European Food Safety Authority

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SCIENTIFIC OPINION

24th list of substances for food contact materials[1]

Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF)

Question N° EFSA-Q-2006-129, EFSA-Q-2007-009, EFSA-Q-2007-032, EFSA-Q-2005-245, EFSA-Q-2008-686, EFSA-Q-2008-683, EFSA-Q-2008-698

Adopted on 17 June 2009

PANEL MEMBERS*

Arturo Anadón, David Bell, Mona-Lise Binderup, Wilfried Bursch, Laurence Castle, Riccardo Crebelli, Karl-Heinz Engel, Roland Franz, Nathalie Gontard, Thomas Haertlé, Trine Husøy, Klaus-Dieter Jany, Catherine Leclercq, Jean-Claude Lhuguenot, Wim Mennes, Maria Rosaria Milana, Karla Pfaff, Kettil Svensson, Fidel Toldrá, Rosemary Waring, Detlef Wölfle.

SUMMARY

Within the general task of evaluating substances intended for use in materials in contact with food according to the Regulation (EC) No.1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with foodstuffs, the CEF Panel evaluated the following substances:

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* K. Pfaff and D. Wölfle declared an interest for the substance REF. No. 13453, as they have provided scientific advice to their Ministry. This was not considered as a conflict of interest and they were invited to participate in the discussion.
M.-L. Binderup declared an interest for the substances REF. No. 95500 as she had prepared the evaluation report of the substance under contract with EFSA. This was considered as a conflict of interest because she could not act at the same time as a representative of the contractor and a member of the Panel with voting rights. She was allowed to stay in the room to answer questions specifically addressed to her but did not participate in the discussion of the opinion. Another Panel member presented the draft opinion.

[1] For citation purposes: Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF) on 24th list of substances for food contact materials. *The EFSA Journal* (2009) 1157-1163, 1-27.

EFSA Question Number:	EFSA-Q-2006-129
Ref. No.:	13453, 13455, 13456, 13457
Name of the substance:	Bis(hydroxyphenyl)methane
CAS number:	001333-16-0, 002467-02-9, 002467-03-0, 000620-92-8
SCF_List:	3
Restriction:	The use of the substance as a precursor for BFDGE is restricted already by the Commission Regulation No 1895/2005 only to the manufacture of coatings applied in large volume containers for repeated use at ambient temperature.
Remark for Commission:	None

EFSA Question Number:	EFSA-Q-2007-009
Ref. No.:	31335
Name of the substance:	Acids, fatty (C8-C22) from animal or vegetable fats and oils, esters with branched alcohols, aliphatic, monohydric, saturated, primary (C3-C22)
CAS number:	-
SCF_List:	3
Restriction:	None
Remark for Commission:	None

EFSA Question Number:	EFSA-Q-2007-032
Ref. No. :	31336
Name of the substance:	Acids, fatty (C8-C22) from animal or vegetable fats and oils, esters with alcohols, linear, aliphatic, monohydric, saturated, primary (C1-C22)
CAS number:	-
SCF_List:	3
Restriction:	None
Remark for Commission:	None

EFSA Question Number:	EFSA-Q-2005-245
Ref. No. :	31348
Name of the substance:	Acids, fatty (C8-C22), esters with pentaerythritol
CAS number:	85116-93-4
SCF_List:	3
Restriction:	None
Remark for Commission:	None

EFSA Question Number:	EFSA-Q-2008-686
Ref. No. :	71980
Name of the substance:	Perfluoro[2-(poly(n-propoxy))propanoic acid]
CAS number:	51798-33-5
SCF_List:	3
Restriction:	Only to be used in the polymerization of fluoropolymers that are processed at temperatures at or above 265°C and are for repeated use articles
Remark for Commission:	None

EFSA Question Number:	EFSA-Q-2008-683
Ref. No. :	71990
Name of the substance:	Perfluoro[2-(n-propoxy)propanoic acid]
CAS number:	13252-13-6
SCF_List:	3
Restriction:	Only to be used in the polymerization of fluoropolymers that are processed at temperatures at or above 265°C and are for repeated use articles
Remark for Commission:	None

EFSA Question Number:	EFSA-Q-2008-698
Ref. No.:	95500
Name of the substance:	N,N',N''-tris(2-methylcyclohexyl)-1,2,3-propane-tricarboxamide
CAS number:	160535-46-6
SCF_List:	3
Restriction:	5 mg/kg food
Remark for Commission:	None

KEYWORDS

Food Contact Materials, Plastics, Additives, Ref. No. 13453, 13455, 13456, 13457, CAS number 001333-16-0, 002467-02-9, 002467-03-0, 000620-92-8, bis(hydroxyphenyl)methane; Ref. No. 31335, acids, fatty (C8-C22) from animal or vegetable fats and oils, esters with branched alcohols, aliphatic, monohydric, saturated, primary (C3-C22); Ref. No. 31336, acids, fatty (C8-C22) from animal or vegetable fats and oils, esters with alcohols, linear, aliphatic, monohydric, saturated, primary (C1-C22); Ref. No. 31348, CAS number 85116-93-4, acids, fatty (C8-C22), esters with pentaerythritol; Ref. No. 71980, CAS number 51798-33-5, perfluoro[2-(poly(n-propoxy))propanoic acid]; Ref. No. 71990, CAS number 13252-13-6, perfluoro[2-(n-propoxy)propanoic acid]; Ref. No. 95500, CAS number 160535-46-6, N,N',N''-tris(2-methylcyclohexyl)-1,2,3-propane-tricarboxamide.

BACKGROUND

Before a substance is authorised to be used in food contact materials and is included in a positive list EFSA´s opinion on its safety is required. This procedure has been established in Articles 8 and 9 of the Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food[2].

TERMS OF REFERENCE

The EFSA is required by Article 10 of Regulation (EC) No. 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food to carry out risk assessments on the risks originating from the migration of substances from food contact materials into food and deliver a scientific opinion on:

1. new substances intended to be used in food contact materials before their authorisation and inclusion in a positive list;
2. substances which are already authorised in the framework of Regulation (EC) No. 1935/2004 but need to be re-evaluated.

ACKNOWLEDGEMENTS*

The European Food Safety Authority wishes to thank Herman Autrup, Mona-Lise Binderup, Laurence Castle, Riccardo Crebelli, Wolfgang Dekant, Roland Franz, Nathalie Gontard, Sander Koster, Eugenia Lampi, Jean-Claude Lhuguenot, François Xavier Malcata, Maria Rosaria Milana, Karla Pfaff, Tjoena Siere, Kettil Svensson, Paul Tobback, Detlef Wölfle and Esther Zondervan for their contribution to the draft opinions.

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* M.-L. Binderup declared an interest for the substance REF. No. 95500, as she had prepared the evaluation report of the substance under contract with EFSA. She presented the evaluation result and another member of the wg was appointed as rapporteur to present it to the Panel.
S. Koster declared an interest for the substance REF. No. 95500 because his Institute had performed some experimental studies for the substance. This was considered as a conflict of interest and he left the room during the discussion.

[2] This Regulation replaces Directive 89/109/EEC of 21 December 1988, OJ L 40, 11.2.1989, P.38

ASSESSMENT

Within this general task the Scientific Panel on food contact materials, enzymes, flavourings and processing aids (CEF) 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". Since in the past the evaluation of substances used in food contact materials was undertaken by the Scientific Committee on Food (SCF), the same system of classification into a "SCF list" is retained for uniformity purposes. The definitions of the various SCF lists and the abbreviations used are given in the appendix.
The studies submitted for evaluation followed the SCF guidelines for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation (http://ec.europa.eu/food/fs/sc/scf/out82_en.pdf).

EFSA-Q-Nr.:	**EFSA-Q-2006-129**
Ref. No.:	**13453, 13455, 13456, 13457**
Name of the substance:	**Bis(hydroxyphenyl)methane**
CAS number:	001333-16-0, 002467-02-9, 002467-03-0, 000620-92-8
Document reference:	SDS EFSA/CEF/FCM/1339-Rev.IIIC/13453 of June 2009
General information:	According to the petitioner, the substance "bis(hydroxyphenyl)methane" (Bisphenol F) with CAS No 001333-16-0 is a mixture of the 2,2'-, 2,4'- and 4,4'-isomers with corresponding CAS Nos 002467-02-9, 002467-03-0, 000620-92-8. It is intended to be used as a precursor to make bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ether (BFDGE) which is then used as a monomer in the manufacture of epoxy resins used exclusively as coatings on large volume containers (EC, 2005). These containers are intended to be used in contact with all types of foodstuffs at ambient temperature and for repeat uses with a surface to volume ratio of no more than 0.5 dm^2/kg.
Previous evaluations (by SCF or AFC):	The substance was evaluated by the Scientific Committee on Food (SCF) in 2000 (EC, 2000 a) and 2002 (EC, 2002). In the latest SCF opinion, it was classified in SCF_List 7 with the request of data on the determination of bisphenol F in a typical final product or into food simulants from a typical final product (http://ec.europa.eu/food/fs/sc/scf/out172_en.pdf).
Available data	

EFSA-Q-Nr.:	**EFSA-Q-2006-129**
Ref. No.:	**13453, 13455, 13456, 13457**
Name of the substance:	**Bis(hydroxyphenyl)methane**

used for this evaluation:

Non-toxicity data:
- Data on identity
- Data on physical and chemical properties
- Data on the intended use and authorisation of the substance
- Data on specific migration of the substance
- Data on residual content

Toxicity data:
- Gene mutation in bacteria tests
- *In vitro* mammalian chromosomal aberration test *In vitro* mammalian cell gene mutations test
- *In vitro co*met assay
- *In vitro* micronucleus test
- *In vivo* unscheduled DNA synthesis (UDS) assay
- Data on biotransformation *in vitro*
- Data on absorption, distribution, metabolism and excretion in rat
- 28-day oral toxicity study
- Data on endocrine activity *in vitro* and *in vivo*

Evaluation:

Glass panels were coated with an epoxy resin made using BFDGE and cured to represent the normal production process. The coated panels were tested for the migration of bis(hydroxyphenyl)methane into water, 10 % ethanol, 3% acetic acid and sunflower oil for 10 days at 40°C. Using the worst case surface/volume ratio of 0.5 dm^2/kg the test results indicated a migration level on first use of 4 µg/kg into 3% acetic acid and 1 µg/kg or lower into the other 3 simulants. Considering the repeated use intended for the large storage containers the migration in actual use during their service life is expected to be lower than these figures.

The substance was not mutagenic in bacteria and not clastogenic in mammalian cells *in vitro*. In an *in vitro* mammalian cell gene mutations test, significant increases in mutant frequencies were only observed with metabolic activation at doses exceeding the maximum recommended toxicity level, while no mutagenic activity was observed in absence of metabolic activation. In tests in hepatoma cells proficient for xenobiotic metabolism, the application of bis(hydroxyphenyl)methane up to the limit of solubility resulted in an increased in primary DNA damage measured by the comet assay but this did not lead to an incresase in micronuclei, measured in the same cells. Clearly negative results were obtained in an *in vivo* unscheduled

EFSA-Q-Nr.:	EFSA-Q-2006-129
Ref. No.:	13453, 13455, 13456, 13457
Name of the substance:	Bis(hydroxyphenyl)methane

DNA synthesis (UDS) assay in rat liver. Based on these experimental data, bis(hydroxyphenyl)methane is considered as non-genotoxic.
Bis(hydroxyphenyl)methane is efficiently absorbed and metabolized *in vivo*, especially to sulfate conjugate. Urine is the main excretion route followed by bile, which may lead to enterohepatic circulation (Cabaton *et al.*, 2006). Studies on biotransformation *in vitro* indicate that hydroxylation by cytochrome P450, followed by glucuronidation and sulfatation, is a major metabolic pathway (Cabaton *et al.*, 2008).

Tests *in vitro* indicate that bis(hydroxyphenyl)methane can exert an estrogenic effect, competing with 17β-estradiol for the binding to the estrogenic receptor alpha and beta (Perez *et al.*, 1998; Strohheker *et al.*, 2004; Cabaton *et al.*, 2009). In these assays bis(hydroxyphenyl)methane was approx. 20,000-fold less active than 17β-estradiol. Tests *in vitro* also indicate weak anti-androgenic activity of the compound (Strohheker *et al.*, 2004; Kitamura *et al.*, 2005; Catabon et al., 2009). In tests for endocrine disruption *in vivo*, bis(hydroxyphenyl)methane exerted estrogenic activity in the immature rat uterotrophic assay when given by gavage at doses ≥ 100 mg/kg bw/day for four days (Stroheker *et al.*, 2003) or injected subcutaneously at 200 mg/kg bw (Yamasaki *et al.*, 2002), while no androgen agonistic or antagonistic activity was observed after ten daily oral administrations at doses up to 1000 mg/kg bw (Yamasaki *et al.*, 2003). In a modified 28-day oral toxicity study in rats, proposed as screening test for endocrine disruptors (draft "Enhanced OECD Test Guideline 407"), no estrogen-mediated toxic effects of bis(hydroxyphenyl)methane were detected, while increased liver weight, with no histological alterations, was observed at the highest administered dose of 500 mg/kg bw (Higashihara *et al.*, 2007).
Based on the above experimental results, no effects on fertility are anticipated at the levels of exposure resulting from the very restricted use, i.e. coatings for large volume containers intended for repeated use.

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

SCF_List: **3**

Restriction: **The use of the substance as a precursor for BFDGE is restricted already by the Commission Regulation No 1895/2005 only to the manufacture of coatings applied in large volume containers for repeated use at ambient temperature.**

Remark for Commission: None

EFSA-Q-Nr.:	**EFSA-Q-2006-129**
Ref. No.:	**13453, 13455, 13456, 13457**
Name of the substance:	**Bis(hydroxyphenyl)methane**

Needed data or information: None

References:

- Unpublished data submitted by the petitioner in September 2006 and August 2008.
- Cabaton N., Chagnon M-C, Lhuguenot J-C, Cravedi J-P, and Zalko D., 2006. Disposition and Metabolic Profiling of Bisphenol F in Pregnant and Nonpregnant Rats; J. Agric. Food Chem. 54: 10307-10314.
- Cabaton N., Zalko D., Rathahao E., Canlet C., Delous G., Chagnon M-C., Cravedi J-P, Perdu E., 2008. Biotransformation of bisphenol F by human and rat liver subcellular fractions. Toxicology in Vitro 22: 1697–1704.
- Cabaton N., Dumont C., Severin I., Perdu E., Zalko D., Cherkaoui-Malki M. and Chanon M-C, 2009. Genotoxic and endocrine activities of bis(hydroxyphenyl)methane (bisphenol F) and its derivatives in the HepG2 cell line. Toxicology 255 (2009) 15–24.
- EC (European Commission), 2005. Commission regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.
- EC (European Commission), 2002. Opinion of the Scientific Committee on Food on the 21st additional list of monomers and additives for food contact materials (adopted by the SCF on 5 March 2003); http://ec.europa.eu/food/fs/sc/scf/out172_en.pdf.
- EC (European Commission), 2000 a. Opinion of the Scientific Committee on Food on the 10th additional list of monomers and additives for food contact materials (adopted by the SCF on 22 June 2000); http://europa.eu.int/comm/food/fs/sc/scf/out62_en.pdf.
- EC (European Commission), 2000 b. Opinion of the Scientific Committee on Food on the 11th additional list of monomers and additives for food contact materials (expressed on 19 October 2000); http://www.europa.eu.int/comm/food/fs/sc/scf/out76_en.pdf.
- EFSA (European Food Safety Authority), 2005. Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to Epoxy Phenolic Novolac Resins (NOGE), Question N° EFSA-Q-2004-158, Adopted on 6 October 2005; http://www.efsa.europa.eu/EFSA/efsa_locale-

EFSA-Q-Nr.:	**EFSA-Q-2006-129**
Ref. No.:	**13453, 13455, 13456, 13457**
Name of the substance:	**Bis(hydroxyphenyl)methane**

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- Higashihara N., Shiraishi K., Miyata K., Oshima Y., Minobe Y., Yamasaki K., 2007. Subacute oral toxicity study of bisphenol F based on the draft protocol for the "Enhanced OECD Test Guideline no. 407". Arch Toxicol 81: 825–832.
- Kitamura S., Suzuki T., Sanoh S., Kohta R., Jinno N., Sugihara K., Yoshihara S., Fujimoto N., Watanabe H., Ohta S., 2005. Comparative Study of the Endocrine-Disrupting Activity of Bisphenol A and 19 Related Compounds. Toxicological Sciences 84: 249–259.
- Perez P., Pulgar R., Olea-Serrano F., Villabona M., Rivas A., Metzler M., Pedraza V., Olea N., 1998. The estrogenicity of bisphenol A-related diphelylalkanes with various substituents at the central carbon and the hydroxy groups. Environmental Health Perspectives 106: 167-174.
- Stroheker T., Picard K., Lhuguenot J.C., Canivenc-Lavier M.C., Chagnon M.C., 2004. Steroid activities comparison of natural and food wrap compounds in human breast cancer cell lines. Food and Chemical Toxicology 42: 887–897.
- Stroheker T, Chagnon MC, Pinnert MF, Berges R, Canivenc-Lavier MC., 2003. Estrogenic effects of food wrap packaging xenoestrogens and flavonoids in female Wistar rats: a comparative study. Reprod Toxicology: 17:421-32
- Yamasaki K., Takeyoshi M., Sawaki M., Imatanaka N., Shinoda K., Takatsuki M., 2003. Immature rat uterotrophic assay of 18 chemicals and Hershberger assay of 30 chemicals. Toxicology: 183:93-115.
- Yamasaki K., Takeyoshi M., Yakabe Y., Sawaki M., Imatanaka N., Takatsuki M., 2002. Comparison of reporter gene assay and immature rat uterotrophic assay of twenty-three chemicals. Toxicology: 170:21-30.

EFSA-Q-Nr.:	**EFSA-Q-2007-009**
Ref. No.:	**31335**
Name of the substance:	**Acids, fatty (C8-C22) from animal or vegetable fats and oils, esters with branched alcohols, aliphatic, monohydric, saturated, primary (C3-C22)**

CAS number: -
Document reference: SDS EFSA/CEF/FCM/933-Rev.IID/31335 of June 2009

General information: According to the petitioner, the substance "acids, fatty (C8-C22) from animal or vegetable fats and oils, esters with branched alcohols, aliphatic, monohydric, saturated, primary (C3-C22)" is intended to be used in the production of various types of plastics materials. In particular, these fatty acid esters are used as release agents, lubricants, and in some instances as plasticizers. Typical use levels are 0.1-1.5% w/w. Finished articles are intended to be used in contact with all types of foodstuffs.

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

Available data used for this evaluation:

Non-toxicity data:
- Data on identity
- Data on physical and chemical properties
- Data on use and authorisation
- Data on migration
- Data on residual content of the substance

Toxicity data: For a range of representative compounds covered by the application:
- Bacterial gene mutation test
- *In vitro* mammalian chromosome aberration test
- *In vitro* mammalian cell gene mutation test
- 90-day oral toxicity study
- Reproduction/teratogenicity studies
- Considerations on biotransformation, excretion and potential accumulation

Evaluation: Commercial products are defined mixtures of esters of linear fatty acids (C8-C22) with branched alcohols, aliphatic, monohydric, saturated, primary (C3-C22).
The physical properties may differ depending on the fatty acid chain length and the alcohol hindrance and the chain length. The calculated log Po/w values were higher than 8 for representative esters (esters of

EFSA-Q-Nr.:	EFSA-Q-2007-009
Ref. No.:	31335
Name of the substance:	Acids, fatty (C8-C22) from animal or vegetable fats and oils, esters with branched alcohols, aliphatic, monohydric, saturated, primary (C3-C22)

iso- C4, C13 and C20 alcohol with fatty acid (C16-C18)).
Specific migration of the substance was calculated by migration modelling for several polymers containing the substance with use levels in the range from 0.5% to 1.5%. From typical scenarios presented by the petitioner with different polymer thicknesses and use levels, migration after 10 days at 40°C was calculated to be up to 27 mg/kg food. On the basis of the obtained results, the Panel concluded that from polyolefins in contact with fatty foods, migration in the conditions of use can correspond up to 100% transfer of the substance contained in the polymer and may approach or even exceed the overall migration limit.

The submitted data on representative esters indicated that fatty acid esters with branched alcohols did not induce mutagenicity in bacteria and did not induce mutagenicity or chromosomal aberration in mammalian cells. Therefore, the compounds covered by the application can be considered as non-genotoxic.
Regarding repeated-dose toxicity, the available data indicate only a low potential for toxicity with a NOAEL of 300 mg/kg bw/day for a structural representative ester (90-day study with propylheptyl caprylate). This NOAEL is based on a severe liver enlargement (up to 30%).
Some branched chain aliphatic acids (2-propylpentanoic acid, 2-ethylhexanoic acid, 2-propylhexanoic acid) have been demonstrated to be teratogenic in rats and in rabbits. Such compounds may be formed as metabolites of fatty acid esters with the corresponding alcohols. However, a model compound (fatty acids (C16-C18) esterified selectively with 2-ethylhexanol), did not induce developmental toxicity when applied at maternal doses of up to 1000 mg/kg bw/day.
Enzymatic hydrolysis rate is available for stearic acid, 2-octyldodecyl ester, which is representative of the compounds covered by the application. The reported value is equivalent to the hydrolysis rates of substances having a hindered ester bond and known to be efficiently cleaved by human lipases and esterases, e.g. di(2-ethylhexyl)phthalate. Consequently, it is expected that esters of long chain alcohols (LCA) including branched chains will be efficiently cleaved in humans to their component alcohols and carboxylic acids. The aliphatic primary alcohols are oxidized to their corresponding carboxylic acids, which

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Ref. No.:	31335
Name of the substance:	Acids, fatty (C8-C22) from animal or vegetable fats and oils, esters with branched alcohols, aliphatic, monohydric, saturated, primary (C3-C22)

are either conjugated and excreted in the urine, or undergo ß-oxidation and cleavage. The aliphatic linear saturated carboxylic acids are endogenous in humans. Moreover, due to the high molecular weight, these LCA esters are likely to be absorbed poorly from the gastrointestinal tract. Therefore saturation of the enzymes involved in the metabolism is considered highly unlikely.
Overall, the data suggest that accumulation in man of these esters from the intended uses is unlikely.

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 received from the petitioner in December 2006, December 2007 and July 2008.

EFSA-Q-Nr.:	EFSA-Q-2007-032
Ref. No.:	31336
Name of the substance:	Acids, fatty (C8-C22) from animal or vegetable fats and oils, esters with alcohols, linear, aliphatic, monohydric, saturated, primary (C1-C22)

CAS number: -
Document reference: SDS EFSA/CEF/FCM/934-Rev.IID/31336 of June 2009

General information: According to the petitioner, the substance "acids, fatty (C8-C22) from animal or vegetable fats and oils, esters with alcohols, linear, aliphatic, monohydric, saturated, primary (C1-C22)" is intended to be used in the production of various types of plastics materials. In particular, these fatty esters are used as release agents, lubricants, and in some instances as plasticizers. Typical use levels are 0.2-1.5% w/w. Finished articles are intended to be used in contact with all types of foodstuffs.

Previous evaluations (by None (new substance)

EFSA-Q-Nr.:	**EFSA-Q-2007-032**
Ref. No.:	**31336**
Name of the substance:	**Acids, fatty (C8-C22) from animal or vegetable fats and oils, esters with alcohols, linear, aliphatic, monohydric, saturated, primary (C1-C22)**

SCF or AFC):

Available data used for this evaluation:

Non-toxicity data:
- Data on identity
- Data on physical and chemical properties
- Data on use and authorisation
- Data on migration
- Data on residual content of the substance

Toxicity data: For a range of representative compounds covered by the application:
- Bacterial gene mutation test
- *In vitro* mammalian chromosome aberration test
- *In vitro* mammalian cell gene mutation test
- *in vivo* mammalian chromosome aberration test
- 90-day oral toxicity study
- Considerations on absorption, distribution, and catabolism

Evaluation:

Commercial products are defined mixtures of esters of fatty acids (C8-C22) with alcohols, linear, aliphatic, monohydric, saturated, primary (C1-C22).

The physical properties may differ depending on the fatty acid and alcohol chain length. The calculated log Po/w values were higher than 8 for representative esters (esters of C4, C12-C18 and C16-C18 alcohol with fatty acid (C16-C18)).

Specific migration of the substance was calculated by migration modelling for several polymers containing the substance with use levels in the range from 0.5% to 1.5%. From typical scenarios presented by the petitioner with different polymer thicknesses and use levels migration after 10 days at 40°C was calculated to be up to 27 mg/kg food. On the basis of the obtained results, the Panel concluded that from polyolefins in contact with fatty foods, migration in the conditions of use can correspond up to 100% transfer of the substance contained in from the polymer and may approach or even exceed the overall migration limit.

The submitted data on representative esters indicate that fatty acid esters with linear alcohols did not induce mutagenicity or

EFSA-Q-Nr.:	EFSA-Q-2007-032
Ref. No.:	31336
Name of the substance:	Acids, fatty (C8-C22) from animal or vegetable fats and oils, esters with alcohols, linear, aliphatic, monohydric, saturated, primary (C1-C22)

chromosomal aberration in mammalian cells and did not induce mutagenicity in bacteria with the exception of methyl linolenate, which showed a weak mutagenic response only in TA 100 and in the absence of metabolic activation. The Panel considers that the compounds covered by the application are non-genotoxic.

Regarding repeated-dose toxicity, the available data indicate only a low potential for toxicity with a NOAEL of 300 mg/kg bw/day for structural analogues (90-day study with propylheptyl caprylate, with branched chain alcohol moiety considered as a worst case model compound due to impaired catabolism of the branched carbon chain). This NOAEL is based on a severe liver enlargement (up to 30%).

Enzymatic hydrolysis rate is available for stearic acid, 2-octyldodecyl ester, a worst case of the compounds covered by the application due to the hindrance of the ester bond. The reported value is equivalent to the hydrolysis rate of substances having a hindered ester bond and known to be efficiently cleaved by human lipases and esterases, e.g. di(2-ethylhexyl)phthalate.

Consequently, it is expected that esters of long chain alcohols (LCA) will be efficiently cleaved in humans to their component aliphatic primary alcohols and carboxylic acids. The aliphatic primary alcohols are oxidized to their corresponding carboxylic acids, which are either conjugated and excreted in the urine, or undergo ß-oxidation and cleavage. The aliphatic linear saturated carboxylic acids are endogenous in humans. Moreover, due to the high molecular weight, these LCA esters are likely to be absorbed poorly from the gastrointestinal tract. Therefore saturation of the enzymes involved in the metabolism is considered highly unlikely.

Overall, the data suggest that accumulation in man of these esters from the intended uses is not a safety concern.

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 received from the petitioner in December 2006,

EFSA-Q-Nr.:	**EFSA-Q-2007-032**
Ref. No.:	**31336**
Name of the substance:	**Acids, fatty (C8-C22) from animal or vegetable fats and oils, esters with alcohols, linear, aliphatic, monohydric, saturated, primary (C1-C22)**

December 2007 and July 2008.

EFSA-Q-Nr.:	**EFSA-Q-2005-245**
Ref. No.:	**31348**
Name of the substance:	**Acids, fatty (C8-C22), esters with pentaerythritol**

CAS number: 85116-93-4
Document reference: EFSA/CEF/FCM/854-Rev.IID/31348 of June 2009

General information: According to the petitioner, the substance "acids, fatty (C8-C22), esters with pentaerythritol" is intended to be used in the production of various types of polymers during injection moulding. The concentration of the substances to be used in polymer (from 0.1 to 1% w/w), the time and the temperature of contact, all depend on the nature of the polymers. Finished articles are intended to be used in contact with all types of foodstuffs.

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

Available data used for this evaluation:

Non-toxicity data:
- Data on identity
- Data on physical and chemical properties
- Data on intended use and authorisation of the substance
- Data on migration
- Data on residual content of the substance

Toxicity data: For representative substances covered by the application and structurally related substances:
- Bacterial gene mutation tests
- Information on *in vitro* mammalian chromosome aberration test, *in vitro* mammalian cell gene mutation test, *in vivo* micronucleus test in mice
- 90-day oral toxicity studies in rats
- Considerations on biotransformation, excretion and potential

EFSA-Q-Nr.:	**EFSA-Q-2005-245**
Ref. No.:	**31348**
Name of the substance:	**Acids, fatty (C8-C22), esters with pentaerythritol**

accumulation

Evaluation:

Commercial products are defined mixtures of esters of fatty acids (C8-C22), esters with pentaerythritol. The fatty acids are obtained from animal or vegetable fats and oils. The degree of esterification of the hydroxyl groups varies from the monoester up to and including the tetraester.

The physical properties of the various commercial products may differ significantly depending on the fatty acid chain length and the degree of esterification. The extremes, mono pentaerythritol ester of C8 fatty acid and tetra pentaerythritol ester of C22 fatty acid have different solubility properties. The calculated log Po/w values were higher than 5 for di-, tri-, and tetra-esters of pentaerythritol.

Based on a range of experiments and mathematic modelling calculations for different plastics covering the intended applications and contact conditions, migration into non fatty food simulants was in the range of <0.01 -7.7 mg/kg and into fatty food simulants <0.01 – 55 mg/kg.

Results from bacterial mutagenicity studies on compounds covered by the application were negative. In addition, pentaerythritol dioleate, has been evaluated by the Scientific Committee on Food in 1998 (EC, 1998) and is considered as non-genotoxic on the basis of three negative genotoxicity tests. Other information reported in the High Production Volume Challenge Program (HPV, 2004) shows the pentaerythritol esters of isooctanoic and C8-10 fatty acids subjected to three different tests for genotoxicity (bacterial reverse mutation assay, *in vitro* mammalian cytogenetic test and *in vivo* micronucleus test) were non genotoxic. Based on the data provided and structure/activity considerations the substances covered by the application are considered as non genotoxic.

One 90-day study was carried out for a mixture of compounds structurally related to the substance (Pentaerythritol esters of pentanoic, isopentanoic and isononanoic acid). The NOAEL in this study was 300 mg/kg bw/day based on fatty degeneration of hepatocytes.

According to a study carried out in the HPV Chemical Challenge Program, pentaerythritol esters of isooctanoic and C8-10 fatty acids did not induce teratogenicity at the upper dose level of 1000 mg/kg bw/day (HPV, 2004).

EFSA-Q-Nr.:	**EFSA-Q-2005-245**
Ref. No.:	**31348**
Name of the substance:	**Acids, fatty (C8-C22), esters with pentaerythritol**

Enzymatic hydrolysis rate data are available for pentaerythritol oleate, which is covered by the application. The reported value is similar to the hydrolysis rates of substances having a hindered ester bond and that are known to be cleaved efficiently by human lipases and esterases, e.g. di(2-ethylhexyl)phthalate.

Consequently, it is expected that esters of pentaerythritol will be efficiently cleaved in humans. Moreover, due to the high molecular weight, these pentaerythritol esters are likely to be absorbed poorly from the gastrointestinal tract. Therefore saturation of the enzymes involved in the metabolism is considered highly unlikely.

Overall, the data suggest that accumulation in man of these esters from the intended uses is unlikely.

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 submitted by petitioner in September 2005 and November 2006.
- EC (European Commission). 1998. Scientific Committee on Food. Opinion on an additional list of monomers and additives for food contact materials (adopted the 18 September 1998); http://ec.europa.eu/food/fs/sc/scf/out16_en.html.
- HPV (High Production Volume) Chemical Challenge Program, August 2004. Test plan for the polyol esters category of the aliphatic esters chemicals, prepared by American Chemistry Council's Aliphatic Esters Panel; http://www.epa.gov/chemrtk/pubs/summaries/alipestr/c13466rt5.pdf.

EFSA Question Number	**EFSA-Q-2008-686**
Ref. No.:	**71980**
Name of the substance:	**Perfluoro[2-(poly(n-propoxy))propanoic acid]**
CAS number:	51798-33-5
Document reference:	SDS EFSA/CEF/FCM/1351-Rev.0C/Polyperfluoro of June 2009

EFSA Question Number	EFSA-Q-2008-686
Ref. No.:	71980
Name of the substance:	Perfluoro[2-(poly(n-propoxy))propanoic acid]

General information:

According to the petitioner, the substance "perfluoro[2-(poly(n-propoxy))propanoic acid]" is used as a polymer production aid during emulsion polymerisation of fluoropolymers. The substance has no function in the final plastic. These materials are processed at high temperatures (265°C - 420°C) to produce items such as tubing, gaskets, seals, pipes, conveyor belts and similar items as well as coatings used on repeated use articles such as frying pans or baking articles.

All materials and articles made using the fluoropolymers are intended for repeated use in contact with any type of foodstuff. Contact conditions are typically between several minutes up to 24 hours at temperatures below 121°C. For coatings the maximum use temperature is about 260°C during frying applications. During baking the temperature at the food/coating interface (not the oven temperature) will most likely not exceed 175ºC.

Previous evaluations (by SCF or AFC):

None (new substance)

Available data used for this evaluation:

Non-toxicity data:

- Data on identity
- Data on physical and chemical properties
- Data on intended use and authorisation
- Data on residual content
- Data on estimated specific migration from residual content

Toxicity data:

On the substance

- Bacterial gene mutation test
- *In vitro* mammalian chromosome aberration test

On the starting substance hexafluoropropylene oxide

- Bacterial gene mutation test by gas phase exposure
- Limited *in vitro* mammalian cell gene mutations test by gas phase exposure
- *In vitro* mammalian chromosome aberration test by gas phase exposure
- *In viv*o micronucleus test by inhalation

EFSA Question Number	**EFSA-Q-2008-686**
Ref. No.:	**71980**
Name of the substance:	**Perfluoro[2-(poly(n-propoxy))propanoic acid]**
Evaluation:	The substance is manufactured from the monomer hexafluoropropylene oxide and has a molecular weight distribution between 600 and 12000 Da. The highest fraction of oligomers with molecular weights below 1000 Da is 13.5%. The substance completely decarboxylates during the production process to form a defined heat stable product. Decarboxylation starts at temperatures above 150°C. The residual content of this product was determined and the worst case migration was calculated using the total mass transfer assumption. For a number of typical polymer applications, these calculation indicated migration from 2 to 26 µg/kg in food for the fraction below 1000 Da. Considering that perfluorinated substances have a smaller size to mass ratio than their non-fluorinated counterparts, these calculations were also made for the fraction below 1500 Da, for comparison. The calculated migration was very slightly higher at levels from 2 to 29 µg/kg. Compared to the real repeated use conditions this total mass transfer assumption would correspond to single exposure event occurring with the first use and followed by zero exposure over the remaining service life of the food contact article. Hexafluoropropylene oxide (HFPO), the starting substance of the polymer, was not genotoxic in bacteria and in a limited mammalian cell gene mutation test. HFPO was positive for the induction of structural chromosomal aberrations *in vitro*, only in the absence of metabolic activation, and negative in an *in vivo* micronucleus assay in mouse bone marrow. All these tests were carried out using gas phase exposure. In conclusion, HFPO is considered as non-genotoxic. It is noted that HFPO brings a structural alert (the epoxy group) which is not present in the substance. The substance was negative in a bacterial mutation test. Results from a chromosomal aberration assay *in vitro*, with and without metabolic activation were inconclusive. In addition, read across from the structurally related perfluoro[2-(n-propoxy)propanoic acid] (Ref. No. 71990), which was evaluated as non-genotoxic, is also possible. In conclusion, perfluoro[2-(poly(n-propoxy))propanoic acid] does not raise concern for genotoxicity. Its decarboxylated product, which in respect to the substance lacks a carboxylic group, is also considered to be non-genotoxic based on structure activity relationships. It is noted that perfluorinated compounds may show a high potential for accumulation in man. Thus, a restriction in use should be applied in order to keep human exposure at a negligible level.

EFSA Question Number	EFSA-Q-2008-686
Ref. No.:	71980
Name of the substance:	Perfluoro[2-(poly(n-propoxy))propanoic acid]

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

SCF_List: **3**

Restriction: **Only to be used in the polymerization of fluoropolymers that are processed at temperatures at or above 265°C and are for repeated use articles**

Remark for Commission: None

Needed data or information: None

References: Unpublished data from the petitioner in September 2008.

EFSA-Q-Nr.:	EFSA-Q-2008-683
Ref. No.:	71990
Name of the substance:	Perfluoro[2-(n-propoxy)propanoic acid]

CAS number: 13252-13-6

Document reference: SDS EFSA/CEF/FCM/1342-Rev.IB/71990 of June 2009

General information: According to the petitioner, the substance "perfluoro[2-(n-propoxy)propanoic acid]" is used as a polymer production aid during emulsion polymerisation of fluoropolymers. The substance has no function in the final plastic. These materials are processed at high temperatures (265°C - 420°C) to produce items such as tubing, gaskets, seals, pipes, conveyor belts and similar items as well as coatings used on repeated use articles such as frying pans or baking articles.

All materials and articles made using the fluoropolymers are intended for repeated use in contact with any type of foodstuff. Contact conditions are typically from several minutes to 24 hours at temperatures below 121°C. For coatings, the maximum use temperature is about 260°C during frying applications. During baking the temperature at the food/coating interface (not the oven temperature) will most likely not exceed 175ºC.

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

Available data

EFSA-Q-Nr.:	**EFSA-Q-2008-683**
Ref. No.:	**71990**
Name of the substance:	**Perfluoro[2-(n-propoxy)propanoic acid]**

used for this evaluation:

Non-toxicity data:
- Data on identity
- Data on physical and chemical properties
- Data on intended use and authorisation
- Data on residual content
- Data on estimated specific migration from residual content

Toxicity data: For the ammonium salt of the substance:
- Bacterial gene mutation test
- *In vitro* mammalian cell gene mutations test
- *In vitro* mammalian chromosome aberration test
- *In vivo* micronucleus and chromosomal aberration assay in mouse bone marrow
- *In vivo* UDS in rat liver

For the decarboxylation product of the substance:
- Bacterial gene mutation test
- Limited *in vitro* mammalian chromosome aberration test
- *In vivo* micronucleus assay in rats by inhalation

Evaluation:

The substance completely decarboxylates under the high temperatures of the production process to a heat stable and volatile product. Due to the high volatility of the decarboxylation product, the applied thermal treatments of the polymers reduce the amount of the product to very low levels.

The residual content of this decarboxylation product was determined and the worst case migration was calculated using the total mass transfer assumption. For a number of typical polymer applications, these calculation indicated migration to be 5 µg/kg in food or less. Compared to the real repeated use conditions this total mass transfer assumption would correspond to single exposure event occurring with the first use and followed by zero exposure over the remaining service life of the food contact articles.

The ammonium salt of perfluoro[2-(n-propoxy)propanoic acid] was not mutagenic in gene mutation assays *in vitro* in bacteria and in mammalian cells. In cytogenetic tests *in vitro*, at the highest dose (10mM) this salt increased the incidence of cells with structural and numerical chromosomal aberrations. *In vivo*, oral exposure to this salt did not induce micronuclei or chromosomal aberrations in mouse bone marrow. There was evidence of exposure of the target tissue under the

EFSA-Q-Nr.:	**EFSA-Q-2008-683**
Ref. No.:	**71990**
Name of the substance:	**Perfluoro[2-(n-propoxy)propanoic acid]**

experimental conditions. Negative results were also obtained in an *in vivo/in vitro* unscheduled DNA synthesis assay in rat liver after oral exposure at the maximum tolerated dose. Thus the ammonium salt of the substance is considered as non-genotoxic. The decarboxylation product of the substance was negative in a limited bacterial mutation test and in a limited cytogenetic tests *in vitro*. Negative results were also reported from a micronucleus assay in rats exposed by inhalation for two weeks. However, no evidence of bone marrow exposure was obtained in this study. The decarboxylation product is structurally related to the non genotoxic ammonium salt of perfluoro[2-(n-propoxy)propanoic acid]. Therefore, read across from data on the ammonium salt to decarboxylation product is reasonable and it indicates lack of genotoxic potential for the decarboxylation product too. On the basis of these data, it is concluded that perfluoro[2-(n-propoxy)propanoic acid] is of no genotoxicity concern.
It is noted that perfluorinated compounds may show a high potential for accumulation in man. Thus, a restriction in use should be applied in order to keep human exposure at a negligible level.

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

SCF_List: **3**

Restriction: **Only to be used in the polymerization of fluoropolymers that are processed at temperatures at or above 265°C and are for repeated use articles**

Remark for Commission: None

Needed data or information: None

References: Unpublished data from the petitioner in September 2008 and February 2009.

EFSA-Q-Nr.:	**EFSA-Q-2008-698**
Ref. No.:	**95500**
Name of the substance:	**N,N',N''-tris(2-methylcyclohexyl)-1,2,3-propanetricarboxamide**
CAS number:	160535-46-6
Document reference:	SDS EFSA/AFC/FCM/1352-Rev.0B/95500 of June 2009

EFSA-Q-Nr.:	**EFSA-Q-2008-698**
Ref. No.:	**95500**
Name of the substance:	**N,N',N''-tris(2-methylcyclohexyl)-1,2,3-propanetricarboxamide**

General information: According to the petitioner, the substance "N,N',N''-tris(2-methylcyclohexyl)-1,2,3-propane-tricarboxamide" is intended to be used as an additive (to improve clarity and gloss) up to 0.25% w/w in the production of polypropylene homopolymers and copolymers materials in contact with all food types at room temperature or below for a long period. In some applications, "hot fill" may be applied. Examples include disposable and reusable drink bottles, food service ware such as pitchers or mugs to hold hot or cold beverages, baby bottles, trays and lunchboxes.

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

Available data used for this evaluation:

Non-toxicity data:
- Data on identity
- Data on physical and chemical properties
- Data on the intended use and authorisation of the substance
- Data on migration of the substance
- Data on residual content

Toxicity data:
- Bacterial gene mutation test
- *In vitro* mammalian cell gene mutation test
- *In vitro* mammalian chromosome aberration test
- *In vivo* mouse bone marrow micronucleus test
- 90-day oral toxicity study in rats
- Absorption, distribution, metabolism, and excretion (ADME) study
- Bacterial gene mutation test on amide/imide impurities

Evaluation: The substance is thermally stable up to 270°C and under the intended conditions of production of polypropylene. The Log Po/w partition coefficient is around 3.

The migration from a polypropylene sample containing 0.25% of the substance was determined into food simulants which are appropriate for all types of foodstuffs. Under the tested conditions of migration the substance is stable.

The results of specific migration corresponding to 2 hours at 121ºC followed by 10 days at 40ºC were 0.3 mg/kg in 3% acetic acid, 0.6 mg/kg in 10% ethanol and 4.9 mg/kg in olive oil. Specific migration results in 50% ethanol after 30 min at 121ºC followed by 10 days at

EFSA-Q-Nr.:	EFSA-Q-2008-698
Ref. No.:	95500
Name of the substance:	N,N',N''-tris(2-methylcyclohexyl)-1,2,3-propanetricarboxamide

40ºC were 4.8 mg/kg. The substance is 99.9% pure. Amide/imide impurities with structures similar to the substance are present at a level of 0.1% in the substance. By analogy their migration would be up to 5 µg/kg.

N,N',N''-tris(2-methylcyclohexyl)-1,2,3-propanetricarboxamide did not induce mutation in bacteria and in mammalian cells, it did not induce chromosomal aberrations in mammalian cells and was not clastogenic and/or aneugenic in an *in vivo* micronucleus assay in mice. Therefore the substance is considered as non-genotoxic.
Only limited genotoxicity data, showing lack of mutagenicity in bacteria, are available on the amide imide impurities. However the compounds are stucturally related to the test substance, which is not genotoxic. No structural alerts were identified.. Thus, it is concluded that neither the amide/imine impurities raise concern for genotoxicity.
A 90-day oral study in rats was conducted with the test substance administered by dietary admixture. In the high–dose male group (3437 mg/ kg bw/day), there was a slight increase in prothrombin time, a decrease in plasma cholesterol and an increase in plasma phospholipids. Alkaline phosphatase activity was increased in mid and high dose female groups during the study but not at the end of the study. There was a slight decrease in the absolute and relative liver weight in the high-dose males. The no observed adverse effect level (NOAEL) was considered to be equal to 665 mg/kg bw/day based on effect on the liver.
An ADME study aimed at providing data on the potential of accumulation in man of the substance was performed in male and female Wistar rats using uniformly labeled N,N',N''-tris(2-methyl[ring-U-^{14}C]cyclohexyl)-1,2,3-propanetricarboxamide.
Based on this study it is concluded that there is no indication of accumulation in man of the substance in organs and tissues.

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:	None

EFSA-Q-Nr.:	**EFSA-Q-2008-698**
Ref. No.:	**95500**
Name of the substance:	**N,N',N''-tris(2-methylcyclohexyl)-1,2,3-propanetricarboxamide**

References: Unpublished data from the petitioner in September 2008.

APPENDIX

DEFINITION OF THE SCF LISTS

The classification into a SCF_List is a tool used for tackling authorisation dossiers and do not prejudice the management decisions that will be taken on the basis of the scientific opinions of the CEF Panel and in the framework of the applicable legislation

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.

Term used relevant to migration:

Overall migration: The sum of the amounts of volatile and non volatile substances, except water, released from a food contact material or article into food or food simulant

Specific migration: The amount of a specific substance released from a food contact material or article into food or food stimulant

List of abbreviations:

AFC	Scientific Panel on additives, flavourings, processing aids and materials in contact with food
ADME	Absorption, distribution, metabolism, and excretion
BFDGE	Bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ether
bw	Body weight
CAS	Chemical abstracts service
CEF	Scientific Panel on food contact materials, enzymes, flavourings and processing aids
Da	Dalton
DNA	Deoxyribonucleic acid
EC	European Commission
EFSA	European Food Safety Authority
FCM	Food contact material(s)
HFPO	Hexafluoropropylene oxide
HPV	High production volume
LCA	Long chain alcohols
NOAEL	No observed adverse effect level
OECD	Organisation for economic co-operation and development
Po/w	Octanol/water partition coefficient
REF No	Reference Number
SCF	Scientific Committee on Food
UDS	Unscheduled DNA synthesis