



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 3 October 2005

N.B. This text has been adapted in the UK to reflect amendments from the October 2005 EC FCM working group meeting.

EMB/1105-rev 3

**WORKING DOCUMENT:
DOES NOT NECESSARILY
REPRESENT THE VIEWS
OF THE COMMISSION**

Draft

COMMISSION DIRECTIVE/EC

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

(briefly called '4th amendment' (of Directive 2002/72/EC))

(EN)

(Text with EEA relevance)

WARNING

Due the limited time available, the substances appearing in this draft can be checked for consistency with EFSA evaluation.

EXPLANATORY NOTE

1. At the previous meeting there was a large consensus to delete the ‘surface biocides’ from the list of substances authorised in the manufacture of plastics for food applications, as there was a need to re-examine this controversial issue. At the same time all agreed on the urgency to adopt the document called briefly ‘3rd amendment’ of Directive 2002/72/EC to update the Community list of substances authorised. Therefore the Commission services decided to postpone the approval of surface biocides and to re-discuss the issue in one of the next meetings on the basis of the results of the discussion held during the November meeting (see the document ‘Conclusions of the November 2004 Meeting’).

2. The issue of the approval at Community level of surface biocides was discussed inside the Commission (DGs SANCO/ENTR/ENV) in view to estimate the possible impact on the environment of these new applications. It was decided to ask for further information from petitioner in order to evaluate whether this impact is significant.

It should be also recalled that:

- (a) Regulation 1935/2004 (the new Framework Regulation) deals with the health problems of the use of the materials and articles only and
- (b) the Directive 98/8/EC concerning the placing of biocidal products on the market excludes in Article 1.2(j) excludes products that are within the scope of legislation relating to materials and articles intended to come into contact with foodstuffs.

It remains unclear why the biocides were excluded from the environmental impact assessment. However this problem becomes irrelevant as all the biocides included in this Directive have been notified in accordance with Art. 16(2) of Directive 98/8 and they will be submitted to an environmental impact. Therefore if an unacceptable negative impact on the environment is discovered, the article 16(4) of that Directive applies and then *‘the Commission shall bring forward proposals for restricting the marketing and use of that substance in accordance with Directive 76//769/EEC’*¹.

3. The list of substances proposed to be regulated by this draft of Regulation includes:
- (a) the surface biocides fully evaluated by EFSA. One of the points to be discussed in this draft is whether or not it is necessary to restrict the authorisation only to the applications inside the industry;
 - (b) the phthalates evaluated by EFSA. The Commission services consulted the relevant professional organisations, which agreed to restrict the use of phthalates to the current applications;
 - (c) Substances recently evaluated by EFSA. Some of the substances needed to be confirmed by EFSA.
 - (d) the exclusion of polymerisation production aids (PPA) acting only as PPA from the definition of ‘additives’ as it is impossible, due to the limited human resources, to evaluate at the same time the additives not yet inserted in the future positive list and the PPA which shall respect also the strict deadlines fixed for the classic additives. The PPA will be regulated as the positive list of additives is completed and enforced.

¹ OJ L 262, 27.9.1976, p. 201 and its amendments.

4. Because the Directive 2002/72/EC, as amended by the Directive 2004/19/EC², sets out that the migration testing in fatty food simulants shall apply from 1st July 2006, it is necessary to introduce in this amendment the Fat (exposure) Reduction Factors to avoid any further postponement of this deadline. These factors take into account that the maximum quantity of fat ingested by a person can not exceed 200 grams and not 1000 grams as assumed conventionally by the current estimation of exposure.

5. Finally to strengthen the co-ordination and responsibility of the persons involved at the previous stages of manufacture, it is provided that at each stage of manufacture of a material or article including that of the starting substances, the responsible persons shall document the compliance with the relevant rules in a Compliance Declaration made available to the customer of his product. At each stage of manufacture, supporting documentation, substantiating the Compliance Declaration is kept available for the enforcement authorities ('Record Keeping System').

6. As regards the management of the Community lists, the format of this amendment is identical to that of the 3rd amendment agreed by the Juridical Service of the Commission.

² O.J. L165 of 30.04.04, p. 1

COMMUNICATION FROM THE COMMISSION

Explanatory Note

1. BACKGROUND

Directive 2002/72/EC of 6 August 2002 is a specific Directive within the meaning of the new framework Regulation 1935/2004, which has established the principles and the procedures to be applied for any type of food contact material (plastics, paper, ceramic, metals etc.). This specific Directive establishes the main rules for the group of materials called ‘plastics’, i.e. the list of authorised substances in their manufacture, the restrictions on their use, the labelling as well as the information to be given to the consumer or to the food industry for a correct use of these materials.

In particular for the list of substances to be used in the manufacture of the plastics the specific Directive has established:

- a) For the monomers: a positive list, *i.e. a list which excludes the use at national level of substances not authorised at Community level;*
- b) For the additives and polymerisation production aids: an incomplete list of substances authorised at Community level pending its future transformation in a positive list already provided by the Directive 2004/19/EC

This progressive approach in harmonising the list of additives was motivated by the huge number of substances (several thousands) admitted by the Member States and the need to update their toxicological evaluation.

2. NEW ISSUES

Since Directive 2002/72/EC has been in place, other monomers and additives have been evaluated or re-evaluated by the European Food Safety Authority (Authority) either because they are new substances or because new data became available for substances already authorised.

Moreover, recently, new applications have been requested by industry to maintain some plastic surfaces more hygienic mainly conveyor belts, kitchen utensils. This effect can be obtained by adding in the plastic formulation some biocides which inhibit the growth of some bacteria on the surface of materials or articles. The use of these substances already diffused in USA, Japan, and Australia was strongly requested by European industry. Additional requirements are necessary to ensure the safety of materials and articles containing these substances. The substances should exhibit efficacy on the plastic surface in the actual condition of use but should not have a preservative effect on the foodstuff.

Due to huge number of substances to be evaluated in the next years it is necessary to exclude the polymerisation production aids from the future positive list of additives.

From 1st July 2006 the migration testing in fatty food may be carried out using the fatty food simulant already set out by the Directives 82/711/EEC and 85/572/EEC. Therefore is necessary to correct the value of the exposure to migrants in fatty food taking into account that the exposure of a person is limited by the content of fat in such foods. A person can not ingest more than 200 grams of fat. As the current system of evaluation of exposure is based on the assumption that a person ingest 1000 grams of fat a new factor called 'Fat (exposure) consumption factor (FRF)' is introduced

Finally to strengthen the co-ordination and responsibility of the persons involved at the previous stages of manufacture, it is provided that at each stage of manufacture of a material or article including that of the starting substances, the responsible persons shall document the compliance with the relevant rules in a Compliance Declaration made available to the customer of his product. At each stage of manufacture, supporting documentation, substantiating the Compliance Declaration is kept available for the enforcement authorities ('Record Keeping System').

3. PROPOSED CHANGES

The objectives of this amendment are the following:

- a) For the monomers and additives to update the list of authorised substances taking into account the evaluations of the Authority; therefore several new substances have been added, several have been subject to the changes of their conditions of use and others have been transferred from a provisional national authorisation to a definitive Community approval;
- b) For additives to introduce in the list of additives a specific positive list for surface biocides. For these substances additional requirements have been set out in view of ensuring their efficacy in the real conditions and to avoid the misleading of the consumer;
- c) To separate the current list in two lists: one for the classic additives and the other for the polymerisation production aids. This last one will be transformed in a positive list only when the evaluation of the additives will be finished.
- d) to correct the migration value of the lipophilic substances by the fat (consumption) reduction factor to take into account that the European consumer daily ingests not more than 200 grams of fat and not 1000 grams as assumed until today.
- (e) to clarify the obligation for the business operators in the supply chain to provide their clients with information on their product to ensure that the compliance of finished material and article is ensured.

Draft

COMMISSION DIRECTIVE ../.../EC

of

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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC³, and in particular Article 5(2) thereof,

After consulting the European Food Safety Authority,

Whereas:

- (1) Directive 2002/72/EC⁴ establishes a list of monomers and other starting substances, which may be used for the manufacture of plastic materials and articles. On the basis of new information related to the risk assessment of such substances, certain monomers provisionally admitted at national level as well as new monomers should be included in the Community list of permitted substances in that Directive.
- (2) Directive 2002/72/EC also contains an incomplete list of additives which may be used in the manufacture of plastic materials and articles. That list should be amended so as to include other additives evaluated by the European Food Safety Authority ('the Authority').
- (3) For certain substances, the restrictions already established at Community level should be amended on the basis of the new information available.
- (4) Special additional rules shall be established to allow the use of certain additives able to improve the hygienic properties of the surface of the material or article in which they have been added ('surface biocides'). These substances should exhibit efficacy on the plastic surface in the actual condition of use but should not have a preservative

3 OJ L 338, 13.11.2004, p. 4.

4 OJ L 220, 15.08.2002, p. 18. Directive as last amended by Directive 2004/19/EC of 1 March 2004 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs (OJ L 71, 10.3.2004, p. 8).

effect on the foodstuff. To avoid misleading of the users of these special applications it is necessary that they are informed about the conditions under which the material or article can act against the micro-organisms (e.g. information on temperature, the duration of efficacy of the biocide, types of food with which they may come into contact, or micro-organisms for which the efficacy is expected or not expected). Therefore it is necessary to differentiate the list of these additives from the other lists.

- (5) In view of a better estimation of exposure of the consumer, it is introduced a new reduction factor of the migration to take into account the limited ingestion of the fat content in the daily diet.
- (6) The current list of additives includes also some polymerisation production aids (PPA). Some of the PPA can act also as additives and, therefore, they are included in the future positive list of additives provided by the Directive 2004/19/EEC. The others, acting only as PPA, will be regulated later as for practical reasons it is impossible to proceed to their evaluation inside the deadlines fixed by the abovementioned Directive. Therefore these last PPA are excluded from the current definition of additives which includes both types of PPA.
- (7) Article 9 of the Directive 2002/72/EC lays down that the materials and articles shall be accompanied by a written declaration (Compliance Declaration) attesting that they comply with the rules applicable to them. To strengthen the co-ordination and responsibility of the persons involved at the previous stages of manufacture, it is provided that at each stage of manufacture of a material or article including that of the starting substances, the responsible persons shall document the compliance with the relevant rules in a Compliance Declaration made available to the customer of his product. At each stage of manufacture, supporting documentation, substantiating the Compliance Declaration is kept available for the enforcement authorities ('Record Keeping System').
- (8) Directive 2002/72/EC should therefore be amended accordingly.
- (9) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 2002/72/EC is amended as follows:

1. The article 4 (2) shall be replaced as follows:
 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 paragraph of Directive 82/711/EEC and Article 1 of Directive 85/572/EEC shall apply from *(1 year + 1 day after the adoption by the Commission)*;
2. The following Article 6a is inserted:

'Article 6a

1. Only those substances inhibiting the growth of bacteria on the surface of materials or articles referred to as 'surface biocides' which are listed in Annex III bis may be used for the manufacture of the layers of plastic materials and articles subject to the restrictions set out therein ('Positive list'). These materials and articles shall be adequately labelled to indicate that they contain surface biocides.

These substances shall comply also with the following requirements⁵:

- a) Unless it is specified otherwise in the Annex III bis, they can be used only for industrial applications;
- b) Their use shall not replace the need for good hygiene in accordance with the provisions of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs⁶;
- c) They are suitable and shall show an efficacy on the surface under the real conditions of use;
- d) They shall be accompanied by special labelling containing the instructions to be observed for their safe and appropriate use⁷;

⁵ Remark: during the 2004 November meeting some delegations were in favour to restrict the use of surface biocides only:

(a) to materials and articles intended to be used inside the industrial plants and

(b) to materials and articles intended to be used repeatedly;

⁶ OJ L 139, 30.04.2004, p. 1.

⁷ This note will be deleted in the official draft. It is maintained here as explanation. In accordance with the EFSA panel expert, Mr. Moseley it is necessary that the industry is aware that not in all situation the substance is effective and, then, the labelling should be appropriate. For instance Triclosan is not expected to have a biocide action on Pseudomonas. In Practical Guide some guidance should be given on the criteria to be used for an appropriate labeling.

- e) The labelling and the instructions shall not mislead the consumer in accordance with Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs⁸.
2. The list in Annex III bis 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.
- 2bis. The following Article 7a is inserted:

‘Article 7a

1. *Plastic multi-layers shall comply with the following rules:*
- (a) *each layer shall be manufactured from substances complying with the Community list (“authorised Community substances”). In absence of a Community list, the substances shall comply with the national lists (“authorised national substances”). In absence specific national lists, only “permitted substances” such as defined in paragraph 3 of this Directive may be used;*
 - (b) *each layer shall comply with any relevant restrictions applicable to it or to the substances used for its manufacture by virtue of Community legislation, or in its absence, national food contact legislation applicable to that layer or, in its absence, in accordance with Article 3 of Regulation (EC) No 1935/2004;*
 - (c) *if a substance is regulated by an SML by virtue of this Directive, this SML applies to the plastic material or article independently from the layer from which it derives;*
 - (d) *the finished article shall comply with the overall migration limit referred to in Article 2.*
- (a) *By derogation from paragraph 1(a)(b) and (c), a layer, not in direct contact with food and separated by the food by a functional barrier, may be:*
- (a) *Manufactured with substances other than those referred to in paragraph 1(a) and (b);*
 - (b) *not in compliance with any relevant restriction mentioned in 1(b).*
3. *To be considered as a “Functional Barrier” for the purpose of paragraph 2 a barrier shall comply with the following definitions:*
- 3.1 *“Functional Barrier” is a barrier consisting of one or more layers which shall (a) ensure that the migration of the authorised substances does not exceed the overall*

⁸ OJ L 109 of 6.5.2000, p. 29 as amended by Commission Directive 2001/101/EC (OJ L 310, 28.11.2001, p.19).

migration limit or their specific migration limit or the restriction applicable to them and that the migration of permitted substances is below a concentration that could endanger human health, (b) prevent the migration of the substances referred to in Article 13, paragraph 2, their reaction products and their impurities into food or food simulants;

- 3.2 *“Authorised Community substances” are substances used in the manufacture of materials and articles intended to come into contact with foodstuffs which are authorised by the Community;*
- 3.3 *“Authorised national substances” are substances used in the manufacture of materials and articles intended to come into contact with foodstuffs which are authorised at national level;*
- 3.4 *“permitted substances” are substances other than authorised Community substances or national substances which are substances used in the manufacture of materials and articles intended to come into contact with foodstuffs and for which evidence is provided in Compliance Declaration or its supporting documentation referred to Article 9 that the final material and article containing these substances complies with Article 3 of Regulation (EC) No 1935/2004.*
4. *For the purpose of control, the migration of the substances under 3.1 shall not exceed 0.01 mg/kg, measured with statistical certainty by a method of analysis in accordance with Article 11 of Regulation (EC) 882/2004 of the European Parliament and of the Council on Official feed and food controls⁹. This value shall apply to the sum of migration of a group of compounds, if they are structurally and toxicologically related related, e.g. isomers.*
4. *The substances referred to in paragraph 2 shall not belong to the following categories:*
- (a) *Classified as proved or suspect “carcinogenic”, “mutagenic” or “toxic to reproduction” substances in Annex I of Directive 67/548/EEC on dangerous substances¹⁰ 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.’*

2bis. *Article 8 of 2002/72/EC is replaced by the following:*

‘Article 8

Compliance with specific restrictions of substances

1. *To check the compliance, the migration values shall be always expressed in mg/kg in accordance with the rules set out in*

However in the following cases:

⁹ OJ L 165 of 30 April 2004, p.1. Relevant articles are included in Appendix II of this document

¹⁰ OJ 196, 16.8.1967,p.1. as last amended . ? (to be filled)

- (a) Containers and other articles, including, at the marketing stages other than the retail stage, sheets and films and similar containing or intended to be contain a quantity of foods, less than¹¹ millilitres or grams or more than 10 litres;
- (b) Materials and articles for which, due to their form it is impracticable to estimate the relationship between the surface area of such material or articles and the quantity of food in contact therewith;

The value of migration shall be expressed in mg (of substance)/dm² of total food contact surface. In these cases to check the compliance the migration values in mg/dm² shall be multiplied by the factor S/V of 6.

- 2. Caps, gaskets stoppers and similar sealing articles

See Annex I

- 3. derogation of paragraphs 1 and 2, In the case of materials and articles containing food intended for infants and young children as defined by Commission Directive 91/321/EEC and 96/5/EC the value of migration shall be expressed always in mg/kg to be compared to the limit¹²
- 4. The results obtained in migration testing with foods prevail over the results obtained with any type of simulant and simulant substitute.

- 3. The article 9 is replaced by the following:

‘Article 9

- 1 In the application of Article 16(1) of the Regulation (EC) No 1935/2004, at the marketing stages other than the retail stages, plastic materials and articles shall be accompanied by a written declaration.

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 regulations. The written declaration shall be reviewed regularly and whenever necessary.

- 2. The declaration of compliance for the final material or article shall contain the following information:
 - (a) Name and address of the company in the European Union which manufactures or imports the finished material or article;
 - (b) Product name;
 - (c) Identity of the plastic materials and articles;

¹¹ It should be decided by hierarchy.

¹² Other possibilities are (1) to insert this sentence near to ESBO

- (d) Date of the declaration;
 - (e) The confirmation that the material or article complies with the requirements of EU Regulation and, when appropriate, of national law under the conditions of use identified under sub-paragraph (g) hereunder. The references of the legislation complied with and the specific provisions shall be quoted;
 - (f) Adequate information relative to all substances used for which specific restrictions are in place under relevant Community or national legislation to allow the downstream user to ensure compliance with those restrictions;
 - (g) Conditions of use such as
 - (i) type or types of food;
 - (ii) time and temperature of storage or treatment of the said material or article;
 - (iii) ratio S/V for which in the worst situation the compliance with the restrictions can be ensured.
3. When a surface biocide is used the following additional specific information shall be added to the declaration of compliance:
- (a) The indication that the material and article contains an authorized surface antimicrobial substance;
 - (b) The conditions of use of the material or article as well as the specific cautions to obtain and maintain the antimicrobial efficacy;
 - (c) The estimated minimum duration of the antimicrobial efficacy in the case of material or article under continuing use;
 - (d) Information on effects on non-targeted microorganisms.
4. Business operators shall keep appropriate documentation necessary to suitably demonstrate that the products, subject of compliance declaration, satisfy the rules applicable to them (record-keeping of compliance supporting documentation).
- This compliance supporting documentation 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 recognized scientific principles, including exposure assessments, carried out to demonstrate compliance, and any other pertinent legal, regulatory and scientific rationale;
4. Annexes I, II, III are amended in accordance with Annexes I to III to this Directive.

5. Annex III bis is inserted between Annexes IV and V in accordance with Annex IV to this Directive.
6. Annexes V and VI are amended in accordance with Annexes V and VI to this Directive.

Article 2

Member States shall adopt and publish, by [*insert date 1 year + 1 day after the adoption by the Commission*] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

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

- (a) permit the trade in and use of plastic materials and articles intended to come into contact with food and complying with this Directive, from (*1 year + 1 day after the adoption by the Commission*);
- (b) prohibit the manufacture and importation into the Community of plastic materials and articles intended to come into contact with food and which do not comply with this Directive, from [*two years+ 1 day after the adoption by the Commission*]

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

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

Article 3

Amendments to Directive 85/572/EEC

Directive 85/572/EEC is hereby amended with effect from the date of application of this Directive as follows:

1. In Annex the point 3 of the Table is replaced by the following:

‘When ‘X’ is followed by an oblique stroke and a figure, the result of the migration tests should be divided by the number indicated. In the case of certain types of fatty food, this figure, known as ‘Simulant D reduction factor’ (DRF), is conventionally used to take into account of the greater extractive capacity of the simulant for such foodstuffs.’

2. In Annex the following point 4a is inserted between points 4 and 5:

‘Where the letter (b) is shown in brackets after the ‘X’, the indicated test shall be carried out with ethanol 50% (v/v).’

3. In Annex the heading mentioned under reference number 07 of the Table referring to 'Milk products' is replaced by the following:

'07	Milk products					
07.01	Milk:					
	Whole	X			X(b)	
	Partly dried	X			X(b)	
	Skimmed or partly skimmed	X			X(b)	
	Dried					
07.02	Fermented milk such as yoghurt, buttermilk and similar products		X		X(b)	
07.03	Cream and sour cream	X(a)	X(a)		X(b)	
07.04	Cheeses:					
	Whole, with not edible rind					
	All others	X(a)	X(a)			X/3*'
07.05	Rennet					
	A. In liquid or viscous form	X(a)	X(a)			
	B. Powdered or dried					

Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels, [...]

For the Commission

[...]

Member of the Commission

ANNEX I

Annex I is amended as follows:

The following point 5a entitled 'CORRECTION OF SPECIFIC MIGRATION BY FAT (CONSUMPTION) REDUCTION FACTOR (FRF)' is inserted:

General rules

The exposure of the substances migrating into fatty food (lipophilic substances) is usually calculated assuming that a person ingest daily 1 kg of fatty food. It is known that a person can ingest at maximum 200 grams of fat. Therefore the exposure of a person is limited by the percentage of fat in fatty food. A correction of the value of the exposure shall be made through the correction of the specific migration as indicated below.

For the purpose of this Directive 'lipophilic substances' are the substances marked by an asterisk in the 'European Community Lists of Substances Authorised' appearing at the following internet address :

http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/documents_en.htm.

The specific migration of lipophilic substances (M) shall be corrected by a Fat (consumption) Reduction Factor (FRF) variable from > 1 up to 5 (M_{FRF}). The following equations shall be applied before comparison with the legal limit:

$$M_{FRF} = M / FRF \quad (1)$$

Where:

M_{FRF} is the specific migration corrected by the FRF, in mg/kg or mg/dm²;

M is the specific migration value, in mg/kg or mg/dm²

FRF is the Fat (consumption) Reduction Factor

and

$$FRF = (g \text{ fat in food/kg of food})/200 = (\% \text{ fat} \times 5) / 100 \quad (2)$$

Where:

% fat is the mass percentage of fat in the food tested or simulated in the migration testing.

This correction (equation 2) is not applicable in the following cases:

- (a) when the material or articles is or is intended to be put in contact with food containing less than 20% fat;
- (b) when the material or article is or is intended to be put in contact with a food intended for infants and young children as defined by Commission Directives 91/321/EEC and 96/5/EC;

- (c) substances in the Community lists having a restriction in column (4) SML= ND;
- (d) when the specific migrations of the substance(s) exceeds the overall migration limit (OML).

‘Case 1: specific migration in foods

The specific migration of lipophilic substances into food shall be corrected in accordance with equation (1).

Case 2: specific migration in food simulants

The specific migration of lipophilic substances into simulant D and its substitutes shall be corrected by the following factors:

- (a) the reduction factor referred to in Directive 85/572/EEC 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 foodstuffs⁹, hereinafter indicated as simulant D Reduction Factor (DRF) or
- (b) the FRF in accordance with:
 - (i) the requirements mentioned in general rules and, in addition,
 - (ii) when the specific migration does not exceed 80% of the content of the substance in material and article *or, when the specific migration exceeds 80% but there is experimental or specific evidence that in the worst situation, the migration in food is lower to 80%,*or
- (c) the Total Reduction Factor (TRF) obtained by multiplying the DRF by the FRF with a maximum value of 5, when both factors are applicable.’

2. *The following point 5a is inserted after the point 5:*

‘5a Caps, gaskets, stoppers and similar sealing articles

- (a) *If the intended use of these articles is known, such articles shall 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. The results shall be expressed in mg/kg or mg/dm² in accordance to the rules of Articles 2 and 7.*
- (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 used or intended to be used and the result shall be*

⁹ O.J. L 372, 31.12.1985, p. 14.

expressed in mg/kg or mg/dm² taking into account the total area of the lid and the container in accordance to the rules of Articles 2 and 7.

ANNEX II

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

(1) Point 2 of the general introduction is replaced by the following:

‘2. The following substances are not included even if they are intentionally used and 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:*

(i) *substances whose name contains ‘... acid(s), salts’ which appear in the lists, if the corresponding free acid(s) is (are) not mentioned*

(ii) *substances referred to in note 39 of Annex V*

(c) Ionic salts (including double salts and acid salts) of metals of authorised acids, phenols or alcohols. For these salts the restrictions applicable to the acid and cationic metal shall apply independently from their source’

(2) Section A is amended as follows:

(a) The following lines are inserted in the table in numerical order:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
15267	000080-08-0	4,4'-Diaminodiphenyl sulphone	SML = 5 mg/kg
24886	046728-75-0	5-Sulphoisophthalic acid, monolithium salt (to be confirmed by EFSA)	SML = 5 mg/kg and for Lithium SML(T)= 0.6 mg/kg (8) (expressed as Lithium)’

(b) In the following lines the content of the column ‘Restrictions and/or specifications’ is replaced by the following:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
12786	000919-30-2	3-aminopropyltriethoxy-silane (to be confirmed by EFSA)	QM < 3 mg (of extractable residual content) /kg (of filler) when used for the reactive surface treatment of inorganic fillers and SML = 0.05 mg/kg when used for the surface treatment of materials and articles.
16450	000646-06-0	1,3-Dioxolane (to be confirmed by EFSA)	SML = 5 mg/kg
25900	000110-88-3	Trioxane (to be confirmed by EFSA)	SML = 5 mg/kg

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)

ANNEX III

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

(1) Point 1 is replaced by the following:

‘1. This Annex contains the list of substances which are incorporated into plastics to achieve a technical effect in the finished product, including ‘polymeric additives’. They are intended to be present in the finished articles;

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

The list does not include:

- (a) the substances which directly influence the formation of polymers;
- (b) the substances only used to provide a suitable medium in which polymerisation occurs (‘polymerisation production aids’)
- (c) colorants.’

(2) Point 2 of the general introduction is replaced by the following:

‘2. The following substances are not included even if they are intentionally used and 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) Ionic salts (including double salts and acid salts) of metals of authorised acids, phenols or alcohols. For these salts the restrictions applicable to the acid and cationic metal shall apply independently from their source.’

(3) Section A is amended as follows:

(a) The following lines are inserted in numerical order:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
42080	001333-86-4	Carbon black	In compliance with the specifications laid down in Annex V.
71960	003825-26-1	perfluorooctanoic acid, ammonium salt	Only to be used in repeated use articles, sintered at high temperatures.
93760	000077-90-7	Tri-n-butyl acetyl citrate' (to be confirmed by EFSA)	

(b) In the following lines the content of the columns 'Name' and 'Restrictions and/or specifications' is replaced by the following:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
47600	084030-61-5	Di-n-dodecyltin bis(isooctyl mercaptoacetate)	SML(T) = 0.05 mg/kg food (41) (as sum of mono-n-dodecyltin tris(isooctyl mercaptoacetate, Ref.No 67360), di-n-dodecyltin bis(isooctyl mercaptoacetate, Ref.No 47600), mono-dodecyltin trichloride and di-dodecyltin dichloride) expressed as the sum of mono- and di-dodecyltin chloride
67360	067649-65-4	Mono-n-dodecyltin tris(isooctyl mercaptoacetate)	SML(T) = 0.05 mg/kg food (41) (as sum of mono-n-dodecyltin tris(isooctyl mercaptoacetate, Ref.No 67360), di-n-dodecyltin bis(isooctyl mercaptoacetate, Ref.No 47600), mono-dodecyltin trichloride and di-dodecyltin dichloride) expressed as the sum of mono- and di-dodecyltin chloride'

(c) The following lines are deleted:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)

(4) Section B is amended as follows:

(a) The following lines are inserted in numerical order:

Ref. No	CAS No	Name	
(1)	(2)	(3)	
38885	002725-22-6	2,4-bis(2,4-dimethylphenyl)6-(2-Hydroxy-4-n-octylphenyl)-1,3,5-triazine	SML= 0.05 mg/kg. For aqueous foodstuffs only.
47500	153250-52-3	N,N'-Dicyclohexyl-2,6-naphthalene dicarboxamide	SML = 5 mg/kg.
72081/10	088526-47-0	Petroleum hydrocarbon resins (hydrogenated)	SML = 5 mg/kg (1)
74560	000085-68-7	Phthalic acid, benzyl butyl ester	See Commission Regulation ¹⁰ (references of the act included)
74640	000117-81-7	Phthalic acid, bis(2-ethylhexyl) ester	See Commission Regulation..... (references of the act included)
74880	000084-74-2	Phthalic acid, dibutyl ester	See Commission Regulation..... (references of the act included)
75100	068515-48-0 028553-12-0	Phthalic acid, diesters with primary, saturated C8-C10 branched alcohols, more than 60% C9.	See Commission Regulation..... (references of the act included)
75105	068515-49-1 026761-40-0	Phthalic acid, diesters with primary, saturated C9-C11 alcohols more than 90% C10	See Commission Regulation..... (references of the act included)
93970	- . -	Tricyclodecanedimethanol bis(hexahydrophthalate) (to be confirmed by EFSA)	SML = 0.05 mg/kg'

¹⁰ Commission Regulation (EC) No ./. of [...] relating to restrictions applied to materials and articles intended to come into contact with foods or substances used in these materials and articles (under discussion).

(b) In the following lines the content of the columns ‘Name’ and ‘Restrictions and/or specifications’ is replaced by the following:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)

(c) The following line is deleted:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)

ANNEX IV

‘ANNEX III BIS

List of authorized surface antimicrobial substances (positive list)

Nota bene. Unless specified in the column (4), the use of these substances is restricted only for industrial applications and not to the consumer use.

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
86432	-	Silver-containing glass (Silver-magnesium-calcium-phosphate-borate)	SML(T) = 0.05 mg/kg (43) (as silver) and in accordance with the requirements of Article 6a
86434	-	Silver sodium hydrogen zirconium phosphate	SML(T) = 0.05 mg/kg (43) (as silver) and in accordance with the requirements of Article 6a
86437	-	Silver zeolite A	SML(T) = 0.05 mg/kg (43) (as silver) and in accordance with the requirements of Article 6a . Maximum content in polymer: 10% (w/w) of silver zeolite A containing ≤ 5% silver. Only for repeated use articles made from polyolefins (up to 40°C for contact times below 1 day) and for poly(alkylene terephthalate) based polymers (up to 99°C for contact times below 2 hours)

Ref. No	CAS No	Name	Restrictions and/or specifications
86437/50		Silver zinc glass	SML(T) = 0.05 mg/kg (43) (as silver), SML(T) = 1 mg/kg (12) (expressed as Barium), SML(T) = 6 mg/kg (23) and not more than 1% in plastic. It shall comply with the requirements of Article 6a and with the specifications laid down in Annex V.
86438	-	Silver zinc zeolite A (= silver-zinc sodium alumino silicate calcium metaphosphate), silver content 1-1.6% (w/w)	SML(T) = 0.05 mg/kg (36) (expressed as Silver) and not more than 1% in plastic. It shall comply with the specifications laid down in Annex V.
86438/50		Silver zinc zeolite A (= silver-zinc sodium alumino silicate calcium phosphate), silver content 0.34-0.54% (w/w)	SML(T) = 0.05 mg/kg (36) (expressed as Silver) and not more than 1% in plastic. It shall comply with the specifications laid down in Annex V.
93930	003380-34-5	2,4,4'-Trichloro-2'-hydroxydiphenyl ether	SML = 5 mg/kg and in accordance with the requirements of Article 6a'

ANNEX V

In Annex V new specifications are added for Ref. No:

'Ref. No	OTHER SPECIFICATIONS
'42080	<p>Carbon black</p> <ul style="list-style-type: none"> - Specifications for carbon black: - Toluene extractables : maximum 0.1%, determined according to ISO method 6209; - UV absorption of cyclohexane extract at 386 nm: <0.02 AU for a 1 cm cell or <0.1 AU for a 5 cm cell, determined according to German BfR, BIII, Reinheitsprüfung von Russen, Stand 1.7.1972 - Benzo(a)pyrene content: max 0.25 mg/kg carbon black - Maximum use level of carbon black in the polymer: 2.5% w/w
71960	<p>Perfluorooctanoic acid, ammonium salt</p> <p>Only to be used in repeated use articles, sintered at high temperatures.</p>
86437/50	<p>Silver zinc glass</p> <p>The composition of the substance is :Silver-zinc- aluminium – boron – phosphate glass, mixed with 5-20% barium sulphate, silver content 0.35-0.6% (w/w)</p>
86438	<p>Silver zinc zeolite A (= silver-zinc sodium alumino silicate calcium metaphosphate), silver</p>

	<p>content 1-1.6% (w/w)</p> <p>The composition of the substance, expressed as weight % is:</p> <ul style="list-style-type: none"> • Silver zinc zeoliteA (silver-zinc sodium alumino silicate calcium metaphosphate), silver content 1 -1.6 % • 60% AgZn zeolite A ($x_1\text{Na}_2\text{O} \bullet x_2\text{Ag}_2\text{O} \bullet x_3\text{ZnO}$) • Al_2O_3 • $y\text{SiO}_2$ • $m\text{H}_2\text{O}$ • $\text{Ca}(\text{PO}_3)_2$ • 30% ZnO • 10% SZ100S, dispersion agent consisting of 6.8% ZnO, 2.5% SiO_2, 0.3% polydimethylsiloxane, 0.4% H_2O • total silver content: 1 – 1.6 %
86438/50	<p>Silver zinc zeolite A (= silver-zinc sodium magnesium alumino silicate calcium phosphate), silver content 0.34 - 0.54 %</p> <p>The composition of the substance is:</p> <ul style="list-style-type: none"> • 20% AgZn Zeolite A ($x_1\text{Na}_2\text{O} \bullet x_2\text{Ag}_2\text{O} \bullet x_3\text{MgO} \bullet x_4\text{ZnO}$) • Al_2O_3 • $y\text{SiO}_2$ • $m\text{H}_2\text{O}$ • $\text{Ca}(\text{PO}_3)_2$ • 70% ZnO • 10% DHT-4A-2 (dispersion agent: $\text{MgAl}_2(\text{OH})\text{CO}_3$) • total silver content: 0.34 – 0.54%’

ANNEX VI

Annex VI is amended as follows:

1. The notes (8), (12) and (23) are replaced by the following:
 - ‘(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: 24886, 38000, 42400, 64320, 66350, 67896, 73040, 85760, 85840, 85920 and 95725.
 - (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, 86437/50 and 92000.
 - (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, 86437/50 and 87040.
2. The notes 41, 42 and 43 are added:
 - (41) 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: 47600, 67360, mono-dodecyltin trichloride (CAS No 051375-45-2) and di-dodecyltin dichloride (CAS No 005827-58-7), expressed as the sum of mono- and di-dodecyltin chloride.

- (42) 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.: 75100 and 75105
- (43) 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: 86432, 86434, 86437, 86437/50, 86438 and 86438/50.

(to be included in Practical Guide)

ANNEX

LIPOPHILIC SUBSTANCES

REF_N(x)	CAS_N	NAME
31520(x)	061167-58-6	Acrylic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenyl ester
31530(x)	123968-25-2	Acrylic acid, 2,4-di-tert-pentyl-6-[1-(3,5-di-tert-pentyl-2-hydroxyphenyl)ethyl]phenyl ester
31920(x)	000103-23-1	Adipic acid, bis(2-ethylhexyl) ester
34230(x)	-	Alkyl(C8-C22)sulphonic acids
35760(x)	001309-64-4	Antimony trioxide
38240(x)	000119-61-9	Benzophenone
38515(x)	001533-45-5	4,4'-Bis(2-benzoxazolyl)stilbene
38560(x)	007128-64-5	2,5-Bis(5-tert-butyl-2-benzoxazolyl)thiophene
38700(x)	063397-60-4	Bis(2-carbobutoxyethyl)tin-bis(isooctyl mercaptoacetate)
38800(x)	032687-78-8	N,N'-Bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)hydrazide
38810(x)	080693-00-1	Bis(2,6-di-tert-butyl-4-methylphenyl)pentaerythritol diphosphite
38820(x)	026741-53-7	Bis(2,4-di-tert-butylphenyl) pentaerythritol diphosphite
38840(x)	154862-43-8	Bis(2,4-dicumylphenyl)pentaerythritol-diphosphite
39060(x)	035958-30-6	1,1-Bis(2-hydroxy-3,5-di-tert-butylphenyl)ethane
39090(x)	-	N,N-Bis(2-hydroxyethyl)alkyl(C8-C18)amine
39120(x)	-	N,N-Bis(2-hydroxyethyl)alkyl(C8-C18)amine hydrochlorides
39680(x)	000080-05-7	2,2-Bis(4-hydroxyphenyl)propane
39925(x)	129228-21-3	3,3-Bis(methoxymethyl)-2,5-dimethylhexane
40000(x)	000991-84-4	2,4-Bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine
40020(x)	110553-27-0	2,4-Bis(octylthiomethyl)-6-methylphenol
40800(x)	013003-12-8	4,4'-Butylidene-bis(6-tert-butyl-3-methylphenyl-ditridecyl phosphite)
42000(x)	063438-80-2	(2-Carbobutoxyethyl)tin-tris(isooctyl mercaptoacetate)
46720(x)	004130-42-1	2,6-Di-tert-butyl-4-ethylphenol
47210(x)	026427-07-6	Dibutylthiostannoic acid polymer [= thiobis(butyl-tin sulphide), polymer]
47540(x)	027458-90-8	Di-tert-dodecyl disulphide
47600(x)	084030-61-5	Di-n-dodecyltin bis(isooctyl mercaptoacetate)
48800(x)	000097-23-4	2,2'-Dihydroxy-5,5'-dichlorodiphenylmethane
48880(x)	000131-53-3	2,2'-Dihydroxy-4-methoxybenzophenone
49485(x)	134701-20-5	2,4-Dimethyl-6-(1-methylpentadecyl)-phenol
49600(x)	026636-01-1	Dimethyltin bis(isooctyl mercaptoacetate)
49840(x)	002500-88-1	Diocetadecyl disulphide
50160(x)	-	Di-n-octyltin bis(n-alkyl(C10-C16) mercaptoacetate)
50240(x)	010039-33-5	Di-n-octyltin bis(2-ethylhexyl maleate)
50320(x)	015571-58-1	Di-n-octyltin bis(2-ethylhexyl mercaptoacetate)
50360(x)	-	Di-n-octyltin bis(ethyl maleate)
50400(x)	033568-99-9	Di-n-octyltin bis(isooctyl maleate)
50480(x)	026401-97-8	Di-n-octyltin bis(isooctyl mercaptoacetate)
50560(x)	-	Di-n-octyltin 1,4-butanediol bis(mercaptoacetate)

REF_N(x)	CAS_N	NAME
50640(x)	003648-18-8	Di-n-octyltin dilaurate
50720(x)	015571-60-5	Di-n-octyltin dimaleate
50800(x)	-	Di-n-octyltin dimaleate, esterified
50960(x)	069226-44-4	Di-n-octyltin ethyleneglycol bis(mercaptoacetate)
51040(x)	015535-79-2	Di-n-octyltin mercaptoacetate
51120(x)	-	Di-n-octyltin thiobenzoate 2-ethylhexyl mercaptoacetate
51680(x)	000102-08-9	N,N'-Diphenylthiourea
52000(x)	027176-87-0	Dodecylbenzenesulphonic acid
52320(x)	052047-59-3	2-(4-Dodecylphenyl)indole
52645(x)	010436-08-5	cis-11-Eicosenamide
53200(x)	023949-66-8	2-Ethoxy-2'-ethyloxanilide
54300(x)	118337-09-0	2,2'-Ethylidenebis(4,6-di-tert-butyl phenyl) fluorophosphonite
58960(x)	000057-09-0	Hexadecyltrimethylammonium bromide
59120(x)	023128-74-7	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide)
59200(x)	035074-77-2	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)
60320(x)	070321-86-7	2-[2-Hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl]benzotriazole
60400(x)	003896-11-5	2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole
60480(x)	003864-99-1	2-(2'-Hydroxy-3,5'-di-tert-butylphenyl)-5-chlorobenzotriazole
61280(x)	003293-97-8	2-Hydroxy-4-n-hexyloxybenzophenone
61360(x)	000131-57-7	2-Hydroxy-4-methoxybenzophenone
61600(x)	001843-05-6	2-Hydroxy-4-n-octyloxybenzophenone
66360(x)	085209-91-2	2,2'-Methylene bis(4,6-di-tert-butylphenyl) sodium phosphate
66400(x)	000088-24-4	2,2'-Methylene bis(4-ethyl-6-tert-butylphenol)
66480(x)	000119-47-1	2,2'-Methylene bis(4-methyl-6-tert-butylphenol)
66560(x)	004066-02-8	2,2'-Methylenebis(4-methyl-6-cyclohexylphenol)
66580(x)	000077-62-3	2,2'-Methylenebis(4-methyl-6-(1-methyl-cyclohexyl) phenol)
67360(x)	067649-65-4	Mono-n-dodecyltin tris(isooctyl mercaptoacetate)
67520(x)	054849-38-6	Monomethyltin tris(isooctyl mercaptoacetate)
67600(x)	-	Mono-n-octyltin tris(alkyl(C10-C16) mercaptoacetate)
67680(x)	027107-89-7	Mono-n-octyltin tris(2-ethylhexyl mercaptoacetate)
67760(x)	026401-86-5	Mono-n-octyltin tris(isooctyl mercaptoacetate)
68078(x)	027253-31-2	Neodecanoic acid, cobalt salt
68145(x)	080410-33-9	2,2',2''-Nitrilo[triethyl tris(3,3',5,5'-tetra-tert-butyl-1,1'-bi-phenyl-2,2'-diyl)phosphite]
68320(x)	002082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate
68400(x)	010094-45-8	Octadecylceramide
69840(x)	016260-09-6	Oleypalmitamide
71635(x)	025151-96-6	Pentaerythritol dioleate
71670(x)	178671-58-4	Pentaerythritol tetrakis (2-cyano-3,3-diphenylacrylate)
72160(x)	000948-65-2	2-Phenylindole
72800(x)	001241-94-7	Phosphoric acid, diphenyl 2-ethylhexyl ester
73160(x)	-	Phosphoric acid, mono- and di-n-alkyl (C16 and C18) esters
74010(x)	145650-60-8	Phosphorous acid, bis(2,4-di-tert.-butyl-6-methylphenyl) ethyl ester
74400(x)	-	Phosphorous acid, tris(nonyl-and/or dinonylphenyl) ester
76866(x)	-	Polyesters of 1,2-propanediol and/or 1,3- and/or 1,4-butanediol and/or polypropyleneglycol with adipic acid, also end-capped with acetic acid or fatty acids C12-C18 or n-octanol and/or n-decanol
77440(x)	-	Polyethyleneglycol diricinoleate

REF_N(x)	CAS_N	NAME
78320(x)	009004-97-1	Polyethyleneglycol monoricinoleate
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]
83599(x)	068442-12-6	Reaction products of oleic acid, 2-mercaptoethyl ester, with dichlorodimethyltin, sodium sulphide and trichloromethyltin
83700(x)	000141-22-0	Ricinoleic acid
84800(x)	000087-18-3	Salicylic acid, 4-tert-butylphenyl ester
89170(x)	013586-84-0	Stearic acid, cobalt salt
89200(x)	007617-31-4	Stearic acid, copper salt
92320(x)	-	Tetradecyl-polyethyleneglycol(EO=3-8) ether of glycolic acid
92560(x)	038613-77-3	Tetrakis(2,4-di-tert-butyl-phenyl)-4,4'-biphenylene diphosphonite
92700(x)	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
92800(x)	000096-69-5	4,4'-Thiobis(6-tert-butyl-3-methylphenol)
92880(x)	041484-35-9	Thiodiethanol bis(3-(3,5-di-tert-butyl-4-hydroxy phenyl) propionate)
93120(x)	000123-28-4	Thiodipropionic acid, didodecyl ester
93280(x)	000693-36-7	Thiodipropionic acid, dioctadecyl ester
95270(x)	161717-32-4	2,4,6-Tris(tert-butyl)phenyl-2-butyl-2-ethyl-1,3-propanediol phosphite
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
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
95600(x)	001843-03-4	1,1,3-Tris(2-methyl-4-hydroxy-5-tert-butylphenyl) butane