccern (TORC), but within X years(period to be fixed) from the entry into force of this Directive/Regulation, the Commission shall study, on the basis of the experience gained by the Member States in verifying compliance with the record-keeping obligation of Article 14' (new) and of Article 2 of Directive 89/109/EEC:*

a. the possible need to provide more specific record keeping requirements to ensure compliance of food contact materials with the requirements of Article 2 of Directive 89/109/EEC, in particular with respect to the substances referred to in Annex I, paragraph 2 of this Directive;

b. the possible need to adapt the record keeping requirements to ensure their practicality and enforceability;

c. the possibility to provide that categories of materials and articles that are not subject to positive list requirements under this Directive, including polymerisation production aids and the substances referred to in Article 5.3, are suitably regulated at the Community level by the requirements set out in Article 2 of Directive 89/109/EEC and the certification and record keeping obligations of this Directive and, therefore, that these requirements shall constitute full harmonisation of the rules applicable to these categories of materials and articles;

d. for those categories of materials and articles for which experience would demonstrate that the requirements set out in Article 2 of Directive 89/109/EEC and the certification and record keeping obligations of this Directive are not sufficient, the possible need to extend the positive list to also cover these categories of materials and articles.

HAPTER III

ENFORCEMENT AND COMPLIANCE

Article 15
*Compliance with OML, SML **and QMA***

1. Compliance testing regarding OML and SML[62] in food or food simulants shall be carried out in accordance with the rules laid down in Annexes VIII and IX respectively.

2. Compliance with the SML can also be demonstrated by assuming complete migration of the residual substance in the material or article.

3. Compliance with the SML may also be ensured by the determination of the content of a substance in the material or article, provided a relationship between the content and the specific migration of the substance has been established either by an adequate experimentation or by the application of generally recognised migration models based on scientific evidence. If the content of a substance in a material or article is less than the SML for that substance the material or article may be considered in compliance with the rules. Non-compliance of a material or article with an SML must be demonstrated by experimental testing.

3a. Compliance with the OML and SML may be ensured by achieving compliance for materials and articles of similar composition which belong to the same product family and which could be considered a worst case for migration in that product family.

3b Compliance with the OML and SML may be ensured by adding together the migration of the different layers or parts used to make the material or article, or of building blocks[63] of similar composition to the layers or parts which could be considered a worst case for migration for those layers or parts.

4. Compliance with the SML can be demonstrated also on the basis of other conclusive experimental data or scientific evidence.

5. ***Compliance with QMA shall be carried out in accordance with the rules laid down in Annex X.***

Article 16
Inspection and control measures

Member States shall ensure that inspections and other control measures, as appropriate, are carried out to ensure compliance with this Directive.

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62 QM or QMA shall only be applied to materials and articles consisting of a single layer. For multilayer materials or articles QM shall never be applied and QMA shall be replaced, where possible, by the equivalent SML.

63 The Professional organisation are requested to explain better this sentence

Article 17

Methods of analysis

The methods of analysis used to verify the compliance with the restrictions set out in Article 8 shall be in accordance with the requirements of [Regulation of the European Parliament and of the Council on official feed and food controls][64]

CHAPTER IV

FINAL PROVISIONS

Article 18[65]

Repeals

1. The following Directives are repealed:

- *Council Directive 78/142/EEC]*
- *Commission Directive 80/766/EEC*
- *Commission Directive 81/432/EEC*
- *Council Directive 82/711/EEC*
- *Council Directive 85/572/EEC*
- *Commission Directive 93/8/EEC*
- *Commission Directive 97/48/EC*
- *Commission Directive 2002/72/EC, as amended by the Directives set out in Annex XI*[66]*, 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 XI, 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 XI.

Article 19

Entry into force

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

It shall apply from [1 year following adoption] with exception of Article 14 ***which*** shall apply from [2 years after the adoption of the Directive].

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64 COM (2003)52 final. Relevant articles are included in Appendix III of this document

65 The legal service expressed a favourable opinion on this Article. It should be checked with the legal service whether or not the amendments of the Directives 82/711 and 2002/72 should be inserted.

66 To be introduced if necessary.

It does not apply to materials and articles that have been lawfully placed on the market before the date of application of this Directive.

Article 20

Final provision

This Directive is addressed to the Member States.

Done at Brussels,

For the Commission

Member of the Commission

ANNEX I

COMMON REQUIREMENTS OF THE LISTS OF SUBSTANCES

1. The lists referred to in Annexes II, III and IV shall contain the substances intentionally used in the manufacture of a plastic material and article. However, the following substances are not included even if they are authorised:

(a) salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium and sodium of authorised acids, phenols or alcohols. However, names containing '... acid(s), salts' appear in the lists, if the corresponding free acid(s) is (are) not mentioned;

(b) salts (including double salts and acid salts) of zinc of authorised acids, phenols or alcohols. For these salts a Group SML = 25 mg/kg (expressed as Zn) apply. The same restriction for Zn applies to the names containing '... acid(s), salts' which appear in the lists, if the corresponding free acid(s) is (are) not mentioned.

(c) *mixtures obtained by* ***mixing authorised substances without a chemical reaction*** of the components.

(d) natural or synthetic polymeric substances capable of functioning as the main structural component of finished materials and articles provided they comply with the requirements of this Directive.

(e) mixtures obtained by mixing natural or synthetic polymeric substances referred to under (d) without a chemical reaction of the components

2. The following substances not intentionally used in the manufacture of a plastic material and article do not appear in the lists, even if they may be present in the materials or articles:

(a) impurities in the substances used;

(b) reaction intermediates formed during the polymerisation process, such as oligomers;

(c) decomposition or reaction products.

3. The materials and articles which contain the substances indicated **in paragraph 2** under (a), (b) and (c) shall comply with the requirements stated in Article 2 of Directive 89/109/EEC. **These substances are indicated as "Permitted Community substances"**[67]

4. Substances shall be of good technical quality as regards the purity criteria**. The composition shall be known to the producer and presented to the authorities on request.**

5. The lists contain the following information:

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[67] Norway asked to transfer this paragraph in a new article. These substances should not be detectable (DL= X ppb) and should be notified to EFSA and listed in a Community Register. (see ref. n. 24 at 69.1.1.17).

(a) column 1 (Ref. No) : the EC reference number of the substances on the list. The sign x which appears near the reference number identifies the substances for which the Fat (consumption) Reduction Factor referred to in Annex VII, paragraph 4 shall be applied

(b) column 2 (CAS No) : the CAS (Chemical Abstracts) Registry number;

(c) column 3 (Name) : the chemical name;

(d) column 4 (Restrictions): They may include:

(i) SML expressed in mg (of substance)/kg of foods or food simulant;

(ii) QM expressed in mg (of substance)/kg of material and article;

(iii) QMA expressed in mg (of substance) in the material and article/6 dm^2(of surface in contact with food);

(iii bis) ND means "not detectable"

(iii ter) DL means detection limit conventionally established at 0.01 mg/kg of food or food simulant

(iv) any other restriction specifically mentioned;

(v) any type of specification related to the substance or polymer;

(vi) a number between brackets, the meaning of which is explained in the provisions set out in the Chapters of Part II.

The values of SML, QM and QMA do not include analytical tolerance[68].

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. In case of 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.

[68] Likely a guideline for the reference analytical tolerances can be given in the CEN documents.

ANNEX II

POSITIVE LIST OF MONOMERS AND OTHER STARTING SUBSTANCES[69,70]

Ref. No	CAS No.	Name	Restrictions and/or specifications (expressed as mg/kg of food or food simulant)[71]
(1)	(2)	(3)	(4)
10030	000514-10-3	Abietic acid	
10060	000075-07-0	Acetaldehyde	SML(T) = 6 (2)
10090	000064-19-7	Acetic acid	
10120	000108-05-4	Acetic acid, vinyl ester	SML = 12
10150	000108-24-7	Acetic anhydride	
10210	000074-86-2	Acetylene	
10599/90A	061788-89-4	Acids, fatty, unsaturated (C18), dimers, distilled	SML(T) = 0.05 (27)
10599/91	061788-89-4	Acids, fatty, unsaturated (C18), dimers, non distilled	SML(T) = 0.05 (27)
10599/92A	068783-41-5	Acids, fatty, unsaturated (C18), dimers, hydrogenated, distilled	SML(T) = 0.05 (27)
10599/93	068783-41-5	Acids, fatty, unsaturated (C18), dimers, hydrogenated, non distilled	SML(T) = 0.05 (27)
10630	000079-06-1	Acrylamide	SML = ND (DL = 0.01)
10660	015214-89-8	2-Acrylamido-2-methylpropanesulphonic acid	SML = 0.05
10690	000079-10-7	Acrylic acid	SML(T) = 6 (37)
10750	002495-35-4	Acrylic acid, benzyl ester	SML(T) = 6 (37)
10780	000141-32-2	Acrylic acid, n-butyl ester	SML(T) = 6 (37)
10810	002998-08-5	Acrylic acid, sec-butyl ester	SML(T) = 6 (37)
10840	001663-39-4	Acrylic acid, tert-butyl ester	SML(T) = 6 (37)
11000	050976-02-8	Acrylic acid, dicyclopentadienyl ester	SML = 0.05
11245	002156-97-0	Acrylic acid, dodecyl ester	SML = 0.05 (1)
11470	000140-88-5	Acrylic acid, ethyl ester	SML(T) = 6 (37)
11530	00999-61-1	Acrylic acid, 2-hydroxypropyl ester	SML (T)= 0.05 for acrylic acid, 2-hydroxypropyl ester and acrylic acid, 2-hydroxyisopropyl ester and in compliance with the specifications laid down in Annex V
11590	000106-63-8	Acrylic acid, isobutyl ester	SML(T) = 6 (37)
11680	000689-12-3	Acrylic acid, isopropyl ester	SML(T) = 6 (37)
11710	000096-33-3	Acrylic acid, methyl ester	SML(T) = 6 (37)
11830	000818-61-1	Acrylic acid, monoester with ethyleneglycol	SML(T) = 6 (37)
11890	002499-59-4	Acrylic acid, n-octyl ester	SML(T) = 6 (37)
11980	000925-60-0	Acrylic acid, propyl ester	SML(T) = 6 (37)
12100	000107-13-1	Acrylonitrile	SML = ND (DL = 0.01)
12130	000124-04-9	Adipic acid	
12265	004074-90-2	Adipic acid, divinyl ester	SML(T)= 0.05 (36) or use only as comonomer.

[70] See AFSSA comment on some substances (to be checked) (See ref. N. 38 of " First compilation of all remarks")

[71] See also the restrictions referred to in Annex I, paragraphe 1(b). N.B. This sentence will be maintained in the final version of the proposal.

12280	002035-75-8	Adipic anhydride	
12310		Albumin	
12340		Albumin, coagulated by formaldehyde	
12375		Alcohols, aliphatic, monohydric, saturated, linear, primary (C4-C22)	
12670	002855-13-2	1-Amino-3-aminomethyl-3,5,5-trimethylcyclohexane	SML = 6
12761	000693-57-2	12-Aminododecanoic acid	SML = 0.05
12763	000141-43-5	2-Aminoethanol	SML = 0.05 . Not for use in polymers contacting foods for which simulant D is indicated in Part I, Annex V, Section I, Table 3 and for indirect food contact only, behind the PET layer
12765	084434-12-8	N-(2-Aminoethyl)-beta-alanine, sodium salt	SML = 0.05
12788	002432-99-7	11-Aminoundecanoic acid	SML = 5
12789	007664-41-7	Ammonia	
12820	000123-99-9	Azelaic acid	
12970	004196-95-6	Azelaic anhydride	
13000	001477-55-0	1,3-Benzenedimethanamine	SML = 0.05
13060	004422-95-1	1,3,5-Benzenetricarboxylic acid trichloride	SML = 0.05 (measured as 1,3,5-Benzenetricarboxylic acid).
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
13210	001761-71-3	Bis(4-aminocyclohexyl)methane	SML = 0.05
13323	000102-40-9	1,3-Bis(2-hydroxyethoxy)benzene	SML = 0.05 mg/kg
13390	000105-08-8	1,4-Bis(hydroxymethyl)cyclohexane	
13395	004767-03-7	2,2-Bis(hydroxymethyl)propionic acid	SML = 0.05
13460	054208-63-8	Bis(2-hydroxyphenyl)methane bis(2,3-epoxypropyl) ether (=BFDGE)	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 foods (OJ L 51, 22.2.2002, p. 27)
13480	000080-05-7	2,2-Bis(4-hydroxyphenyl)propane	SML(T) = 0.6 mg/kg (28).
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 foods (OJ L 51, 22.2.2002, p. 27)
13530	038103-06-9	2,2-Bis(4-hydroxyphenyl)propane bis(phthalic anhydride)	SML = 0.05
13600	047465-97-4	3,3-Bis(3-methyl-4-hydroxyphenyl)2-indolinone	SML = 1.8
13614	038103-06-9	Bisphenol A bis(phthalic anhydride)	See "2,2-Bis(4-hydroxyphenyl)propane bis(phthalic anhydride) "
13620	010043-35-3	Boric acid	SML(T) = 6 (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	SML = not detectable (DL = 0.01)
13690	000107-88-0	1,3-Butanediol	
13720	000110-63-4	1,4-Butanediol	SML(T) = 0.05 (24)
13780	002425-79-8	1,4-Butanediol bis(2,3-epoxypropyl) ether	SML(T) = 0.01 (expressed as Epoxy group, Mw = 43)(35)
13810	000505-65-7	1,4-Butanediol formal	SML = 0.05
13840	000071-36-3	1-Butanol	
13870	000106-98-9	1-Butene	
13900	000107-01-7	2-Butene	
13932	000598-32-3	3-Buten-2-ol	SML = ND (DL = 0.01). To be used only as a co-monomer for the preparation of polymeric additive
14020	000098-54-4	4-tert-Butylphenol	SML = 0.05
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 (5)
14230	002123-24-2	Caprolactam, sodium salt	SML(T) = 15 (5) (expressed as Caprolactam)
14320	000124-07-2	Caprylic acid	
14350	000630-08-0	Carbon monoxide	
14380	000075-44-5	Carbonyl chloride (=Phosgene)	SML= 0.01
14411	008001-79-4	Castor oil	
14500	009004-34-6	Cellulose	
14530	007782-50-5	Chlorine	
14650	000079-38-9	Chlorotrifluoroethylene	SML = 0.5
14680	000077-92-9	Citric acid	
14710	000108-39-4	m-Cresol	
14740	000095-48-7	o-Cresol	
14770	000106-44-5	p-Cresol	
14800	003724-65-0	Crotonic acid	SML(T) = 0.05 (33)
14841	000599-64-4	4-Cumylphenol	SML = 0.05
14950	003173-53-3	Cyclohexyl isocyanate	SML(T) = ND (DL= 0.01 , expressed as NCO) (26).
15030	000931-88-4	Cyclooctene	SML = 0.05 . For use only in polymers contacting foods for which simulant A is indicated in Part I, Annex V, Section I, Table 3
15070	001647-16-1	1,9-Decadiene	SML = 0.05
15095	000334-48-5	Decanoic acid	
15100	000112-30-1	1-Decanol	
15130	000872-05-9	1-Decene	SML = 0.05
15250	000110-60-1	1,4-Diaminobutane	
15310	000091-76-9	2,4-Diamino-6-phenyl-1,3,5-triazine (=Benzoguanamine)	SML= 5
15565	000106-46-7	1,4-Dichlorobenzene	SML = 12
15610	000080-07-9	4,4'-Dichlorodiphenyl sulphone	SML= 0.05
15700	005124-30-1	Dicyclohexylmethane-4,4'-diisocyanate	SML(T) = ND (DL= 0.01 , expressed as NCO) (26).
15760	000111-46-6	Diethyleneglycol	SML(T) = 30 (3)
15790	000111-40-0	Diethylenetriamine	SML = 5
15820	000345-92-6	4,4’-Difluorobenzophenone	SML = 0.05
15880	000120-80-9	1,2-Dihydroxybenzene (=Pyrocatechol)	SML = 6

15910	000108-46-3	1,3-Dihydroxybenzene (=Resorcinol)	SML = 2.4
15940	000123-31-9	1,4-Dihydroxybenzene (=Hydroquinone)	SML = 0.6
15970	000611-99-4	4,4'-Dihydroxybenzophenone	SML(T) = 6 (15)
16000	000092-88-6	4,4'-Dihydroxybiphenyl	SML = 6
16090	000080-09-1	4,4'-Dihydroxydiphenyl sulphone (=Bisphenol S)	SML = 0.05
16150	000108-01-0	Dimethylaminoethanol	SML = 18
16210	006864-37-5	3,3'-Dimethyl-4,4'-diaminodicyclohexylmethane	SML = 0.05 mg/kg (32). To be used only in polyamides.
16240	000091-97-4	3,3'-Dimethyl-4,4'-diisocyanatobiphenyl	SML(T)= ND (DL = 0.01 , expressed as NCO) (26).
16360	000576-26-1	2,6-Dimethylphenol	SML = 0.05
16390	000126-30-7	2,2-Dimethyl-1,3-propanediol (=Neopentylglycol)	SML = 0.05
16450	000646-06-0	1,3-Dioxolane	SML = 0.05
16480	000126-58-9	Dipentaerythritol	
16540	000102-09-0	Diphenyl carbonate	SML = 0.05 mg/kg
16600	005873-54-1	Diphenylmethane-2,4'-diisocyanate	SML(T)= ND = 0.01 (expressed as NCO) (26).
16630	000101-68-8	Diphenylmethane-4,4'-diisocyanate	SML(T) = ND = 0.01 (expressed as NCO) (26).
16650	000127-63-9	Diphenyl sulphone	SML(T) = 3 (25)
16660	000110-98-5	Dipropyleneglycol	
16690	001321-74-0	Divinylbenzene	SML = ND (DL = 0.01) for the sum of divinylbenzene and ethylvinylbenzene and in compliance with the specifications laid down in Part I, Annex I Section 2
16694	013811-50-2	N,N'-Divinyl-2-imidazolidinone	SML(T) = 0.05 (36)
16697	000693-23-2	n-Dodecanedioic acid	
16704	000112-41-4	1-Dodecene	SML = 0.05
16750	000106-89-8	Epichlorohydrin	SML= 0.01
16780	000064-17-5	Ethanol	
16950	000074-85-1	Ethylene	
16960	000107-15-3	Ethylenediamine	SML = 12
16990	000107-21-1	Ethyleneglycol	SML(T) = 30 (3)
17005	000151-56-4	Ethyleneimine	SML = ND (DL = 0.01)
17020	000075-21-8	Ethylene oxide	SML= 0.01
17050	000104-76-7	2-Ethyl-1-hexanol	SML = 30
17110	016219-75-3	5-Ethylidenebicyclo[2.2.1]hept-2-ene	SML(T) = 0.05 or QMA= 0.05 mg/6dm². If QMA is used the ratio surface/quantity of food shall be lower than 2 dm²/kg
17160	000097-53-0	Eugenol	SML = ND (DL = 0.01)
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 (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 (1)
18250	000115-28-6	Hexachloroendomethylenetetrahydrophthalic acid	SML = ND (DL = 0.01)
18280	000115-27-5	Hexachloroendomethylenetetrahydrophthalic anhydride	SML = ND (DL = 0.01)
18310	036653-82-4	1-Hexadecanol	

18430	000116-15-4	Hexafluoropropylene	SML = ND (DL = 0.01)
18460	000124-09-4	Hexamethylenediamine	SML = 2.4
18640	000822-06-0	Hexamethylene diisocyanate	SML(T) = ND (DL = 0.01 , expressed as NCO) (26).
18670	000100-97-0	Hexamethylenetetramine	SML(T) = 15 (22) (expressed as Formaldehyde)
18700	000629-11-8	1,6-Hexanediol	SML = 0.05 mg/kg
18820	000592-41-6	1-Hexene	SML = 3
18880	000099-96-7	p-Hydroxybenzoic acid	
18896	001679-51-2	4-(Hydroxymethyl)-1-cyclohexene	SML = 0.05 mg/kg
18897	016712-64-4	6-Hydroxy-2-naphthalenecarboxylic acid	SML = 0.05
18898	000103-90-2	N-(4-Hydroxyphenyl) acetamide	SML = 0.05 mg/kg
19000	000115-11-7	Isobutene	
19060	000109-53-5	Isobutyl vinyl ether	SML(T) = 0.05 (36)
19110	004098-71-9	1-Isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	SML(T) = 0.01 (expressed as NCO) (26).
19150	000121-91-5	Isophthalic acid	SML = 5
19210	001459-93-4	Isophthalic acid, dimethyl ester	SML = 0.05
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
19510	011132-73-3	Lignocellulose	
19540	000110-16-7	Maleic acid	SML(T) = 30 (4)
19960	000108-31-6	Maleic anhydride	SML(T) = 30 (4) (expressed as maleic acid)
19990	000079-39-0	Methacrylamide	SML = ND (DL = 0.01)
20020	000079-41-4	Methacrylic acid	
20050	000096-05-9	Methacrylic acid, allyl ester	SML = 0.05
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
20410	002082-81-7	Methacrylic acid, diester with 1,4-butanediol	SML = 0.05
20440	000097-90-5	Methacrylic acid, diester with ethyleneglycol	SML = 0.05 mg/kg
20530	002867-47-2	Methacrylic acid, 2-(dimethylamino)-ethyl ester	SML = ND (DL = 0.01)
20590	000106-91-2	Methacrylic acid, 2,3-epoxypropyl ester	SML(T) = ND (DL = 0.01) (35)
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	
21400	054276-35-6	Methacrylic acid, sulphopropyl ester	SML = 0.05
21460	000760-93-0	Methacrylic anhydride	
21490	000126-98-7	Methacrylonitrile	SML = ND (DL = 0.01)
21520	001561-92-8	Methallylsulphonic acid, sodium salt	SML = 5
21550	000067-56-1	Methanol	
21640	000078-79-5	2-Methyl-1,3-butadiene (=Isoprene)	SML = ND (0.01)
21730	000563-45-1	3-Methyl-1-butene	SML = 0.006 . For use only in Polypropylene.
21765	106246-33-7	4,4'-Methylenebis(3-chloro-2,6-diethylaniline)	SML = 0.05

21940	000924-42-5	N-Methylolacrylamide	SML = ND (DL = 0.01)
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	SML = 5
22332	-	Mixture of (40% w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60% w/w) 2,4,4-trimethylhexane-1,6-diisocyanate	SML(T) = ND (DL = 0.01 , expressed as NCO) (26).
22350	000544-63-8	Myristic acid	
22360	001141-38-4	2,6-Naphthalenedicarboxylic acid	SML = 5
22390	000840-65-3	2,6-Naphthalenedicarboxylic acid, dimethyl ester	SML = 0.05
22420	003173-72-6	1,5-Naphthalene diisocyanate	SML(T) = ND (DL = 0.01 , expressed as NCO) (26).
22450	009004-70-0	Nitrocellulose	
22480	000143-08-8	1-Nonanol	
22552	-	Novolac glycidyl ethers	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 foods (OJ L 51, 22.2.2002, p. 27)
22600	000111-87-5	1-Octanol	
22660	000111-66-0	1-Octene	SML = 15
22763	000112-80-1	Oleic acid	
22775	000144-62-7	Oxalic acid	SML(T) = 6 mg/kg (29)
22778	007456-68-0	4,4'-Oxybis(benzenesulphonyl azide)	SML = 0.05
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
22937	001623-05-8	Perfluoropropylperfluorovinyl ether	SML(T) = 0.05 (36)
22960	000108-95-2	Phenol	
23050	000108-45-2	1,3-Phenylenediamine	SML= ND (DL=0.01)
23070	000102-39-6	1,3-Phenylenedioxy)diacetic acid	SML = 0.05
23170	007664-38-2	Phosphoric acid	
23175	000122-52-1	Phosphorous acid, triethyl ester	SML = ND (DL= 0.01)
23200	000088-99-3	o-Phthalic acid	
23230	000131-17-9	Phthalic acid, diallyl ester	SML = ND (DL = 0.01)
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>6800)	In compliance with the specifications laid down in Part I, Annex I, Section 2
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
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 (2) (expressed as Acetaldehyde)

23950	000123-62-6	Propionic anhydride	
23980	000115-07-1	Propylene	
24010	000075-56-9	Propylene oxide	SML = ND (DL = 0.01)
24057	000089-32-7	Pyromellitic anhydride	SML = 0.05 (expressed as Pyromellitic acid)
24070	073138-82-6	Resin acids and Rosin acids	
24073	000101-90-6	Resorcinol diglycidyl ether	SML = 0.005 - Not for use in polymers contacting foods for which simulant D is indicated in Part I, Annex V, Section I, Table 3 and for indirect food contact only, behind the PET layer.
24100	008050-09-7	Rosin (= Rosin gum)	
24160	008052-10-6	Rosin tall oil	
24190	065997-05-9	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	Styrenesulphonic acid	SML = 0.05
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
24888	003965-55-7	5-Sulphoisophthalic acid, monosodium salt, dimethyl ester	SML = 0.05
24910	000100-21-0	Terephthalic acid	SML = 7.5
24940	000100-20-9	Terephthalic acid dichloride	SML(T) = 7.5 (expressed as Terephthalic acid)
24970	000120-61-6	Terephthalic acid, dimethyl ester	
25080	001120-36-1	1-Tetradecene	SML = 0.05
25090	000112-60-7	Tetraethyleneglycol	
25120	000116-14-3	Tetrafluoroethylene	SML = 0.05
25150	000109-99-9	Tetrahydrofuran	SML = 0.6
25180	000102-60-3	N,N,N',N'-Tetrakis(2-hydroxypropyl)ethylenediamine	
25210	000584-84-9	2,4-Toluene diisocyanate	SML(T) = ND (DL = 0.01 , expressed as NCO) (26).
25240	000091-08-7	2,6-Toluene diisocyanate	SML(T) = ND (DL = 0.01 , expressed as NCO) (26).
25270	026747-90-0	2,4-Toluene diisocyanate dimer	SML(T) = ND (DL = 0.01 , expressed as NCO) (26).
25360		Trialkyl(C5-C15)acetic acid, 2,3-epoxypropyl ester	SML(T) = 0.01 (expressed as Epoxy group, Mw=43) (35)
25380	-	Trialkyl acetic acid (C7-C17), vinyl esters (=Vinyl versatate)	SML(T) = 0.05 (36)
25385	000102-70-5	Triallyamine	In compliance with the specifications laid down in Part I, Annex I, Section 2
25420	000108-78-1	2,4,6-Triamino-1,3,5-triazine (=Melamine)	SML = 30
25450	026896-48-0	Tricyclodecanedimethanol	SML= 0.05

25510	000112-27-6	Triethyleneglycol	
25600	000077-99-6	1,1,1-Trimethylolpropane	SML = 6
25840	003290-92-4	1,1,1-Trimethylolpropane trimethacrylate	SML = 0.05
25900	000110-88-3	Trioxane	SML = 0.05
25910	024800-44-0	Tripropyleneglycol	
25927	027955-94-8	1,1,1-Tris(4-hydroxyphenol)ethane	**SML = 0.05** For use only in polycarbonates]
25960	000057-13-6	Urea	
26050	000075-01-4	Vinyl chloride	**SML = 0.01**
26110	000075-35-4	Vinylidene chloride	SML = ND (DL = 0.05)
26140	000075-38-7	Vinylidene fluoride	SML = 5
26155	001072-63-5	1-Vinylimidazole	SML(T) = 0.05 (36)
26170	003195-78-6	N-Vinyl-N-methylacetamide	**SML = 0.05**
26320	002768-02-7	Vinyltrimethoxysilane	SML(T) = 0.05 (36)
26360	007732-18-5	Water	In compliance with Directive 98/83/EC

ANNEX III[72]

INCOMPLETE COMMUNITY LIST OF AUTHORISED ADDITIVES AND POLYMERISATION PRODUCTION AIDS

SECTION A

Incomplete list of additives and polymerisation production aids fully harmonised at Community level

Ref. No	CAS No.	Name	Restrictions and/or specifications (expressed as mg/kg of food or food simulant)
(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(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, C2-C24, 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, C2-C24, aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters	
30960	-	Acids, aliph., monocarb. (C6-C22), esters with polyglycerol	

[72] Section B will be deleted and the substances appearing in it will be added to Section A as after 30 June 2006 there is no need to differentiate the status of these substances.

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-hydroxyphenyl)ethyl)phenyl ester	SML = 5
31730	000124-04-9	Adipic acid	
33120	-	Alcohols , aliph, monoh., sat., linear, primary (C4-C24)	
33350	009005-32-7	Alginic acid	
33801	-	n-Alkyl(C10-C13)benzenesulphonic acid	SML = 30
34281	-	Alkyl(C8-C22)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	
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/EC 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 Dir 85/572
34895	000088-68-6	2-Aminobenzamide	SML = 0.05 mg/kg. To be used only for PET for water and beverages.
35120	013560-49-1	3-Aminocrotonic acid, diester with thiobis (2-hydroxyethyl) ether	
35160	006642-31-5	6-Amino-1,3-dimethyluracil	SML = 5
35170	000141-43-5	2-Aminoethanol	SML = 0.05. Not for use in polymers contacting foods for which simulant D is indicated in Part I, Annex V, Section 1, Table 3and for indirect food contact only, behind the PET layer
35284	000111-41-1	N-(2-Aminoethyl)ethanolamine	SML= 0.05. Not for use in polymers contacting foods for which simulant D is indicated in Part I, Annex V, Section 1, Table 3 and for indirect food contact only, behind the PET layer.
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	According to Commission Directive …. amending Directive

			2002/72/EC as regards the suspension of the use of azodicarbonamide as blowing agent (OJ L …, p…)
36840	012007-55-5	Barium tetraborate	SML(T) = 1 expressed as Barium (12) and SML(T) = 6(23) (expressed as Boron) without prejudice to the provisions of Directive 98/83/EC.
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 IV
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 Part I, Annex I, Section 2
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
38515	001533-45-5	4,4'-Bis(2-benzoxazolyl)stilbene	SML = 0.05(1)
38810	080693-00-1	Bis(2,6-di-tert-butyl-4-methylphenyl)pentaerythritol diphosphite	SML = 5 (sum of phosphite and phosphate)
38840(x)	154862-43-8	Bis(2,4-dicumylphenyl)pentaerythritol-diphosphite	SML = 5 (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
39680	000080-05-7	2,2-Bis(4-hydroxyphenyl)propane	SML(T)= 0.6 mg/kg (28)
39815	182121-12-6	9,9-Bis(methoxymethyl)fluorene	SML = 0.05
39890	087826-41-3 069158-41-4 054686-97-4 081541-12-0	Bis(methylbenzylidene)sorbitol	
39925(x)	129228-21-3	3,3-Bis(methoxymethyl)-2,5-dimethylhexane	SML = 0.05
40120	068951-50-8	Bis(polyethyleneglycol)hydroxymethylphosphonate	SML = 0.6
40320	010043-35-3	Boric acid	SML(T) = 6(23) (expressed as Boron) without prejudice to the provisions of Directive 98/83/EC.
40400	010043-11-5	Boron nitride	
40570	000106-97-8	Butane	
40580	000110-63-4	1,4-Butanediol	SML(T) = 0.05(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	Calcium sulphoaluminate	

	037293-22-4		
41680	000076-22-2	Camphor	In compliance with note 9 in Annex IV
41760	008006-44-8	Candelilla wax	
41840	000105-60-2	Caprolactam	SML(T) = 15(5)
41960	000124-07-2	Caprylic acid	
42160	000124-38-9	Carbon dioxide	
42320	007492-68-4	Carbonic acid, copper salt	SML(T) = 30 (7) (expressed as Copper)
42500	-	Carbonic acid, salts	
42640	009000-11-7	Carboxymethylcellulose	
42720	008015-86-9	Carnauba wax	
42800	009000-71-9	Casein	
42880	008001-79-4	Castor oil	
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	SML = 0.9
44160	000077-92-9	Citric acid	
44640	000077-93-0	Citric acid, triethyl ester	
45195	007787-70-4	Copper bromide	SML(T) = 30(7) (expressed as Copper)
45200	001335-23-5	Copper iodide	SML(T) = 30(7) (expressed as Copper) and SML = 1(11) (expressed as Iodine)
45280	-	Cotton fibers	
45450	068610-51-5	p-Cresol-dicyclopentadiene-isobutylene, copolymer	SML = 5 mg/kg
45560	014464-46-1	Cristobalite	
45600	003724-65-0	Crotonic acid	SML = 0.05 mg/kg (33)
45640	005232-99-5	2-Cyano-3,3-diphenylacrylic acid, ethyl ester	SML = 0.05 mg/kg
45760	000108-91-8	Cyclohexylamine	
45920	009000-16-2	Dammar	
45940	000334-48-5	n-Decanoic acid	
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	
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
46720(x)	004130-42-1	2,6-Di-tert-butyl-4-ethylphenol	SML = 4.8
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
47210(x)	026427-07-6	Dibutylthiostannoic acid polymer [= Thiobis(butyl-tin sulphide), polymer]	In compliance with the specifications laid down in Part I, Annex I, Section 2.
47440	000461-58-5	Dicyanodiamide	
47540(x)	027458-90-8	Di-tert-dodecyl disulphide	SML = 0.05
47680	000111-46-6	Diethyleneglycol	SML(T) = 30(3)
48460	000075-37-6	1,1-Difluoroethane	
48620	000123-31-9	1,4-Dihydroxybenzene (=Hydroquinone)	SML = 0.6
48720	000611-99-4	4,4'-Dihydroxybenzophenone	SML(T) = 6(15)
49485	134701-20-5	2,4-Dimethyl-6-(1-methylpentadecyl)phenol	SML = 1
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
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(7) (expressed as Copper)
53650	000107-21-1	Ethyleneglycol	SML(T) = 30(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
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
55040	000064-18-6	Formic acid	
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 (C14-C18) and with acids, aliph.,	

		unsat., linear, with an even number of carbon atoms (C16-C18)	
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	
56535	-	Glycerol, esters with nonanoic acid	
56540	-	Glycerol, esters with oleic acid	
56550	-	Glycerol, esters with palmitic 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	
59280	000100-97-0	Hexamethylenetetramine	SML(T) = 15 mg/kg (22) (expressed as Formaldehyde)
59360	000142-62-1	Hexanoic acid	
59760	019569-21-2	Huntite	
59990	007647-01-0	Hydrochloric acid	
60030	012072-90-1	Hydromagnesite	
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(x)	003864-99-1	2-(2'-Hydroxy-3,5'-di-tert-butylphenyl)-5-chlorobenzotriazole	SML(T) = 30(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(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(6)
66580	000077-62-3	2,2'-Methylenebis (4-methyl-6-(1-methylcyclohexyl)phenol)	SML(T) = 3(6)
66640	009004-59-5	Methylethylcellulose	
66695	-	Methylhydroxymethylcellulose	
66700	009004-65-3	Methylhydroxypropylcellulose	
66755	002682-20-4	2-Methyl-4-isothiazolin-3-one	SML = ND (0.01)
67120	012001-26-2	Mica	
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(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	
68078(x)	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.
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 (sum of phosphite and phosphate

68960	000301-02-0	Oleamide	
69040	000112-80-1	Oleic acid	
69760	000143-28-2	Oleyl alcohol	
69920	000144-62-7	Oxalic acid	SML(T) = 6 mg/kg (29)
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. Not for use in polymers contacting foods for which simulant D is indicated in Part I, Annex V, Section 1, Table 3
71670	178671-58-4	Pentaerythritol tetrakis (2-cyano-3,3-diphenylacrylate)	SML = 0.05
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(x)	-	Phosphoric acid, mono- and di-n-alkyl (C16 and C18) esters	SML = 0.05
73720	000115-96-8	Phosphoric acid, trichloroethyl ester	SML = ND (0.01)
74010	145650-60-8	Phosphorous acid, bis(2,4-di-tert-butyl-6-methylphenyl) ethyl ester	SML = 5 (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	
76320	000085-44-9	Phthalic anhydride	
76721	009016-00-6 063148-62-9	Polydimethylsiloxane (Mw>6800)	In compliance with the specifications laid down in Part I, Annex I, Section 2
76730	-	Polydimethylsiloxane, gamma-hydroxypropylated	SML = 6
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 C12-C18 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 (C6- C22) and their ammonium and sodium sulphates	
77895	068439-49-6	Polyethyleneglycol (EO = 2-6) monoalkyl (C16-C18) ether	SML = 0.05 mg/kg and in compliance with the specifications laid down in Annex V'
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 (C2-C4) 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
81515	087189-25-1	Poly(zinc glycerolate)	SML(T) = 30(38) (expressed as Zinc)
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(7) (expressed as Copper); SML = 48 (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	
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(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	
85601	-	Silicates, natural (with the exception of asbestos)	

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(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(23) (expressed as Boron) without prejudice to the provisions of Directive 98/83/EC.
87200	000110-44-1	Sorbic acid	
87280	029116-98-1	Sorbitan dioleate	
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 Part I, Annex I, Section 2
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(7) (expressed as Copper)
89440	-	Stearic acid, esters with ethyleneglycol	SML(T) = 30(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(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	
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

92930	120218-34-0	Thiodiethanolbis(5-methoxycarbonyl-2,6-dimethyl-1,4-dihydropyridine-3-carboxylate)	SML = 6
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 (=Melamine)	SML = 30
94320	000112-27-6	Triethyleneglycol	
94960	000077-99-6	1,1,1-Trimethylolpropane	SML = 6
95000	028931-67-1	Trimethylolpropane trimethacrylate-methyl methacrylate copolymer	
95200	001709-70-2	1,3,5-Trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene	
95270(x)	161717-32-4	2,4,6-Tris(tert-butyl)phenyl-2-butyl-2-ethyl-1,3-propanediol phosphite	SML = 2 (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(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 Part I, Annex I, Section 2
95883	-	White mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks	In compliance with the specifications laid down in Part I, Annex I, Section 2
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 and polymerisation production aids referred to in Article 5

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(10) (expressed as Manganese)
31520(x)	061167-58-6	Acrylic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenyl ester	SML = 6
31920(x)	000103-23-1	Adipic acid, bis(2-ethylhexyl) ester	SML = 18(1)
34230(x)	-	Alkyl(C8-C22)sulphonic acids	SML = 6
34650	151841-65-5	Aluminium hydroxybis [2,2'-methylenebis (4,6-di-tert.butylphenyl) phosphate	SML = 5 mg/kg
35760(x)	001309-64-4	Antimony trioxide	SML = 0.01 (expressed as Antimony)
36720	017194-00-2	Barium hydroxide	SML(T) = 1(12) (expressed as Barium)
36800	010022-31-8	Barium nitrate	SML(T) = 1(12) (expressed as Barium)
38000	000553-54-8	Benzoic acid, lithium salt	SML(T) = 0.6 mg/kg (8) (expressed as Lithium)

38240(x)	000119-61-9	Benzophenone	SML = 0.6
38560(x)	007128-64-5	2,5-Bis(5-tert-butyl-2-benzoxazolyl)thiophene	SML = 0.6
38700(x)	063397-60-4	Bis(2-carbobutoxyethyl)tin-bis(isooctyl mercaptoacetate)	SML = 18
38800(x)	032687-78-8	N,N'-Bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)hydrazide	SML = 15
38820(x)	26741-53-7	Bis(2,4-di-tert-butylphenyl) pentaerythritol diphosphite	SML = 0.6
39060(x)	035958-30-6	1,1-Bis(2-hydroxy-3,5-di-tert-butylphenyl)ethane	SML = 5
39090(x)	-	N,N-Bis(2-hydroxyethyl)alkyl(C8-C18)amine	SML(T) = 1.2(13)
39120(x)	-	N,N-Bis(2-hydroxyethyl)alkyl(C8-C18)amine hydrochlorides	SML(T) = 1.2(13) expressed as Tertiary amine (expressed excluding HCl)
39665	054208-63-8	Bis(2-hydroxyphenyl)methane bis(2,3-epoxypropyl) ether (=BFDGE)	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 foods (OJ L 51, 22.2.2002, p. 27)
39700	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 foods (OJ L 51, 22.2.2002, p. 27)
40000(x)	000991-84-4	2,4-Bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	SML = 30
40020(x)	110553-27-0	2,4-Bis(octylthiomethyl)-6-methylphenol	SML= 6
40160	061269-61-2	N,N'-Bis(2,2,6,6-tetramethyl-4-piperidyl)hexamethylenediamine-1,2-dibromoethane, copolymer	SML = 2.4
40720	025013-16-5	tert-Butyl-4-hydroxyanisole (=BHA)	SML = 30 mg/kg
40800(x)	013003-12-8	4,4'-Butylidene-bis(6-tert-butyl-3-methylphenyl-ditridecyl phosphite)	SML = 6
40980	019664-95-0	Butyric acid, manganese salt	SML(T) = 0.6(10) (expressed as Manganese)
42000(x)	063438-80-2	(2-Carbobutoxyethyl)tin-tris(isooctyl mercaptoacetate)	SML = 30
42400	010377-37-4	Carbonic acid, lithium salt	SML(T) = 0.6(8) (expressed as Lithium)
42480	000584-09-8	Carbonic acid, rubidium salt	SML = 12
43600	004080-31-3	1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	SML = 0.3
43680	000075-45-6	Chlorodifluoromethane	SML = 6 and in compliance with the specifications laid down in Part I, Annex I, Section 2.
44960	011104-61-3	Cobalt oxide	SML(T) = 0.05(14) (expressed as Cobalt)
45440	-	Cresols, butylated, styrenated	SML = 12
45650	006197-30-4	2-Cyano-3,3-diphenylacrylic acid, 2-ethylhexyl ester	SML = 0.05
46640	000128-37-0	2,6-Di-tert-butyl-p-cresol (=BHT)	SML = 3.0 mg/kg
47600(x)	084030-61-5	Di-n-dodecyltin bis(isooctyl mercaptoacetate)	SML = 12
48640	000131-56-6	2,4-Dihydroxybenzophenone	SML(T) = 6(15)

48800(x)	000097-23-4	2,2'-Dihydroxy-5,5'-dichlorodiphenylmethane	SML = 12
48880(x)	000131-53-3	2,2'-Dihydroxy-4-methoxybenzophenone	SML(T) = 6(15)
49600(x)	026636-01-1	Dimethyltin bis(isooctyl mercaptoacetate)	SML(T) = 0.18(16) (expressed as Tin)
49840(x)	002500-88-1	Dioctadecyl disulphide	SML = 3
50160(x)	-	Di-n-octyltin bis(n-alkyl(C10-C16) mercaptoacetate)	SML(T) = 0.04(17) (expressed as Tin)
50240(x)	010039-33-5	Di-n-octyltin bis(2-ethylhexyl maleate)	SML(T) = 0.04(17) (expressed as Tin)
50320(x)	015571-58-1	Di-n-octyltin bis(2-ethylhexyl mercaptoacetate)	SML(T) = 0.04(17) (expressed as Tin)
50360(x)	-	Di-n-octyltin bis(ethyl maleate)	SML(T) = 0.04(17) (expressed as Tin)
50400(x)	033568-99-9	Di-n-octyltin bis(isooctyl maleate)	SML(T) = 0.04(17) (expressed as Tin)
50480(x)	026401-97-8	Di-n-octyltin bis(isooctyl mercaptoacetate)	SML(T) = 0.04(17) (expressed as Tin)
50560(x)	-	Di-n-octyltin 1,4-butanediol bis(mercaptoacetate)	SML(T) = 0.04(17) (expressed as Tin)
50640(x)	003648-18-8	Di-n-octyltin dilaurate	SML(T) = 0.04(17) (expressed as Tin)
50720(x)	015571-60-5	Di-n-octyltin dimaleate	SML(T) = 0.04(17) (expressed as Tin)
50800(x)	-	Di-n-octyltin dimaleate, esterified	SML(T) = 0.04(17) (expressed as Tin)
50880	-	Di-n-octyltin dimaleate, polymers (n = 2-4)	SML(T) = 0.04(17) (expressed as Tin)
50960(x)	069226-44-4	Di-n-octyltin ethyleneglycol bis(mercaptoacetate)	SML(T) = 0.04(17) (expressed as Tin)
51040(x)	015535-79-2	Di-n-octyltin mercaptoacetate	SML(T) = 0.04(17) (expressed as Tin)
51120(x)	-	Di-n-octyltin thiobenzoate 2-ethylhexyl mercaptoacetate	SML(T) = 0.04(17) (expressed as Tin)
51570	000127-63-9	Diphenyl sulphone	SML(T) = 3(25)
51680(x)	000102-08-9	N,N'-diphenylthiourea	SML = 3
52000(x)	027176-87-0	Dodecylbenzenesulphonic acid	SML = 30
52320(x)	052047-59-3	2-(4-Dodecylphenyl)indole	SML = 0.06
52880	023676-09-7	4-Ethoxybenzoic acid, ethyl ester	SML = 3.6
53200	023949-66-8	2-Ethoxy-2'-ethyloxanilide	SML = 30
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)
58960(x)	000057-09-0	Hexadecyltrimethylammonium bromide	SML = 6
59120(x)	023128-74-7	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide)	SML = 45
59200(x)	035074-77-2	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)	SML = 6
60320(x)	070321-86-7	2-[2-Hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl]benzotriazole	SML = 1.5
60400(x)	003896-11-5	2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole	SML(T) = 30(19)
60800	065447-77-0	1-(2-Hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethyl piperidine-succinic acid, dimethyl ester, copolymer	SML = 30
61280(x)	003293-97-8	2-Hydroxy-4-n-hexyloxybenzophenone	SML(T) = 6(15)
61360(x)	000131-57-7	2-Hydroxy-4-methoxybenzophenone	SML(T) = 6(15)

61440	002440-22-4	2-(2'-Hydroxy-5'-methylphenyl)benzotriazole	SML(T) = 30(19)
61600(x)	001843-05-6	2-Hydroxy-4-n-octyloxybenzophenone	SML(T) = 6(15)
63200	051877-53-3	Lactic acid, manganese salt	SML(T) = 0.6(10) (expressed as Manganese)
64320	010377-51-2	Lithium iodide	SML(T) = 1(11) (expressed as Iodine) and SML(T) = 0.6(8) (expressed as Lithium)
65120	007773-01-5	Manganese chloride	SML(T) = 0.6(10) (expressed as Manganese)
65200	012626-88-9	Manganese hydroxide	SML(T) = 0.6(10) (expressed as Manganese)
65280	010043-84-2	Manganese hypophosphite	SML(T) = 0.6(10) (expressed as Manganese)
65360	011129-60-5	Manganese oxide	SML(T) = 0.6(10) (expressed as Manganese)
65440	-	Manganese pyrophosphite	SML(T) = 0.6(10) (expressed as Manganese)
66360(x)	085209-91-2	2,2'-Methylene bis(4,6-di-tert-butylphenyl) sodium phosphate	SML = 5
66400(x)	000088-24-4	2,2'-Methylene bis(4-ethyl-6-tert-butylphenol)	SML(T) = 1.5(20)
66480(x)	000119-47-1	2,2'-Methylene bis(4-methyl-6-tert-butylphenol)	SML(T) = 1.5(20)
67360(x)	067649-65-4	Mono-n-dodecyltin tris(isooctyl mercaptoacetate)	SML = 24
67520(x)	054849-38-6	Monomethyltin tris(isooctyl mercaptoacetate)	SML(T) = 0.18(16) (expressed as Tin)
67600(x)	-	Mono-n-octyltin tris(alkyl(C10-C16) mercaptoacetate)	SML(T) = 1.2(18) (expressed as Tin)
67680(x)	027107-89-7	Mono-n-octyltin tris(2-ethylhexyl mercaptoacetate)	SML(T) = 1.2(18) (expressed as Tin)
67760(x)	026401-86-5	Mono-n-octyltin tris(isooctyl mercaptoacetate)	SML(T) = 1.2(18) (expressed as Tin)
67896	020336-96-3	Myristic acid, lithium salt	SML(T) = 0.6 mg/kg (8) (expressed as Lithium)
68200	-	Novolac glycidyl ethers	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 foods (OJ L 51, 22.2.2002, p. 27)
68320(x)	002082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	SML = 6
68400(x)	010094-45-8	Octadecylerucamide	SML = 5
68860	004724-48-5	n-Octylphosphonic acid	SML = 0.05
69840(x)	016260-09-6	Oleylpalmitamide	SML = 5
71935	007601-89-0	Perchloric acid, sodium salt monohydrate	SML = 0.05 mg/kg (31)
72160(x)	000948-65-2	2-Phenylindole	SML = 15
72800(x)	001241-94-7	Phosphoric acid, diphenyl 2-ethylhexyl ester	SML = 2.4
73040	013763-32-1	Phosphoric acid, lithium salts	SML(T) = 0.6(8) (expressed as Lithium)
73120	010124-54-6	Phosphoric acid, manganese salt	SML(T) = 0.6(10) (expressed as Manganese)
74400(x)	-	Phosphorous acid, tris(nonyl-and/or dinonylphenyl) ester	SML = 30
76680	068132-00-3	Polycyclopentadiene, hydrogenated	SML = 5 mg/kg (1)

77440(x)	-	Polyethyleneglycol diricinoleate	SML = 42
77520	061791-12-6	Polyethyleneglycol ester of castor oil	SML = 42
78320(x)	009004-97-1	Polyethyleneglycol monoricinoleate	SML = 42
81200(x)	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
81680	007681-11-0	Potassium iodide	SML(T)= 1(11) (expressed as Iodium)
82020	019019-51-3	Propionic acid, cobalt salt	SML(T) = 0.05(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 and in compliance with the specifications laid down in Part I, Annex I, Section 2.
83700(x)	000141-22-0	Ricinoleic acid	SML = 42
84800(x)	000087-18-3	Salicylic acid, 4-tert-butylphenyl ester	SML = 12
84880	000119-36-8	Salicylic acid, methyl ester	SML = 30
85760	012068-40-5	Silicic acid, lithium aluminium salt(2:1:1)	SML(T) = 0.6(8) (expressed as Lithium)
85920	012627-14-4	Silicic acid, lithium salt	SML(T) = 0.6(8) (expressed as Lithium)
86480	007631-90-5	Sodium bisulphite	SML(T) = 10 mg/kg (30) (expressed as $S0_2$)
86800	007681-82-5	Sodium iodide	SML(T) = 1(11) (expressed as Iodine)
86880	-	Sodium monoalkyl dialkylphenoxybenzenedisulphonate	SML = 9
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 $S0_2$)
87120	007772-98-7	Sodium thiosulphate	SML(T) = 10 mg/kg (30) (expressed as $S0_2$)
89170(x)	013586-84-0	Stearic acid, cobalt salt	SML(T) = 0.05(14) (expressed as Cobalt)
92000	007727-43-7	Sulphuric acid, barium salt	SML(T) = 1(12) (expressed as Barium)
92320(x)	-	Tetradecyl-polyethyleneglycol(EO=3-8) ether of glycolic acid	SML = 15
92560(x)	038613-77-3	Tetrakis(2,4-di-tert-butyl-phenyl)-4,4'-biphenylylene diphosphonite	SML = 18
92800(x)	000096-69-5	4,4'-Thiobis(6-tert-butyl-3-methylphenol)	SML = 0.48
92880(x)	041484-35-9	Thiodiethanol bis(3-(3,5-di-tert-butyl-4-hydroxy phenyl) propionate)	SML = 2.4
93120(x)	000123-28-4	Thiodipropionic acid, didodecyl ester	SML(T) = 5(21)
93280(x)	000693-36-7	Thiodipropionic acid, dioctadecyl ester	SML(T) = 5(21)
94400	036443-68-2	Triethyleneglycol bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl) propionate]	SML = 9 mg/kg
94560	000122-20-3	Triisopropanolamine	SML = 5
95280(x)	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
95360(x)	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

95600(x)	001843-03-4	1,1,3-Tris(2-methyl-4-hydroxy-5-tert-butylphenyl) butane	SML = 5

ANNEX IV

PRODUCTS OBTAINED BY MEANS OF BACTERIAL FERMENTATION

Ref. No	CAS No.	Name	Restrictions
(1)	(2)	(3)	(4)
18888	080181-31-3	3-Hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer	SML = 0.05 for Crotonic acid (as impurity) and in compliance with the specifications laid down in Annex V, Part B

ANNEX V

SPECIFICATIONS

PART A: General specifications

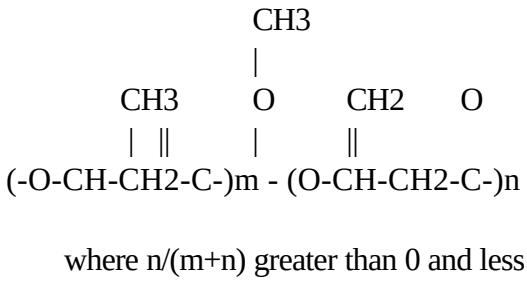
Material and articles shall not release primary aromatic amines (expressed as aniline) in a detectable quantity (DL = 0.01 mg/kg[73] of food or food simulant). The migration of the primary aromatic amines appearing in the lists are excluded from this restriction[74].

PART B: Other specifications

Ref. No	OTHER SPECIFICATIONS
11530	**Acrylic acid, 2-hydroxypropyl ester**. It may contain up to 25% (m/m) of acrylic acid, 2-hydroxyisopropyl ester (CAS N. 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

[73] *In accordance with the provision set out in Part I, Annex I, Section 1, paragraph 4, the value does not longer included the analytical tolerance.*

[74] Norway proposed to delete "manufactured from aromatic isocyanates or colorants prepared by diazo-coupling" as the aromatic amines can derive from other sources (ref.n 10),

		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	
	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	SML for crotonic acid is 0.05
	Purity	Prior to granulation the raw material copolymer powder must contain:
	- Nitrogen	Not more than 2500 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
23547	**Polydimethylsiloxane (Mw>6800)** Minimum viscosity 100 x 10^{-6} m^2/s (=100 centistokes) at 25°C	
25385	**Triallylamine** 40 mg/kg hydrogel at a ratio of 1kg 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>6800)** Minimum viscosity $100x10^{-6}$ m^2/s (=100 centistokes) at 25°C
77895	**Polyethyleneglycol (E0 = 2-6) monoalkyl (C16-C18) ether** The composition of this mixture is as follows: - polyethyleneglycol (E0=2-6)monoalkyl (C16-C18) ether (approx. 28%) - fatty alcohols (C16-C18) (approx. 48%) - ethyleneglycol monoalkyl (C16-C18) ether (approx. 24%)'
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: - 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 x 10^{-6} m^2/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 x 10^{-6} m^2/s (=8.5 centistokes) at 100°C -Average molecular weight not less than 480

ANNEX VI

NOTES RELATED TO THE COLUMN 4 "RESTRICTIONS" REFERRED TO IN ANNEXES II, III AND IV

(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: 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 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 (expressed as Iodine) 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, 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 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) 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: 14950, 15700, 16240, 16570, 16600, 16630, 18640, 19110, 22332, 22420, 22570, 25210, 25240 and 25270.

(27) 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: 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 Ref. 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 Ref. 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 Ref. 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) 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: 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 Ref. Nos: 55200, 55280 and 55360.

(35)[75] 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: 13780, 20590 and 25360.

(36) 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: 12265, 16694, 19060, 22937, 25380, 26155, 26170 and 26320.

(37)[76] 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: 10690, 10750, 10780, 10810, 10840, 11470, 11590; 11680, 11710. 11830. 11890 and 11980.

ANNEX VII

LIST OF RECOGNISED FUNCTIONAL BARRIERS.[77]

1. Glass (e.g. bottle, jar);

2. Metal layer of at least 8 µm thickness (e.g. can or aluminium layer);

[75] Notes 35 and 36 have been introduced because the SCF opinions of these substances were related to the functional groups epoxy (allocated to SCF-list 4A) and vinyl (allocated to SCF-list 6A). However in some cases the substances containing these groups were classified otherwise on the basis of the toxicological data available. Therefore these last substances were not included in the notes of the previous Directives by mistake.

[76] In accordance with the past evaluation of SCF (t-TDI = 0.1 mg.kg.bw). The justification given in the past i.e. the smell of these substances is such that it is not possible to use these substances if they migrate more than 6 mg/kg is not longer considered valid. These substances will be inserted either in the Superdirective or in the 2nd amendment of Directive 2002/72/EC.

[77] It is possible to include the description of a "Functional barrier" (FB) if there is a conclusive proof (experimental or by modelling) that a layer complies with the requirements of the paragraphs 13(2) and 13(3). The FB may be described by the type of the materials and by the conditions under which the layer can be used as functional barrier i.e. conditions of contact, characters of the substances for which the FB is ensured taking into account also the lag time. For these FB there is no longer the need of an experimental test. If a layer is not included in the Annex III of Part I, the user of the layer shall describe the FB in the "Supporting justification documents" referred to in Article 13 (3).

ANNEX VIII

BASIC RULES FOR THE VERIFICATION OF THE COMPLIANCE OF MIGRATION IN FOODS

1. OVERALL MIGRATION

*For most types of foods, the proper determination of overall migration into foods is technically impossible. However, the sum of the migration of the individual components analysed, **including volatile substances except water** must be below the overall migration limit.*

2. SPECIFIC MIGRATION FOR MATERIALS ALREADY IN CONTACT WITH FOODS

2.1. Testing procedure[78]

The food shall be sampled from the marketplace or from food industry and stored as indicated on the packaging label or under normal conditions if no instructions are given. The food shall be removed from contact with the material or article before its expiration date or any date by which the manufacturer has indicated the product should be used for reasons of quality or safety. It shall be treated in accordance with the instructions or normal practice. Parts of the food which are not intended to be eaten shall be removed and discarded. The remainder shall be homogenised and analysed for migration. Foods that are intended to be reconstituted or concentrated, for example by the addition or removal of water, shall be treated as labelled or according to normal practice, and the analytical results shall be expressed on the basis of the treated food mass.

2.2. Calculation of results

The specific migration of a substance into food, is calculated as follows:

$$M = m/Q \qquad (1)$$

or

$$M = m / S \qquad (1a)$$

Where:

M *is the specific migration value in mg (of substance)/kg(of food) or in mg (of substance)/dm² (of surface in contact)*

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

Q *is the quantity in kg of food as eaten.*

[78] See AFSSA comment (ref.n. 38 of "First compilation of all remarks"). To be discussed in task force.

S *is the surface in dm² of the article in contact with the food in the real conditions.*

3. TESTING MATERIALS OR ARTICLES FOR SPECIFIC MIGRATION INTO FOODS

3.1. The migration test

The material or article shall be sampled from the marketplace and treated as described by accompanying instructions or shall be manufactured specially for the purpose. A specimen of food shall be placed in contact with the sample under examination and kept under the worst foreseeable conditions used in practice or conditions selected from Table 4 of Section 2. At the end of the exposure period, the food shall be removed from the material or article. For the further treatment: see point 2.1.

3.2. Calculation of results

3.2.1 Determination in the real conditions of contact

If the specific migration of a substance is determined for the article itself and with the real amount of food it is in contact with, the migration value is calculated as follows:

$$M = m / Q \qquad (2)$$

or for materials and articles mentioned in paragraphs 11(2)(a) and 12(2)(b)

$$M = m / S \qquad (3)$$

Where:

M *is the specific migration value in mg (of substance)/kg(of food) or in mg (of substance)/dm² (of surface in contact)*

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

Q *is the quantity in kg of food as eaten.*

S *is the surface in dm² of the article in contact with the food in the real conditions.*

3.2.2 Determination in conditions other than in the real contact[79]

If the specific migration of a substance is determined for a sample taken from the material or article or for a specially manufactured test sample, the result shall be calculated for the size and for the amount of food as in real use:

[79] Franz is against the application of this paragraph (see ref. n. 23 of "Compilation of all remarks on Superdirective Rev.5"). To be discussed in Task force.

$$M = \frac{M_{EXP} \times S_2}{Q_2} = \frac{m \times S_2}{S \times Q_2} \qquad (4)$$

Where:

M *is the specific migration in mg (of substance)/kg (of food) in contact with the material or article as put on the market;*

M_{EXP} *is the measured migration in mg (of substance)/dm² (of surface in contact with the sample);*

m *is the measured mass of the substance in mg;*

S *is the surface area in dm² of the sample of material or article used for the migration test;*

S_2 *is the surface area in dm² of the material or article in real conditions of use;*

Q_2 *is the quantity in kg of food in contact with the material or article in real conditions of use.*

4. CORRECTION OF THE SPECIFIC MIGRATION VALUE BY THE FAT (CONSUMPTION) REDUCTION FACTOR (FRF)

For substances for which the specific Directive provide the correction of the specific migration by the FRF, the specific migration value calculated in accordance with the equations set out in paragraph 3 (M) is corrected by the following formula before it is compared with the legal limit:

$$M_{FRF} = M / FRF \qquad (5)$$

Where:

M_{FRF} *is the specific migration value corrected by the FRF, in mg/kg;*

M *is the specific migration value, in mg/kg;*

FRF *is the Fat (consumption) Reduction Factor;*

and

$$FRF = (\%fat \times 5) / 100 \qquad (6)$$

Where:

% fat *is the mass percentage of fat in the food tested for migration.*

This correction (equation 6) is applied only when food contains more than 20% fat. Otherwise the FRF is set to 1.

5. COMPLIANCE WITH SML

5.1. Substances for which the FRF is not applicable

The migration of the substance into the foods calculated by formula (1), (2),(3) or (4) is compared with the SML.

5.2 Substances for which the FRF is applicable

The migration of the substance into the foods calculated by formula (5) is compared with the SML.

5.3 Materials and articles in contact with foodstuffs intended specifically for infants (children under the age of 12 months) and young children (children aged between one and three years)

The migration of the substance into foodstuffs is compared by 1/X[80] of the SML.[81]

ANNEX IX

BASIC RULES FOR THE VERIFICATION OF THE COMPLIANCE OF MIGRATION IN FOOD SIMULANTS

GENERAL INTRODUCTION

1. OVERALL MIGRATION

Overall migration shall be determined using the "reference food simulants" A, B, C and D laid down in Section 1 and the "conventional migration test conditions" specified in Section 3.

If the method of analysis does not enable to use stimulant D or an oil substitute for simulant D, regulated simulant D substitutes may be used under conditions readjusted as shown in Table 5 ("Substitute tests").

The value of the specific migration of volatile substances shall be added to the value of the overall migration obtained in accordance with the rules here laid down.

2. SPECIFIC MIGRATION

The specific migration shall be determined with the reference food simulants A, B, C and D laid down in Section 1 and the "conventional migration test conditions" specified in Section 2. For dry food, provision are laid down in point 2.2.3 of this Section.

If the use of the reference food simulant is inappropriate for technical reasons, e.g. because the substance reacts with the simulant, the migration[82] shall be determined using the

[80] The value of X depend on the opinion of the Authority, which should deliver its advice before the adoption of this Directive

[81] Professional organisations asked for the deletion of this para 5.3 as it is not justified as TDI is valid also for infant (see ref.18,21). Norway requested a factor 20 (see ref. n.40)

"regulated simulant D substitutes" according to Section 3 or "non-regulated simulant substitutes" according to Section 4.

3. NON REGULATED SUBSTITUTE SIMULANTS

The use of non-regulated substitute simulants is permitted in accordance with Section 4, provided a "comparison migration test" showed equivalence with the reference simulant or food.

a) For demonstration of compliance, migration into the substitute must be equal or higher than that into the reference simulant or food.

b) For demonstration of non-compliance, migration into the substitute must be equal or lower than that into the reference simulant or food **and be higher than relevant SMLs or OML**.

4. COMMON RULES

It is acceptable:

(a) to reduce the tests to that generally recognised to be the most severe on the basis of scientific evidence;

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

(c) to avoid to repeat the migration testing if it can be proved that the manufacturing process is reproducible.

5 EVALUATION OF THE RESULTS

The following rules apply:

(a) In case of disagreement of results determined with regulated or unregulated simulants, the result obtained by the regulated simulant, i.e. reference food simulant or regulated simulant D substitutes, prevails.

(b) The results obtained in migration testing with food prevails on the results obtained with any type of simulant and simulant substitute.

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[82] Grob proposed the following conditions
(a) a migrate component reacts with the reference food simulants or in incompletely known way with food components;
(b) for compositional migrate analysis when reactive migrants may be present;
(c) replacement of a regulated simulant D substitute if there is scientific evidence that these do not adequately simulate simulant D.

SECTION 1

REFERENCE FOOD SIMULANTS

INTRODUCTION

As it is not always possible to use foods for testing food contact materials, reference food simulants were introduced. They are classified by convention as having the characteristics of one or more food types.

1. FOOD TYPES AND REFERENCE FOOD SIMULANTS

The food types and the reference food simulants to be used for testing migration through direct contact with a material or article are listed in Table 1. When food types are mixed, for instance fatty and aqueous foods, more than one reference food simulant apply.

Table 1

Food types and reference food simulants

Food type	Conventional classification	Food simulant to be used
(1)	(2)	(3)
Aqueous foods i.e. aqueous foods having a pH > 4,5	Foods for which test with simulant A only is prescribed in Table 3 of this Section	Simulant A
Acidic foods i.e. aqueous foods having a pH ≤ 4,5	Foods for which test with simulant B only is prescribed in Table 3 of this Section	Simulant B
Alcoholic foods	Foods for which test with simulant C only is prescribed in Table 3 of this Section	Simulant C. This concentration shall be adjusted to the actual alcoholic strength of the food if it exceeds 10% (v/v)
Fatty foods	Foods for which test with simulant D only is prescribed in Table 3 of this Section	Simulant D or other simulants D oil substitutes such as sunflower oil, mixture of synthetic triglycerides etc.
Dry foods	*Food for which no test with simulants A, B, C and D are prescribed in Table 3 of this Section.*	*Where necessary, special simulant in accordance with point 2.2.3 of this Section*[83].

83 DK comment "The wordings "where necessary" is not easy to enforce, and not too much help is found in 2.2.3 either. To take this migration problem serious, some kind of obligation for the responsible part to act should be specified."

2. SELECTION OF REFERENCE FOOD SIMULANTS

2.1 Materials and articles intended for contact with all food types

2.1.1 General case

The tests shall be carried out using the reference food simulants mentioned below considered the most severe, at the test conditions specified in Table 4 of Section 2, taking a new test specimen of the material or article for each simulant:

– *Simulant C*

– *Simulant D*

2.1.2 Particular cases

(a) In the case of materials and articles, which may contain liquids or beverages of an alcoholic strength exceeding 10 % vol., the test shall be carried out using aqueous solutions of ethanol of a similar strength;

(b) When food acidity (pH less than or equal to 4.5) is expected to lead to significantly higher migration than obtained with 10% ethanol, the polymer or adjuvant is acid-sensitive, or trans-esterification occurs in ethanol solutions, 10% ethanol shall be replaced by 3% acetic acid;

(c) Simulant D may be replaced by a simulant D oil substitute. If the migration limits are exceeded with these substitutes, for the judgement of non-compliance a confirmation of the result by using olive oil is obligatory, when technically feasible. If this is technically not feasible and the material or article exceeds the migration limits, it shall be deemed not in compliance with this Directive. **If tested with the appropriate food type and migration is not exceeded then the material or article is compliant.**

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

2.2.1 This case refers to the following situations:

(a) the material or article is or is intended to be in contact with a known food included in Table 3;

(b) when the material or article is accompanied, according to Article 6 of Directive 89/109/EEC, by a specific indication stating with which food(s) or group(s) of foods mentioned in the Table 3 they may or may not be used. This indication shall be expressed:

(i) at the marketing stages other than retail, by the "reference number" or "description of foods" provided in the Table 3;

(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.

(c) the material or article is accompanied, according to 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".

In these situations the tests shall be carried out using for the case (b) the reference food simulant(s) mentioned in the Table 3 and for the case under (a) and (c) the reference food simulant(s) indicated as examples in Table 2. Where the food(s) or group(s) of foods is (are) not included in the list specified in the Table 3, select the item from the Tables 2 or 3 which corresponds most closely to the food(s) or group(s) of foods under examination.

2.2.2 **Particular cases**

In the particular situations mentioned under point *2.1.2* the same provisions therein set out apply.

2.2.3 ***Dry food***

No migration testing and, then, no reference food simulant is provided for dry foods in Tables 1, 2, 3 of this Annex. However the producer or the importer of the material and article shall assess the potential risk of migration in those situations where it may be reasonably expected that a migration in a dry food may occur e.g. presence of volatile substances in the finished material or article or an intimate continuous contact between the material and the dry foods. In these situations, a migration testing with the food itself under the worst foreseeable conditions or a simulant appropriate to that specific foodstuff shall be carried out. It is generally recognised that the use of modified polyphenylene oxide as simulant for dry food under conditions selected from Table 4 represents in the majority of the cases the worst case migration.

Table 2

General rules on selecting reference food simulants for for testing food contact materials in special cases

Contact foods types	Reference food simulant
(1)	(2)
Dry foods	*See point 2.2.3 of this Section*
Only aqueous foods	Simulant A
Only acidic foods	Simulant B
Only alcoholic foods	Simulant C
Only fatty foods	Simulant D
All aqueous and acidic foods	Simulant B
All alcoholic and aqueous foods	Simulant C
All alcoholic and acidic foods	Simulant C [84]
All fatty and aqueous foods	Simulant D and A
All fatty and acidic foods	Simulant D and B
All fatty, alcoholic and aqueous foods	Simulant D and C
All fatty, alcoholic and acidic foods	Simulant D, C and B

[84] B is deleted for consistency with point 2.3.7(b)

2.3 List of simulants for specific food types

2.3.1 Table 3 specifies the reference food simulants to be used for migration tests with a non-exhaustive list of foods or group of foods. For each of these, only the simulant(s) indicated by an 'X' is (are) to be applied, using for each simulant a new sample of the materials or article to be tested.

2.3.2 When X is followed by an oblique stroke and a figure, the result of the migration tests should be divided by the number indicated, called 'simulant D Reduction Factor' (DRF). This conventional factor, applicable only to certain types of fatty foods, takes account of the higher extractive capacity of simulant D for such foods.

2.3.3. Where the letter 'a' is shown in brackets after the 'X', the choice of the simulant depends on the acidity of the food: A is used if the pH is higher than 4.5, B if it is 4.5 or less.

2.3.4 Where the letter 'b' is shown in brackets after the 'X', the indicated test shall be used only where the pH is 4,5 or less

2.3.5. Where the letter 'c' is shown in brackets after the 'X' and the beverage has an alcoholic strength exceeding 10%, the indicated test shall be carried out with aqueous solutions of ethanol of a strength similar to the beverage.

2.3.6 Where the letter 'd' is shown in brackets after the 'X', the test with simulant D may be omitted if it can be demonstrated by means of an appropriate test generally recognised that there is no `fatty contact' with the material or article.

2.3.7 The following additional rules apply:

(a) Where a food is listed under both a specific and a general heading, only the simulant(s) indicated under the specific heading is (are) to be used.

(b) It is accepted to replace simulants A **or** B by simulant C, since the latter is considered more severe.

(c) The reference food simulants can be replaced by substitute simulants in accordance with the rules specified in Sections 3 and 4.

(d) Testing for volatile compounds migrating through air or gas is not considered in this table (see Point 2.3).

(e) Without prejudice with the rule under (d), the blank rows in the Table 3 means that no testing is required

Table 3

List of simulants to be used for specific food types[85]

Reference number	Description of food	Food simulants to be used			
		A	B	C	D

[85] AFSSA made some comments on this table (see ref.n. 38 of "First compilation of all remarks")

(1)	(2)	(3)	(4)	(5)	(6)
01	**Beverages**				
01.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than 5% vol.: Waters, ciders, fruit or vegetable juices of normal strength or concentrated, musts, fruit nectars, lemonades and mineral waters, syrups, bitters, infusions, coffee, tea, liquid chocolate, beers and other[86]	**X(a)**	**X(a)**		
01.02	Alcoholic beverages of an alcoholic strength equal to or exceeding 5% vol.: wines, spirits, liquers as well any beverage shown under heading 01.01 but with an alcoholic strength equal to or exceeding 5% vol.:		X(a)	X(c)	
01.03	Miscellaneous: undenaturated ethyl alcohol		X(b)	X(c)	
02	**Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares**				
02.01	Starches				
02.02	Cereals, unprocessed, puffed, in flakes (including popcorn, corn flakes and the like)				
02.03	Cereal flour and meal				
02.04	Macaroni, spaghetti and similar products				
02.05	Pastry, biscuits, cakes and other bakers' wares, dry:				
	A. With fatty substances on the surface				X/5
	B. Other				
02.06	Pastry, cakes and other bakers' wares, fresh:				
	A. With fatty substances on the surface				X/5
	B. Other	X			
03	**Chocolate, sugar and products thereof Confectionery products**				
03.01	Chocolate, chocolate-coated products, substitutes and products coated with substitutes				X/5
03.02	Confectionery products:				
	In solid form:				
	I. With fatty substances on the surface				X/5
	II. Other				
	In paste form:				
	I. With fatty substances on the surface				X/3
	II. Moist	X			
03.03	Sugar and sugar products				
	In solid form				
	Honey and the like	X			
	Molasses and sugar syrups	X			
04	**Fruit, vegetables and products thereof**				

[86] Norway asked to reduce the SML for beverages mentioned in 01.01 by a factor 3 or 5 as the ingestion of beverages is largely higher than 1 liter. To be discussed in WG meeting.

04.01	Whole fruit, fresh or chilled				
04.02	Processed fruit:				
	Dried or dehydrated fruit, whole or in the form of flour or powder				
	Fruit in the form of chunks, purée or paste	X(a)	X(a)		
	Fruit preserves (jams and similar products – whole fruit or chunks or in the form of flour or powder, preserved in a liquid medium):				
	I. In an aqueous medium	X(a)	X(a)		
	II. In an oily medium	X(a)	X(a)		X
	III. In an alcoholic medium (≥ 5% vol.)		X(b)	X	
04.03	Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others):				
	Shelled, dried				
	Shelled and roasted				X/5(d)
	In paste or cream form	X			X/3(d)
04.04	Whole vegetables, fresh or chilled				
04.05	Processed vegetables:				
	Dried or dehydrated vegetables whole or in the form of flour or powder				
	Vegetables, cut, in the form of purées	X(a)	X(a)		
	Preserved vegetables:				
	I. In an aqueous medium	X(a)	X(a)		
	II. In an oily medium	X(a)	X(a)		X
	III. In an alcoholic medium (≥ 5% vol.)		X(b)	X	
05	**Fats and oils**				
05.01	Animals and vegetable fats and oils, whether natural or treated (including cocoa butter, lard, resolidified butter)				X
05.02	Margarine, butter and other fats and oils made from water emulsions in oil				X/2
06	**Animal products and eggs**				
06.01	Fish:				
	Fresh, chilled, salted, smoked	X			X/3(d)
	In the form of paste	X			X/3(d)
06.02	Crustaceans and molluscs (including oysters, mussels, snails) not naturally protected by their shells	X			
06.03	Meat of all zoological species (including poultry and game):				
	Fresh, chilled, salted, smoked	X			X/4
	In the form of paste, creams	X			X/4
06.04	Processed meat products (ham, salami, bacon and other)	X			X/4
06.05	Preserved and part-preserved meat and fish:				
	In an aqueous medium	X(a)	X(a)		

	In an oily medium	X(a)	X(a)		X
06.06	Eggs not in shell:				
	Powdered or dried				
	Other	X			
06.07	Egg yolks:				
	Liquid	X			
	Powdered or frozen				
06.08	Dried white of egg				
07	**Milk products**				
07.01	Milk:				
	Whole[87,88]	*[X]*		*[X]*	*[X]*
	Partly dried	X			
	Skimmed or partly skimmed	X			
	Dried				
07.02	Fermented milk such as yoghurt, buttermilk and such products in association with fruit and fruit products		X		
07.03	Cream and sour cream	X(a)	X(a)		
07.04	Cheeses:				
	Whole, with rind				
	Processed cheeses	X(a)	X(a)		
	Cheese containing less than 20% of fat				*X/5*
	All others	*X(a)*	*X(a)*		*X/2(d)*
07.05	Rennet:				
	In liquid or viscous form	X(a)	X(a)		
	Powdered or dried				
08	**Miscellaneous products**				
08.01	Vinegar		X		
08.02	Fried or roasted foods:				
	Fried potatoes, fritters and the like				X/5
	Of animal origin				X/4
08.03	Preparations for soups, broths, in liquid, solid or powder form (extracts, concentrates); homogenised composite food preparations, prepared dishes:				
	Powdered or dried:				
	I. With fatty substances on the surface				X/5
	II. Other				
	Liquid or paste:				
	I. With fatty substances on the surface	X(a)	X(a)		X/3
	II. Other	X(a)	X(a)		
08.04	Yeasts and raising agents:				

[87] Piringer proposed to insert an X/5 or X/3 in the fourth column as it has scientific experimental evidence that this contact is a "fatty" contact. L. Castle proposes X in Simulant C. There is also an EFSSA comment on this issue (see ref. n.38 of “First compilation of all remarks”). Under discussion at the task force level.

	In paste form	X(a)	X(a)		
	Dried				
08.05	Salt				
08.06	Sauces:				
	Without fatty substances on the surface	X(a)	X(a)		
	Mayonnaise, sauces derived from mayonnaise, salad creams and other oil in water emulsions	X(a)	X(a)		X/3
	Sauce containing oil and water forming two distinct layers	X(a)	X(a)		X
08.07	Mustard (except powdered mustard under heading 08.17)	X(a)	X(a)		X/3(d)
08.08	Sandwiches, toasted bread and the like containing any kind of food:				
	With fatty substances on the surface				X/5
	Other				
08.09	Ice-creams	X			
08.10	Dried foods:				
	With fatty substances on the surface				X/5
	Other				
08.11	Frozen or deep-frozen foods				
08.12	Concentrated extracts of an alcoholic strength equal to or exceeding 5% vol.		X(b)	X	
08.13	Cocoa:				
	Cocoa powder				X/5(d)
	Cocoa paste				X/3
08.14	Coffee, whether or not roasted, decaffeinated or soluble, coffee substitutes, granulated or powdered				
08.15	Liquid coffee extracts	X			
08.16	Aromatic herbs and other herbs: Camomile, mallow, mint, tea, lime blossom and others				
08.17	Spices and seasonings in the natural state: Cinnamon, cloves, powdered mustard, pepper, vanilla, saffron and other				

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SECTION 2

MIGRATION TEST CONDITIONS

1. SAMPLES AND CONDITIONS OF CONTACT

1.1. Samples

Migration is determined on the material or article or, if this is impractical, on specimens taken from the material or article, or specimens representative of this material or article. The test shall be carried out taking a new test specimen for each simulant.

1.2. Conditions of contact

The sample shall be placed in contact with the appropriate food simulant in a manner representing the worst of the foreseeable conditions of use. Only those parts of the sample which are intended to come into contact with foods in actual use should be in contact with the food simulant. Duration and temperature during the contact are selected in accordance with the provisions of Table 4. Then the total quantity of migrants (overall migration) and/or the quantity of individual substances (specific migration) released by the sample is measured.

1.3. Specific cases

1.3.1 Materials and articles intended for repeated uses

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 this Section, using another sample of the food or simulant(s) on each occasion. ***In the first test, materials and articles must not exceed the migration limits by more than a factor of 3, and they must remain within the limit in the third. User instructions with respect to the cleaning of the material before use must be followed before performing the migration test.*** 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.

1.3.2 Caps, gaskets, stoppers and similar sealing articles

(a) If the intended use of these articles is known, migration from caps, gaskets, stoppers or similar devices for sealing must be tested by applying them to the containers to which they are intended under conditions of closing corresponding to the normal or foreseeable use. It is assumed that these articles are in contact with a quantity of food filling the container.

(b) **If the intended use of these articles is unknown, such articles shall be tested in a separate test and the result of the migration testing shall be expressed in mg/article. The value obtained shall be added to the quantity migrated from the container for which it is made or intended to be used and expressed in mg/kg or mg/dm² according to the rules referred to in Articles 11 and 12.**

1.3.3 Tubing and pipes **for repeated use**

Pipes and tubing shall be tested according to the worst foreseeable conditions and the value of migration calculated as articles and materials intended for repeated use.

2. DURATION AND TEMPERATURE OF CONTACT

2.1 Monolayer and multilayer materials or articles

For the migration tests, those durations and temperatures specified in Table 4 are selected which correspond to the worst foreseeable conditions of contact and to labelling information on maximum temperature for use. If the material or article is intended for a food contact application covered by a combination of two or more durations 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.

Table 4[89]

Conventional conditions for migration tests with food simulants

Conditions of contact in worst Foreseeable use	**Test conditions**
Contact time	*Duration of test*
t ≤ 5 min	See the conditions in point 4.4
5 min < t ≤ 0.5 hour	0.5 hour
0.5 h < t ≤ 1 hour	1 hour
1 h < t ≤ 2 hours	2 hours
2 h < t ≤ 4 hours	4 hours
4 h < t ≤ 24 hours	24 hours
T > 24 hours	10 days (see footnote[90]***)***
Contact temperature	*Test temperature*
T ≤ 5 °C	5 °C
5 °C < T ≤ 20 °C	20 °C
20 °C < T ≤ 40 °C	40 °C
40 °C < T ≤ 70 °C	70 °C
70 °C < T ≤ 100 °C	100 °C or reflux temperature
100 °C < T ≤ 121 °C	121 °C(*)
121 °C < T ≤ 130 °C	130 °C (*)
130 °C < T ≤ 150 °C	150 °C (*)
T > 150 °C	175 °C (*)

(*) This temperature shall be used only for simulant D. For simulants A, B or C, the test may be performed at 100 °C or reflux temperature, but four times longer than according to the general rules of the upper part of this table ***and ensuring that there is a minimal evaporation from the test article/cell. Any evaporation must be adjusted for.***

2.2. ***Multilayers materials may contain substances for which the diffusional behaviour is such that the omission of the "lag time" (see definition in Article 2) in the migration test may influence the judgement of compliance of the multilayers. In***

[89] In the table or a specific paragraph the conditions for testing microwave oven shall be proposed by the task force.

[90] In the case of contact between monolayers plastic with beverages described in table 3, Section 1 under item 01.01 the test shall be carried out for 3 days at 65°C.

these specific cases the test shall be carried out taking into account the lag time in accordance with generally recognised procedures.[91]

3. TESTING CONDITIONS IF TEMPERATURES AND/OR DURATION OF CONTACT ARE UNDEFINED

a) If labelling or other instructions do not restrict contact temperature and duration, the materials and articles shall be tested for 4 hours at 100 °C **if it used simulant A or B or C** and for 2 hours at 175 °C with simulant D.

b) Materials or articles labelled for use at or below room temperature or by their nature obviously intended for use at or below room temperature for an unspecified duration shall be tested at 40 °C for 10 days.

4. SPECIAL CASES

4.1. Materials and articles intended for use in microwave ovens may be tested in a conventional or a microwave oven, provided the worst-case duration and temperature conditions are selected from Table 4.

4.2. If tests under the contact conditions specified in Table 4 cause physical or other changes in the material or article which do not occur under worst foreseeable real conditions of use, the worst conditions not causing these changes should be used.

4.3. If the real conditions of use are not covered by the test conditions in Table 4 (for instance temperatures higher than 175°C or contact time less than 5 minutes), contact conditions more appropriately corresponding to the worst foreseeable conditions of contact for the materials or articles being studied should be used.

SECTION 3

REGULATED SIMULANT D SUBSTITUTES

1. If the method of analysis does not enable to use simulant D or an oil substitute for simulant D, regulated simulant D substitutes, i.e. isooctane, 95% ethanol and Modified Poly Phenylene Oxide, may be used under conditions readjusted as shown in Table 5 ("Substitute tests").

2. Tests must be performed with **the** substitute tests provided in Table 5, unless one or two of them are generally recognised as not appropriate for the sample under consideration on the basis of scientific evidence.

3. To ascertain compliance with migration limits, the substitute resulting in the highest migration is selected, unless there is evidence that this overestimates migration into food.

[91] The Commission services intends to give some guidance for the application of this paragraph in "Practical Guide". The TF is charged to prepare this very technical document.

4. If tests under the contact conditions specified in Table 4 cause physical or other changes in the material or article which do not occur under worst foreseeable conditions of use, the worst conditions not causing these changes should be used.

Table 5

Conventional test conditions for simulant D and simulant D substitute tests(*)

Simulant D	Isooctane	Ethanol 95%	MPPO(**)
10 d at 5 °C	0.5 d at 5 °C	10 d at 5 °C	-
10 d at 20 °C	1 d at 20 °C	10 d at 20 °C	-
10 d at 40 °C	2 d at 20 °C	10 d at 40 °C	-
2 h at 70 °C	0.5 h at 40 °C	2.0 h at 60 °C	-
0.5 h at 100 °C	0.5 h at 60 °C (***)	2.5 h at 60 °C	0.5 h at 100 °C
1 h at 100 °C	1.0 h at 60 °C (***)	3.0 h at 60 °C (***)	1 h at 100 °C
2 h at 100 °C	1.5 h at 60 °C (***)	3.5 h at 60 °C (***)	2 h at 100 °C
0.5 h at 121 °C	1.5 h at 60 °C (***)	3.5 h at 60 °C (***)	0.5 h at 121 °C
1 h at 121 °C	2.0 h at 60 °C (***)	4.0 h at 60 °C (***)	1 h at 121 °C
2 h at 121 °C	2.5 h at 60 °C (***)	4.5 h at 60 °C (***)	2 h at 121 °C
0.5 h at 130 °C	2.0 h at 60 °C (***)	4.0 h at 60 °C (***)	0.5 h at 130 °C
1 h at 130 °C	2.5 h at 60 °C (***)	4.5 h at 60 °C (***)	1 h at 130 °C
2 h at 150 °C	3.0 h at 60 °C (***)	5.0 h at 60 °C (***)	2 h at 150 °C
2 h at 175 °C	4.0 h at 60 °C (***)	6.0 h at 60 °C (***)	2 h at 175 °C

(*) Preliminary test: immerse a test specimen in olive oil under the appropriate conditions. If the physical properties are changed (e.g. melting, deformation), the material is considered unsuitable for use at that temperature.

(**) MPPO = Modified polyphenylene oxide

(***) Solvent substitutes isooctane and ethanol 95% are used up to a maximum temperature of 60 °C.

SECTION 4

NON-REGULATED SIMULANT SUBSTITUTES

1. Simulant substitutes other than those regulated in Section 3 ("non-regulated simulant substitutes") shall be used in migration tests ("substitute tests"):

(a) when a known migrate component reacts with the reference food simulants or in incompletely known way with food components;

(b) when a compositional migrate analysis shall be carried out and unknown migrants may be present in the material which could react with the reference food simulants;

(c) to replace a regulated simulant D substitute if there is scientific evidence that this regulated substitute does not adequately simulate simulant D.

2. Compliance with migration limits may be shown using non-regulated simulant substitutes and testing conditions other than those mentioned in Section 3, provided there is evidence that migration into the non-regulated simulant substitute under re-adjusted test conditions is equal or higher than into the reference food simulant. This evidence may be obtained from literature or experiments, e.g. based on the comparison with the migration of non-reactive components of similar structure.

3. Non-compliance with migration limits can be shown with non-regulated simulant substitutes and non-regulated test conditions on the basis of evidence that the value of migration is not higher than that into the reference food simulant.

SECTION 5

CALCULATION OF THE MIGRATION INTO FOOD SIMULANTS

1. INTRODUCTION

1.1 For the calculation of the results of the migration tests specified in the previous sections, the specific gravity of the food simulants (or their substitutes) is conventionally assumed to be 1. Therefore the migration (M_{EXP}) measured in milligrams of substance(s) released per litre of food simulant (mg/l) corresponds to milligrams per kilogram of food simulant and milligrams per kilogram of food.

1.2 The experimentally determined migration may need to be corrected to the ratio of surface area and the amount of food in contact with this surface in real use, i.e. the surface/volume (S/V) ratio.[92]

1.3 Where appropriate, migration into simulant D and its substitutes shall be corrected by the simulant D reduction factor (DRF), the fat consumption reduction factor (FRF) or the combination of both, the total reduction factor (TRF).

2. CORRECTION BY SURFACE/VOLUME (S/V) RATIO[93]

The overall and specific migration measured in the test shall be corrected to the S/V ratio in the real application of the material or article:

$$M = \frac{M_{EXP} \times S_2}{V_2} = \frac{m \times S_2}{S_1 \times V_2} \qquad (5)$$

Where:

M is the overall or specific migration in mg (of substance)/kg (of food simulant or its substitute);

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[92] See ref. n. 35 from France. To be discussed in task force.

[93] Franz criticised the application of the formula when the solubility limits the migration (see ref..n.23 of Compilation of all remarks on Superdirective rev. 5)

M_{EXP} is the measured migration in mg (of substance)/dm² (of surface in contact);

m is the mass in mg of the measured substance;

S_1 is the surface area in dm² of the sample of material or article used for the migration test;

S_2 is the surface area in dm² of the material or article in real conditions of use;

V_2 is the volume in litre (=quantity in kilograms) of food in contact with the material or article in real conditions of use.

3. CORRECTION BY THE SIMULANT D REDUCTION FACTOR (DRF)

When materials and articles are dedicated for use in contact with certain types of foods, the overall and specific migration into simulant D or its substitutes shall be corrected by the DRF provided in Table 3 of Section 2:

$$M_{DRF} = M / DRF \qquad (6)$$

Where:

M_{DRF} is the overall or specific migration corrected by the DRF, in mg/kg;

M is the experimentally determined migration, possibly corrected according to formula (5), in mg/kg.

4. CORRECTION BY THE FAT CONSUMPTION REDUCTION FACTOR (FRF)

*For the lipophilic substances marked by an asterisk in the Community lists of Annexes **II, III and IV**, the specific migration into simulant D or its substitutes shall be corrected by the FRF:*

$$M_{FRF} = M / FRF \qquad (7)$$

Where:

M_{FRF} *is the specific migration value corrected by the FRF, in mg/kg*

M is the migration corrected to the S/V ratio of the real use by formula (5), in mg/kg;

This correction is applied only when the simulated food contains more than 20% fat. Otherwise the FRF is set to 1.

5. CORRECTION BY THE TOTAL REDUCTION FACTOR (TRF)

Specific migration into simulant D or its substitutes shall be corrected by the TRF, obtained by multiplying the DRF by the FRF with a maximum value of 5, when

- *the material or article is in contact with a food for which Table 3 of Section 2 provides the application of the DRF and*

- *it is applicable the correction by the FRF for the substance examined.*

$$M_{TRF} = M / TRF \qquad (8)$$

Where:

M_{TRF} *is the specific migration corrected by TRF, in mg/kg ;*

M is the migration corrected to the S/V ratio of the real use by formula (5), in mg/kg;

6. COMPLIANCE WITH THE SPECIFIC MIGRATION LIMIT

6.1. With the exception of materials and articles referred to in paragraph 6.2 the values obtained in formula (6), (7) and (8) are compared with the SML taking into account the analytical tolerance of the procedure.

6.2 *Materials and articles in contact with foodstuffs intended specifically for infants (children under the age of 12 months) and young children (children aged between one and three years)*

The migration of the substance into foodstuffs is compared by 1/X[94] of the SML.

7. COMPLIANCE WITH THE OVERALL MIGRATION LIMIT

The following analytical tolerances have been established:

– 20 mg/kg or 3 mg/dm² in migration tests using simulant D,

– 12 or 2 mg/dm² in migration tests using the other reference food simulants or substitutes including simulant D substitutes referred to in Tables 1, 2 or 3 of Section 1.

– **A material and article can be assumed to comply with this Directive, if the migration using stimulant D is below 80 mg/kg or 13 mg/dm² and the migration using the other reference food simulants or substitutes including simulant D substitutes referred to in Tables 1, 2 or 3 of Section 1 is below 72 mg/kg or 12 mg/dm².**

Remark: Migration tests using simulant D 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 technically inapplicable.

[94] The value of X depends on the opinion of Authority, which should deliver its advice before the adoption of this Directive. Norway proposed X= 20 (see ref.n. 40) and professional organisations asked the deletion of this paragraph (see ref.n. 18 and 21)

ANNEX X

DETERMINATION OF QMA[95]

The determination of the QMA is carried out by a total extraction with an appropriate solvent of the substance from the material or article. For samples having a thickness, D, greater than 0,25 mm, the total quantity of substance should be divided by D/0,25, e.g. if the sample has a thickness of 1 mm the total quantity released should be divided by 4.[96]

However for plasticized materials, for 'foamed' plastics (e.g. foamed/expanded polystyrene) and for other plastics which have open structures produced by a physical process, the maximum thickness rule of 0,25mm should not be applied because migration from depths greater than 0,25 mm may occur.

[95] Franz is against the use of QMA (see ref. n. 23 of "Compilation of all remarks on Superdirective Rev.5"). To be discussed in Task Force.

[96] See the remarks from Franz in ref.n. 23. To be discussed in task force.

ANNEX XI[97] [98]

CORRELATION TABLE

(to be revised in accordance with legal service criteria)

This Directive	Dir. 78*142/EEC*	Dir. 80/766/EEC	Dir. 81/432/EEC	Dir. 82/711/EEC	Dir. 85/572/EEC	Dir. 2002/72/EC
Art. 1, par.1						
Art. 1, par.2						Art.1(1)
Art. 1, par.3(1)(a)(b)						Art.1(2)(a)(b)
Art. 1, par.3(1)(c)						-
Art. 1, par.4						Art. 1, par.3
Art. 2						-
Art. 3						-
Art. 4(1)						Art. 3(1)
-						Art. 3(2)

[97] The articles of the current draft of the 1st amendment of Directive 2002 such as it was sent to 1st Standing Committee are included.

[98] The legal service should be consulted to check if it is necessary or not to include a table containing all the date of application of the repealed Directives (see for analogy the Annex Annex VII of Directive 2002/72/EC.

Art. 4(2)						Art. 3(3)
Art. 4(3)						Art.3(4)
Art. 4(4)						Art.4(5)
Art. 5(1)						Art.4(1), subpar.1
Art. 5(2)						Art.4(2), subpar.2
Art. 5(3)						-
Art. 6						-
Art. 7						Art. 5(a)
Art. 8						Art. 5
Art.9						Art. 6(1)
-						Art. 6(2)
Art. 10						-
Art. 11(1)						Art. 8(1)
Art. 11(2)(3)						Art. 7.2
Art. 12						Art. 2
Art. 13						-

Art. 14(1)						Art. 9(1)
Art. 14 (2)(3)						-
Art. 15(1)						Art. 8(1)
Art. 15(2)						Art. 8(3))
Art. 15(3)						Art. 8(4)
Art. 15(4)						Art. 8(2)
Art. 16						-
Art. 17						-
Art. 18						-
Art. 19						-
Art. 20						Art. 11
Art. 21						Art. 12
Annex I, point 1						Annex II, point 2
Annex I, point 2						Annex II, point 3
Annex I, point 3						-
Annex I, point 4-7						Annex II, points 4-7

Annex II, Table	Annex I and II					
Annex III						Annex III
Annex IV						Annex IV
Annex V						Annex V
Annex VI						Annex VI
Annex VII						-
Annex VIII						-
Annex IX				Annex, points 1-4		
Annex IX, Section 1 Points 1-2.2				Annex, Chapter I		
Annex IX, Section 1 Points 2.3					Annex	
Annex IX, Section 2				Annex, Chapter II		
Annex IX, Section 3				Annex, Chapter III		
Annex IX, Section 4				Annex, Chapter IV		
Annex IX, Section 5				-		
Annex X						

END OF THE SUPERDIRECTIVE