The EFSA Journal (2004) 161, 1-13

Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission related to

a 6th list of substances for food contact materials

Question N° EFSA-Q-2003-230, EFSA-Q-2004-116, EFSA-Q-2004-047, EFSA-Q-2004-110, EFSA-Q-2004-052, EFSA-Q-2004-141

Adopted on 8 December 2004

SUMMARY

Within the general task of evaluating substances intended for use in materials in contact with food according to Council Directive 89/109/EEC of 21 December 1988 relating to materials and articles intended to come into contact with foodstuffs, the AFC Panel evaluated the following substances.

Ref. No.:	31542
Name of the substance:	Acrylic acid, methyl ester, telomer with 1-dodecanethiol, C16-C18 alkyl esters
CAS number:	174254-23-0
Classified in list:	3
Restriction:	Maximum quantity 0.5% w/w in the final article

Ref. No.:	38940
Name of the substance:	2,4-Bis(dodecylthiomethyl)-6-methylphenol
CAS number:	110675-26-8
Classified in list:	3
Restriction:	Group restriction of 5 mg/kg food as sum of 2,4-bis(dodecylthiomethyl)-6-methylphenol and 2,4-bis(octylthiomethyl)-6-methylphenol

Ref. No.:	62245
Name of the substance:	Iron Phosphide
CAS number:	12751-22-3
Classified in list:	3
Restriction:	None (Inert, insoluble material)

Ref. No.:	64990
Name of the substance:	Maleic anhydride-styrene, copolymer, sodium salt
CAS number:	25736-61-2
Classified in list:	3

Restriction:	None
Ref. No.:	76815
Name of the substance:	Polyester of adipic acid with glycerol or pentaerythritol, esters with even numbered unbranched C12-C22 fatty acids
CAS number:	-
Classified in list:	3
Restriction:	Specifications: Fraction with Mw <1000D less than 5%
Ref. No.:	79600
Name of the substance:	Polyethyleneglycol tridecyl ether phosphate
CAS number:	9046-01-9
Classified in list:	3
Restriction:	5 mg/kg

KEY WORDS

Food Contact Materials, Plastics, Monomers, Additives, Acrylic acid, methyl ester, telomer with 1-dodecanethiol, C16-C18 alkyl esters, REF. No 31542, CAS No 174254-23-0, 2,4-Bis(dodecylthiomethyl)-6-methylphenol, REF. No 38940, CAS No 110675-26-8, Iron Phosphide, REF. No 62245, CAS No 12751-22-3, maleic anhydride-styrene, copolymer, sodium salt, REF. No 64990, CAS No 25736-61-2, Polyester of adipic acid with glycerol or pentaerythritol, esters with even numbered unbranched C12-C22 fatty acids, REF. No 76815, Polyethyleneglycol tridecyl ether phosphate REF. No 79600, CAS No 9046-01-9.

BACKGROUND

According to Article 3(3) of the Council Directive 89/109/EEC of 21 December 1988 it is necessary to consult the Scientific Committee on Food (SCF) on the risks connected with the migration of substances into food from food contact materials in which they are used. This competence was transferred to the European Food Safety Authority (EFSA) by virtue of the Regulation (EC) 178/2002.The opinion of the EFSA is required before a substance is authorised to be used in food contact materials and be included in a positive list when this is established in the relevant legislation.

TERMS OF REFERENCE

The Commission asks EFSA to carry out risk assessments on:

1. all new substances used in food contact materials before their authorisation and inclusion in a positive list;
2. substances which are already authorised in the framework of Council Directive 89/109/EEC but need to be re-evaluated.

ASSESSMENT

Within this general task the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) evaluated the following substances used in food contact materials. The substances examined are listed in ascending order of their Reference Number (REF No.), with their chemical name, Chemical Abstract Number (CAS No.) and classification according to the "SCF list". (Previously the evaluation of substances used in food contact materials was undertaken by the Scientific Committee on Food (SCF). The definitions of the various SCF lists and the abbreviations used are given in the appendix.

Ref. No.:	**31542**
Name of the substance:	**Acrylic acid, methyl ester, telomer with 1-dodecanethiol, C16-C18 alkyl esters**
CAS number:	174254-23-0
Document reference:	EFSA/AFC/FCM/330-Rev.IB/31542 of December 2004
General information:	According to the petitioner acrylic acid, methyl ester, telomer with 1-dodecanethiol, C16-C18 alkyl esters is intended for use as co-stabiliser and/or dispersant for fillers, pigments, stabilisers, nucleating agents, and chemical blowing agents in plastics, particularly in polyolefins
Previous evaluations (by SCF or AFC):	The substance was first evaluated by EFSA- AFC Panel in 2003 (EFSA-AFC, 2003) and it was classified in List 7 Data available: data on specification, on use , and on specific migration from PP, HDPE, and LDPE into 10 % and 95 % ethanol Gene mutation in bacteria with a low molecular weight fraction (negative) SDS, December 2003 = CS/PM/4061 REV.0C/31542.
Available data used for this evaluation:	
Non-toxicity data:	Data on identity, chemical and physical properties, intended use, authorisation, specific migration from polypropylene, high density polyethylene and low density polyethylene into 10 % and 95 % ethanol and (new) method for the determination of the residual content
Toxicity data	Gene mutation in bacteria with a low molecular weight fraction
Evaluation:	Acrylic acid, methyl ester, telomer with 1-dodecanethiol, C16-18-alkyl esters is requested as a co-stabiliser and/or dispersant for additives (fillers, pigments, stabilisers, nucleating agents, and chemical blowing agents). The substance would be used in amounts up to 0.5 % in polymers, particularly in polyolefins. No restrictions of use of the final articles are foreseen by the petitioner. The requested substance is a polymeric additive having a molecular weight of >10000 D, the fraction <1000 D is 1.35 %.

Ref. No.:	31542
Name of the substance:	Acrylic acid, methyl ester, telomer with 1-dodecanethiol, C16-C18 alkyl esters

Based on the assumption that 0.5 % of the substance is present in the final article, the worst case migration of the fraction <1000 D is calculated to be 1 mg/kg food.

Taking into account the maximum concentration of 30 ppm of dodecyl mercaptane in the polymeric additive, the worst case migration of dodecyl mercaptane is calculated to be 2.25 µg/kg food. The migration of the polymeric additive into 10 % and 95 % ethanol was tested from PP, HDPE, and LDPE containing 0.53, 0.31 and 0.21 % respectively of the additive at conditions representing hot fill and long term storage. The highest migration was determined to be 1.25 mg/kg in 95 % ethanol from low density polyethylene (LDPE) containing 0.21% of the substance. .

An analytical method for the determination of the requested substance in polymers has been provided. Applying this method the actual level of the substance in an LDPE sample with a nominal concentration of 0.21% of the substance was found to be 0.205 ± 0.008%.

Although for polymeric additives with average molecular weight > 1000 D no toxicological data are requested according to the SCF Guidelines, the petitioner provided a test for gene mutations in bacteria with a low molecular weight fraction. This test showed no induction of gene mutations.

For the starting substances methyl acrylate [REF.No 11710, SCF List 2, Group t-TDI = 0,1 mg/kg bw (as acrylic acid)], cetyl alcohol and stearyl alcohol (REF No. 33120, SCF List 3 without restriction) no further data are needed. Dodecyl mercaptane is a chain stopper, a category which is not specifically regulated yet. Taking into account the low potential migration, no further toxicity data are requested.

Conclusion: Based on the above-mentioned data the substance is classified:

SCF_List: **3**

Restriction: **Maximum quantity 0.5% w/w in the final article**

Remark for Commission: Restriction on maximum quantity (QM) is proposed to control migration of dodecylmercaptane if any.

Needed data or information -

References:

Unpublished data submitted by the petitioner (13 June 2002; 25 August 2004)

EFSA AFC Opinion on a 1st list of substances for food contact materials , 2003: http://www.efsa.eu.int/pdf/afc/opinion_afc_01_en.pdf

Ref. No.:	**38940**
Name of the substance:	**2,4-Bis(dodecylthiomethyl)-6-methylphenol**
CAS number:	110675-26-8
Document reference:	*EFSA/AFC/FCM/344-Rev.0A/38940 of November 2004*

General information: According to the petitioner, 2,4-Bis(dodecylthiomethyl)-6-methylphenol is used as an antioxidant in polystyrene (PS), impact polystyrene (IPS, HIPS) and styrene-butadiene-styrene block copolymers (SBS). Maximum percentage in formulation is 0.2% in PS, 0.3% in SBS and 0.2% in HIPS. For PS, IPS and HIPS contact with all foods is requested. For SBS contact with non-fatty food only is requested as SBS does not withstand contact with fat.

Previous evaluations (by SCF or AFC): None (new substance)

Available data used for this evaluation:

Non-toxicity data: Data on identity, chemical and physical properties, intended use, authorisation, specific migration into food simulants, data on actual content.

Toxicity data: <u>On the substance itself:</u>
Mutagenicity in bacteria, chromosome aberration in mammalian cells, 28-day oral gavage study in rats
<u>On 2,4-Bis(octylthiomethyl)-6-methylphenol (REF No. 40020):</u>
Evaluation by the Scientific Committee on Food in 1992 (SCF, 1992)

Evaluation: Specific migration of 2,4-bis(dodecylthiomethyl)-6-methylphenol was determined. Migration tests were performed by total immersion of PS and SBS plates in 3% acetic acid, 10% ethanol and synthetic triglyceride mixture HB307 (except SBS which was tested only in the aqueous food simulants), after 10 days 40°C and 2 hr 70°C. Recovery of 2,4-bis(dodecylthiomethyl)-6-methylphenol from simulants after 2 hours 70°C ranges from 66 - 103%. Significant loss of 2,4-bis(dodecylthiomethyl)-6-methylphenol occurs after 10 days 40°C, in 3% acetic acid and 10% ethanol. Recovery values ranged from 31 - 48% after 10 days 40°C in the aqueous food simulants, while in HB307 60 - 94% recovery was found. There is no indication for reaction or decomposition of the substance. An acceptable explanation for the low recovery is the precipitation of the substance from the aqueous simulant. Specific migration of 2,4-bis(dodecylthiomethyl)-6-methylphenol was not detectable; the detection limit of the method being 0.8 mg/kg fat simulant or 0.005 mg/kg aqueous food simulant.

The migration of 2,4-bis(dodecylthiomethyl)-6-methylphenol from HIPS was estimated by migration modelling, using the Piringer equation. The results obtained were compared to experimental values as determined with 2,4-bis(octylthiomethyl)-6-methylphenol, which only differs in alkyl chain length from 2,4-bis(dodecylthiomethyl)-6-methylphenol. Migration of 2,4-

Ref. No.:	38940
Name of the substance:	**2,4-Bis(dodecylthiomethyl)-6-methylphenol**

bis(dodecylthiomethyl)-6-methylphenol from HIPS into food simulants was estimated to be 0.3 mg/kg food, which is an overestimate based on the results obtained for the 2,4-bis(octylthiomethyl)-6-methylphenol. The results obtained show that migration of these substances is controlled mainly by diffusion.
The actual content of the additive was found to be lower than the intended level, most probably due to grafting of the substance to the polymer.
2,4-bis-(dodecylthiomethyl-6-methyl-phenol) was negative in *in vitro* genotoxicity studies performed under appropriate quality control. From a 28-day oral gavage study with the compound, a NOAEL of 1000 mg/kg bw was determined.

The NOAEL of the structurally closely related compound, 2,4-Bis(octylthiomethyl)-6-methylphenol (REF No 40020), was also 1000 mg/kg bw in a 90-day oral gavage study in rats and in a 90 day gavage study with dogs, a NOEL of 10 mg/kg bw was determined. The compound was also negative in the complete set of *in-vitro* genotoxicity assays and in an *in-vivo* micronucleus study. The substance has been allocated by SCF a Tolerable Daily Intake (TDI) of 0.1 mg/kg bw on the basis of 1 and 3 months oral rat and the 3 month oral dog studies and teratogenicity studies in rats. (SCF, 1992)

Conclusion: Based on the above-mentioned data the substance is classified:

SCF_List: **3**

Restriction: **Group restriction of 5 mg/kg food as sum of 2,4-bis(dodecylthiomethyl)-6-methylphenol and 2,4-bis(octylthiomethyl)-6-methylphenol**

Remark for Commission: *FRF is applicable*

Needed data or information: -

References:

- Unpublished data provided by petitioner on 16 August 2004
- SCF Opinion on certain additives used in the manufacture of plastic materials intended to come into contact with foodstuffs, 33rd series, May 1992.
  http://europa.eu.int/comm/food/fs/sc/scf/reports/scf_reports_33.pdf

Ref. No.:	62245
Name of the substance:	**Iron Phosphide**

CAS number: 12751-22-3

Document reference: *EFSA/AFC/FCM/304-Rev.0C/62245 of December 2004*

General information: According to the petitioner, iron phosphide is an undefined mixture composed mainly of (di)iron phosphide (Fe_2P), (mono)iron phosphide (FeP) and iron silicide (FeSi). It is requested as additive for PET polymers and copolymers, destined to come into contact with all types of foods under conditions of hot fill and storage for any time at room temperature

Ref. No.:	**62245**
Name of the substance:	**Iron Phosphide**

Previous evaluations (by SCF or AFC): None (new substance)

Available data used for this evaluation:

Non-toxicity data:
- Identity of the substance
- Intended use
- Solubility in 0.1 N HCl
- specific migration tests from PET to 3% acetic acid, 15% ethanol, 95% ethanol

Toxicity data:
- 3 *in vitro* mutagenicity assays

Evaluation:

Specific migration was determined from PET samples containing worst case concentration of iron phosphide that may occur in real use under contact conditions of 0.5h at 100°C followed by 10 d at 40°C or only 10d at 40°C. After treatment with a mixture of hydrochloric acid and nitric acid the total amount of iron was determined by inductively coupled plasma-atomic emission spectroscopy (ICP-AES)..

The migration of iron into the food simulants 3% acetic acid, 15% ethanol and 95% ethanol, after a contact period of 0.5 hour at 100 °C followed by 10 days at 40 °C gave mean values of 12, 15 and 10 µg Fe/kg food simulant respectively. The migration of iron into 3% acetic acid after 10 days at 40 °C gave a mean value of 11 µg Fe/kg food simulant.

Iron phosphide is insoluble in water, in 0.1N HCl , and common organic solvents and it has been demonstrated that the low amounts of migrating iron came from soluble compounds of iron and phosphorous (e.g. phosphates) present as trace contaminants in iron phosphide.

Iron phosphide was tested with negative results in a bacterial reversion test, and in forward mutation and chromosomal aberration assays in cultured mammalian cells. On the basis of the results obtained, it is concluded that iron phosphide is not genotoxic.

Conclusion: Based on the above-mentioned data the substance is classified:

SCF_List: **3**

Restriction: **None (Inert, insoluble material)**

Remark for Commission: It is requested only for use in PET polymers and co-polymers

Needed data or information: none

References: Unpublished data submitted by the petitioner (March and November 2004)

Ref. No.:	**64990**
Name of the substance:	**Maleic anhydride-styrene, copolymer, sodium salt**
CAS number:	25736-61-2
Document reference:	*EFSA/AFC/FCM/341-Rev.0B/64990 of December 2004*

General information:

According to the petitioner maleic anhydride-styrene, copolymer, sodium salt is an emulsifier used as a polymerisation production aid in the production of styrene polymers and copolymers. The emulsifier is added to a styrene polymer dissolved in an organic solvent in order to allow precipitation of the polymer to form aggregates and to avoid self adhering and adhering to pipes. The amount added to the polymer is approximately 0.33%. However due to the good solubility in the aqueous phase the major part of the maleic anhydride-styrene, copolymer, sodium salt is removed by filtration of the aqueous phase.

Previous evaluations (by SCF or AFC):

None (new substance)

Available data used for this evaluation:

Non-toxicity data: Data on identity, including Mw distribution; physical and chemical properties; intended use; authorization; residual content of the polymeric additive and the starting substances.

Toxicity data: Three *in vitro* mutagenicity assays with maleic anhydride-styrene, copolymer, sodium salt (bacterial reversion test, gene mutation test in cultured mammalian cells, and chromosomal aberration test)

Evaluation:

Maleic anhydride-styrene, copolymer, sodium salt has a Mw varying from 130,000 – 190,000 g/mol with a Mn of 38,000 – 44,000 g/mol. The fraction < 1000D is <0.05%. Residual content of styrene and maleic acid in the emulsifier is <7mg/kg and < 1.6% respectively. The actual content of maleic anhydride-styrene, copolymer, sodium salt in a typical polymer was found to be 77 mg/kg polymer. Properly in-house validated analytical methods were provided. Based on the worst case assumption that maleic anhydride-styrene, copolymer, sodium salt is present at the level of 100 mg/kg polymer, the worst case migration of the fraction <1000D, styrene and maleic acid was calculated, taking into account a 6 dm² sheet with a thickness of 0.25 mm. Under these conditions worst case migration of the fraction <1000D is 0.8 µg/kg food. Worst case migration of styrene and maleic acid was calculated to be < 0.01 kg/food and <24 µg/kg food respectively.

Maleic anhydride-styrene, copolymer, sodium salt, is a high MW polymer with < 0.05% of constituents with molecular mass < 1000 D. An acqueous formulation of the copolymer was not genotoxic when tested in three *in vitro* genotoxicity assays (bacterial reversion test, gene mutation test in cultured mammalian cells, and chromosomal aberration assay). However, based on the molecular weight distribution and migration level, only toxicity data on starting substances are required

Starting substances of maleic anhydride-styrene, copolymer, sodium salt,

Ref. No.:	64990
Name of the substance:	**Maleic anhydride-styrene, copolymer, sodium salt**

are styrene, classified in List 4B, maleic acid, classified in list 2 with group TDI of 0.5 mg/kg bw, and sodium hydroxide (List 1, SML not specified). Of these, only styrene is of toxicological concern. However, considering the very low residual content of styrene in the copolymer (7 mg/kg polymer), it can be concluded that the expected migration of styrene in foodstuff is negligible (<0.01 µg/kg food), and that the copolymer is toxicologically acceptable for the intended use.

Conclusion: Based on the above-mentioned data the substance is classified

SCF_List: **3**

Restriction: **None**

Remark for Commission: none

Needed data or information none

References:

- Unpublished data provided by petitioner on 4-8-2004

Ref. No.:	76815
Name of the substance:	**Polyester of adipic acid with glycerol or pentaerythritol, esters with even numbered unbranched C12-C22 fatty acids**

CAS number: Not assigned for the group of substances

Document reference: *EFSA/AFC/FCM/271-Rev.0/768150C of December 2004*

General information:

According to the petitioner, Polyester of adipic acid with glycerol or pentaerythritol, esters with C12-C22 fatty acids are used as additive in the plastics production, e.g. in the production of PVC articles as plasticizer and internal lubricant . Maximum percentage in formulation is <5%.

Previous evaluations (by SCF or AFC):

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Available data used for this evaluation:

Non-toxicity data:

Data on identity. Physical/chemical data, use, authorization and data on migration modeling are based on a reference substance which is considered to be representative for the subject substance : "Hexanedioc acid, polymer with 2,2-bis(hydroxymethyl)-1,3-propanediol octadecanoate" (Pentaerythritol-Adipate-Stearate).
An analytical method for the determination of the reference substance in aqueous solution is available.

Toxicity data:

- Gene mutation in bacteria,
- 90-day oral studies in rats and dogs.

Evaluation:

One combined dossier has been submitted for the pentaerythritol esters and the glycerol esters. Most information provided in the dossier is related to the reference substance "*hexanedioic acid, polymer with 2,2-bis(hydroxymethyl)-1,3-propanediol, octadecanoate (CAS No = 68130-34-7)"*. This substance is used as a reference substance which is considered to

Ref. No.:	76815
Name of the substance:	Polyester of adipic acid with glycerol or pentaerythritol, esters with even numbered unbranched C12-C22 fatty acids

be representative for the pentaerythritol esters as well as for the glycerol esters.
The substance is intended for use in all food contact plastics.
Estimation of migration used mathematical modellimg instead of migration measurements.
The substance is poorly soluble in olive oil and so a polymer:stimulant partition coefficient of 1000 was used as an input parameter for the modelling. The test case was PVC and migration of the fraction of the substance with molecular weight <2000 was modeled. The maximum calculated migration value was maximum 0.011 mg/kg.
Polyester of adipic acid with glycerol or pentaerythritol, esters with C12-C22 fatty acids was not mutagenic in bacteria and a NOAEL of 171 mg/kg b.w. is derived from the results of the 90-day studies. In dogs, poly pentaerythritol-adipate stearate was administered with diet at levels of 3300 and 10000 mg/kg for 90 days. The rat study was performed with a administration of 1000, 2500 and 20000 mg/kg (in diet) of poly pentaerythritol-adipate stearate for 90 days.
In dogs, no effects were observed at the 10000 mg/kg level in the study and a NOAEL of 10000 mg/kg corresponding to around 770 mg/kg b.w. can be derived from the data. In the rat study, marginal increases in serum potassium levels and mononuclear cell infiltration and bile duct proliferation in the liver was seen in a very modest extend after the 20000 mg/kg dose. These effects were absent in the lower dose groups and a NOAEL of 2500 mg/kg corresponding to 171 mg/kg b.w. for male rats and 204 mg/kg b.w. for female rats can be derived. However, the reports available (dated from 1975) do not give specifications of the materials tested then and do not permit conclusions on the conformity of the test material used then with the material covered by the application

Given the high molecular weight of the substance and the fact that the low molecular weight fraction are esters which are expected to be hydrolysed to naturally ocuring fatty acids, no toxicological studies are needed. It is considered, however, appropriate to set specifications on Molecular weight distribution.

Conclusion: Based on the above-mentioned data the substance is classified*:*

SCF_List: **3**

Restriction: **Specifications: Fraction with Mw <1000D less than 5%**

Remark for Commission: None

Needed data or information -

References: Unpublished data submitted by the petitioner on 23-03-2004

Ref. No.:	**79600**
Name of the substance:	Polyethyleneglycol tridecyl ether phosphate
CAS number:	9046-01-9
Document reference:	EFSA/AFC/FCM/361-Rev.0B/79600 of December 2004

General information: According to the petitioner, Polyethyleneglycol tridecyl ether phosphate is used as an emulsifier in the manufacture of styrene copolymers with butadiene and/or isoprene and polybutadiene. The emulsifier is used during precipitation of polymers after polymerisation, at a level up to 550 mg/kg with respect to the polymer. Food contact materials containing the emulsifier are intended for contact with aqueous foods only.

Previous evaluations (by SCF or AFC): None (new substance)

Available data used for this evaluation:

Non-toxicity data: Information of identity, physical/chemical properties, use, authorization, migration and actual content.

Toxicity data: Gene mutation in bacteria, gene mutation in mammalian cells, chromosome aberration in mammalian cells, *in vivo* mouse micronucleus test, rat liver DNA repair (UDS) test, 28-day oral gavage study in rats, 90-day study in rats with NOAEL of 1500 ppm equivalent to 125 mg/kg/day).

Evaluation: Specific migration of Polyethyleneglycol tridecyl ether phosphate has been determined in 3% acetic acid and 10% ethanol. Styrene-poly(ethylene-butene)-styrene block copolymers and a styrene butadiene copolymer were tested by total immersion for 2 hours 70°C and 10 days 40°C. Maximum migration of the emulsifier was found to be 0.24 mg/kg or mg/kg food, after 10 days 40°C in 10% ethanol.
The actual content of the emulsifier in the samples tested was determined.
One borderline positive mutagenic response in the mammalian cell assay, other mutagenicity endpoints consistently negative in the performed studies *in vitro* and in a mouse micronucleus and a rat liver UDS-assay. Therefore, the compound is not considered as genotoxic. Based on the results of a recent 90-day feeding study, a NOAEL of 125 mg/kg/day in rats is derived.
Although it is an organophosphate compound, there is no indication from the toxicity studies that the compound has a potential for neurotoxicity…….

Conclusion: Based on the above-mentioned data the substance is classified*:*

SCF_List: **3**

Restriction: **5 mg/kg**

Remark for Commission: Specifications:
Polyethyleneglycol (EO ≤11) tridecyl ether phosphate (mono- and dialkyl ester) with a maximum 10% content of polyethyleneglycol (EO≤11) tridecyl ether

Needed data or information -

Ref. No.:	**79600**
Name of the substance:	Polyethyleneglycol tridecyl ether phosphate

References: Unpublished data provided by petitioner, September 2004

ACKNOWLEDGEMENTS

The Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food wishes to thank Chr. Boehme, K. Pfaff, M.A.H. Rijk, T.G. Siere, S. Rossi and D. Woelfle for their contribution to the draft opinion.

List of abbreviations:

FRF: Fat (Consumption) Reduction Factor, see Opinion of the SCF in 2002
http://europa.eu.int/comm/food/fs/sc/scf/out149_en.pdf
SM: Specific migration
SML: Specific migration limit

APPENDIX

DEFINITION OF THE SCF LISTS

List 0 Substances, e.g. foods, which may be used in the production of plastic materials and articles, e.g. food ingredients and certain substances known from the intermediate metabolism in man and for which an ADI need not be established for this purpose.

List 1 Substances, e.g. food additives, for which an ADI (=Acceptable Daily Intake), a t-ADI (=temporary ADI), a MTDI (=Maximum Tolerable Daily Intake), a PMTDI (=Provisional Maximum Tolerable Daily Intake), a PTWI (=Provisional Tolerable Weekly Intake) or the classification "acceptable" has been established by this Committee or by JECFA.

List 2 Substances for which this Committee has established a TDI or a t-TDI.

List 3 Substances for which an ADI or a TDI could not be established, but where the present use could be accepted.
Some of these substances are self-limiting because of their organoleptic properties or are volatile and therefore unlikely to be present in the finished product. For other substances with very low migration, a TDI has not been set but the maximum level to be used in any packaging material or a specific limit of migration is stated. This is because the available toxicological data would give a TDI, which allows that a specific limit of migration or a composition limit could be fixed at levels very much higher than the maximum likely intakes arising from present uses of the additive.
Depending on the available toxicological studies a restriction of migration into food of 0.05 mg/kg of food (3 mutagenicity studies only) or 5 mg/kg of food (3 mutagenicity studies plus 90-day oral toxicity study and data to demonstrate the absence of potential for bio-accumulation in man) may be allocated.

List 4 **(for monomers)**

4A Substances for which an ADI or TDI could not be established, but which could be used if the substance migrating into foods or in food simulants is not detectable by an agreed sensitive method.

4B Substances for which an ADI or TDI could not be established, but which could be used if the levels of monomer residues in materials and articles intended to come into contact with foodstuffs are reduced as much as possible.

List 4 **(for additives)**

Substances for which an ADI or TDI could not be established, but which could be used if the substance migrating into foods or in food simulants is not detectable by an agreed sensitive method.

List 5 Substances that should not be used.

List 6 Substances for which there exist suspicions about their toxicity and for which data are lacking or are insufficient.
The allocation of substances to this list is mainly based upon similarity of structure with that of chemical substances already evaluated or known to have functional groups that indicate carcinogenic or other severe toxic properties.

6A Substances suspected to have carcinogenic properties. These substances should not be detectable in foods or in food simulants by an appropriate sensitive method for each substance.

6B Substances suspected to have toxic properties (other than carcinogenic). Restrictions may be indicated.

List 7 Substances for which some toxicological data exist, but for which an ADI or a TDI could not be established. The required additional information should be furnished.

List 8 Substances for which no or only scanty and inadequate data were available.

List 9 Substances and groups of substances which could not be evaluated due to lack of specifications (substances) or to lack of adequate description (groups of substances).
Groups of substances should be replaced, where possible, by individual substances actually in use. Polymers for which the data on identity specified in "SCF Guidelines" are not available.

List W "Waiting list". Substances not yet included in the Community lists, as they should be considered "new" substances, i.e. substances never approved at national level. These substances cannot be included in the Community lists, lacking the data requested by the Committee.