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

a 9th list of substances for food contact materials

Question N° EFSA-Q-2004-071, EFSA-Q-2004-094, EFSA-Q-2003-214, EFSA-Q-2003-222

Adopted on 29 June 2005

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 AFC Panel evaluated the following substances:

Ref. No.:	15267
Name of the substance:	4,4'-Diaminodiphenyl sulphone
CAS number:	80-08-0
Classified in list:	3
Restriction:	5 mg/kg food

Ref. No.:	42080
Name of the substance:	Carbon black
CAS number:	1333-86-4
Classified in list:	3
Restriction:	Specifications for CB: - Toluene extractables : maximum 0.1%, determined according to ISO method 6209; - UV absorption of cyclohexane extract at 386 nm: <0.02 AU for a 1 cm cell or <0.1 AU for a 5 cm cell, determined according to German BfR, BIII, Reinheitsprufung von Rußen, Stand 1.7.1972 - Benzo(a)pyrene content: max 0.25 mg/kg Carbon Black - Maximum use level of Carbon Black in the polymer: 2.5% w/w

Ref. No.:	71960
Name of the substance:	Perfluorooctanoic acid, ammonium salt
CAS number:	3825-26-1
Classified in list:	3

Restriction:	Only to be used in repeated use articles, sintered at high temperatures
Ref. No.:	72081/10
Name of the substance:	Petroleum hydrocarbon resins (hydrogenated)
CAS number:	088526-47-0
Classified in list:	3
Restriction:	5 mg/kg food

KEY WORDS
Food Contact Materials, Plastics, Monomers, Additives, 4,4'-Diaminodiphenyl sulphone, REF. No 15267, CAS No 80-08-0, Carbon black, REF. No 42080, CAS No 1333-86-4, Perfluorooctanoic acid, ammonium salt, APFO, PFOA, REF. No 71960, CAS No 3825-26-1, Petroleum hydrocarbon resins (hydrogenated), REF. No 72081/10, CAS No 088526-47-0

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.

TERMS OF REFERENCE
The EFSA is required by the Articles 10 of the Regulation (EC) No 1935/2004 of the European Parliament and of the Council to carry out risk assessment 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.

ASSESSMENT
Within this general task the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) evaluated the following substances used in food contact materials. The substances examined are listed in ascending order of their Reference Number (REF No.), with their chemical name, Chemical Abstract Number (CAS No.) and classification according to the "SCF list". (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.

Ref. No.:	**15267**
Name of the substance:	**4,4'-diaminodiphenyl sulphone**
CAS number:	80-08-0
Document reference:	EFSA/AFC/FCM/291-Rev.IA/15267 of May 2005

General information: According to the petitioner 4,4'-diaminodiphenyl sulphone is used as monomer in the plastics production of polyetherimide. The final polymer is intended to be used in contact with all types of food and at any time/temperature condition

Previous evaluations (by SCF or AFC): None

Available data used for this evaluation:

Non-toxicity data: Identity, physical/chemical properties, use, authorisation
Migration into simulants and residual content in a polymer

Toxicity data:
- Gene mutation assays in bacteria

In vitro mammalian cell gene mutation test
In vitro mammalian chromosome cell aberration test
In vivo mouse micronucleus test
Carcinogenicity study
Unwanted effects in humans after therapeutic use

Evaluation: Migration of 4,4'-diaminodiphenyl sulphone was determined in 10% ethanol and 3% acetic acid applying test conditions of 2h at 121°C followed by 10 days at 40°C. In oil the migration was determined after 1 h at 200°C followed by 10 days at 40°C. The monomer was determined by HPLC and UV detection. The method was properly validated for precision and recovery of the monomer. The monomer was not detectable at the level of 0.008 mg/6 dm².
The residual content of 4,4'-diaminodiphenyl sulphone in the polymer was 4.8 µg/g polymer.
4,4'-Diaminodiphenyl sulphone was not mutagenic in bacteria and mammalian cells *in vitro*. 4,4'-Diaminodiphenyl sulphone did not induce micronucleus formation *in vivo*. However, high toxicity prevented the application of high doses. Information regarding induction of chromosomal aberrations in mammalian cells is inconsistent with no to weak effects. The negative mutagenicity studies in bacteria and in mammalian cells suggest that 4,4'-diaminodiphenyl sulphone is not genotoxic., The Panel noted that the compound is an aromatic amine, however, the data set indicates that the substance is not genotoxic *in vitro* and *in vivo*. A bone marrow micronucleus

Ref. No.:	15267
Name of the substance:	**4,4'-diaminodiphenyl sulphone**
	test in mice was negative, but, due to marked mortality, doses higher then 100 mg/kg bw could not be administered. In a two year carcinogenicity study, 4,4'-diaminodiphenyl sulphone caused splenic tumours in male rats after administering doses in diet of approximately 50 and 100 mg/kg bw/day to rats and 120 and 240 mg/kg bw/day to mice. 4,4'-Diaminodiphenyl sulfone did not induce increase tumour incidence in female rats and in both sexes of mice. The splenic and peritoneal tumours observed in male rats may be caused by the damage to the spleen induced by methaemoglobinemia due to 4,4'-diaminodiphenyl sulphone. The compound is a potent inducer of methaemoglobinemia in rats and humans and administration of 4,4'-diaminodiphenyl sulfone in such doses as those in the carcinogenicity study causes pronounced induction of methaemoglobinemia. In a reproduction study, no compound related effects (up to 200 mg/kg) on foetuses were observed. The no observed effect level for immunotoxicity was 13.5 mg/kg bw/day. 4,4'-Diaminodiphenyl sulphone has been widely used in human therapy of leprosy and some infectious diseases and methaemoglobinemia is dose-limiting in human therapy. Therapeutic doses in humans are 100 mg/person/day, which are considered safe even for longterm treatment of leprosy.
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
References:	Unpublished data submitted by the petitioner on 07.05.2004, 03.02.2005 and 15.04.2005

Ref. No.:	42080
Name of the substance:	**Carbon Black**
CAS number:	1333-86-4
Document reference:	EFSA/AFC/FCM/352-Rev.0C/42080 of May 2005
General information:	According to the petitioner, Carbon black (CB) is used as additive (UV stabiliser and black pigment) mainly in Polyolefins, but more generally in all plastic materials. The

Ref. No.:	42080
Name of the substance:	Carbon Black

polymers containing CB are destined to all kind of foods in conditions of time and temperature depending on the physical properties of the final polymer. The maximum requested percentage of use is 2.5% w/w.

Previous evaluations (by SCF or AFC): Carbon black is classified in SCF List 3. SCF Opinion reported in Synoptic document:" Criteria purity shall be established. Carbon black should be free from aromatic hydrocarbons (CS/PM/2041)."
(This is the outcome of the discussion of the SCF WG meeting No 52).

Available data used for this evaluation:

Non-toxicity data:

- Identity, Physicochemical properties, Intended applications, Existing authorisation, Purity
- Specifications
- Specific Migration of PolyAromatic Hydrocarbons in fat simulant
- Residual content of CB in the polymer and PolyAromatic Hydrocarbons in CB
- Calculated worst case migration of PolyAromatic Hydrocarbons
- Information on production process

Toxicity data:

Evaluation: CB does not migrate as itself, but it is known that it may contain variable amounts of Poly Aromatic Hydrocarbons (PAH) impurities that may migrate in apolar media, such as edible oils. Benzo(a)pyrene (BaP) is considered as a marker for the occurrence and effect of carcinogenic PAHs in food (SCF, 2002) .
To determine PAH migration, four different typical carbon black grades, with different levels of PAH residues, (containing <0.25 mg BaP/kg CB and <40mg total 22 PAH/kg CB) were compounded at 2.5% w/w in LDPE as a worst case polymer. The level of CB in the LDPE plaques was confirmed by Thermogravimetric method. The PAH residues in the four grades of CB were determined by a properly validated High Resolution Gas Chromatography/Low Resolution Mass Spectrometry (HRGC/LRMS) method, focused on the

Ref. No.:	42080
Name of the substance:	Carbon Black

determination of 22 PAH. The migration of 22 PAH in the fat simulant HB307, a synthetic mixture of triglycerides, was determined after 10 days at 40°C. HB307 was used in order to get a proper blank solution. All the results were calculated including also the levels of the detection limits for each of the PAH analysed but not detected. No migration of BaP was detected at the detection levels ranging from 0.002 to 0.006 µg/dm². The LDPE plaques without CB gave a migration of total PAH of 0.818 µg/dm². From the LDPE plaques with added CB the migration of total PAH increased up to 1.576 µg/dm² for one of the tested grades of carbon blacks; the migrating PAHs were shown to be only low molecular weight non-carcinogenic compounds. For the other three carbon blacks the migration was in the same range of the migration from the LDPE plaques without CB.

In view of this and taking into account the different grades of Carbon Black, in order to limit migration of undesirable impurities, specifications are necessary. Based on compositional and migration data, specification of the BaP content (as a marker for the occurrence of PAHs), is appropriate. Traditional quality control parameters such as "Toluene extractables" and "UV absorption" are less specific for PAH, but they can be used as general purity parameters. Moreover, a maximum use level of 2.5% w/w of CB in the polymer is indicated.

Based on the above considerations and taking into account the maximum levels of contaminants in some food matrices established by Regulation (EC) No. 466/2001 and Regulation (EC) No. 208/2005, the specifications for CB are the following:

- Toluene extractables : maximum 0.1%, determined according to ISO method 6209;
- UV absorption of cyclohexane extract at 386 nm: <0.02 AU for a 1 cm cell or <0.1 AU for a 5 cm cell, determined according to German BfR, BIII, Reinheitsprufung von Rußen, Stand 1.7.1972
- Benzo(a)pyrene content: max 0.25 mg/kg Carbon Black
- Maximum use level of Carbon Black in the polymer: 2.5 % w/w

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

Ref. No.:	42080
Name of the substance:	Carbon Black
	classified:
SCF_List:	3
Restriction:	specifications for CB: - Toluene extractables : maximum 0.1%, determined according to ISO method 6209; - UV absorption of cyclohexane extract at 386 nm: <0.02 AU for a 1 cm cell or <0.1 AU for a 5 cm cell, determined according to German BfR, BIII, Reinheitsprufung von Rußen, Stand 1.7.1972 - Benzo(a)pyrene content: max 0.25 mg/kg Carbon Black - Maximum use level of Carbon Black in the polymer: 2.5% w/w
Remark for Commission:	None
Needed data or information	None
References:	– Unpublished data submitted by the petitioner, June 2004 and May 2005 – Opinion of the Scientific Committee on Food on the risks to human health of Polycyclic Aromatic Hydrocarbons in food , 4 December 2002¸ http://europa.eu.int/comm/food/fs/sc/scf/out153_en.pdf and Annex http://europa.eu.int/comm/food/fs/sc/scf/out154_en.pdf – Commission Regulation EC No 466/2001 ,8 March 2001 setting maximum levels for certain contaminants in foodstuffs. on OJ L 77, 16.3.2001 p1 – Commission Regulation EC 208/2005 ”amending Regulation (EC) No 466/2001 as regards polycyclic aromatic hydrocarbons “ , 4 February 2005 on OJ L 34, 8.2.2005 p3

Ref. No.:	71960
Name of the substance:	Perfluorooctanoic acid, ammonium salt
CAS number:	3825-26-1
Document reference:	*EFSA/AFC/FCM/124-Rev.1B/71960 of June 2005*

Ref. No.:	71960
Name of the substance:	Perfluorooctanoic acid, ammonium salt

General information:

According to the petitioner, perfluorooctanoic acid, ammonium salt is used as an emulsifier/dispersing agent during the polymerisation process of fluoropolymers (polytetrafluoroethylene (PTFE) polymer, and copolymers of tetrafluoroethylene with hexafluoropropylene and/or perfluoropropylperfluorovinyl ether). These fluoropolymers are processed to produce articles for repeated use (parts for food processing equipment, tubes, tapes, coatings on cooking utensils and glass cloth), for all types of foodstuffs. The maximum addition level is 0.5 %.

According to the data provided, perfluorooctanoic acid, ammonium salt is a defined mixture with molecular formula nominally CnF2n+1-CO2(-) NH4(+), where n is mainly 7. The main components (96-97%) are represented by C_8F_{15} structures, the remaining being lower and higher homologues.

Previous evaluations (by SCF or AFC):

None

Available data used for this evaluation:

Non-toxicity data:

- Identification of the components of the defined mixture
- Physical and chemical properties
- Intended use of substance
- Existing authorisation
- Determination of residual content in the food contact material
- Calculated worst case migration

Toxicity data:

- Gene mutation assay in bacteria
- Gene mutation assay in cultured mammalian cells
- Chromosomal aberration assay in cultured mammalian cells
- Mouse bone marrow micronucleus test
- Published study on induction of oxidative DNA damage in vivo
- Subchronic oral toxicity studies in the rat
- Subchronic oral toxicity study in monkey
- Chronic toxicity/oncogenicity study in the rat
- Developmental toxicity studies in rat and rabbit
- Published studies on general toxicity, reproductive toxicity, neuroendocrine effects and carcinogenicity
- Review on general toxicity and carcinogenicity of perfluorooctanoic acid and its salts
- Published studies on determinations of perfluorooctanoic acid in human body fluids

Ref. No.:	71960
Name of the substance:	Perfluorooctanoic acid, ammonium salt
Evaluation:	Specific migration was not determined, but maximum possible migration was calculated based on the determination of the residual perfluorooctanoic acid, ammonium salt in a homogeneous fluoropolymeric sample containing the substance and obtained by extrusion and sintering at high temperature. The analytical method was not reported properly. However, residual perfluorooctanoic acid, ammonium salt was never detected in the fluoropolymeric sample; based on the detection limit of 0.022 mg/kg polymer, the calculated worst case migration was 0.017 mg/kg food, (sample thickness 0.6 cm, 6dm^2 /kg food, first use data). Perfluorooctanoic acid, ammonium salt was not clastogenic in a chromosomal aberration assay in vitro, and did not induce micronuclei in mouse bone marrow in vivo. Limited experiments on gene mutation induction in bacteria and in mammalian cells gave negative results. Overall, the available data indicate that perfluorooctanoic acid, ammonium salt, similar to other perfluorinated chemicals, is not genotoxic. Subchronic toxicity studies show that liver is the primary target organ of the toxicity of ammonium perfluorooctanoate both in rats, where toxic effects are mainly related to the induction of peroxisome proliferation, and in monkey. The LOAEL for general toxicity in monkey, based on evidence of increased liver weight due to mitochondrial proliferation, was 3.0 mg/kg b.w./day. Reproduction/developmental toxicity studies with APFO in rats and rabbits indicated no specific adverse effect on reproductive endpoints (mating, fertility, delivery), but an adverse effect on oestrous cycling was observed in rats following i.p. administration of the related substance perfluorooctane sulfonate (LOAEL 1 mg/kg b.w./day). In a two-generation study in rats, perfluorooctanoic acid, ammonium salt affected sexual maturation (NOAEL 10 mg/kg b.w./day), and induced body and organ weight changes in parental and F1 males at all doses (LOAEL 1 mg/kg b.w.). Chronic toxicity/carcinogenicity studies with perfluorooctanoic acid, ammonium salt in rats showed treatment related increased incidence of hepatocellular adenomas, Leydig cell adenomas and pancreatic acinar cell adenomas. Ammonium perfluorooctanoate was shown to act as a tumor promoter in initiation-promotion experiments. ADME studies indicate that perfluorooctanoic acid is rapidly absorbed after oral administration. Perfluorooctanoic acid is not biotransformed, and liver, blood and kidney are the major deposition sites in the rat. The half-life of perfluorooctanoic acid varies from hours or days in rats, to years in humans.

Ref. No.:	71960
Name of the substance:	Perfluorooctanoic acid, ammonium salt
	Overall, the toxicological database indicates that ammonium perfluorooctanoate is a non-genotoxic carcinogen and a tumor promoter in rats. The available data do not allow the setting of a TDI. The extended half-life of perfluorooctanoic acid in humans suggests that the substance has a high potential for persistence. Based on the available toxicological information, perfluorooctanoic acid, ammonium salt could be used only in conditions associated with negligible consumer exposure.
Conclusion:	Based on the above-mentioned data the substance is classified:
SCF_List:	3
Restriction:	Only to be used in repeated use articles, sintered at high temperatures
Remark for Commission:	The substance is a perfluoroalkyl compound, which are a class of persistent, widespread environmental pollutants. Within the framework of the general use of the perfluorinated chemicals, consumer exposure from use of perfluorooctanoic acid, ammonium salt in repeated use articles, sintered at high temperatures is considered negligible
Needed data or information :	None
References:	- Unpublished data submitted by the petitioner and the following publications: - Buttenhoff, J., Costa, G., Elcombe, C., *et al* (2002) Toxicity of ammonium perfluorooctanoate in male cynomolgus monkeys after oral dosing for 6 months. Toxicol. Sci., 69, 244-257. - Biegel, L.B., Hurtt, M.E., Frame, S.R., O'Connor, J.C, and Cook, J.C. (2001) Mechanisms of extrahepatic tumor induction by peroxisome proliferators in male CD rats. Toxicol. Sci., 60, 44-55. - Abdellatif, A.G., Preat, V., Taper, H.S., Roberfroid, M. (1991) The modulation of rat liver carcinogenesis by perfluorooctanoic acid, a peroxisome proliferator. Toxicol. Applied Pharmacol., 111, 530-537. - Staples, R.E., Burgess, B.A., Kerns, W.D. (1984) The embryo-fetal toxicity and teratogenic potential of ammonium perfluorooctanoate (APFO) in the rat. Fundam. Appl. Toxicol. 4, 429-440. - Butenhoff J.L., Kennedy Jr. G.L., Frame S.R. et al (2004) The reproductive toxicology of ammonium perfluorooctanoate (APFO) in the rat. Toxicology 196, 95-116. - Lau C., Butenhoff J.L., Rogers J.M. (2004) The developmental

Ref. No.:	71960
Name of the substance:	Perfluorooctanoic acid, ammonium salt

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Ref. No.:	72081/10
Name of the substance:	Petroleum Hydrocarbon Resins (hydrogenated)
CAS number:	088526-47-0
Document reference:	EFSA/AFC/FCM/96-Rev.VF/72081/10 of March 2005
General information:	According to the petitioner the Petroleum hydrocarbon resins (hydrogenated) are used as a polymeric additive in polyethylene and polypropylene to improve processability, gas/vapour permeability, transparency and stiffness
Previous evaluations (by SCF or AFC):	The substance was first evaluated in 1998 (SCF 1998) on the basis of three mutagenicity studies (performed with the hydrogenated hydrocarbon resin) but was classified in SCF_List 7 on the basis of inadequate migration data. (Needed: In first instance, migration data on the polymeric additive; explanation why the residual amount of the hydrogenated monomers and unpolymerizable components are rather high (in the product), more information on specification, i.e. information on hydrogenation, purification and viscosity of final product.) The substance was again evaluated in 2000 (SCF 2000). Because of

	the high migration to be expected in fatty food the substance was again classified in SCF_List 7, requesting in first instance reduction of the residues of the hydrogenated monomers and non-polymerisable components (by technical processing). In the 3rd evaluation (SCF, 2002), a bioaccumulation study with a representative sample of hydrocarbon resins was requested.
Available data used for this evaluation:	
Non-toxicity data:	- See SCF 1998, 2000 and 2003
Toxicity data:	- See SCF 1998, 2000 and 2003 - Data on bio-accumulation of a representative sample of hydrocarbon resins
Evaluation:	Resin with the lowest molecular weight and mean molecular weight distribution was examined for residual content of non-hydrogenated and hydrogenated monomers. Residual non-hydrogenated and hydrogenated monomers are not detectable at a quantification limit of 2 and 50 mg/kg polymeric additive respectively. Overall migration was determined from PP films containing 10 or 15% resin and from a PE film containing 5% resin. Overall migration was determined in aqueous food simulants (15% ethanol and 3% acetic acid) under conditions of 10 days at 40°C and 1 h at reflux temperature. In addition migration in olive oil and 95% ethanol (10 d-40°C) was determined. Migration of resin into aqueous simulant under conditions mentioned was close to 1 mg/kg. Migration into olive oil and 95% ethanol from a PP with 10% resin was 51 mg/kg and 11.6 mg/kg respectively. Petroleum hydrocarbon resin (hydrogenated) tested negative in assays for the induction of gene mutations in bacteria and mammalian cells and in a chromosomal aberration assay in CHO cells. In view of the polymeric nature of the test substance the result of the chromosomal aberration assay was accepted, even if the test protocol was not in full accordance with the guidelines. In a 90-day oral rat study including an in utero exposure phase with Petroleum hydrocarbon resin (hydrogenated) administered in the diet at 0, 1000, 6000 and 36000 mg/kg of diet, a NOAEL of 36000 mg/kg in the diet could be established, equivalent to about 1800 mg/kg bw/d. [3H]-labelled Polycyclopentadiene (REF No 76680), administered as a representative Petroleum hydrocarbon resin (hydrogenated) to male rats, was rapidly but incompletely absorbed. Within 48 hours the majority of the dose was excreted via feces (≥91%) and via urine (3-4%), 3.1% of the low dose was found in tissues and in the

	residual carcass, *i.e.* roughly half of the absorbed proportion of the administered dose was retained in the body. Only a low amount of [3H]-labelled material was distributed into the tissues (0.69%) with the highest concentrations in liver and mesenteric lymph nodes. Following the administration of 14 daily oral doses of 10 mg [3H]-Polycyclopentadiene /kg, the terminal elimination of [3H]-material from tissues was slow, particularly from fat and mesenteric lymph nodes. For [3H]-Polycyclopentadiene terminal elimination half-lives of 22 and 24 days were determined for liver and kidney (in freeze-dried samples). Given the possibility of tritium exchange reactions, the prolonged terminal half-lives in the tissues are considered as worst-case data. Based on these data, while the accumulation potential in man of Petroleum hydrocarbon resins cannot be ruled out, it is expected to be low and no adverse effects were observed in the 90-day study which included high dose levels. According to the package of toxicological studies available a restriction of 5 mg/kg food is proposed.
Conclusion:	Based on the above-mentioned data the substance is classified:
SCF List:	**3**
Restriction:	**5 mg/kg food**
Remark for Commission:	FRF is applicable The migration limit may be exceeded into fatty foods No specific migration method provided
Needed data or information:	
References:	- Unpublished data submitted by the petitioner. - SCF (1998 and 2000): 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://europa.eu.int/comm/food/fs/sc/scf/out76_en.pdf - SCF (2003): Opinion of the Scientific Committee on Food on the 21st additional list of monomers and additives for food contact materials (expressed on 5 March 2003) http://europa.eu.int/comm/food/fs/sc/scf/out172_en.pdf

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List of abbreviations:

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

LOAEL Lowest observed adverse effect level

NOAEL No observed adverse effect level

APPENDIX

DEFINITION OF THE SCF LISTS

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

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

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

List 3 Substances for which an ADI or a TDI could not be established, but where the present use could be accepted.

Some of these substances are self-limiting because of their organoleptic properties or are volatile and therefore unlikely to be present in the finished product. For other substances with very low migration, a TDI has not been set but the maximum level to be used in any packaging material or a specific limit of migration is stated. This is because the available toxicological data would give a TDI, which allows that a specific limit of migration or a composition limit could be fixed at levels very much higher than the maximum likely intakes arising from present uses of the additive.

Depending on the available toxicological studies a restriction of migration into food of 0.05 mg/kg of food (3 mutagenicity studies only) or 5 mg/kg of food (3 mutagenicity studies plus 90-day oral toxicity study and data to demonstrate the absence of potential for bio-accumulation in man) may be allocated.

List 4 **(for monomers)**

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

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

List 4 **(for additives)**

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

List 5 Substances that should not be used.

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

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

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

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

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

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

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