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 5th list of substances for food contact materials

(Question N° EFSA-Q-2004-034, EFSA-Q-2004-053, EFSA-Q-2004-044, EFSA-Q-2004-097, EFSA-Q-2004-045, EFSA-Q-2004-033, EFSA-Q-2003-213, EFSA-Q-2004-034, EFSA-Q-2003-183, EFSA-Q-2003-218, EFSA-Q-2003-201, EFSA-Q-2004-041)

adopted on 22 October 2004 by written procedure

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.:	11500
Name of the substance:	Acrylic acid, 2-ethylhexyl ester
CAS number:	000103-11-7
Classified in list:	3
Restriction:	0,05 mg/kg of food

Ref. No.:	13720
Name of the substance:	1,4-butanediol
CAS number:	000110-63-4
Classified in list:	3
Restriction:	5 mg/kg food

Ref. No.:	14260
Name of the substance:	Caprolactone
CAS number:	000502-44-3
Classified in list:	3
Restriction:	0.050 mg/kg food expressed as the sum of caprolactone and 6-hydroxyhexanoic acid

Ref. No.:	22210
Name of the substance:	Alpha-methylstyrene
CAS number:	000098-83-9
Classified in list:	3
Restriction:	0.05 mg/kg food

Ref. No.:	22932
Name of the substance:	Perfluoromethyl perfluorovinyl ether
CAS number:	1187-93-5
Classified in list:	3
Restriction:	0.05 mg/kg food

Ref. No.:	24903 (ex 92070)
Name of the substance:	syrups, hydrolysed starch, hydrogenated
CAS number:	68425-17-2
Classified in list:	3
Restriction:	In compliance with the purity criteria for maltitol syrup, E 965 (ii)

Ref. No.:	30340
Name of the substance:	12-(Acetoxy)stearic acid, 2,3-bis(acetoxy)propyl ester
CAS number:	330198-91-9
Classified in list:	3
Restriction:	None

Ref. No.:	31500
Name of the substance:	2-ethylhexyl acrylate-acrylic acid copolymer
CAS number:	25134-51-4
Classified in list:	3
Restriction:	Group restriction 6mg/kg food for acrylic acid and 0.05 mg/kg food for acrylic acid, 2-ethylhexyl ester

Ref. No.:	43480
Name of the substance:	Charcoal, activated
CAS number:	64365-11-3
Classified in list:	3
Restriction:	Only to be used in polyethylene terephthalate (PET) at a maximum amount of 10 mg/kg polymer. Purity criteria: in compliance with vegetable carbon (E 153), except for the ash content which can be up to 10%

Ref. No.:	77370 (ex 77850)
Name of the substance:	Polyethyleneglycol-30 dipolyhydroxystearate (PEG-30 dipolyhydroxystearate)
CAS number:	70142-34-6
Classified in list:	3
Restriction:	none

Ref. No.:	85950
Name of the substance:	Silicic acid, magnesium-sodium-fluoride salt
CAS number:	037296-97-2
Classified in list:	3
Restriction:	0.15 mg fluoride/kg food

Ref. No.:	95265

Name of the substance: 1,3,5-Tris(4-benzoylphenyl) benzene
CAS number: 227099-60-7
Classified in list: 3
Restriction: 0.05 mg/kg food

KEY WORDS

Food Contact Materials, Plastics, Monomers, Additives, Acrylic acid, 2-ethylhexyl ester, REF. No 11500, CAS No 000103-11-7, 1,4-butanediol, REF. No 13720, CAS No 000110-63-4, Caprolactone, REF. No 14260, CAS No 000502-44-3, Alpha-methylstyrene, REF. No 22210, CAS No 000098-83-9, Perfluoromethyl perfluorovinyl ether, REF. No 22932, CAS No 1187-93-5, syrups, hydrolysed starch, hydrogenated, REF. No 24903 (ex 92070), CAS No 68425-17-2, 12-(Acetoxy)stearic acid, 2,3-bis(acetoxy)propyl ester, REF. No 30340, CAS No 330198-91-9, 2-ethylhexyl acrylate-acrylic acid copolymer , REF. No 31500, CAS No 25134-51-4, Charcoal, activated , REF. No 43480, CAS No 64365-11-3, Polyethyleneglycol-30 dipolyhydroxystearate (PEG-30 dipolyhydroxystearate), REF. No 77370 (ex 77850), CAS No 70142-34-6 Silicic acid, magnesium-sodium-fluoride salt, REF. No 85950, CAS No 037296-97-2, 1,3,5-Tris(4-benzoylphenyl) benzene, REF. No 95265, CAS No 227099-60-7.

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.:	**11500**
Name of the substance:	**Acrylic acid, 2-ethylhexyl ester**
Document reference:	*EFSA/AFC/FCM/213-Rev.IIIA/11500 of September 2004*
General information:	Acrylic acid, 2-ethylhexyl ester is a co-monomer used in the manufacture of polymers for coating plastics.
Previous evaluations (by SCF or AFC):	The substance was first evaluated by the SCF in 2000 (SCF, 2000) and was classified in List 7. Available: data on hydrolysis in simulated saliva (18% after 4 h at 37°C); specific migration in 3% acetic acid, 15% ethanol and 95% ethanol (10 days at 40°C): < 0.05 mg/kg into food; two gene mutation tests in bacteria; four gene mutation assays in cultured mammalian cells; chromosomal aberration, micronucleus, SCE, UDS and transformation tests in vitro; chromosomal aberration assay in vivo; subchronic inhalation and dermal chronic toxicity/oncogenicity studies; data on acute and subacute toxicity, ADME, sensitisation and irritation. Needed: *In vivo* unscheduled DNA synthesis (UDS) assay
Available data used for this evaluation:	
Non-toxicity data:	This aspect has been evaluated by the SCF in 2000 (SCF, 2000)
Toxicity data:	*in vivo* UDS assay in rat liver
Evaluation:	Acrylic acid, 2-ethylhexyl ester was negative in an adequately performed *in vivo* UDS assay in rat liver. On the basis of the results of this study, and those considered in the previous SCF evaluation (SCF, 2000) it is concluded that acrylic acid, 2-ethylhexyl ester is not genotoxic. The results of subchronic and chronic toxicity/oncogenicity studies performed using the inhalational and dermal routes of exposure, respectively, are not relevant for the definition of safe oral intakes.
Conclusion:	Based on the above mentioned data the substance is classified:
SCF_List:	**3**
Restriction:	**0.05 mg/kg of food**
Remark for Commission:	
Needed data or information	
References:	Opinion of the Scientific Committee on Food on the 10th additional list of monomers and additives for food contact materials (22 June 2000) http://europa.eu.int/comm/food/fs/sc/scf/out62_en.pdf unpublished data submitted by the petitioner on 22.12.2003

Ref. No.:	**13720**
Name of the substance:	**1,4-butanediol**
CAS number:	**000110-63-4**
Document reference:	EFSA/AFC/FCM/297-Rev.IIIA/13720 of September 2004

Ref. No.:	13720
Name of the substance:	1,4-butanediol

General information:

1,4-Butanediol is a monomer used in the production of poly(butylene-terephthalate) and thermoplastic polyurethane. Maximum percentage in the formulation is 40%.

Previous evaluations (by SCF or AFC):

The substance was first evaluated by SCF in 2001(SCF, 2001) and it was classified in List 3 with a Restriction of 0.05 mg/kg food based on the reduced core set of toxicological data according to the migration level.

Available: migration data in aqueous food simulants and olive oil; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative); acute and 28-day oral studies (original reports are not available); teratogenicity study (original report is not available); distribution, metabolism and excretion studies (original reports are not available); dermal toxicity study (original report is not available); inhalation study (original report is not available).
RIVM/UK/TNO SDS, September 2000 = CS/PM/3150 REV.II/13720.

(Adopted by the SCF at the 127th meeting, 30 May 2001)

Available data used for the present evaluation:

Non-toxicity data
- As for the previous evaluation (SCF, 2001)

Toxicity data
- Three negative mutagenicity studies
- 28-day and 90 day oral studies
- Long term/carcinogenicity study
- Reproduction/developmental study
- Teratogenicity study
- Distribution, metabolism and excretion studies

Evaluation:

This evaluation deals only with the toxicological properties of the substance, other aspects having been completely evaluated by SCF in 2001. (SCF, 2001).

Genotoxicity:
On the basis of the three supplied mutagenicity studies, 1,4-butanediol is not considered to be genotoxic.

Metabolism:
Although no direct results on 1,4-butanediol have been reported, 90 day studies in rats and mice with the corresponding lactone have been performed by the National Toxicity Program (NTP). Evidence has been provided that the diol is metabolised to γ-hydroxybutyric acid and then to the γ-butyrolactone. Thus a toxicity test on the lactone also covers 1,4-butanediol.

Subchronic toxicity :
The 90 day study with the lactone demonstrated no organ-specific toxicity even though chemical-related mortality occurred at the highest dose administered (1400 mg/kg bw/day for rats and 1050 mg/kg bw/day for mice).

Long term toxicity / carcinogenicity:
No data are available on the substance itself. However, NTP stated "that because the toxicity and carcinogenicity of γ-hydroxybutyric acid was

Ref. No.:	13720
Name of the substance:	1,4-butanediol

fully evaluated in the NTP pre-chronic and chronic studies of γ – butyrolactone, with a lack of toxic or carcinogenic potential being demonstrated, it is concluded that there is a high likelihood that 1,4-butane diol would be negative in a similar set of studies".

Reproduction/ Developmental toxicity:

On the basis of the available results, a NOEL of 100 mg/kg bw/day, based on reductions in fetal body weight and an increasing trend in skeletal defects, could be agreed for the substance.

According to the available studies on 1,4-butanediol, γ-hydroxybutyric acid and γ–butyrolactone, a NOEL of 100 mg/kg bw/day, based on developmental toxicity, could be derived.

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

SCF_List: **3**

Restriction: **5 mg/kg food**

Remark for Commission: None

Needed data or information

References:

- Opinion of the Scientific Committee on Food on the 13th additional list of monomers and additives for food contact materials (30 May 2001) http://europa.eu.int/comm/food/fs/sc/scf/out86_en.pdf
- Unpublished data submitted by the petitioner, May 2004.

Ref. No.:	14260
Name of the substance:	**Caprolactone**
CAS number:	000502-44-3
Document reference:	*EFSA/AFC/FCM/224-Rev.IIA/14260, June 2004*

General information:

Caprolactone is a monomer used in the production of polycaprolactones. High molecular weight polycaprolactone can be used as thermoplastics. Polycaprolactones can also be reacted with isocyanates to produce polyurethanes and with polyesters or polyethers to form copolyesters of polyester ethers.

Previous evaluations (by SCF or AFC):

The substance was evaluated by the SCF in 1999 (SCF, 1999) and classified in List 7.
Available: specific migration in four simulants; maximum in 15% ethanol after 10 days at 40 °C of 0.012 mg/kg food; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (inadequate); gene mutation assay in cultured mammalian cells (inadequate).
Needed: additional data concerning recovery and stability of caprolactone from food simulants, including migration period and complete sample work-up; chromosomal aberration assay in cultured mammalian cells; gene mutation assay in cultured mammalian cells.
(RIVM/ISS/TNO SDS, April 1999 = CS/PM/1585 REV. I/14260).

Available data used for this evaluation:

Non-toxicity data:

-Specific migration in four simulants; maximum in 15% ethanol after 10 days 40°C of 0.012 mg/kg food.
- recovery data for caprolactone added to food simulants at the outset of the migration test period. (new)
- hydrolysis data in aqueous buffer, as a function of pH (new)
- evidence that the hydrolysis product is 6-hydroxyhexanoic acid (new)

Toxicity data:

- gene mutation assay in bacteria (negative)
- a gene mutation assay in cultured mammalian cells (negative) (new)
- gene mutation assay in cultured mammalian cells (inadequate)
- chromosomal aberration assay in cultured mammalian cells (inadequate)
- a micronucleus assay in mice (negative) (new)
- considerations on the toxicity of 6-hydroxyhexanoic acid (new)

Evaluation:

Caprolactone is used in the production of polycaprolactone.
After processing, low levels of caprolactone are likely to remain (typically < 0.05%). In aqueous food products caprolactone will hydrolyse to aliphatic monocarboxylic terminated polyesters at a rate dependent on pH. Aliphatic monocarboxylic terminated polyesters will completely degrade to simple breakdown products (CO2) by enzymatic attack. In oils and fats, caprolactone will be inert. In aqueous alcoholic solutions hydrolysis will predominate.
Specific migration of ε-caprolactone has been determined in water, 3% acetic acid, 15% ethanol and olive oil. The sample was a polycaprolactone film, which was tested by total immersion in a closed migration cell for 10 days at 40°C.
Specific migration of ε-caprolactone was found to be maximum 0.012 mg/6 dm² in 15% ethanol. The results presented may be misleading as caprolactone may be unstable in food simulants. The migration values are low, but taking the residual content of <0.05% and the thickness of the test

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Name of the substance:	**Caprolactone**

specimen (20 µm), then the worst case migration could be up to 0.6 mg/kg. Therefore additional data were needed to establish reliability of the data presented.
From the results of the recovery tests it can be concluded that the earlier migration data for 3% acetic acid simulant were misleading because the recovery is very low at less than 1%. For 15% ethanol the recovery was approximately 50% and so the migration could be about double the previously reported level of 0.012 mg /kg. The recovery from olive oil was quantitative and so the previously reported level of not detectable, < 4 µg/kg is unchanged.
If the worst-case migration is ca. 20 µg/kg, of which ca 10 µg/kg is caprolactone and 10 µg/kg is the hydrolysis product 6-hydroxyhexanoic acid, then the hydrolysis product should be evaluated too and a restriction placed upon it, either directly or indirectly via a limit on caprolactone, if this is appropriate.

From the results of a published study (McCann et al., 1975), caprolactone was negative in the Salmonella reversion test. Literature data submitted previously on gene mutation and chromosomal aberration induction in mammalian cells were inadequate for an evaluation. In two additional mutagenicity tests, a mammalian cell gene mutation test and an in vivo micronucleus assay, caprolactone did not show genotoxic properties.
Relevant toxicological data for the hydrolysis product 6-hydroxyhexanoic acid are not available. 6-Hydroxyhexanoic acid can be considered as a substance with properties which are intermediate between hexanoic acid in SCF List 0 (SCF, 1991) and adipic acid in SCF List 1 (SCF, 1990). Based on the structure of 6-hydroxyhexanoic acid and based on a comparison with similar structures, 6-hydroxyhexanoic acid is expected to be non-genotoxic.

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

SCF_List: **3**

Restriction: **0.05 mg/kg food expressed as the sum of caprolactone and 6-hydroxyhexanoic acid**

Remark for Commission: None

Needed data or information None

References:

- Unpublished data submitted by the petitioner, February 2004
- Opinion of the Scientific Committee on Food on an additional list of monomers and additives for food contact materials. Adopted at the 118th SCF meeting (23 September 1999) http://europa.eu.int/comm/food/fs/sc/scf/out41_en.pdf
- Scientific Committee for Food, reports: 30th series (19 June 1991) http://europa.eu.int/comm/food/fs/sc/scf/reports/scf_reports_30.pdf
- Scientific Committee for Food, reports: 25th series (18 May 1990) http://europa.eu.int/comm/food/fs/sc/scf/reports/scf_reports_25.pdf
- J. McCann, E. Choi, E. Yamasaki, and B.N. Ames (1975) Detection of carcinogens as mutagens in the Salonella/microsome test: assay of 300 chemicals. PNAS U.S.A., 72, 5135-5139.

Ref. No.:	22210
Name of the substance:	**Alpha-methylstyrene**
CAS number:	000098-83-9

Ref. No.:	**22210**
Name of the substance:	**Alpha-methylstyrene**

Document reference: *EFSA/AFC/FCM/290-Rev.IA/22210 of September 2004*

General information: According to the petitioner, alpha-methylstyrene is used as a comonomer in the production of several types of copolymers (e.g. acrylonitrile butadiene styrene/alpha-methylstyrene copolymers, acrylonitrile/ alpha-methylstyrene copolymers and acrylonitrile styrene butylacrylate/ alpha-methylstyrene copolymers), for articles of repeated use, for all kinds of foods

Previous evaluations (by SCF or AFC): The substance was evaluated by the SCF in 1998 (SCF, 1998) and classified in List 7.
Available: Inadequate migration data; log Po/w; three (negative) mutagenicity studies; acute toxicity; 90-day oral rat study.
Needed: Detailed information concerning actual conditions of migration experiments; 2 year oral rat study or a metabolism study to provide reassurance of lack of accumulation.
(RIVM/TNO SDS, February 1997 = CS/PM/2992 /22210).

Available data used for this evaluation:

Non-toxicity data:
- Intended use
- Information about production process
- Migration of alpha-methylstyrene from ABS/alpha-methylstyrene copolymer, 10 days 40°C, in 3% acetic acid, 15% ethanol, fatty food simulant HB307
- Properly reported specific migration method

Toxicity data:
- Three (negative) mutagenicity studies; (evaluated during the previous evaluation by SCF in 1998)
- 90-day oral rat study. (evaluated during the previous evaluation by SCF in 1998)

Evaluation:

Specific migration of alpha-methylstyrene from ABS/ alpha-methylstyrene typical new copolymer was measured by single side test cell, for 10 days 40°C, in 3% acetic acid, 15% ethanol and fatty food simulant HB307. A Head Space Gas Chromatography-Mass Spectrometry/Single Ion Monitoring (GC-MS/SIM) method properly described was used. Migration of alpha-methylstyrene was 5 µg/kg food in 15% ethanol, 8.3 µg/kg food in 3% acetic acid (after correction for recovery), lower than 14 µg/kg food in fat simulant HB307.
Alpha-methylstyrene did not show genotoxic properties under *in vitro* conditions in an Ames test and in gene mutation and chromosomal aberration assay in cultured mammalian cells. In an oral 13-week study, using rats, a NOAEL of 40 mg/kg bw was found.
On the basis of the new migration data, long-term and metabolism studies are no longer considered necessary.

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

SCF_List: **3**

Restriction: **0.05 mg/kg food**

Remark for Commission: none

Needed data or information: none

References:
- Unpublished data submitted by the petitioner, July 2004

Ref. No.:	**22210**
Name of the substance:	**Alpha-methylstyrene**

- Opinion of the Scientific Committee on Food and additional list of monomers and additives for food contact materials. Adopted at the 111th SCF meeting (18-19 March 1998).
http://europa.eu.int/comm/food/fs/sc/scf/out10_en.pdf

Ref. No.:	**22932**
Name of the substance:	PERFLUOROMETHYL PERFLUOROVINYL ETHER

CAS number: 1187-93-5
Document reference: *EFSA/AFC/FCM/306-Rev.IA/22932of September 2004*

General information:

According to the petitioner, perfluoromethyl perfluorovinyl ether (MVE) is a gaseous comonomer used in the polymerisation process of fluoropolymers. These fluoropolymers are processed at temperatures 340-380°C to produce metallic articles with anti-stick coatings used in both baking industry, such as moulds for cakes, and household cookware, such as frying pans. All the articles are for repeated use for all types of foodstuffs. The maximum level of MVE used in fluoropolymers formulations is 7%. Final coated articles are destined to be used at temperatures higher than 200°C for times up to 2 hours.

Previous evaluations (by SCF or AFC):

The substance was first evaluated by the SCF in 2001 (SCF, 2001) and it was classified in List 7.
Available:
inadequate migration data; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells, (positive); gene mutation assay in cultured mammalian cells (negative); *in vivo* micronucleus assay (negative).
Needed:
Clarification concerning initial amount of subject substance in relation to chemical structure of the polymer
Examples of typical food contact materials
Detailed information concerning actual conditions of migration experiments, i.e. whether tests were carried out in a gastight system, dimensions of test samples to justify surface/volume ratio 1
Recovery experiments in food simulants, including migration period.
RIVM/ISS/TNO SDS, July 2000 =CS/PM/3454/22932.
Remark for Commission: need for notification was raised.

Available data used for this evaluation:

Non-toxicity data:
- Intended use of the substance
- Typical examples of application
- Specific migration in 15% ethanol and olive oil with validation data
- Determination of residual content in the food contact material
- Calculated worst case migration

Toxicity data: This aspect was previously evaluated by the SCF in 2001 (SCF, 2001)

Evaluation:

Specific migration experiments in 15% ethanol and olive oil were performed in both single side migration cell and headspace closed vial. A Head Space Gas Chromatographic method with Flame Ionization Detection (HS-GC/FID) was used. The test sample was a homogeneous sheet (500 µm thickness) made of a terpolymer containing 7% MVE as starting comonomer and representing worst case with respect to thickness

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Name of the substance:	PERFLUOROMETHYL PERFLUOROVINYL ETHER

of the actual final products. Recovery and repeatability tests were carried out and described properly. Migration was below the detection limits in all the experiments. However, difficulties in recovery due to high volatility of MVE were reported. Therefore, worst case migration of MVE was calculated on the basis of the residual amount in the test sample, obtained by direct HS-GC/FID determination properly validated. No residual MVE was detected at a detection limit of 14 µg/6dm^2. Assuming 100% migration the calculated worst case migration was less than 14 µg /kg of food. In view of all this, a QMA restriction is deemed suitable for MVE

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

SCF_List: **3**

Restriction: **0.05 mg/kg food**

Remark for Commission: QMA restriction of 0.05 mg/6dm^2 could be more appropriate for enforcement purposes. Only to be used for anti-stick coatings.

Needed data or information: None

References:

- Unpublished data submitted by the petitioner, March 2004
- Opinion of the Scientific Committee on Food on the 12th additional list of monomers and additives for food contact materials , adopted at the 126th SCF meeting, 28 February 2001
http://europa.eu.int/comm/food/fs/sc/scf/out84_en.pdf

Ref. No.:	24903
Name of the substance:	**syrups, hydrolysed starch, hydrogenated**

CAS number: 68425-17-2

Document reference: EFSA/AFC/FCM/182-Rev.0A/24903 (ex 92070) of June 2004

General information: According to the petitioner, the substance "syrups, hydrolysed starch, hydrogenated" is used as a cross-linking agent with Poly acrylic acid (PAA) at a maximum of 1.5% w/w. The PAA coating functions as oxygen and water vapour barrier, used in laminated films as a layer not in direct contact with food.

Previous evaluations (by SCF or AFC): None on the substance itself but two evaluations (SCF 1985 and SCF 1999) on maltitol syrups with different polysaccharide contents.

Available data used for this evaluation:

Non-toxicity data:
- Data on identity, use and authorisation of the substance.
- Data on overall migration

Toxicity data:
- This aspect was evaluated by the SCF in 1985 and 1999

Evaluation: The substance "syrups, hydrolysed starch, hydrogenated" is produced by hydrogenation of hydrolysed corn syrup and is a mixture with the following composition as determined by HPLC with differential refractometer detection:
sorbitol 2-5%,
maltitol 9-14%,
maltotriitol 11-16%,
hydrogenated oligosaccharides 67-76%.
This differs in composition from the already accepted food additive

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Name of the substance:	syrups, hydrolysed starch, hydrogenated

Maltitol Syrup (E 965) by having a higher content of hydrogenated polysaccharides.

The overall migration was measured from a test sample consisting of a polyacrylic acid coating of a thickness less than 1.4 µm, containing 1.5% Polyglycitol Syrup, coated on PET and on the side not in contact with food. The largest overall migration was 1.8 mg/dm^2 equivalent to10.8 mg/kg of food, in 3% acetic acid.

An ADI not specified has been allocated to the maltitol syrup by the SCF (SCF, 1985). Maltitol syrup is an authorised food sweetener listed in the Annex of the European Parliament and Council Directive 94/35/EC.

The SCF (SCF, 1999) also expressed an Opinion on a second maltitol syrup with the following specifications:

- Maltitol…… 50-55%
- Sorbitol…… not more than 2%
- Maltotriitol…….. not defined
- Hydrogenated polysaccharides….. 40-50% containing more than three glucose units

The evaluation was focused on the polysaccharide content of the new product which in this case was higher than in the previously evaluated maltitol syrup, 40-50% as opposed to not more than 30%.

The Committee concluded that hydrogenated starch syrups do not exhibit toxicological effects and the use of the new product did not raise additional safety concerns in relation to existing maltitol syrups

The composition of the product under evaluation here has a higher content (67-76%) of hydrogenated polysaccharides than the maltitol syrup evaluated by the SCF in 1985 for which an ADI "not specified" was allocated. According to the SCF opinion expressed in 1999, a higher content of hydrogenated polysaccharides did not raise any additional toxicological concerns.

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

SCF_List: **3**

Restriction: **In compliance with the purity criteria for maltitol syrup, E 965 (ii)**

Remark for Commission: None

Needed data or information None

References:

- Unpublished data submitted by the petitioner.
- Reports of the SCF, 16th series, 1985

http://europa.eu.int/comm/food/fs/sc/scf/reports/scf_reports_16.pdf

- European Parliament and Council Directive 94/35 on sweeteners for use in foodstuffs.

http://europa.eu.int/eur-lex/en/consleg/pdf/1994/en_1994L0035_do_001.pdf

- Commission Directive 95/31/EC of July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs. OJ L 178, 28.07.1995

http://europa.eu.int/eur-lex/en/consleg/pdf/1995/en_1995L0031_do_001.pdf

- SCF Opinion on a maltitol syrup not covered by the current specifications, SCF/CS/ADD/EDUL/191 final 6/12/9, Annex IV to the minutes of the 119th Plenary meeting.

Ref. No.:	**30340**
Name of the substance:	**12-(Acetoxy)stearic acid, 2,3-bis(acetoxy)propyl ester**
CAS number:	330198-91-9
Document reference:	EFSA/AFC/FCM/116-Rev.IB/30340 of July 2004

General information: According to the petitioner 12-(Acetoxy)stearic acid, 2,3-bis(acetoxy)propyl ester is used mainly as plasticizer in PVC film.

Previous evaluations (by SCF or AFC): The substance, a castor oil derivative, was first evaluated in 2002 by SCF (SCF, 2003) on the basis of two mutagenicity tests, one chromosome aberration assay (incomplete), a 2-week palatability study, a 13-week gavage toxicity study (interpretation not possible) and a peroxisome proliferation study and thus classified in SCF List 7. Because of the high migration, the full core set of toxicity data (unless it can be shown that the substance is metabolised to constituents which occur normally in the diet) was requested.

Available data used for this evaluation:

Non-toxicity data:
- Hydrolysis data in three digestive fluid simulants (complete hydrolysis in intestinal fluid)
- Specific migration from PVC film in 3% acetic acid, 15% ethanol (0.06 mg/kg food) and sunflower oil (62 mg/kg food)

Toxicity data:

Previously evaluated by the SCF and re-evaluated by EFSA:
- gene mutation assays in bacteria
- chromosomal aberration assay in cultured mammalian cells (incomplete)
- gene mutation assay in cultured mammalian cells
- 13-week gavage toxicity study on rats (with further analysis of data)
- peroxisome proliferation
- review of the metabolism of triacylglcerols with specific reference to the test substance

New data submitted to EFSA:
- chromosomal aberration assay in cultured mammalian cells (complete; repeat study)
- 92(93)-day dietary toxicity study on rats
- absorption, distribution, biotransformation and excretion study
- peroxisome proliferation
- an updated review of the metabolism of triacylglcerols with specific reference to the test substance
- a review of the toxicity of 12-hydroxy-octadecanoic acid, 12-acetoxyoctadecanoic acid and the systemic toxicity of acetic acid

Evaluation: Specific migration of 12-(Acetoxy)stearic acid, 2,3-bis(acetoxy)propyl ester into 3% acetic acid and 15% ethanol from PVC film was found to be 0.06 mg/kg food. Migration into sunflower oil was higher and found to be 10.3 mg/dm² or 61.8 mg/kg into food.

12-(Acetoxy)stearic acid, 2,3-bis(acetoxy)propyl ester is not significantly hydrolysed by either saliva simulant or gastric juice simulant. The test substance is extensively hydrolysed *in vitro* by intestinal fluid simulant into glycerol, acetate, 12-hydroxystearic acid and 12-acetoxystearic acid. Most of the total 12-hydroxystearic acid is present as 12-acetoxystearic acid.

An Absorption, Distribution, Metabolism and Excretion (ADME) study was performed with (1),2,3-diacetoxy-propyl (12-[1-

Ref. No.:	30340
Name of the substance:	12-(Acetoxy)stearic acid, 2,3-bis(acetoxy)propyl ester

14C]acetoxy)octadecanoate. The results of this study are consistent with an extensive hydrolytic cleavage of the 12-acetyl ester bonds from the labelled test substance. The process *in vivo* requires, however, much longer time before the amount of labelled compound is metabolised. Nevertheless, it results in the catabolism of the majority (77 % within 72 hours) of the released ^{14}C-labelled acetate to $^{14}CO_2$. The remainder of the labelled test substance is excreted in the faeces and in the urine, except for a small part retained in the carcass probably due to re-incorporation into ^{14}C acetate.

The test substance produced negative results in assays for the induction of gene mutations in bacteria and cultured mammalian cells. Since the first chromosomal aberration study in mammalian cells submitted was incomplete, a full study was performed which was negative. In summary the substance is considered non-genotoxic.

In a 13-week sub-chronic toxicity study in SD rats involving administration by gavage of the test compound at doses of 3, 8.5 and 20 ml/kg bw/day a number of significant changes in biological parameters (food consumption, haematology, clinical chemistry, organ weights and histopathology; e.g. the heart) were reported, possibly indicating a disturbed metabolism at high dose levels (20 ml/kg bw/day). However, the administration of corn oil to the control group resulted in a number of biological changes, which presented difficulties in interpreting the outcome of the 13-week toxicity study. The results from this study did not allow the derivation of a NOAEL for the test substance and therefore could not be used in the overall conclusion.

Adverse effects could not be confirmed in a recent 92 (93) day oral toxicity study on rats dosed up to 5000 mg of test substance/kg bw/day in the diet. This study did not result in any adverse signs of toxicity. The NOAEL was considered to be 5000 mg/kg bw/day for males and females. Therefore, in the absence of adverse heart effects, seen in the 13-week gavage study, the test substance is considered not to give rise to any adverse effects up to the dose level of 5000 mg/kg/day when administered in the diet. Considering this NOAEL of 5000 mg/kg bw/day compared to the maximum theoretical intake of 1 mg/kg bw/day derived from the overall migration limit of 60 mg/kg of food (equal to 1mg/kg bw for an individual of 60 kg consuming 1 kg of packaged food) would leave a large margin of safety for its intended use. This conclusion stands even when considering that this NOAEL is established in a 90-day subchronic oral toxicity study in the absence of a 2-year oral toxicity study requested by the SCF Guidelines.

The substance was considered not active as a peroxisome proliferator.

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

SCF_List: **3**

Restriction: **None**

Remark for Commission: FRF is applicable

Needed data or information None

References:

- Unpublished data submitted by the petitioner, September and October 2003 and January and March 2004
- Opinion of the Scientific Committee on Food on the 21st additional list of monomers and additives for food contact materials (5 March 2003)
  http://europa.eu.int/comm/food/fs/sc/scf/out172_en.pdf

Ref. No.:	31500
Name of the substance:	2-Ethylhexyl acrylate - acrylic acid copolymer
CAS number:	25134-51-4
Document reference:	EFSA/AFC/FCM/212-Rev.IA/31500 of September 2004
General information:	According to the petitioner the copolymer of acrylic acid and 2-ethylhexyl acrylate is a suspending agent, used up to 0.4 % in the suspension polymerisation of all types of polystyrene. The average molecular weight is given as 1.600.000 D, the percentage of constituents with MW <1000 D is < 0.6 %.
Previous evaluations (by SCF or AFC):	The substance was evaluated by the SCF in 2002 (SCF, 2002). The average MW of the copolymer is > 1000 D. Therefore, no toxicological data on the copolymer itself are needed. One of the starting substances (acrylic acid) is in List 2 (Group t-TDI: 0.1 mg/kg bw) whereas the other (2-ethylhexyl acrylate) is in List 7 (needed: *in vivo* UDS assay). Classification: List 7 (SCF SDS CS/PM/3931/31500, January 2002)
Available data used for this evaluation:	
Non-toxicity data:	Data on use, molecular weight distribution (incomplete), calculation of worst case migration
Toxicity data:	see above, opinion on acrylic acid, 2-ethylhexyl ester (REF No 11500) for information on *in vivo* UDS assay leading to classification of the substance in List 3.
Evaluation:	Due to the high average MW of the copolymer no toxicological data on the copolymer itself are needed. The starting substances are in List 2 (acrylic acid, Group t-TDI: 0.1 mg/kg b.w.) and in List 3 (2-ethylhexyl acrylate, Restriction 0.05 mg/kg food).
Conclusion:	
SCF_List:	**3**
Restriction:	**Group restriction 6mg/kg food for acrylic acid and 0.05 mg/kg food for acrylic acid, 2-ethylhexyl ester**
Remark for Commission: Needed data or information	
References:	- Unpublished data submitted by the petitioner (26-09-2001). - SDS EFSA/AFC/FCM/213-Rev.IIIA/11500 on acrylic acid, 2-ethylhexyl ester (September 2004) - Opinion of the Scientific Committee on Food on the 20th additional list of monomers and additives for food contact materials (25 September 2002) http://europa.eu.int/comm/food/fs/sc/scf/out142_en.pdf

Ref. No.:	43480
Name of the substance:	**Charcoal, activated**
CAS number:	**64365-11-3**
Document reference:	SDS EFSA/AFC/FCM/309-Rev.0B/43480 of September 2004
General information:	According to the petitioner, activated charcoal is used as an IR (infra-red) absorbent and dye stuff in polyethylene terephthalate (PET)
Previous evaluations (by SCF or AFC):	Vegetable carbon was evaluated as a direct food additive by SCF in 1977 and was found acceptable for general use when devoid of polycyclic

Ref. No.:	43480
Name of the substance:	Charcoal, activated

aromatic hydrocarbons (SCF 1977).

Available data used for this evaluation:

Non-toxicity data: -Information on identity, chemical and physical data, use and authorization
- Information on the presence of polycyclic hydrocarbons

Toxicity data: - The previous SCF evaluation of vegetable carbon as a direct food additive was the basis for the evaluation.(SCF, 1977)

Evaluation: Activated charcoal is requested as an IR absorbent additive and a dye stuff in PET at a concentration of 10 mg/kg PET. The petitioner has no method available to determine the migration nor the content of the substance in the polymer. The Panel was independently informed that no such method exists. Activated charcoal is frequently used for medical purposes and is therefore unlikely to cause any problem when applied at the very low level of 10 mg/kg in PET.
The charcoal activated complies with the purity criteria including those for heavy metals as laid down for vegetable carbon (E153) used as a food additive, with the exception of the ash content. The ash content of the charcoal under investigation is 10% whereas in the charcoal used in food it should be maximum 4%. The high ash content is due to omission of an acid washing step normally used in production of food additive grade vegetable carbon. Due to the higher ash content the use in food contact materials should be restricted to the requested maximum amount of 10 mg/kg polymer.

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

SCF_List: **3**

Restriction: **Only to be used in polyethylene terephthalate (PET) at a maximum amount of 10 mg/kg polymer.**
Purity criteria: in compliance with vegetable carbon (E 153), except for the ash content which can be up to 10%

Remark for Commission: Needed data or information

References:

- Unpublished data submitted by the petitioner.

- SCF 1977. Reports of the Scientific Committee for Food, Fourth Series, 1977 (http://europa.eu.int/comm/food/fs/sc/scf/reports/scf_reports_04.pdf)
- Commission Directive 95/45/EC, laying down specific purity criteria for use in foodstuffs http://europa.eu.int/eur-lex/en/consleg/pdf/1995/en_1995L0045_do_001.pdf

Ref. No.:	77370 (ex 77850)
Name of the substance:	Polyethyleneglycol-30 dipolyhydroxystearate (PEG-30 dipolyhydroxystearate)

CAS number: 70142-34-6
Document reference: EFSA/AFC/FCM/89-Rev.IA/77370 (ex 77850) of June 2004

General information: According to the petitioner, this substance is a polymeric additive and is used as an emulsifier in the manufacture of expanded polystyrene up to

0.5%. The final articles are intended for use with all types of foodstuffs from cold storage and long term storage at room temperature up to brief contact at temperatures of 75 to 80°C

Previous evaluations (by SCF or AFC): The substance was first evaluated by the SCF in 2002 (SCF, 2002). The molecular weight is given as 6970, the percentage of constituents with MW <1000 D is 0.22%. Data on molecular weight distribution and on MS spectra were incomplete and following data were requested:

- molecular weight distribution curve (differential and cumulative)
- details on MS spectra
- clarification that there is inconsistency in the data from the petitioner in respect to the solubility of the test compound in various solvents.

Available data used for this evaluation:

Non-toxicity data: Data on identity, physical and chemical data, use, authorisation
New data on MW distribution, MS spectra and solubility

Toxicity data: -

Evaluation: All data for polymeric additives according to the Note for Guidance are given. The molecular weight of Polyethyleneglycol-30 dipolyhydroxystearate (PEG-30 dipolyhydroxystearate) is given as 6970 D, the percentage of constituents with MW <1000 D is 0.22 %.
The average MW of the copolymer is > 1000 D and the starting substances 12-hydroxystearic acid and polyethyleneglycol are respectively in List 3 and List 2 without any special restriction. (SCF, 2003 and 1978) Therefore, no toxicological data are needed.

Conclusion: Based on the abovementioned data the substance is classified:

SCF_List: 3
Restriction: none
Remark for Commission: none
Needed data or information none

References:

- Unpublished data submitted by the petitioner
- Opinion of the Scientific Committee on Food on the 20th additional list of monomers and additives for food contact materials, September 2002
  http://europa.eu.int/comm/food/fs/sc/scf/out142_en.pdf
- Opinion of the Scientific Committee on Food on the 23rd additional list of monomers and additives for food contact materials, April 2003
  http://europa.eu.int/comm/food/fs/sc/scf/out181_en.pdf
- Reports of the SCF, sixth series, 1978
  http://europa.eu.int/comm/food/fs/sc/scf/reports/scf_reports_06.pdf

Ref. No.:	**85950**
Name of the substance:	**Silicic acid, magnesium-sodium-fluoride salt**

CAS number: 037296-97-2
Document reference: SDS CS/PM/4102-Rev.0E/85950 of July 2004

General information: According to the petitioner silicic acid, magnesium-sodium-fluoride salt is used as a filler in plastics not in direct contact with the foodstuff.

Previous evaluations (by None

Ref. No.:	**85950**
Name of the substance:	**Silicic acid, magnesium-sodium-fluoride salt**

SCF or AFC):

Available data used for this evaluation:

Non-toxicity data: General information on the identity, physical and chemical properties, use, authorisation and migration data in 3% acetic acid and 10 % ethanol

Toxicity data:
- gene mutation assay in bacteria
- chromosomal aberration assay in cultured mammalian cells
- gene mutation assay in cultured mammalian cells
- Council Directive 1998/83/EC, OJ L 330, 5.12.1998
- SCF Opinion, 25th Series, 1991 (on silicates)

Evaluation:

Migration of fluoride ions was determined from a multi layer system composed of 20 µm oriented polypropylene (food contact layer), 0.3 µm primer (polyester resin/polyisocyanate) and 2 µm of coating (ethylene vinylalcohol copolymer) containing 20% silicic acid, magnesium-sodium-fluoride salt. Migration experiments were conducted using 3% acetic acid or 10% ethanol as simulants and contact conditions of 10 days at 40ºC or 2 h at 100ºC. Migration of fluoride was not detectable at a detection level of 0.12 mg/kg food simulant. Recovery of fluoride ions spiked as NaF from 3% acetic acid and 10% ethanol (after 10 days at 40ºC) was 87 ± 5.2% and 107 ± 1.5% respectively. Migration in fat simulant was not determined as aqueous simulants are considered worst case simulants.

Magnesium-sodium-fluoride-silicate was found to be not mutagenic in a gene mutation assay in bacteria, a chromosomal aberration assay in cultured mammalian cells and a gene mutation assay in cultured mammalian cells.

Silicates have been evaluated by the SCF in 1991 and have been allocated an ADI not specified (SCF, 1991).

The upper limit for fluoride in water for human consumption is 1.5 mg/l (Council Directive 1998/83/EC) based on increasing risk of dental fluorosis, and progressively higher concentrations lead to increasing risks of skeletal fluorosis (IPCS, 2002)).

Taking into account the above mentioned data, the Panel considers that a concentration of fluoride in foods, migrating from Food Contact Materials, not exceeding the 10% of the upper limit in drinking water poses no risk to human health.

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

SCF_List: **3**

Restriction: **0.15 mg fluoride/kg food**

Remark for Commission: This is a Group Restriction. No direct contact intended. Restriction may include this condition of use if necessary.

Needed data or information: None

References:

- Unpublished data submitted by the petitioner
- Council Directive 1998/83/EC, OJ L 330, 5.12.1998 http://europa.eu.int/eurlex/en/consleg/pdf/1998/en_1998L0083_do_001.pdf
- SCF Opinion, 25th Series, 1991 http://europa.eu.int/comm/food/fs/sc/scf/reports/scf_reports_25.pdf
- IPCS (2002) Fluorides, Geneva, WHO (Environmental Health Criteria 227)

Ref. No.:	95265
Name of the substance:	**1,3,5-Tris(4-benzoylphenyl) benzene**
CAS number:	227099-60-7
Document reference:	*EFSA/AFC/FCM/238-Rev.IA/95265 of June 2004*

General information: According to the petitioner, 1,3,5-Tris(4-benzoylphenyl)benzene is a photoinitiator, which in the presence of a catalyst, activates an oxygen scavenging polymer.

Previous evaluations (by SCF or AFC): The substance was evaluated by the SCF in 2003 (SCF, 2003) and it was classified in List 7 due to inadequate analytical data. New analytical data were submitted in 2004.

Available data used for this evaluation:

Non-toxicity data:

- Data on identity, physical and chemical properties, use and authorisation of the substance.
- Inadequate migration data from multi-layer film samples; maximum migration 38.9 μg/kg food in olive oil. However these data could not be evaluated properly.
- Migration of the test substance up to 47 μg/kg into olive oil (New)
- Evidence of extensive transformation of the test substance when films are 'triggered' with UV light. (New)
- A theoretical evaluation of the likely transformation products (New)
- Limited experimental evidence on the absence of migration of the transformation products into food simulants (New)

Toxicity data: Ames assay (negative); in-vitro chromosomal aberration assay (negative); in vitro mammalian cell gene mutation assay (negative). This aspect was evaluated by the SCF in 2003.

Evaluation: Specific migration of 1,3,5-Tris(4-benzoylphenyl)benzene into 10% ethanol and 3% acetic acid was found to be not-detectable or < 23.25 μg/kg food. In olive oil, maximum migration was found to be 38.9 μg/kg food.

Additional recovery tests have been conducted which demonstrate that the test substance is stable during the migration tests and can be recovered. Two additional films have been tested for migration and the test methods have been described adequately. There was no detectable migration of the test substance into 3% acetic acid and 15% ethanol under conditions of 10 days at 40ºC, using a method of analysis with a detection limit of 4.8 μg/kg. Migration into olive oil, with test conditions of 10 days at 40ºC, was 47 μg/kg.

Reaction of the test substance under photo initiation conditions was extensive. For one film with a starting content of 801 mg/kg the residual content after photo-activation was 182 mg/kg. For a second film, the starting content was 465 mg/kg and the residual content after photo-activation was just 22 mg/kg. There was no evidence of any migration of photodegradation products into the food simulants, with limits of detection estimated to be 5 μg/kg for the aqueous simulants and 26 μg/kg for olive oil. A description of the photochemistry expected for the test substance is provided and this concludes that reaction is expected to render the material significantly less extractable than the starting compound. The reaction products are expected to be high molecular weight substances and/or polymer bound, and are therefore unlikely to be of genotoxic concern.

1,3,5-Tris(4-benzoylphenyl)benzene did not show genotoxic properties in

Ref. No.:	95265
Name of the substance:	1,3,5-Tris(4-benzoylphenyl) benzene

the three *in vitro* mutagenicity studies required by the SCF Guidelines on food contact materials

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

SCF_List: **3**

Restriction: **0.05 mg/kg food**

Remark for Commission: None

Needed data or information None

References:

- Opinion of the Scientific Committee on Food on the 22nd additional list of monomers and additives for food contact materials (4 April 2003) http://europa.eu.int/comm/food/fs/sc/scf/out180_en.pdf
- Unpublished data submitted by the petitioner, (October 2000 and February 2004)

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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
QMA: Maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm^2 of the surface in contact with foodstuffs
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.