

Ministeriet for Fødevarer, Landbrug og Fiskeri

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TAJ/DLI/JHC

FVM 056

GRUNNOTAT TIL FOLKETINGETS EUROPAUDVALG

om forslag til 1. ændring af Kommissionens direktiv 2002/72/EF om plastmaterialer og -genstande bestemt til at komme i berøring med levnedsmidler

SANCO/2003/949, rev. 7

Resumé

Forslaget introducerer bl.a. et ansøgningskoncept med henblik på at opnå en harmoniseret positivliste for additiver i fællesskabet inden udgangen af 2005. Forslaget præciserer, at anden EU-regulering vil have forrang ved regelkollision. Hensigten dermed er at tage højde for regulering i bl.a. tilsætningsstoffreglerne. Mht. tilsætningsstoffer introducerer forslaget en pligt for emballageproducenten til at oplyse, hvorvidt emballagen indeholder stoffer, som anvendes som tilsætningsstoffer i fødevarer, for at fødevareproducenterne kan tage højde derfor ved forarbejdning. Videre stiller forslaget krav om, at genstande skal være ledsaget af dokumentation for overensstemmelse med lovgivningen, til trods for at der er tale om genstande, som klart er beregnet til kontakt med fødevarer. Yderligere tilføjes nye vurderede stoffer til listerne over monomerer og additiver i plast. En vedtagelse af forslaget skønnes at øge beskyttelsesniveauet i Danmark.

Baggrund

Kommissionen har ved dokument SANCO/2003/949, rev. 7, fremsendt forslag om 1. ændring af Kommissionens direktiv 2002/72/EF om plastmaterialer og -genstande bestemt til at komme i berøring med levnedsmidler.

Forslaget er fremsat med hjemmel i art. 3 i Rådets direktiv 89/109/EØF af 21. december 1988 om indbyrdes tilnærmelse af medlemslandenes lovgivning om materialer og genstande bestemt til at komme i berøring med levnedsmidler.

Forslaget behandles i en III a-procedure i Den Stående Komité for Fødevarekæden og Dyrer sundhed. Hvis der er kvalificeret flertal, udsteder Kommissionen direktivet. Opnås der ikke kvalificeret flertal, forelægger Kommissionen sagen for Rådet, der kan vedtage forslaget uændret med kvalificeret flertal eller ændre det med enstemmighed. Handler Rådet ikke inden en frist på højst tre måneder, kan Kommissionen udstede direktivet.

Nærheds- og proportionalitetsprincippet

Forslaget er en ændring af en gennemførelsesretsakt til Rådets direktiv 89/109 om indbyrdes tilnærmelse af medlemsstaternes lovgivning om materialer og genstande bestemt til at komme i berøring med levnedsmidler. Kommissionens begrundelse for at fremsætte forslaget er ønsket om harmonisering af grænseværdier af hensyn til samhandel og samtidigt om at sikre et reduceret indtag som følge af migration af stoffer fra plastmaterialer og -genstande til fødevarer for at undgå risici for menneskers sundhed. Forslaget vurderes at være i overensstemmelse med nærheds- og proportionalitetsprincippet.

Formål og indhold

Forslaget sigter på en udtømmende regulering på fællesskabsplan af indholdsstofferne i plastmaterialer og -genstande bestemt til at komme i kontakt med fødevarer med henblik på at undgå risici for menneskers sundhed og derved højne beskyttelsesniveauet. Hovedformålet er at vedtage rammerne for etablering af en fuldstændig positivliste for additiver til plast. På nuværende tidspunkt indeholder EU reguleringen følgende lister over stoffer, som må anvendes ved fremstilling af plast til kontakt med fødevarer:

- En fuldstændig positivliste over monomerer og andre udgangsstoffer.
- En ufuldstændig liste over additiver, der er fuldt harmoniseret på fællesskabsplan.
- En ufuldstændig liste over additiver, som er tilladt på nationalt plan i ét eller flere EU medlemslande.

Forslaget til ændringen af plastdirektivet indeholder følgende hovedpunkter:

1. Specificering af anvendelsesområde for additiver.
2. Ansøgningsordning for additiver.
3. Valg af regulering ved regelkollision (af stoffer omfattet af flere regelsæt).
4. Emballageproducentens oplysningsforpligtelse.
5. Ledsagelse af skriftlig erklæring.
6. Udbygning og opdatering af direktivets bilag med grænseværdier for diverse stoffer.

Ad 1) Specificering af anvendelsesområde for additiver.

Forslaget indeholder bestemmelse om afgrænsningen af, hvilke additiver der er omfattet af reglerne. Forslaget angiver, at regulering af følgende additiver endnu ikke er omfattet af de specifikke regler for additiver:

- additiver, som alene anvendes til produktion af: overfladebelægning fremstillet på basis af harpikser eller polymerer i flydende form, pulver eller dispersionsform såsom fernis, lak, maling osv., epoxyharpikser, klæbemidler og klæbeaktivatorer og tryksværte,
- farvestoffer og
- opløsningsmidler.

Disse stofgrupper er omfattet af de generelle regler om migration fra materialer og genstande, herunder plast, og er ikke specifikt reguleret. Tilsvarende indeholder gældende regler en opremsning af visse typer af monomerer, som ikke er omfattet af den specifikke regulering.

Ad 2) Ansøgningsordning for additiver.

Forslaget lægger op til en fremgangsmåde til at få lavet en fuldstændig harmonisering af additiver til plast. Positivlisten oprettes på baggrund af ansøgninger, som industrien inden udgangen af 2004 sender til EFSA (Den Europæiske Fødevarsikkerhedsautoritet). Ansøgning med angivelse af de relevante og nødvendige data indsendes for samtlige de ikke-harmoniserede stoffer, som p.t. anvendes, og som ønskes optaget på positivlisten. Kommissionen forpligter sig til efter udtalelse fra EFSA inden udgangen af 2005 at fastsætte en dato for, hvornår de indkomne data kan være færdigvurderet og for, hvornår bilaget på baggrund af EFSA's endelige vurderinger skal udgøre en positivliste. I perioden fra primo 2005 og til positivlisten foreligger, er Kommissionen forpligtet til at føre en liste over additiver, der er søgt optaget på positivlisten, mens vurderingerne afventes, således at det er muligt for medlemslandene at danne et overblik over, hvilke additiver der er tilladt anvendt i den mellemliggende periode.

Ad 3) Valg af regulering ved regelkollision (stoffer omfattet af flere regelsæt).

Det foreslås, at anden EU-regulering, der kan have indflydelse på plastmaterialer og -genstande, får forrang frem for reglerne i det pågældende direktiv. Her har hensigten været at tage hensyn til bl.a. tilsætningsstofreglerne. Det vil sige, at tilsætningsstofreglerne har forrang frem for reglerne om materialer og genstande i tilfælde af afsmitning af stoffer, der både er indholdsstoffer i plast og er tilsætningsstoffer til fødevarer, som f.eks. citronsyre og ascorbylpalmitat. Hensigten er, at de strengeste grænseværdier gælder, samt at andre krav fx mærkningskrav også skal overholdes.

Ad 4) Emballageproducentens oplysningsforpligtelse.

Med forslaget præciseres emballageproducenternes oplysningspligt overfor fødevarerproducenter, idet forslaget fastslår, at producenterne skal oplyse om emballagens indhold af stoffer, som også anvendes som tilsætningsstoffer til fødevarer. Dette betyder, at fødevarerproducenten vil kunne tage højde for en evt. migration fra emballagen og sikre, at det totale indhold af disse stoffer i fødevarerne kan overholde grænserne for tilsætningsstoffer til fødevarer. I denne forbindelse fastslås det endvidere, at nogle typer aktiv emballage o. lign indtil videre vil henhøre under national lovgivning og ikke er EU-reguleret.

Ad 5) Ledsagelse af skriftlig erklæring.

Forslaget præciserer, at også materialer eller genstande, som klart er bestemt til kontakt med fødevarer, fx krus, røreskåle mv., skal være omfattet af kravet om dokumentation for oprindelse og anvendelse. Krav til selve dokumentationen omfatter oprindelse og anvendelse samt sammensætningen, dvs. alle indholdsstoffer. Den gældende lovgivning stiller alene krav om, at varen skal ledsages af en skriftlig erklæring, hvori det attesteres, at varen er i overensstemmelse med gældende regler. Ændring af dokumentationskravet sker primært for at forhindre, at plasten afgiver stoffer i strid med lovgivningen for tilsætningsstoffer til fødevarer, samt med henblik på bedre identifikation af producentlandet. Information om sammensætningen er dog ikke påkrævet for stoffer, hvor det er beviseligt, at migrationen udgør under 5% af grænseværdien angivet i tilsætningsstoflovgivningen.

Ad 6) Udbygning og opdatering af direktivets bilag med grænseværdier for diverse stoffer.

Forslaget indeholder en udbygning og opdatering af listerne over stoffer, der kan anvendes til fremstilling af plast. Stoffer, der allerede er på listerne, opdateres som forudsat i den gældende regulering, og der tilføjes en række nye stoffer, som har været underkastet en sundhedsmæssig vurdering af SCF (EU's videnskabelige komite for fødevarer). Samtidig udgår visse additiver og monomerer, enten på grund af at de relevante data for at vurdere stofferne ikke har været forelagt SCF, eller at man på baggrund af vurderingen har fundet, at stofferne skal udgå.

Gældende dansk ret

Bekendtgørelse nr. 111 af 20. februar 2003 om materialer og genstande bestemt til kontakt med fødevarer indeholder dels generelle bestemmelser om materialer og genstande hidrørende fra Rådets direktiv 89/109/EØF af 21. december 1988 om indbyrdes tilnærmelse af medlemsstaternes lovgivning om materialer og genstande bestemt til at komme i berøring med fødevarer, dels specifikke regler fra gennemførelsesretsakter på området for materialer og genstande, herunder om plast. For de stoffer, der både er omfattet af disse regler samt andre regler, som

fx regler om tilsætningsstoffer, vil ændringen ikke medføre behov for ændring af eksisterende bestemmelser, men evt. tilføjelser i vejledningen på området.

Konsekvenser

En vedtagelse af forslaget skønnes at ville øge beskyttelsesniveauet i Danmark.

Vedtagelse af forslaget vil nødvendiggøre en ændring af bekendtgørelse nr. 111 af 20. februar 2003 om materialer og genstande bestemt til kontakt med fødevarer.

Forslaget skønnes ikke at få statsfinansielle eller samfundsøkonomiske konsekvenser for Danmark.

Høring

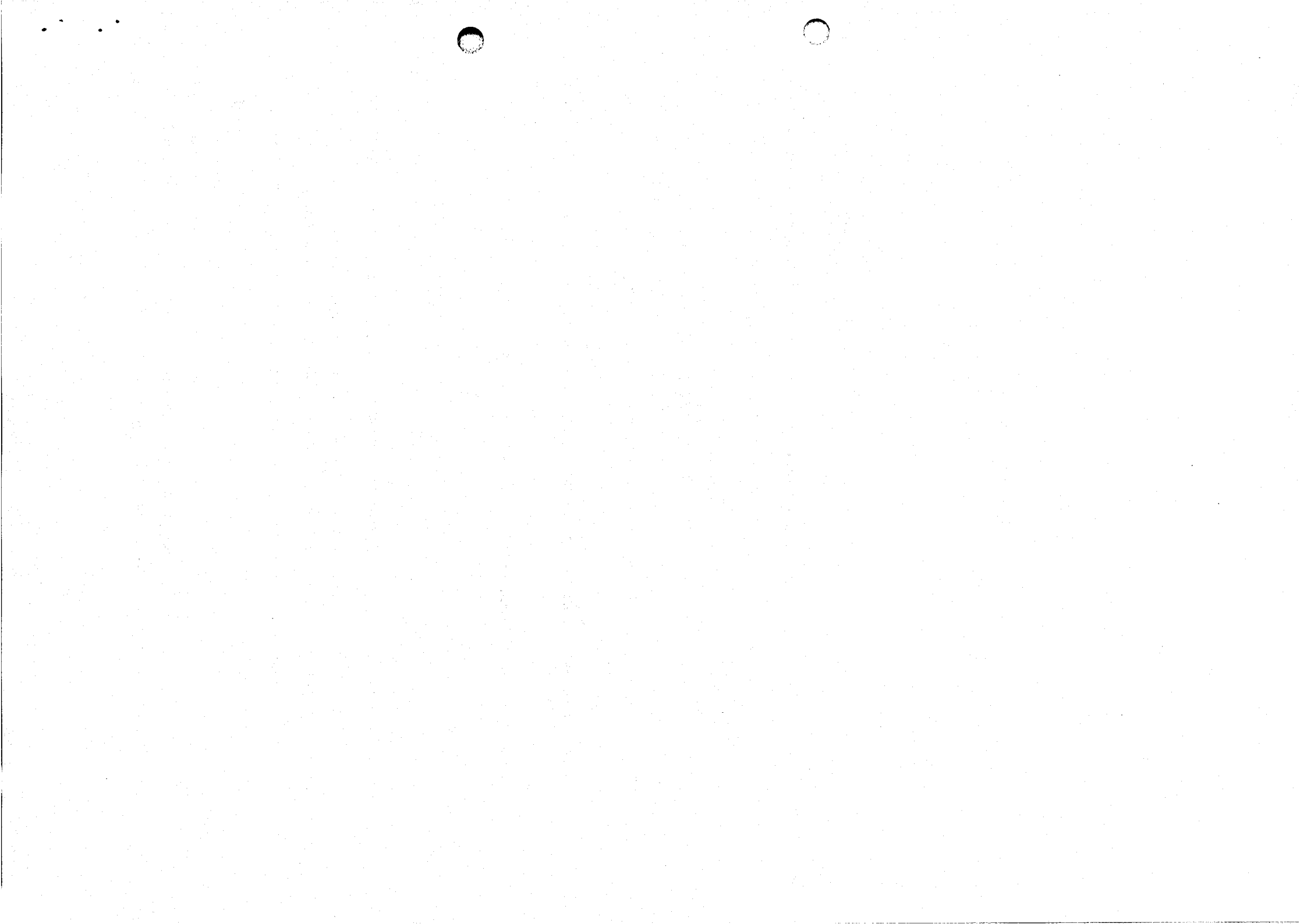
Forslaget har i medfør af Fødevarelovens § 6, stk. 1 været sendt i høring. Forslaget har endvidere været sendt i høring i Det Rådgivende Fødevareudvalg.

Danisco støtter forslaget og hilser velkommen, at der nu bliver berammet tidsfrister for fastlæggelse af positivlister for additiver.

Følgende har meddelt, at man ikke har bemærkninger til forslaget: Coop Danmark, Den Danske Dyrlægeforening, SiD KVL, FødevareIndustrien samt Landbrugsraadet på vegne af Dansk Landbrug, Danske Slagterier og Mejeriforeningen.

Tidligere forelæggelse for Folketingets Europaudvalg

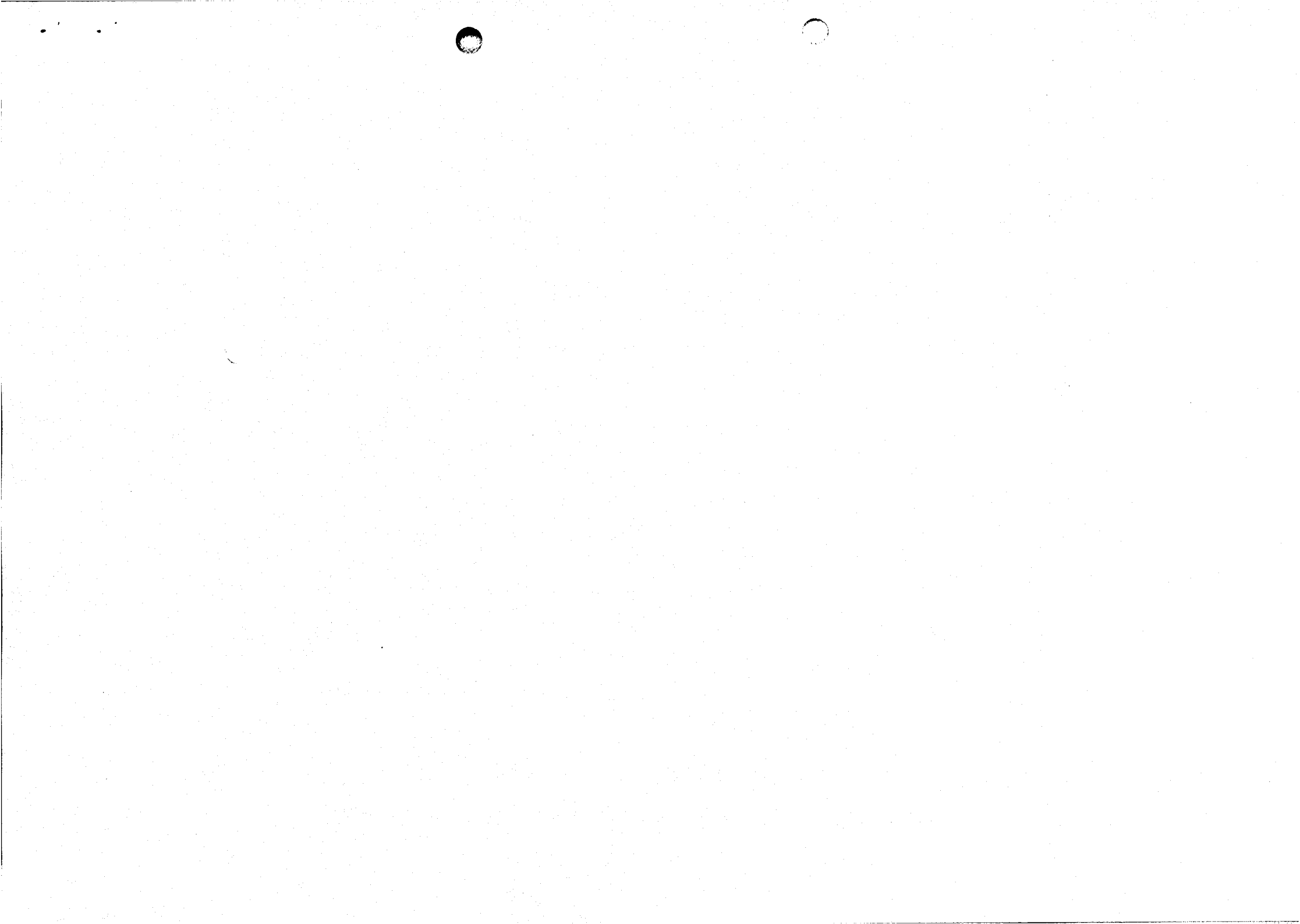
Forslaget har ikke tidligere været forelagt Folketingets Europaudvalg.



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DRF 48/03

SANCO/2003/949





COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 20.2.2003
SANCO/2003/949

EMB/843 Rev. 7

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

COMMUNICATION FROM THE COMMISSION

Explanatory Note

Draft

COMMISSION DIRECTIVE ./.../EC

of [...]

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

(called "1st Amendment" of Directive 2002/72/EC)

(EN)

(Text with EEA relevance)

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 Framework Directive 89/109/EEC which has established the principles and the procedures to be applied for any type of food contact material. This specific Directive establishes the main rules for the group of materials called "plastics", i.e. the list of authorised substances, the restrictions on their use, the labelling of the materials and articles and the information to be given to the consumer or to the food industry for a correct use of these materials.

2. NEW ISSUES

Since the Directive 2002/72/EC has been in place other substances have been evaluated by the SCF either because they are new substances or because new data are available which allow a new classification of these substances and thus a new legal status.

Having evaluated most of the additives authorised at national level, it is now appropriate to fix a time limit to obtain the toxicological data for all those remaining substances which are not yet approved at Community level but permitted at national level. Knowing the number of dossiers received within this deadline the Commission will be able to establish the date as from which the list of authorised substances will become a Community positive list.

Questions have been raised by Member States on which restrictions should apply to substances that are subject to different restrictions in this Directive and other EU directives e.g. on foodstuffs and the environment.

The approval of some substances for use at the same time as substances for food contact materials and as food additives or flavours has required a clarification of the relationship between these directives and has raised the need to specify which restrictions should be applied in each specific case. Moreover the food industry should be informed by the packaging manufacturers on the level of the release of these multiple function substances from the packaging into the food, in order to be able to comply with the relevant food legislation.

3. PROPOSED CHANGES

The objectives of this amendment are the following:

- a) To update the list of authorised substances taking into account the evaluations of the Scientific Committee on Food; therefore several new substances have been added and several have been subject to the change of their legal status;
- b) To clarify that, when a substance is regulated by various Directives establishing different restrictions, the more severe restriction applies, where appropriate;

- c) To establish a deadline (31 December 2004) for the presentation of the toxicological data for all the substances not yet included in the Community list of additives, but which are permitted at national level. Based on the data received a subsequent Directive will establish when the list of additives will become a Community positive list and, therefore, all the other additives approved at national level may not longer be authorised;
- d) To state that a substance for which toxicological data were submitted within the deadline, may be maintained at national level even after the establishment of the Community lists if EFSA has not yet finished its evaluation;
- e) To clarify the relationship between this Directive and the Directives on food additives (including flavours) in cases where a substance may be used in both applications;
- f) To establish the obligation for the packaging manufacturer to inform the user of these materials and articles about the release of substances which can be used also as food additives or flavourings. This information will allow the user of the packaging to avoid exceeding the maximum level authorised for the substance in food.

1 Draft

2 COMMISSION DIRECTIVE ../.../EC

3 of [...]

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

6 (called "1st Amendment" of Directive 2002/72/EC)

7 THE COMMISSION OF THE EUROPEAN COMMUNITIES,

8 Having regard to the Treaty establishing the European Community,

9 Having regard to Council Directive 89/109/EEC of 21 December 1988 on the approximation of the
10 laws of the Member States relating to materials and articles intended to come into contact with
11 foodstuffs¹, and in particular Article 3 thereof,

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

13 Whereas:

14 (1) Plastic materials and articles subject to the Commission Directive 2002/72/EC of 15
15 August 2002 relating to plastic materials and articles intended to come into contact with
16 foodstuffs² as well as substances used in their manufacture must comply with the
17 requirements set by other Community legislation applicable to them.

18 (2) On the basis of new information available to the EFSA, certain monomers provisionally
19 admitted at national level as well as other monomers requested for use following the
20 adoption of Commission Directive 2002/72/EC may be included in the Community list of
21 permitted substances in Annex II to Directive 2002/72/EC.

22 (3) Annex III to Directive 2002/72/EC contains an incomplete list of additives which may be
23 used in the manufacture of plastic materials and articles. That list should be amended so as
24 to include other additives evaluated by the SCF.

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

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

¹ OJ L 40, 11.2.1989, p. 38

² OJ L 220, 15.08.2002, p. 18

30 (6) The current list of additives should become a positive list in order to harmonise the use of
31 these substances in the Community. For the additives which are already placed on the
32 market in one or more of the Member States, sufficient time should be allowed for the
33 submission of the data necessary for their safety evaluation by the EFSA. Therefore the
34 deadline for the submission of the data is set not later than 31 December 2004.

35
36 If the data are in compliance with the EFSA requirements, these additives shall continue to
37 be used in accordance with national law until their evaluation is completed. If the data are
38 not in compliance with the EFSA requirements or have been submitted later than 31
39 December 2004 these additives will not be included in the first positive list.

40 (7) The date when the list of additives will become a positive list will be fixed not later than 31
41 December 2005 as it is impossible now to know the number of substances for which the
42 data required by the EFSA will be supplied; this date will be fixed taking into account the
43 time needed for the EFSA to evaluate all the applications supplied on time.

44 (8) Some substances used to manufacture plastic materials and articles intended to come into
45 contact with food are also added directly to food, e.g. food additives. These substances
46 should not migrate from the materials or articles into the food in quantities that could
47 exceed the limits set in the relevant food legislation. When these substances are used in
48 materials and articles intended to come into contact with food in which their use is not
49 permitted, they should not migrate in quantities having a technological function in the
50 given food. The users of materials and articles which may release these substances into
51 food must be appropriately informed in order to be able to comply with other relevant food
52 legislation.

53 (9) Member States should retain the right to lay down rules concerning substances used as
54 active components in active food contact material systems until Community provisions are
55 adopted.

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

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

59 HAS ADOPTED THIS DIRECTIVE:

60 *Article 1*

61 Directive 2002/72/EC is amended as follows:

62 1. The following paragraph 5 is added to Article 1:

63 "5. This Directive shall apply without prejudice to the rules applicable to plastic
64 materials and articles and the substances used in their manufacture by virtue of
65 other Community legislation."

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

67 "1. Only those monomers and other starting substances listed in Annex II, Section A
68 may be used for the manufacture of plastic materials and articles subject to the
69 restrictions specified therein.

- 70 2. By way of derogation from the first paragraph the monomers and other starting
71 substances listed in Annex II, Section B may continue to be used until 31 December
72 2004 at latest, pending their evaluation by the EFSA.”
- 73 3. Article 4 is replaced by the following:
- 74 “Article 4
- 75 1. An incomplete list of additives which may be used for the manufacture of plastic
76 materials and articles, together with the restrictions and/or specifications on their
77 use, is set out in Annex III, Sections A and B.
- 78 2. For the substances in Annex III, Section B, the verification of compliance with the
79 specific migration limits in simulant D or in test media of substitute tests as laid
80 down in Directive 82/711/EEC and 85/572/EEC is applied as from 31 December
81 2005.
- 82 3. The lists appearing in Annex III, Sections A and B do not yet include the following
83 additives:
- 84 a) additives used only in the manufacture of:
- 85 – surface coatings obtained from resinous or polymerised products in
86 liquid, powder or dispersion form, such as varnishes, lacquers, paints,
87 etc.,
- 88 – epoxy resins,
- 89 – adhesives and adhesion promoters,
- 90 – printing inks
- 91 b) colorants
- 92 c) solvents
- 93 4. The list of additives referred to in paragraph 1 shall become a Community list of
94 authorised additives to the exclusion of all others (positive list). In view of the
95 establishment of the positive list, any person interested in the authorisation of an
96 additive, which is already placed on the market in one or more of the Member
97 States, shall submit data for its safety evaluation by the “European Food Safety
98 Authority” (‘EFSA’) not later than 31 December 2004. For the submission of the
99 required data the applicant shall consult the “Guidelines of the Scientific Committee
100 on Food for the presentation of an application for safety assessment of a substance
101 to be used in food contact materials prior to its authorisation”³.
- 102 5. The Commission will establish not later than 31 December 2005:
- 103 a) the date when the list of authorised additives will become a positive list;

³ The Guidelines of the Scientific Committee on food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation” is updated on 13 December 2001 and it is available on: http://europa.eu.int/comm/food/fs/sc/scf/out82_en.pdf

- 104 b) a provisional list of additives which may continue to be used subject to
105 national law until the EFSA has evaluated them. They shall fulfil the
106 following conditions:
- 107 (i) they are permitted in one or more of the Member States not later than 31
108 December 2004;
- 109 (ii) the data mentioned in paragraph 4 have been supplied in accordance
110 with EFSA requirements not later than 31 December 2004;

111 If during the examination of the data the EFSA requires supplementary information,
112 these substances shall continue to be used subject to national law, even after the
113 positive list is established and until the EFSA has issued an opinion, provided that
114 the information is submitted within the time limits specified by the EFSA.

115 6. "New additives", i.e. additives never evaluated by the SCF or EFSA may always be
116 added to the list of substances authorised at Community level following the safety
7 evaluation by the EFSA.

118 7. The additives referred to in paragraph 3 will not be included in the initial
119 establishment of the Community list referred to in paragraph 4."

120 4. The following Article 5a is inserted:

121 "Article 5a

122 1. Substances referred to in Articles 3, 4 and 5, which are also permitted as food
123 additives as defined in Council Directive 89/107/EEC of 21 December 1988⁴ and its
124 implementing measures^{5,6,7,8} or flavourings as defined in Council Directive
125 88/388/EEC⁹ and appearing in the Commission Decision of 23 February¹⁰

126 – shall not migrate into food for which their use is permitted as food additives
127 or flavourings in quantities exceeding the restrictions specified in the relevant
128 food legislation or this Directive whichever provides the lower restriction.

129 – shall not migrate into food for which their use is not permitted as food
130 additives or flavourings in quantities having a technological function in the
131 final foodstuff and provided that they comply with the restrictions set in this
132 Directive.

133 In addition, the information requirements in Art. 9(1b) shall be respected in both
134 cases.

⁴ OJ L 40, 11.2.1989, p. 27, as amended by European Parliament and Council Directive 94/34/EC of 30 June 1994 (OJ L 237, 10.9.1994, p.1)

⁵ OJ L 237, 10.9.1994, p.13

⁶ OJ L 237, 10.9.1994, p. 3, as amended by European Parliament and Council Directive of 19 December 1996 (OJ L 48, 19.2.1997, p. 16)

⁷ OJ L 61, 18.3.1995, p. 1 as last amended by European Parliament and Council Directive of 12 February 2001 (OJ L 55, 24.2.2001, p. 59)

⁸ OJ L 48, 19.2.1997, p. 13

⁹ OJ L 184, 15.7.1988, p. 61

¹⁰ OJ L 84, 27.3.1999, p. 1

135 2. By way of derogation, when the substances referred to in the first indent of the first
136 paragraph are used as active components of active food contact material systems,
137 they may be subject to national provisions pending the adoption of Community
138 provisions.

139 5. Article 7 is replaced by the following:

140 "Article 7

141 The specific migration limits in the list set out in Annexes II and III are expressed in
142 mg/kg. However, such limits are expressed in mg/dm² in the following cases:

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

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

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

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

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

154 7. Article 9(1) is replaced by the following:

155 "At the marketing stages up to the retail, plastic materials and articles which are intended
156 to be placed in contact with food shall be accompanied by a written declaration, which
157 shall:

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

159 (b) provide for substances which are also subject to a restriction in food adequate
160 information obtained by experimental data or theoretical calculation about the level
161 of their specific migration and, where appropriate, purity criteria in accordance with
162 the relevant Commission Directives^{11,12,13} to enable the user of these materials and
163 articles to comply with the relevant Community provisions or, in their absence, with
164 national provisions applicable to food.

165 8. Article 9(2) is deleted.

166 9. Annexes II, III, IV, V and VI are amended as set out in Annex I to V to this Directive.

¹¹ Commission Directive 95/31/EC of 5 July 1995 (OJ L 178, 28.7.1995, p.1) as last amended by Commission Directive 2001/52/EC of 3 July 2001 (OJ L 190, 12.7.2001, p.18)

¹² Commission Directive 95/45/EC of 26 July 1995 (OJ L 226, 22.9.1995, p.1) as last amended by Commission Directive 2001/50/EC of 3 July 2001 (OJ L190, 12.7.2001, p.14)

¹³ Commission Directive 96/77/EC of 2 December 1996 (OJ L 339, 30.12.1996, p.1) as last amended by Commission Directive 2001/30/EC of 2 May 2001 (OJ L 146, 31.05.2001, p.1)

167

Article 2

168 1. Member States shall adopt and publish, by (one year after the adoption by the
169 Commission) at the latest, the provisions necessary to comply with this Directive. They
170 shall forthwith inform the Commission thereof.

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

172 (a) permit the trade in and use of plastic materials and articles intended to come into
173 contact with food and complying with this Directive, from (one year after the
174 adoption by the Commission);

175 (b) prohibit the manufacture and importation into the Community of plastic materials
176 and articles intended to come into contact with food and which do not comply with
177 this Directive, from (two year after the adoption by the Commission).

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

181

Article 3

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

184

Article 4

185 This Directive is addressed to the Member States.

186 Done at Brussels,

87

For the Commission

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189

Member of the Commission

190

ANNEX I

191 1. Annex II is amended as follows:

192 (a) In point 8, the definition of QM is replaced by the following:

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

193 (b) The following monomers and other starting substances are inserted in Section A:

Ref. No	CAS No.	Name	Restrictions and/or specifications	Notes
(1)	(2)	(3)	(4)	(5)
13323	000102-40-9	1,3-Bis(2-hydroxyethoxy)benzene	SML = 0.05 mg/kg	New substance
16540	000102-09-0	Diphenyl carbonate	SML = 0.05 mg/kg	New substance. To be confirmed by SCF March or April meeting).
18896	001679-51-2	4-(Hydroxymethyl)-1-cyclohexene	SML = 0.05 mg/kg	New substance. To be confirmed by SCF March or April meeting).
20440	000097-90-5	Methacrylic acid, diester with ethyleneglycol	SML = 0.05 mg/kg	New substance. To be confirmed by SCF March or April meeting).
22775	000144-62-7	Oxalic acid	SML(T) = 6 mg/kg (29)	New substance. Same as 59920
23070	000102-39-6	(1,3-Phenylenedioxy)diacetic acid	QMA = 0.05 mg/6dm ²	New substance

194 (c) For the following monomers and other starting substances of Section A, the content
 195 of the columns “Name” or “CAS No” or “Restrictions and/or specifications” is
 196 replaced by the following:

Ref. No	CAS No.	Name	Restrictions and/or specifications	Notes
(1)	(2)	(3)	(4)	(5)
11530	00999-61-1	Acrylic acid, 2-hydroxypropyl ester	QMA = 0.05 mg/6 dm ² for	Restriction is changed as it is necessary to clarify

		hydroxypropyl ester	hydroxypropyl ester and acrylic acid, 2-hydroxyisopropyl ester and in compliance with the specifications laid down in Annex V	the legal status of the substance to follow better the SCF opinion.
13480	000080-05-7	2,2-Bis(4-hydroxyphenyl)propane	SML(T) = 0.6 mg/kg (28).	Restriction is changed from 3 to 0.6 mg/kg
14950	003173-53-3	Cyclohexyl isocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO) (26).	Restriction is changed by adding "in FP" omitted in 7th amendment and, then, in Directive 2002/72.
16690	001321-74-0	Divinylbenzene	QMA = 0.01 mg/6 dm ² or SML = ND (DL = 0.02 mg/kg, analytical tolerance included) for the sum of divinylbenzene and ethylvinylbenzene and in compliance with the specifications laid down in Annex V	Specification is changed in line with the SCF opinion issued in its meeting n. 133.
18898	000103-90-2	N-(4-Hydroxyphenyl)acetamide	SML = 0.05 mg/kg	Restriction changed. To be confirmed by SCF (March or April meeting).
22150	000691-37-2	4-Methyl-1-pentene	SML = 0.05 mg/kg	Restriction is changed from 0.02 into 0.05 mg/kg. SCF Report N. 42 issued the new evaluation. This change was never inserted in a Directive.
22331	025513-64-8	Mixture of (35-45% w/w) 1,6-diamino-2,2,4-trimethylhexane and (55-65% w/w) 1,6-diamino-2,4,4-trimethylhexane	QMA = 5 mg/6 dm ²	The petition is referred to the mixture and not to the 15370/15400, which then shall be deleted (see later). See SCF opinion issued in internet on December 2002.
22332	-	Mixture of (40% w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60% w/w) 2,4,4-trimethylhexane-1,6-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (26).	CAS was deleted because referred to trimethylhexamethylene diisocyanate.
24190	065997-05-9	Rosin wood		The CAS_N was changed from 009014-63-5 into 065997-05-9 in accordance with a new enquiry

(d) The following monomers and other starting substances are transferred from Section B to Section A:

Ref. No	CAS No.	Name	Restrictions and/or specifications	Notes
(1)	(2)	(3)	(4)	(5)
10599/90A	061788-89-4	Acids, fatty, unsaturated (C18), dimers, distilled	QMA(T) = 0.05 mg/6 dm ² (27)	Transferred from Section B to A
10599/91	061788-89-4	Acids, fatty, unsaturated (C18), dimers, non distilled	QMA(T) = 0.05 mg/6 dm ² (27)	Transferred from Section B to A
10599/92A	068783-41-5	Acids, fatty, unsaturated (C18), dimers, hydrogenated, distilled	QMA(T) = 0.05 mg/6 dm ² (27)	Transferred from Section B to A
10599/93	068783-41-5	Acids, fatty, unsaturated (C18), dimers, hydrogenated, non distilled	QMA(T) = 0.05 mg/6 dm ² (27)	Transferred from Section B to A
14800	003724-65-0	Crotonic acid	QMA(T) = 0.05 mg/6dm ² (33)	Transferred from Section B to A
16210	006864-37-5	3,3'-Dimethyl-4,4'-diaminodicyclohexylmethane	SML = 0.05 mg/kg (32). To be used only in polyamides.	Substance is not stable in fat simulant
17110	016219-75-3	5-Ethylidenebicyclo[2.2.1]hept-2-ene	QMA = 0.05 mg/6dm ² . The ratio surface/quantity of food shall be lower than 2 dm ² /kg	Transferred from Section B to A. To be confirmed by SCF (March or April meeting).
18700	000629-11-8	1,6-Hexanediol	SML = 0.05 mg/kg	Transferred from Section B to A
21400	054276-35-6	Methacrylic acid, sulphopropyl ester	QMA = 0.05 mg/6dm ²	To be confirmed by SCF (March or April meeting)

199

(e) The following monomers and other starting substances are deleted from Section A:

Ref. No	CAS No.	Name	Restrictions and/or specifications	Notes
(1)	(2)	(3)	(4)	(5)
15370	003236-53-1	1,6-Diamino-2,2,4-trimethylhexane	QMA(T) = 5 mg/6 dm ²	Deleted because it is not used (no petition is available). It is used only the mixture 22331 for which data have been submitted.
15400	003236-54-2	1,6-Diamino-2,4,4-trimethylhexane	QMA(T) = 5 mg/6 dm ²	Idem as 15370

ANNEX II

200

201 Annex III is amended as follows:

202 1. Point 1 is replaced by the following:

203 "1. This Annex contains the list of:

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

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

209 All these substances are hereinafter called "additives".

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

215 The list does not yet include:

216 a) the substances which directly influence the formation of polymers (e.g. the
217 catalytic system);

218 b) colorants;

219 c) solvents."

220 2. Section A is amended as follows:

221 (a) The following additives are inserted

Ref No	CAS No	Name	Restrictions and/or specifications	Notes
(1)	(2)	(3)	(4)	(5)
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 RF less than 3; (b) in PET at 0.25 % (w/w) in contact with foods other of those for which the simulant D is laid down in Dir 85/572	To be confirmed by SCF (March or April meeting).

34895	000088-68-6	2-Aminobenzamide	SML = 0.05 mg/kg. To be used only for PET for water and beverages.	New substance. To be confirmed by SCF (March or April meeting).
39680	000080-05-7	2,2-Bis(4-hydroxyphenyl)propane	SML(T) = 0.6 mg/kg (28)	New addition//Same 13480 already regulated.
42880	008001-79-4	Castor oil		New addition//Same 14411
45600	003724-65-0	Crotonic acid	QMA(T) = 0.05 mg/6dm ² (33)	See SCF opinion on 14800
45640	005232-99-5	2-Cyano-3,3-diphenylacrylic acid, ethyl ester	SML = 0.05 mg/kg	New substance
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	This substance replaces 67170 (in Section A)
46720	004130-42-1	2,6-Di-tert-butyl-4-ethylphenol	QMA = 4.8 mg/6 dm ²	New addition in Section A and deletion of the same into Section B as in Section B should not appear substances having a QM or QMA//
56535	-	Glycerol, esters with nonanoic acid		It replaces Ref.n° 56565 which appeared in the 3rd amendm. The change in the 1 st amendment was justified by the name and the listing in line with alphabetical order.
59280	000100-97-0	Hexamethylenetetramine	SML(T) = 15 mg/kg (22) (expressed as Formaldehyde)	New addition. Same as 18670. It is in Section A because 18670 was adopted in the past without any derogation from fatty test.
68078	027253-31-2	Neodecanoic acid, cobalt salt	SML(T) = 0.05 mg/kg (expressed as Neodecanoic acid) and SML(T) = 0.05 mg/kg (14) (expressed as Cobalt). Not for use in polymers contacting foods for which simulant D is laid	Transferred from Section B into A because there is no sense to maintain it in Section B as it is not authorised for fat contact.

			down in Directive 85/572/EEC.	
69920	000144-62-7	Oxalic acid	SML(T) = 6 mg/kg (29)	New addition//Same of 22775
76866	-	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	SML = 30 mg/kg	This item replaces 76865. C10 was changed into C12 in line with the SCF evaluation and petition.
85601	-	Silicates, natural (with the exception of asbestos)		It replaces 85600
95000	028931-67-1	Trimethylolpropane trimethacrylate-methyl methacrylate copolymer		Transferred from Section B into A as there is no restriction

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224

- (b) For the following additive of Section A, the content of the column "Restrictions and/or specifications" is replaced by the following (the change is indicated in bold characters)

Ref. No	CAS No.	Name	Restrictions and/or specifications	Notes
(1)	(2)	(3)	(4)	(5)
36640	000123-77-3	Azodicarbonamide	For use only as blowing agent and not to be used for alcoholic beverages	To be confirmed by SCF (March or April meeting).
45450	068610-51-5	p-Cresol-dicyclopentadiene-isobutylene, copolymer	SML = 5 mg/kg	Restriction is changed. The SCF has re-evaluated this substance in SCF_M 132 and SML was increased. Then the note (1) is not longer necessary as the migration data found were 78 ppb.

225

- (c) The following additives are deleted:

Ref. No	CAS No.	Name	Restrictions and/or specifications	Notes
(1)	(2)	(3)	(4)	(5)
56565	-	Glycerol, esters with pelargonic acid		Deleted because replaced by 56535.
67170	-	Mixture of (80 to 100% w/w) 5,7-di-tert-butyl-3-(3,4-dimethylphenyl)-2(3H)-benzofuranone and	SML = 5 mg/kg	This substance was here deleted because replaced by Ref. No 46700.

		(0 to 20% w/w)5,7-di-tert-butyl-3-(2,3-dimethylphenyl)-2(3H)-benzofuranone		
76865	-	Polyesters of 1,2-propanediol and/or 1,3-and/or 1,4-butanediol and/or polypropyleneglycol with adipic acid, also end-capped with acetic acid or fatty acids C10-C18 or n-octanol and/or n-decanol	SML = 30 mg/kg	Deleted because replaced by 76866. By mistake was introduced in 5th amendment. In fact the petition as well as the SCF opinion referred to C12 and not to C10.
85600	-	Silicates, natural		Deleted because replaced by 85601 in accordance with the SCF which in M67 added the specification "with the exception of asbestos".

226

227 3. Section B is amended as follows:

228 (a) The following additives are inserted:

Ref. No	CAS No.	Name	Restrictions and/or specifications	Notes
(1)	(2)	(3)	(4)	(5)
34650	151841-65-5	Aluminium hydroxybis [2,2'-methylenebis (4,6-di-tert.butylphenyl) phosphate	SML = 5 mg/kg	New substance. To be confirmed by SCF (March or April meeting)
38000	000553-54-8	Benzoic acid, lithium salt	SML(T) = 0.6 mg/kg (8) (expressed as Lithium)	New addition
40720	025013-16-5	tert-Butyl-4-hydroxyanisole (=BHA)	SML = 30 mg/kg	New addition
46640	000128-37-0	2,6-Di-tert-butyl-p-cresol (=BHT)	SML = 3.0 mg/kg	New addition
54880	000050-00-0	Formaldehyde	SML(T) = 15 mg/kg (22)	New addition. Same of 17260.
55200	001166-52-5	Gallic acid, dodecyl ester	SML(T) = 30 mg/kg (34)	New addition
55280	001034-01-1	Gallic acid, octyl ester	SML(T) = 30 mg/kg (34)	New addition
55360	000121-79-9	Gallic acid, propyl ester	SML(T) = 30 mg/kg (34)	New addition
67896	020336-96-3	Myristic acid, lithium salt	SML(T) = 0.6 mg/kg (8) (expressed as Lithium)	New substance. To be confirmed by SCF (March or April meeting).

71935	007601-89-0	Perchloric acid, sodium salt monohydrate	SML = 0.05 mg/kg (31)	New addition
86480	007631-90-5	Sodium bisulphite	SML(T) = 10 mg/kg (30) (expressed as SO ₂)	The limit 10 ppm fixed here is equal to the limit established in the Directives related to direct food additives.
86920	007632-00-0	Sodium nitrite	SML = 0.6 mg/kg	See note on 86480
86960	007757-83-7	Sodium sulphite	SML(T) = 10 mg/kg (30) (expressed as SO ₂)	See note on 86480
87120	007772-98-7	Sodium thiosulphate	SML(T) = 10 mg/kg (30) (expressed as SO ₂)	See note on 86480
94400	036443-68-2	Triethyleneglycol bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl) propionate]	SML = 9 mg/kg	New substance

229

(b) The following additives are deleted:

Ref. No	EAS No.	Name	Restrictions and/or specifications	Notes
(1)	(2)	(3)	(4)	(5)
46720	004130-42-1	2,6-Di-tert-butyl-4-ethylphenol	QMA = 4.8 mg/6 dm ²	New addition in Section A and deletion of the same into Section B as in Section B should not appear substances having a QM or QMA
68078	027253-31-2	Neodecanoic acid, cobalt salt	SML(T) = 0.05 mg/kg (expressed as Neodecanoic acid) and SML(T) = 0.05 mg/kg (14) (expressed as Cobalt). Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC.	Transferred from Section B into A because there is no sense to maintain it in Section B as it is not authorised for fat contact.
95000	028931-67-1	Trimethylolpropane trimethacrylate-methyl methacrylate copolymer		Deleted here and added in Section A as there is no restriction.

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ANNEX III

231 The Annex IV is replaced by the following text:

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“PRODUCTS OBTAINED BY MEANS OF BACTERIAL FERMENTATION

Ref. No.	CAS No.	Name	Restrictions and/or specifications	Notes
(1)	(2)	(3)	(4)	(5)
18888	080181-31-3	3-Hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer	In compliance with specifications included in Annex V.	This is a copolymer obtained by fermentation. Restriction on crotonic acid changed from SML into QMA

233 ”

235 Annex V is amended as follows:

236 1. The previous specifications in Part B for Ref. No 16690 and 18888 are replaced by the
237 following:

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	<p>3-Hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer</p> <p>Definition The copolymers are produced by the controlled fermentation of <i>Alcaligenes eutrophus</i> using mixtures of glucose and propanoic acid as carbon sources. The organism used has not been genetically engineered and has been derived from a single wild-type organism <i>Alcaligenes eutrophus</i> 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.</p> <p>Chemical name Poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate)</p> <p>CAS number 080181-31-3</p> <p>Structural formula</p> $ \begin{array}{cccc} & & \text{CH}_3 & \\ & & & \\ & & \text{CH}_3 & \text{O} & \text{CH}_2 & \text{O} \\ & & & & & \\ & & (-\text{O}-\text{CH}-\text{CH}_2-\text{C}-)_m & - & (\text{O}-\text{CH}-\text{CH}_2-\text{C}-)_n \end{array} $ <p>where $n/(m+n)$ greater than 0 and less or equal to 0.25</p> <p>Average molecular weight Not less than 150 000 Daltons (measured by gel permeation chromatography).</p> <p>Assay Not less than 98% poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate) analysed after hydrolysis as a mixture of 3-D-hydroxybutanoic and 3-D-hydroxypentanoic acids.</p> <p>Description White to off-white powder after isolation</p> <p>Characteristics</p> <p>Identification tests:</p> <p>Solubility Soluble in chlorinated hydrocarbons such as chloroform or dichloromethane but practically insoluble in ethanol, aliphatic alkanes and water.</p>

<u>Restriction</u>	QMA for crotonic acid is 0.05 mg/6 dm ²
<u>Purity</u>	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

238

ANNEX V

239 The Annex VI is replaced by the following text:

240

“ANNEX VI

241

NOTES RELATED TO THE COLUMN “RESTRICTIONS AND/OR SPECIFICATIONS”

242

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

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(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.

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(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.

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(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.

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(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.

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(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.

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257

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(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.

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(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.

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(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.

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(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.

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(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.

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(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.

- 274 (13) SML(T) in this specific case means that the restriction shall not be exceeded by the sum
275 of the migration levels of the following substances mentioned as Ref. Nos: 39090 and
276 39120.
- 277 (14) SML(T) in this specific case means that the restriction shall not be exceeded by the sum
278 of the migration levels of the following substances mentioned as Ref. Nos: 44960, 68078,
279 82020 and 89170.
- 280 (15) SML(T) in this specific case means that the restriction shall not be exceeded by the sum
281 of the migration levels of the following substances mentioned as Ref. Nos: 15970, 48640,
282 48720, 48880, 61280, 61360 and 61600.
- 283 (16) SML(T) in this specific case means that the restriction shall not be exceeded by the sum
284 of the migration levels of the following substances mentioned as Ref. Nos: 49600, 67520
285 and 83599.
- 286 (17) SML(T) in this specific case means that the restriction shall not be exceeded by the sum
287 of the migration levels of the following substances mentioned as Ref. Nos: 50160, 50240,
288 50320, 50360, 50400, 50480, 50560, 50640, 50720, 50800, 50880, 50960, 51040 and
289 51120.
- 290 (18) SML(T) in this specific case means that the restriction shall not be exceeded by the sum
291 of the migration levels of the following substances mentioned as Ref. Nos: 67600, 67680
292 and 67760.
- 293 (19) SML(T) in this specific case means that the restriction shall not be exceeded by the sum
294 of the migration levels of the following substances mentioned as Ref. Nos: 60400, 60480
295 and 61440.
- 296 (20) SML(T) in this specific case means that the restriction shall not be exceeded by the sum
297 of the migration levels of the following substances mentioned as Ref. Nos: 66400 and
298 66480.
- 299 (21) SML(T) in this specific case means that the restriction shall not be exceeded by the sum
300 of the migration levels of the following substances mentioned as Ref. Nos: 93120 and
301 93280.
- 302 (22) SML(T) in this specific case means that the restriction shall not be exceeded by the sum
303 of the migration levels of the following substances mentioned as Ref. Nos: 17260, 18670,
304 54880 and 59280.
- 305 (23) SML(T) in this specific case means that the restriction shall not be exceeded by the sum
306 of the migration levels of the following substances mentioned as Ref. Nos: 13620, 36840,
307 40320 and 87040.
- 308 (24) SML(T) in this specific case means that the restriction shall not be exceeded by the sum
309 of the migration levels of the following substances mentioned as Ref. Nos: 13720 and
310 40580.
- 311 (25) SML(T) in this specific case means that the restriction shall not be exceeded by the sum
312 of the migration levels of the following substances mentioned as Ref. Nos: 16650 and
313 51570.

- 314 (26) QM(T) in this specific case means that the restriction shall not be exceeded by the sum of
315 the residual quantities of the following substances mentioned as Ref. Nos: 14950, 15700,
316 16240, 16570, 16600, 16630, 18640, 19110, 22332, 22420, 22570, 25210, 25240 and
317 25270.
- 318 (27) QMA(T) in this specific case means that the restriction shall not be exceeded by the sum
319 of the residual quantities of the following substances mentioned as Ref. Nos: 10599/90A,
320 10599/91, 10599/92A and 10599/93.
- 321 (28) SML(T) in this specific case means that the restriction shall not be exceeded by the sum
322 of the migration levels of the following substances mentioned as Ref. Nos: 13480 and
323 39680.
- 324 (29) SML(T) in this specific case means that the restriction shall not be exceeded by the sum
325 of the migration levels of the following substances mentioned as Ref. Nos: 22775 and
326 69920.
- 327 (30) SML(T) in this specific case means that the restriction shall not be exceeded by the sum
328 of the migration levels of the following substances mentioned as Ref. Nos: 86480, 86960
329 and 87120.
- 330 (31) Compliance testing when there is a fat contact should be performed using saturated fatty
331 food simulants as simulant D.
- 332 (32) Compliance testing when there is a fat contact should be performed using isooctane as
333 substitute of simulant D (unstable).
- 334 (33) QMA(T) in this specific case means that the restriction shall not be exceeded by the sum
335 of the residual quantities of the following substances mentioned as Ref. Nos: 14800 and
336 45600.
- 337 (34) SML(T) in this specific case means that the restriction shall not be exceeded by the sum
338 of the migration levels of the following substances mentioned as Ref. Nos: 55200, 55280
339 and 55360.