European Food Safety Authority

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SCIENTIFIC OPINION

22nd 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-2008-298, EFSA-Q-2007-182, EFSA-Q-2007-199, EFSA-Q-2008-295, EFSA-Q-2008-001, EFSA-Q-2007-006, EFSA-Q-2006-315, EFSA-Q-2007-007

Adopted on 29 January 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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* M.-L. Binderup declared an interest for the substances REF. No. 14876, 49080 and 92460, as her Institute had prepared the evaluation reports of the substances 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.
K. Pfaff and D. Wölfle declared an interest for the substance Ref. No. 92460 as they were involved in the risk assessment of the substance in their Institute. This was not considered as a conflict of interest and they were invited to participate in the discussion.

[1] For citation purposes: Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF) on 22nd list of substances for food contact materials. *The EFSA Journal (2009). The EFSA Journal* (2009) ON-959-963, 966-968, 1-29.

EFSA Question Number:	EFSA-Q-2008-298
Ref. No.:	14876
Name of the substance:	1,4-Cyclohexanedicarboxylic acid
CAS number:	001076-97-7
SCF_List:	3
Restriction:	5 mg/kg food Only to be used for manufacture of polyesters
Remark for Commission:	None

EFSA Question Number:	EFSA-Q-2007-182
Ref. No.:	19965
Name of the substance:	Malic acid
CAS number:	6915-15-7
SCF_List:	1
Restriction:	ADI "not specified" Only to be used as a comonomer in aliphatic polyesters up to the level of 1 % on a molar basis
Remark for Commission:	None

EFSA Question Number:	EFSA-Q-2007-199
Ref. No. :	49080
Name of the substance :	N-(2,6-Diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-1H-benzo[de]isoquinolin-1,3(2H)-dione
CAS number:	852282-89-4
SCF_List:	3
Restriction:	0.05 mg/kg food
Remark for Commission:	The migration limit may be exceeded at elevated temperature and/or from plastics containing the substance at the maximum intended level and/or in contact with high alcoholic foods. The FRF is applicable.

EFSA Question Number:	EFSA-Q-2008-001
Ref. No.:	55610
Name of the substance:	Glass powder, ground, made from post consumer recycled glass (up to 100%)
CAS number :	65997-17-3
SCF_List:	5
Restriction:	The recycled glass powder produced by this process should not be used in materials in contact with food.
Remark for Commission:	None

EFSA Question Number:	EFSA-Q-2007-006
Ref. No.:	68119
Name of the substance:	Neopentyl glycol, diesters and monoesters with benzoic acid and 2-ethylhexanoic acid
CAS number:	-
SCF_List:	3
Restriction:	5 mg/kg food
Remark for Commission:	Migration could be exceeded. The data provided cover only foods simulated by water, 3% acetic acid and 10% ethanol.

EFSA Question Number:	EFSA-Q-2008-295
Ref. No.:	80350
Name of the substance:	Poly(12-hydroxystearic acid)-polyethyleneimine copolymer
CAS number:	124578-12-7
SCF_List:	3
Restriction:	Only to be used in PET, PS, HIPS and PA up to 0.1% w/w. Prepared by the reaction of poly(12-hydroxystearic acid) with polyethyleneimine.
Remark for Commission:	None

EFSA Question Number:	EFSA-Q-2006-315
Ref. No.:	92460
Name of the substance:	Tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo-[4,5-d]imidazol-2,5(1H,3H)-dione as non defined process mixture with tri-, di-, mono- and non-hydroxymethylated derivatives
CAS number:	-
SCF_List:	3
Restriction:	Less than 0.07% of the substance (active ingredients) in the paper-making process water or less than 0.14% when used as a preservative in water-based emulsion coatings. The use of the substance must not result in an anti-microbial effect at the surface of the polymer or on the food itself.
Remark for Commission:	Only a valid analytical method for the determination of the substance in the final product is available.

EFSA Question Number:	EFSA-Q-2007-007
Ref. No.:	94985
Name of the substance:	Trimethylolpropane, mixed triesters and diesters with benzoic acid and 2-ethylhexanoic acid
CAS number:	-
SCF_List:	3
Restriction:	5 mg/kg food
Remark for Commission:	The data provided cover only foods simulated by water, 3% acetic acid and 10% ethanol.

KEYWORDS

Food Contact Materials, Plastics, Additives, Ref. No. 14876, CAS number 001076-97-7, 1,4-Cyclohexanedicarboxylic acid; Ref. No. 19965, CAS number 6915-15-7, Malic acid; Ref. No. 49080, CAS number 852282-89-4, N-(2,6-Diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-1H-benzo[de]isoquinolin-1,3(2H)-dione; Ref. No. 55610, CAS number 65997-17-3, Glass powder, ground, made from post consumer recycled glass (up to 100%); Ref. No. 68119, Neopentyl glycol, diesters and monoesters with benzoic acid and 2-ethylhexanoic acid; Ref. No. 80350, CAS number 124578-12-7, Poly(12-hydroxystearic acid)-polyethyleneimine copolymer; Ref. No. 92460, Tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo-[4,5-d]imidazol-2,5(1H,3H)-dione as non defined process mixture with tri-, di-, mono- and non-hydroxymethylated derivatives; Ref. No. 94985, Trimethylolpropane, mixed triesters and diesters with benzoic acid and 2-ethylhexanoic acid.

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

* M.-L. Binderup declared an interest for the substances REF. No. 14876, 49080 and 92460, as her Institute had prepared the evaluation reports of the substances under contract with EFSA. She presented the evaluation results and other members of the wg were appointed as rapporteurs to finalise the draft opinions and present them to the Panel.
K. Pfaff and D. Wölfle declared an interest for the substance Ref. No. 92460 as they were involved in the risk assessment of the substance in their Institute. This was not considered as a conflict of interest and they were invited to participate in the discussion.
S. Koster declared an interest for the substances REF. No. 19965 because his Institute has submitted the petition on behalf of the industry. This was considered as a conflict of interest and he left the room during the discussion.

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 Question Number	**EFSA-Q-2008-298**
Ref. No.:	**14876**
Name of the substance:	**1,4-Cyclohexanedicarboxylic acid**
CAS number:	001076-97-7
Document reference:	SDS EFSA/CEF/FCM/1272-Rev.IIB/18444 of January 2009
General information:	According to the petitioner, 1,4-Cyclohexanedicarboxylic acid (CHDA) is used as a comonomer up to 15% on a molar basis in the production of polyesters, polyamides and polycarbonates, which are intended to be used as food contact materials for all food types at room temperature.
Previous evaluations (by SCF or CEF):	The substance was assessed at the 75th and 114th SCF meeting in 1998 (EC, 1998) and was classified in SCF_List 7.
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 specific migration of the substance - Data on migration oligomers and reaction products. - Data on residual content of the substance
Toxicity data:	- Bacterial gene mutation test - *In vitro* mammalian cell gene mutation test - *In vitro* mammalian chromosome aberration test

EFSA Question Number	EFSA-Q-2008-298
Ref. No.:	14876
Name of the substance:	1,4-Cyclohexanedicarboxylic acid

- 90-day oral toxicity study

Evaluation:

CHDA is a mixture of the cis and trans isomers. The monomers are hydrophilic with a log Po/w of 1.32 and 0.73 for cis-CHDA and trans-CHDA respectively.

CDHA decomposes above 300°C and is stable under polymer manufacturing and processing conditions except for cis/trans isomerisation.

The residual content of the substance in a polyester test sample containing 14.3% of the substance on a molar basis was measured and found to be below the detection limit of 1.3 mg/kg polymer. Nevertheless, specific migration from this polyester film sample was tested in 3% acetic acid, 10% ethanol and olive oil for 10 days at 40°C. No migration was detected at a detection limit of 4 µg/kg for 3% acetic acid and 10% ethanol, and 8 µg/kg for olive oil.

Migration of oligomers with a molecular weight below 1000 Da was determined into 3% acetic acid, 10% ethanol, 95% ethanol after 10 days at 40°C and into isooctane after 2 days at 20°C. Migration was 29, 39, 1820 and 157 µg/kg simulant, respectively.

No migration results were provided from other types of plastics. Migration of oligomers, in particular from polyamides, could be higher.

From the structure of the monomer it can be inferred that oligomers from polyesters will have low hindrance of the ester bond. Thus, it can be concluded that these oligomers will hydrolyse *in vivo* to the respective monomers.

The substance was not mutagenic in bacteria and mammalian cells. There was no evidence for clastogenicity in an *in vitro* chromosomal aberration test. Therefore the substance is considered as non-genotoxic.

A 90-day oral toxicity study was performed with doses of 0, 100, 300 and 1000 mg/kg bw/day. In the high dose males group, a reduction in thymus and spleen weights, which correlated with lymphoid depletion, was observed. In the high dose females group, a reduction in bodyweight and in the absolute and relative uterus weight and increased liver weight, which correlated with a slight hypertrophy of hepatocytes, were observed. Additionally, in the mid dose females group, the absolute and relative uterus weights were reduced. Therefore, the NOAEL was considered to be 100 mg/kg bw/day based on this latter effect.

EFSA Question Number	EFSA-Q-2008-298
Ref. No.:	**14876**
Name of the substance:	**1,4-Cyclohexanedicarboxylic acid**

According to the structure of the monomer, accumulation in man is not expected.

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

SCF_List: **3**

Restriction: **5 mg/kg food**

Only to be used for manufacture of polyesters

Remark for Commission: None

Needed data or information: None

References:

- Unpublished data from the petition in April 2008.
- EC (European Commission), 1998. Opinion of the Scientific Committee on Food adopted at 114th meeting; http://europa.eu.int/comm/food/fs/sc/scf/out20_en.pdf.

EFSA-Q-Nr.:	EFSA-Q-2007-182
Ref. No.:	**19965**
Name of the substance:	**Malic acid**

CAS number: 6915-15-7

Document reference: SDS EFSA/AFC/FCM/1189-Rev.IC/19965 of January 2009

General information:

According to the petitioner, malic acid is intended to be used in very low amounts as a comonomer with succinic acid and 1,4-butanediol in the production of poly(butylene succinate) which is used in food contact applications such as house-ware, wrapping film and containers. The final product is intended to be in contact with all types of food at and below room temperature. Short-time exposure (max.15min.) up to 100°C and long time storage up to 40°C are also possible.

Malic acid is naturally present in a variety of fruits, vegetables and beverages (EFSA, 2007). It is used as a food additive in concentrations from 3 g/kg in pineapple juice to "quantum satis" for a wide range of processed food (Directive 95/2/CE).

Previous evaluations (by SCF or AFC):

Malate anions were evaluated by the Scientific Committee of Food (SCF) in 1990 (EC, 1990) and were allocated an ADI "not specified". The calcium citrate malate was also evaluated by the EFSA Panel on Food Additives, Flavourings, Processing aids and Materials in Contact

EFSA-Q-Nr.:	EFSA-Q-2007-182
Ref. No.:	19965
Name of the substance:	Malic acid

with Food (AFC) in 2007 (EFSA, 2007) with the conclusion that its use in food for Particular Nutritional Uses (PARNUTS) and foods for the general population is of no safety concern. The exposure estimates to malic acid were at the level of 500 mg/day.

Available data used for this evaluation:

Non-toxicity data:

- Data on identity
- Data on chemical and physical properties
- Data on the intended use and authorisation of the substance
- Data on residual content and analytical method for determination in plastics
- Data on reaction products including identification and migration of oligomers

Toxicity data: This aspect has been evaluated mainly by the Joint Expert Committee on Food Additives (JECFA) (WHO 1967, 1970, 1980), SCF (EC, 1990) and EFSA (EFSA, 2007).

Evaluation:

Malic acid is a hydrophilic substance. The residual content of malic acid in a test sample of a copolymer of 1,4-butanediol, succinic acid and malic acid in its intended use content level was 1.3 mg/kg plastic. This sample was used for specific migration calculations and overall migration tests.

The specific migration of malic acid, calculated as worst case migration, was 49 µg/kg food taking into account a surface to volume ratio equal to 6 dm²/kg food.

Overall migration tests were carried out into 3% acetic acid, 10% ethanol and 95% ethanol for 10 days at 40°C and 2 hours at 70°C in all simulants. The overall migration was up to 35 mg/kg. From size exclusion chromatography with evaporative light scattering detection (SEC-ELSD) and liquid chromatography with mass detection (LC-MS) identification, it was deduced that the migrating substances were linear and/or cyclic oligomers of succinic acid and 1,4-butanediol with molecular weight below 1000 Da. No reaction products of malic acid were detected which is due to the very low level of use in the polymer.

The substance was evaluated by JECFA in 1967, 1970, 1980 (WHO, 1967, 1970, 1980), and the SCF in 1990 (EC, 1990). A group ADI "not specified" was allocated.

EFSA-Q-Nr.:	**EFSA-Q-2007-182**
Ref. No.:	**19965**
Name of the substance:	**Malic acid**

Taking into account the low level of malic acid used in the copolymer and the absence of oligomers with molecular weight below 1000 Da containing malic acid units, the use of malic acid as a comonomer in aliphatic polyesters is of no safety concern.

Conclusion: Based on the above-mentioned data the substance is classified:
SCF_List: **1**
Restriction: **ADI "not specified"**
Only to be used as a comonomer in aliphatic polyesters up to the maximum level of 1% on a molar basis.
Remark for Commission: None
Needed data or information: None

References:

- Unpublished data submitted by the petitioner in December 2007 and September 2008.
- EC (European Commission), 1990: Reports of the Scientific Committee on Food, 25th series, on a first series of Additives of various Technological functions, opinion expressed on18 May 1990, http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_25.pdf
- European Parliament and Council, 1995: Directive N°95/2/CE of 20 February 1995 on food additives other than colours and sweeteners, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0002:EN:HTML
- EFSA (European Food Safety Authority), 2007: Scientific Opinion of the Panel on Food Additives, Flavourings, Processing aids and Materials in Contact with food (AFC) on on a request from the Commission on Calcium citrate malate as source for calcium intended for use in foods for Particular Nutritional Uses (PARNUTS) and in foods for the general population (including food supplements), The EFSA Journal (2007) 612, 1-2, http://www.efsa.europa.eu/EFSA/Scientific_Opinion/afc_op_ej392_potassium%20magnesium%20citrate_op_en,2.pdf
- WHO (World Health Organisation), 1980: Twenty third report of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) on the Evaluation of certain food additives and contaminants, Technical Report Series 648 http://whqlibdoc.who.int/trs/WHO_TRS_648.pdf.
- WHO (World Health Organisation), 1970: thirteenth report of the

EFSA-Q-Nr.:	**EFSA-Q-2007-182**
Ref. No.:	**19965**
Name of the substance:	**Malic acid**

Expert Committee on specifications for the identity and purity of food additives and their toxicological evaluation: Some food colors, emulsifiers, stabilizers, anticaking agents, and certain other substances, FAO Nutrition Meetings report Series, N° 46 - WHO Technical Report Series, N° 445, 16-17 http://whqlibdoc.who.int/trs/WHO_TRS_445.pdf

- WHO (World Health Organisation), 1967: Toxicological evaluation of some antimicrobials, antioxidants, emulsifiers, stabilizers, flour-treatment agents, acids and bases, FAO Nutrition Meetings Report Series No. 40A, B, C. 1967. WHO/FoodAdd./67.29, http://www.inchem.org/documents/jecfa/jecmono/40abcj01.htm

EFSA-Q-Nr.:	**EFSA-Q-2007-199**
Ref. No.:	**49080**
Name of the substance:	**N-(2,6-Diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-1H-benzo[de]isoquinolin-1,3(2H)-dione**
CAS number:	852282-89-4
Document reference:	EFSA/CEF/FCM/1212-Rev.0B/49080 of January 2009

General information: According to the petitioner N-(2,6-Diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-1H-benzo[de]isoquinolin-1,3(2H)-dione is intended to be used in transparent packaging like PET bottles as a UV absorber in order to avoid deterioration of food like juices or milk products. The maximum level is 0.5% w/w for use at all temperature/time conditions for all foodstuffs.

Previous evaluations (by SCF or CEF): 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 of the substance

EFSA-Q-Nr.:	**EFSA-Q-2007-199**
Ref. No.:	**49080**
Name of the substance:	**N-(2,6-Diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-1H-benzo[de]isoquinolin-1,3(2H)-dione**

Toxicity data:
- Bacterial gene mutation test
- *In vitro* mammalian cell gene mutation test
- *In vitro* mammalian chromosome aberration test

Evaluation:

The substance is lipophilic (log Po/w is above 5.2).
The specific migration of the UV absorber was determined in olive oil and 50% ethanol, for 10 days at 40°C. A PET sample containing 0.45% of the substance was tested.
The migration into olive oil was reported to be non-detectable, with a detection limit of 8 µg/kg food. The specific migration of the substance in 50% ethanol was 0.1 mg/kg food.
PET does not represent the worst case for all plastics and the test conditions applied in the migration study (for 10 days at 40°C) do not cover the intended use (all temperature/time conditions).

N-(2,6-Diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-1H-benzo[de]isoquinolin-1,3(2H)-dione did not show mutagenic potential in bacteria or in CHO cells *in vitro* and it did not show clastogenic potential in V79 cells *in vitro*. Based on these three adequately performed tests the substance is considered as non-genotoxic.

Conclusion: Based on the above-mentioned data the substance is classified:
SCF_List: **3**
Restriction: **0.05 mg/kg food**
Remark for Commission: The migration limit may be exceeded at elevated temperature and/or from plastics containing the substance at the maximum intended level and/or in contact with high alcoholic foods.
The FRF is applicable.
Needed data or information: None

References: Unpublished data submitted by the petitioner in September 2007.

EFSA Question Number	EFSA-Q-2008-001
Ref. No.:	55610
Name of the substance:	Glass powder, ground, made from post consumer recycled glass (up to 100%)

CAS number: 65997-17-3
Document reference: SDS EFSA/CEF/FCM/1253-Rev.0B/55610 of January 2009

General information: According to the petitioner, "glass powder, ground, made from post-consumer recycled glass (up to 100%)" is intended to be used as an antiblock additive at a level of 0.6% in all types of plastics for long term storage at ambient temperature.

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

Available data used for this evaluation:

Non-toxicity data:
- Manufacturing process
- Material safety data sheet
- Report on the safety evaluation of powdered recycled glass
- Analytical methods for extractable organics and for acid extractable metals

Toxicity data:
- None

Evaluation: A process is described for the manufacture of glass powder from post-consumer recycled glass:
The collected glass is sorted to eliminate mainly the non-glass objects. Then it is stored in open air. After drying with air between 50 and 150°C, it is ground to powder. Specifications as maximum concentration levels of extractable organic substances and inorganic constituents in recycled glass powder are set by the petitioner. An analytical control of extractable organic substances and inorganic constituents of the recycled glass powder was done to find out if specifications are met. There is no detailed information on the control of the recycled glass powder (frequency, statistical sampling procedure, etc.) and the analytical data are not exhaustive.

The risk associated with the use of this recycled glass is the possible presence of contaminants. The possible contamination of glass containers before collection is not addressed by the petitioner. Moreover, additional contamination in the storage of the recycled glass before grinding can not be excluded.

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Ref. No.:	55610
Name of the substance:	Glass powder, ground, made from post consumer recycled glass (up to 100%)

In the process, there is no decontamination step e.g. washing or high temperature processing. Therefore, the capacity of the manufacturing process to remove possible contaminants of concern was not demonstrated.

In conclusion, there is no proof that the manufacturer takes the necessary precautions to ensure compliance with article 3 of the regulation 1935/2004 (EC, 2004).

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

SCF_List: **5**

Restriction: **The recycled glass powder produced by this process should not be used in materials in contact with food.**

Remark for Commission: None

Needed data or information: None

References:

- Unpublished data submitted by the petitioner in January 2008.
- EC (European Commission), 2004. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJ L 338 13.11.2004, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:338:0004:0017:EN:PDF.

EFSA-Q-Nr.:	EFSA-Q-2007-006
Ref. No.:	68119
Name of the substance:	Neopentyl glycol, diesters and monoesters with benzoic acid and 2-ethylhexanoic acid

CAS number: -

Document reference: EFSA/CEF/FCM/957-Rev.IIC/68119 of January 2009

General information: According to the petitioner, “neopentyl glycol, diesters and monoesters with benzoic acid and 2-ethylhexanoic acid” is intended to be used as plasticizer for flexible poly(vinylchloride) (PVC) (beer hoses, bottle

EFSA-Q-Nr.:	**EFSA-Q-2007-006**
Ref. No.:	**68119**
Name of the substance:	**Neopentyl glycol, diesters and monoesters with benzoic acid and 2-ethylhexanoic acid**

caps, various food hose applications) in contact with acidic and low alcoholic foods. The maximum use level is 32% w/w.

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 migration in food simulants
- Data on residual content

Toxicity data:
- Bacterial gene mutation test
- *In vitro* mammalian cell gene mutation test
- *In vitro* mammalian chromosome aberration test
- 90-day oral toxicity study
- One-generation reproduction toxicity study
- Developmental toxicity study

Evaluation:

The substance is a defined mixture in which the main components are three different diesters: neopentyl glycol, diester with 2-ethylhexanoic acid (14-34% w/w); neopentyl glycol, ester with 2-ethylhexanoic acid and benzoic acid (39-59% w/w); neopentyl glycol, diester with benzoic acid (14-34% w/w).
The mixture contains also minor components, present at a total amount up to 4% w/w, that are neopentyl glycol, monoester with benzoic acid, neopentyl glycol, monoester with 2-ethylhexanoic acid and the starting substance 2-ethylhexanoic acid.

The specific migration into aqueous simulants corresponding to the intended use was studied for 10 days at 40°C in several experiments, including repeated use testing, using PVC samples containing the plasticizer at the intended use level.
The migration of the diesters was up to 0.7 mg/kg in 3% acetic acid and 2.2 mg/kg in 10% ethanol.
The migration of the other components neopentyl glycol, monoester with benzoic acid (A), neopentyl glycol, monoester with 2-ethylhexanoic acid (B) and 2-Ethylhexanoic acid (EHAc) was up to

EFSA-Q-Nr.:	EFSA-Q-2007-006
Ref. No.:	68119
Name of the substance:	Neopentyl glycol, diesters and monoesters with benzoic acid and 2-ethylhexanoic acid

13.4 mg/kg for substance A, up to 2 mg/kg for substance B and lower than the limit of quantitation (<0.05 mg/kg) for EHAc.
The migration of the substance A decreased by 25 -30% from the first to the third migration period, while that of the substance B and the diesters remained constant.
The more hydrophilic monoesters migrate more than the diesters.

The substance was not mutagenic in bacteria and mammalian cells and did not induce chromosome aberrations in mammalian cells. It is thus considered as non-genotoxic.
A 90-day study was conducted with the substance administered by diet at doses of 0, 80, 400 and 1600 mg/kg bw/day. In the liver, hepatocyte hypertrophy, centrilobular and/or periportal in distribution was observed in animals of either sex at the dose level of 1600 mg/kg bw/day. In kidney, and for males only, the two higher dose levels induce eosinophilic deposit in tubular epithelium. At the low dose (80 mg/kg bw), the eosinophilic deposit was of minimal severity and not statistically significant. Therefore, the Panel considers a NOAEL of 80 mg/kg bw/day based on this effect.
In a one-generation reproduction toxicity study, the oral administration of the test substance to male and female rats resulted only in a decrease in body weights of F1 offspring at 1000 mg/kg. No external anomaly of neonates was observed whatever the dose. In a parallel experiment carried out for prenatal developmental toxicity, no treatment-related malformations or variations were recorded after visceral and skeletal examination of fetuses. Therefore, the NOAEL of the test substance is greater than 1000 mg/kg bw/day for toxicity in reproduction, while a NOAEL of 200 mg/kg bw/day based on body weight decrease of F1 offspring can be derived for developmental toxicity.

Benzoic acid and 2-ethylhexanoic are considered as possible metabolites of the monoesters while 2-ethylhexanoic acid is also mentioned as minor component:

- Benzoic acid has been evaluated by the SCF in 2002 (EC, 2002) and it has been allocated a TDI of 5 mg/kg bw/day.
- 2-ethylhexanoic acid is known as a weak embryotoxic compound. An overall NOAEL of 60 mg/kg bw/day for subchronic toxicity (Juberg et al, 1998) has been reported by the German Federal Institute of Risk Assessment (BfR, 2004). Moreover, 2-

EFSA-Q-Nr.:	EFSA-Q-2007-006
Ref. No.:	68119
Name of the substance:	Neopentyl glycol, diesters and monoesters with benzoic acid and 2-ethylhexanoic acid

ethylhexanol, the metabolic precursor of 2-ethylhexanoic acid, has been allocated an ADI of 0.5 mg/kg bw by the Joint FAO/WHO Expert Committee on Food Additives (WHO, 1993).

Consequently, the potential migration levels for benzoic acid and 2-ethylhexanoic acid do not raise a safety concern.

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

SCF_List : **3**

Restriction: **5 mg/kg food**

Remark for Commission: Migration could be exceeded.
The data provided cover only foods simulated by water, 3% acetic acid and 10% ethanol.

Needed data or information: None

References:

- Unpublished data submitted by the petitioner in December 2006, September 2007 and July 2008.
- EC (European Commission), 2002. Opinion of the Scientific Committee on Food on benzoic acid and its salts; http://ec.europa.eu/food/fs/sc/scf/out137_en.pdf.
- WHO (World Heath Organization), 1993. Toxicological Evaluation of Certain Food Additives and Contaminants. WHO Food Additives Series No. 32. Prepared by: The forty-first meeting of the Joint FAO/WHO Expert Committee on Food Additives (JEFCA); http://www.inchem.org/documents/jecfa/jecmono/v32je04.htm.
- BfR (Bundesinstitut für Risikobewertung), 2004: 2-Ethylhexanoic acid in baby food and fruit juices packed in glass containers; Expert opinion of BfR of 20 July 2004; http://www.bfr.bund.de/cm/245/2_ethylhexanoic_acid_in_baby_food.pdf.
- Juberg D.R., David R.M., Katz G.V., Bernhard L.G., Gordon D.R., Vlaovic M.S. and Topping D.C., 1998. 2-ethylhexanoic acid: subchronic toxicity studies in the rat and the mouse. Food Chem. Tox., **36**, 429-436.

EFSA Question Number	EFSA-Q-2008-295
Ref. No.:	80350
Name of the substance:	Poly(12-hydroxystearic acid)-polyethyleneimine copolymer

CAS number: 124578-12-7
Document reference: EFSA/CEF/FCM/1254-Rev.0C/80350 of January 2009

General information: According to the petitioner, the test substance is a polymeric additive intended to be used up to 0.1% w/w in the thermoplastics poly(ethylene terephtalate) (PET), polystyrene (PS), high impact polystyrene (HIPS) and polyamide (PA). The plastics are intended for contact with all types of food under all time and temperature conditions limited only by the nature of the plastic and the food. The additive is intended to help the dispersion of solid materials such as pigments added to the plastics.

Previous evaluations (by SCF or CEF): 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 of the substance
- Estimation of the content of oligomers
- Estimation by modelling of the migration of oligomers
- Data on residual content of ethyleneimine

Toxicity data:
- None

Evaluation: The manufacture of this polymeric additive is based on the approved substances 12-hydroxystearic acid (Ref. No. 61840) which has no migration restriction and ethyleneimine (Ref. No.17005) which has a restriction that there should be no detectable migration using a method with a detection limit of 0.01 mg/kg food or food simulant. These two substances are pre-polymerised separately to make a poly(12-hydroxystearic acid) and a polyethyleneimine. The two pre-polymers are reacted together to make the poly(12-hydroxystearic acid)-polyethyleneimine copolymer. The residual content of ethyleneimine monomer in the pre-polymer is below 0.01 mg/kg and so there will be no detectable migration of ethyleneimine from the final food contact plastic.

The molecular weight of the additive could not be determined experimentally but it is likely to be high since the number-average

EFSA Question Number	EFSA-Q-2008-295
Ref. No.:	80350
Name of the substance:	Poly(12-hydroxystearic acid)-polyethyleneimine copolymer

molecular weight of the two starting pre-polymers is about 2900 Da and 12500 Da respectively.
The oligomeric fraction with a molecular weight less than 1000 Da was estimated conservatively to be up to 49 mg/kg in the finished plastic containing the additive at the maximum concentration of 0.1%.
With the use of migration modelling, a conservative estimation of the migration potential of the low molecular weight oligomeric fraction from the polymers the substance is intended for, was up to 0.038 mg/kg food simulant under contact conditions of 2 hours at 121°C followed by 10 days at 40°C to represent high temperature applications followed by long-term storage.
The worst case calculation of migration of the oligomeric fraction of unreacted polyethyleneimine is up to 0.1 µg/kg food.

No specific genotoxicity data on the copolymer are available. However, in view of absence of genotoxicity of poly(12-hydroxystearic acid), and of the predicted lack of genotoxicity of polyethyleneimine, the migration of the low molecular weight oligomeric fraction of the copolymer is considered of no toxicological concern.

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

SCF_List: **3**

Restriction: **Only to be used in PET, PS, HIPS and PA up to 0.1% w/w.**
Prepared by the reaction of poly(12-hydroxystearic acid) with polyethyleneimine.

Remark for Commission: None

Needed data: None

References: Unpublished data from the petition in April 2008.

EFSA Question Number	EFSA-Q-2006-315
Ref. No.:	92460
Name of the substance:	Tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo-[4,5-d]imidazol-2,5(1H,3H)-dione as non defined process mixture with tri-, di-, mono- and non-hydroxymethylated derivatives

CAS number: -

Document reference: SDS EFSA/CEF/FCM/1003-Rev.ID/92460 of January 2009

EFSA Question Number	EFSA-Q-2006-315
Ref. No.:	92460
Name of the substance:	Tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo-[4,5-d]imidazol-2,5(1H,3H)-dione as non defined process mixture with tri-, di-, mono- and non-hydroxymethylated derivatives

General information:

According to the petitioner, the substance under evaluation is used as an aqueous formaldehyde-donor system and it is a non-defined mixture of the following active ingredients: tetra-methylolacetylenediurea in reversible equilibrium with tri-, di- and mono-methylol acetylenediurea adducts and acetylenediurea.
It is used in commercial preservative formulations in amounts up to 65% (other minor ingredients are water, salts, etc.). These preservative formulations are intended to be used in liquid polymeric dispersions/emulsions with a 50% content of solids at a level of 0.2% (around 0.14% of the active ingredients). This corresponds to a maximum level of 0.4% of preservative formulation (or 0.28% of active ingredients) in the dry coating (film). In addition, it is used as a slimicide in the manufacture of paper and board for food contact applications at a maximum level of 0.1% of preservative formulation (corresponding to around 0.07% of active ingredients) in the process water.

Previous evaluations (by SCF or CEF):

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 (method only)
- Data on the residual content of the substance
- Calculated migration from initial content of the substance

Microbiological data:
- Spectrum of antimicrobial activity
- Minimum inhibitory concentrations
- Lack of biocidal activity in the paper products

Toxicity data:
- Bacterial gene mutation test
- *In vitro* mammalian cell gene mutation test
- *In vitro* mammalian chromosome aberration test
- *In vivo* micronucleus test in mouse bone marrow
- *In vivo* chromosomal aberration test in a rat bone marrow

EFSA Question Number	EFSA-Q-2006-315
Ref. No.:	92460
Name of the substance:	Tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo-[4,5-d]imidazol-2,5(1H,3H)-dione as non defined process mixture with tri-, di-, mono- and non-hydroxymethylated derivatives

- *In vivo* unscheduled DNA synthesis (UDS) test in rat
- Two 28-day oral toxicity studies
- 90-day oral toxicity study

Evaluation:

Specific migration of the substance in food simulants has not been determined. A worst case migration based on the amounts used in the process was calculated to be 3.8 mg/kg food. A proper method is provided for the determination of the content of the active ingredients, *i.e*. non- substituted, mono-, di-, tri- and tetra-methylol acetylenediurea (determined all as acetylenediurea) and formaldehyde in coated paper manufactured with the preservative.

The petitioner has demonstrated that the test preservative formulation has biocidal activity against a wide range of bacteria, both Gram negative and positive. Minimum inhibitory concentrations (MIC) of the substance against the various bacterial species range from 100 to 400 µg/ml agar. Two standard zone of inhibition tests were used to show that coated and uncoated papers did not inhibit growth when placed in contact with *Bacillus subtilis* and *Aspergillus niger* spores in agar.
For these tests the uncoated papers were made using up to 0.1% of the preservative formulation in the paper-making process water and the coated papers were made using the preservative formulation at up to 0.3% in the aqueous emulsion coating.
In another type of standard test involving single-sided contact with coated and uncoated papers with cultures of *Staphylococcus aureus* or *Escherichia coli* there was no antimicrobial activity except for a coated paper prepared using 0.5% of the test substance in the emulsion coating, which reduced the viability of S. aureus by 2 log10.
It is concluded that when used at up to 0.1% in the paper-making process water and when used as described at up to 0.3% as a preservative in water-based emulsion coatings, the preservative formulation will not cause the finished coated or uncoated papers to have antimicrobial activity.

The substance was not genotoxic in bacteria. Equivocal results were obtained in an *in vitro* mammalian cell gene mutation test without metabolic activation, and negative results with metabolic activation. In

EFSA Question Number	EFSA-Q-2006-315
Ref. No.:	92460
Name of the substance:	Tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo-[4,5-d]imidazol-2,5(1H,3H)-dione as non defined process mixture with tri-, di-, mono- and non-hydroxymethylated derivatives

an *in vitro* chromosomal aberration assay in mammalian cells, the test compound was a potent inducer of chromosomal aberrations (mainly exchanges) with and without metabolic activation. An *in vivo* micronucleus assay in bone marrow was performed with negative results which may not fully rule out the presence of exchanges. However, no genotoxic effect was observed in an *in vivo* chromosomal aberration test in a rat bone marrow, and no increase in DNA repair as a response to DNA damage was observed in an *in vivo* UDS assay in rat hepatocytes. Thus the substance is considered as non-genotoxic *in vivo*.

Two oral 28-day and an oral 90-day toxicity study in Wistar rats are available in which the substance was studied at dose levels up to 1000 mg/kg bw/d by gavage. Some marginal treatment related effects were seen in one 28-day toxicity study and in the 90-day study. However, both in control and exposure groups pulmonary infections were observed, possibly attributable to a mycoplasm infection, which might have changed the sensitivity of the studies. Therefore, these studies can not support a NOAEL by themselves but show that there is no relevant toxicological effect at a dose of 250 mg/kg bw/day (mid dose of the 90-day study) or below. This is further supported by the observation that in the second 28-day study in rats without widespread pulmonary infections, no adverse effects were observed at dose levels up to the highest administered dose of 1000 mg/kg bw/day in male and female rats. Taken together these studies indicate that the substance is of low subchronic toxicity.

From the data available there is no indication for induction of gene mutations in bacteria. Additionally there is a lack of antimicrobial activity at the surface of the coated papers. This is considered to preclude the emergence of an antimicrobial-resistant population. Therefore, in the light of the current knowledge and considering the proposed use, there is no basis for concern for induction of antimicrobial resistance.

Based on the data examined, the Panel considers that the substance at the proposed conditions of use does not pose a safety concern.

EFSA Question Number	EFSA-Q-2006-315
Ref. No.:	92460
Name of the substance:	Tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo-[4,5-d]imidazol-2,5(1H,3H)-dione as non defined process mixture with tri-, di-, mono- and non-hydroxymethylated derivatives

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

SCF_List: **3**

Restriction: **Less than 0.07% of the substance (active ingredients) in the paper-making process water or less than 0.14% when used as a preservative in water-based emulsion coatings.**
The use of the substance must not result in an anti-microbial effect at the surface of the polymer or on the food itself.

Remark for Commission: Only a valid analytical method for the determination of the substance in the final product is available.

Needed data or information: None

References: Unpublished data submitted by the petitioner in December 2006, April 2008 and August 2008.

EFSA-Q-Nr.:	EFSA-Q-2007-007
Ref. No.:	94985
Name of the substance:	Trimethylolpropane, mixed triesters and diesters with benzoic acid and 2-ethylhexanoic acid

CAS number: _

Document reference: SDS EFSA/CEF/FCM/1011-Rev.IB/94985 of January 2009

General information: According to the petitioner, trimethylolpropane, mixed triesters and diesters with benzoic acid and 2-ethylhexanoic acid is intended to be used as plasticizer for flexible PVC (beer hoses, bottle caps, various food hose applications) in contact with acidic and low alcoholic foods. The maximum use level is 32% w/w.

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 application and authorisations

EFSA-Q-Nr.:	EFSA-Q-2007-007
Ref. No.:	94985
Name of the substance:	Trimethylolpropane, mixed triesters and diesters with benzoic acid and 2-ethylhexanoic acid

- Data on migration test in food simulants
- Data on residual content
- Data on migration of impurities in food simulants

Toxicity data:
- Bacterial gene mutation test
- *In vitro* mammalian cell gene mutation test
- *In vitro* mammalian chromosome aberration test
- 28-day oral toxicity study
- 90-day oral toxicity study

Evaluation:

The substance is a defined mixture in which the main components are three different triesters: [trimethylolpropane triester with 2-ethylhexanoic acid] (15-35% w/w), [trimethylolpropane, diester with 2-ethylhexanoic acid and monoester with benzoic acid] (30-50% w/w), [trimethylolpropane, diester with benzoic acid and monoester with 2-ethylhexanoic acid] (10-30% w/w).

Minor components of the mixture, present at a total average level of 0-15% w/w are: trimethylolpropane diesters with a free OH group, trimethylolpropane triester with benzoic acid and starting substances (benzoic acid and 2-ethylhexanoic acid sodium salts).

The specific migration into aqueous simulants corresponding to the intended use was studied for 10 days at 40°C in several experiments, including repeated use test, using PVC samples containing the plasticizer at the intended use level. The overall conclusion is that the major migrants are the hydrophilic minor components of the mixture.

The migration of the triesters in 3% acetic acid was not detectable (<0.04 mg/l); in 10% ethanol it reached 0.07 mg/kg food simulant.

The migration of the other components (diesters, benzoic acid, 2-ethylhexanoic acid) was tested in conditions also simulating repeated use. The migration was up to 0.2 mg/kg food simulant for the diesters, up to 0.6 mg/kg food simulant for benzoic acid and up to 0.5 mg/kg food simulant for the 2-ethylhexanoic acid.

The migration of 2-ethylhexanoic acid and benzoic acid decreased by 30 -50% from the first to the third migration period, while that of the diesters remained constant.

Trimethylolpropane, mixed triesters and diesters with benzoic acid and 2-ethylhexanoic acid did not induce mutagenicity in bacteria and in mammalian cells and did not induce chromosome aberrations in mammalian cells. It is therefore considered as non-genotoxic.

EFSA-Q-Nr.:	**EFSA-Q-2007-007**
Ref. No.:	**94985**
Name of the substance:	**Trimethylolpropane, mixed triesters and diesters with benzoic acid and 2-ethylhexanoic acid**

One oral subacute (28-day) study and one subchronic (90-day) study have been performed at doses of 250, 500 and 1000 mg/kg bw. In the 28-day study, minor effects were seen in males at the high dose (1000 mg/kg bw/day). These effects were not reproduced in the 90-day study. Therefore, the Panel considers that a NOAEL of 1000 mg/kg bw/day as derived from the 90-day study can be used.

Benzoic acid and 2-ethylhexanoic acid are impurities of the substance and could be considered as possible metabolites of the diesters also mentioned as impurities.

- Benzoic acid has been evaluated by the SCF in 2002 (EC, 2002) and it has been allocated a TDI of 5 mg/kg bw/day.
- 2-ethylhexanoic acid is known as a weak embryotoxic compound with an overall NOAEL of 60 mg/kg bw/day for subchronic toxicity (Juberg et al, 1998; German Federal Institute of Risk Assessment; BfR, 2004). Moreover, 2-ethylhexanol, the metabolic precursor of 2-ethylhexanoic acid, has been allocated an ADI of 0.5 mg/kg bw by the Joint FAO/WHO Expert Committee on Food Additives (WHO, 1993).

Consequently, the potential migration levels for benzoic acid and 2-ethylhexanoic acid do not raise a safety concern.

The possible risk of accumulation in man of the tested substance was also considered. Since the substance is intended to be used only for aqueous foods, where only the hydrophilic components of the mixture are migrating, accumulation was not considered to be a safety issue.

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

SCF_List: **3**

Restriction: **5 mg/kg food**

Remark for Commission: The data provided cover only foods simulated by water, 3% acetic acid and 10% ethanol.

Needed data or information: None

References:

- Unpublished data submitted by petitioner in December 2006, September 2007 and May 2008.
- EC (European Commission), 2002. Opinion of the Scientific Committee on Food on benzoic acid and its salts; http://ec.europa.eu/food/fs/sc/scf/out137_en.pdf

EFSA-Q-Nr.:	EFSA-Q-2007-007
Ref. No.:	94985
Name of the substance:	Trimethylolpropane, mixed triesters and diesters with benzoic acid and 2-ethylhexanoic acid

- WHO (World Heath Organization), 1993. Toxicological Evaluation of Certain Food Additives and Contaminants. WHO Food Additives Series No. 32. Prepared by: The forty-first meeting of the Joint FAO/WHO Expert Committee on Food Additives (JEFCA). http://www.inchem.org/documents/jecfa/jecmono/v32je04.htm
- BfR (Bundesinstitut für Risikobewertung), 2004: 2-Ethylhexanoic acid in baby food and fruit juices packed in glass containers; Expert opinion of BfR of 20 July 2004; http://www.bfr.bund.de/cm/245/2_ethylhexanoic_acid_in_baby_food.pdf
- Juberg D.R., David R.M., Katz G.V., Bernhard L.G., Gordon D.R., Vlaovic M.S. and Topping D.C., 1998. 2-ethylhexanoic acid: subchronic toxicity studies in the rat and the mouse. Food Chem. Tox., **36**, 429-436.3.

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
ADI	Acceptable daily intake
BfR	German federal institute for risk assessment
bw	body weight
CAS	Chemical abstracts service
CHDA	Cyclohexanedicarboxylic acid
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
EHAc	Ethylhexanoic acid
FAO	Food and Agriculture Organization of the United Nations
FCM	Food Contact Material(s)
HIPS	High impact polystyrene
JECFA	Joint Expert Committee on Food Additives
LC-MS	Liquid chromatography with mass detection
MIC	Minimum Inhibitory Concentration
NOAEL	No observed adverse effect level
PA	Polyamide
PARNUTS	Particular Nutritional Uses
PET	Poly(ethylene terephthalate)
PVC	Polyvinyl chloride
PS	Polystyrene
REF No	Reference Number
SCF	Scientific Committee on food
SEC-ELSD	Size exclusion chromatography with evaporative light scattering detection
TDI	Tolerable daily intake
UDS	Unscheduled DNA synthesis
UV	Ultra-violet
WHO	World Health Organisation
w/w	Weight by weight