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Unit B3 - Management of scientific committees II

SCIENTIFIC COMMITTEE ON FOOD

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OPINION
ON AN ADDITIONAL LIST OF MONOMERS AND ADDITIVES
FOR FOOD CONTACT MATERIALS

(adopted the 19 March 1998)

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OPINION
ON AN ADDITIONAL LIST OF MONOMERS AND ADDITIVES
FOR FOOD CONTACT MATERIALS

(adopted on 19 March 1998)

The Committee (re)evaluated a number of monomers and additives for food contact materials. The substances examined are listed in alphabetical order in the Table, with their Reference Number (REF_N), Chemical Abstract Number (CAS_N.) and classification in a SCF list. The definition of the SCF lists is given in the Appendix. The opinion of the Committee on each of the substances is shown in the same table. Where appropriate, quantitative restrictions (R) on migration in foodstuffs or in the residual quantity in finished products appear in the Table.

TABLE

REF No.	NAME	CAS No.	SCF List	SCF Opinion
13060	1,3,5-BENZENETRIC ARBOXYLIC ACID TRICHLORIDE	04422-95-1	3	R = 0.05 mg/6 dm ² measured as 1,3,5-benzenetricarboxylic acid. Available: Calculation of worst case migration assuming 100% migration of residual monomer, three (negative) in vitro mutagenicity studies. Remark for Commission: no method of analysis is available for the enforcement of an SML. (RIVM/ISS/TNO SDS, October 1997 = CS/PM/3075/13060) (Adopted at 111th SCF meeting) (18-19 March 1998).
14020	4-tert-BUTYLPHENOL	00098-54-4	3	R = 0.05 mg/kg of food. Available: Adequate migration data for polycarbonate; calculation of worst-case migration for epoxy systems and butylated alkylphenolic resins; three (negative) mutagenicity studies. (RIVM/TNO SDS, March 1997 = CS/PM/2991/14020). (Adopted at 111th SCF meeting) (18-19 March 1998)

REF No.	NAME	CAS No.	SCF List	SCF Opinion
14587	4-(CHLOROFORMYL)PHTHALIC ANHYDRIDE	01204-28-0	3	<p>QM = 0.05 mg/6 dm² for the chloride to be measured as trimellitic acid.</p> <p>Available: Hydrolysis data; calculation of worst case migration assuming 100% migration of residual trimellitic acid; two Ames assays (negative); two in vitro cytogenetic assays in Chinese hamster cells (negative); two HPRT assays (negative); acute oral toxicity data; subacute oral toxicity in the rat (trimellitic acid); inadequate subchronic oral toxicity in rat and guinea pig; teratogenicity study in the rat and guinea pig by inhalation; dermal effects in rabbit (trimellitic acid); effect on immune system by inhalation; eye irritation study in rabbit (trimellitic acid); sensitisation study in guinea pigs.</p> <p>(RIVM/ISS/TNO SDS, October 1997 = CS/PM3080/14587).</p> <p>(Adopted at 111th SCF meeting) (18-19 March 1998)</p>
15610	4,4'-DICHLORODIPHENYL SULPHONE	00080-07-9	7	<p>Available: Adequate migration data; Ames tests (negative); mouse lymphoma forward mutation assay (positive); HPRT forward mutation assay in CHO cells (negative); mouse bone marrow micronucleus assay (negative).</p> <p>Needed: In vivo rat liver UDS to rule out significant genotoxicity in vivo.</p> <p>(ISS SDS, August 1997 = CS/PM/3062/15610).</p> <p>(RIVM SDS, February 1992 = CS/PM/1498).</p> <p>(Adopted at 111th SCF meeting) (18-19 March 1998)</p>
16210	3,3'-DIMETHYL-4,4'-DIAMINODICYCLOHEXYLMETHANE	06864-37-5	7	<p>Available: Inadequate migration data; three (negative) mutagenicity studies; 90-day oral rat study.</p> <p>Needed: Confirmation that the monomer is an individual compound or information concerning specification of a mixture; validation of the determination of the specific migration, such as chromatograms to support detection limit, recovery data from fat simulants and repeatability.</p> <p>RIVM/ISS/TNO SDS, April 1997 = CS/PM/2997/16210).</p> <p>(Adopted at 111th SCF meeting) (18-19 March 1998)</p>

REF No.	NAME	CAS No.	SCF List	SCF Opinion
16360	2,6-DIMETHYLPHE NOL	00576-26-1	3	R = 0.05 mg/kg of food. Available: Migration data showing not detectable at <0.012 mg/kg (3% acetic acid, 15% ethanol) or <0.020 mg/kg (olive oil) under test conditions of 30 min. at 100°C followed by 10 days at 40°C; Ames assay (negative); in vitro chromosomal aberration assay (positive); HPRT assay (negative) and in vivo bone marrow cytogenetic assay (negative) (RIVM/DK/UK SDS, October 1997 = CS/PM/3076/16360) (Adopted at 111th SCF meeting) (18-19 March 1998).
16704	1-DODECENE	00112-41-4	3	R = 0.05 mg/kg of food. Available: Adequate migration data, showing specific migration of 1-dodecene is <0.05 mg/kg food; three (negative) mutagenicity studies. (RIVM/ISS/TNO SDS, August 1997 = CS/PM/3063/16704). (Adopted at 111th SCF meeting) (18-19 March 1998).
16752	3,4-EPOXYCYCLO HEXANECARB OXYLIC ACID,3,4- EPOXYCYCLO HEXYLMETHY L ESTER	02386-87-0	6A	Available: Inadequate information concerning identity; calculation of worst case migration on unreliable data of residual ERL-4221 in a coating; two (limited) Ames tests (positive); two (limited) in vitro mammalian cell gene mutation assays; (limited) SCE in vitro positive); inadequate UDS in vitro (inconclusive); SCE in vivo negative); bone marrow nuclear anomaly test (negative); mouse spot test (negative); morphological transformation (inconclusive). Needed: Explanation whether ERL-4221 should be considered an individual compound or a mixture of two components; valid reasons for poor recovery results with the method used to determine the residual content is a coating or new data concerning the residual content, obtained with a reliable method of analysis. In first instance, in vivo UDS assay in rat liver. (RIVM/ISS/TNO SDS, August 1997 = CS/PM/3064/16752). (Adopted at 111th SCF meeting) (18-19 March 1998).

REF No.	NAME	CAS No.	SCF List	SCF Opinion
19060	ISOBUTYL VINYL ETHER	00109-53-5	3	R = 0.05 mg/kg of food. Available: Hydrolysis data for isobutylvinylether, showing rapid total (100%) hydrolysis of the monomer in simulated gastric fluid into isobutanol and acetaldehyde; calculated (worst case) migration is <0.05 mg/kg food, assuming 100% migration of residual isobutylvinylether from a typical dispersion film; three (negative) mutagenicity studies. (RIVM/ISS/TNO SDS, October 1996 = CS/PM/2907/19060). (Adopted at 111th SCF meeting) (18-19 March 1998).
19490	LAUROLACTAM	00947-04-6	7	Available: Inadequate analytical report for the specific migration of lauro lactam into food simulants; three (negative) mutagenicity studies; 90-day oral rat study. Needed: A detailed description of the analytical method, to validate the reliability of the migration data. (RIVM/TNO SDS, March 1997 = CS/PM/2574 Rev I/19490). (Adopted at 111th SCF meeting) (18-19 March 1998).
20050	METHACRYLIC ACID, ALLYL ESTER	00096-05-9	7	Available: Adequate migration data and analytical method; three (negative) in vitro mutagenicity studies. Needed: Data on stability of allyl methacrylate in food simulants. (RIVM/DK/TNO SDS, October 1997 = CS/PM/3077/20050). (Adopted at 111th SCF meeting) (18-19 March 1998).

REF No.	NAME	CAS No.	SCF List	SCF Opinion
20260	METHACRYLIC ACID, CYCLOHEXYL ESTER	00101-43-9	7	Available: Migration data in deionised water, 3% acetic acid, 15% ethanol and isooctane; three (negative) mutagenicity studies. Needed: Data on solubility in food simulants and solvents, especially in isooctane, 95% ethanol and olive oil; data on precision and recovery of the analytical method for the determination of the specific migration of cyclohexyl methacrylate. (RIVM/DE SDS, October 1997 = CS/PM/3078/20260). (Adopted at 111th SCF meeting) (18-19 March 1998).
21520	METHALLYLS ULPHONIC ACID, SODIUM SALT	01561-92-8	7	Available: Migration in water, 3% acetic acid, 15% ethanol and sunflower oil from a latex coated paper; three (negative) mutagenicity studies; 90-day oral rat study. Needed: Additional information on the analytical method for the determination of the specific migration (calibration curve, typical chromatograms, data on the establishment of the detection limit and on repeatability). (RIVM/DE SDS, October 1997 = CS/PM/3079/21520). (Adopted at 111th SCF meeting) (18-19 March 1998).
22190	2-METHYL-1,3-PROPANEDIOL	02163-42-0	3	R = 5 mg/kg of food. Available: Worst case migration < 0.6 mg/kg food; log Po/w; three (negative) mutagenicity studies; 14-day oral rat study; 90-day oral rat study. (RIVM/ISS/TNO SDS, April 1997 = CS/PM/2998/22190). (Adopted at 111th SCF meeting) (18-19 March 1998).

REF No.	NAME	CAS No.	SCF List	SCF Opinion
22210	alpha-METHYLSTYRENE	00098-83-9	7	Available: Inadequate migration data; log Po/w; three (negative) mutagenicity studies; acute toxicity; 90-day oral rat study. Needed: Detailed information concerning actual conditions of migration experiments; 2 year oral rat study or a metabolism study to provide reassurance of lack of accumulation. (RIVM/TNO SDS, February 1997 = CS/PM/2992 /22210). (Adopted at 111th SCF meeting) (18-19 March 1998).
22333	MONOCHLOROACETIC ACID	00079-11-8	W7	Available: Inadequate migration data; six mutagenicity studies; 16-day oral rat and mouse studies; 90-day oral rat and mouse studies; 2-year oral rat and mouse studies. Needed: A properly described, validated and well-documented analytical method for the determination of the specific migration of monochloro-acetic acid in water. (RIVM/DE/TNO SDS, August 1997 = CS/PM/3065/22333). (Adopted at 111th SCF meeting) (18-19 March 1998).
22360	2,6-NAPHTHALENE DICARBOXYLIC ACID	01141-38-4	7	Available: Migration tests according to EU directives; extraction tests according to FDA; log Po/w = -1.77; acute toxicity data; skin and eye irritation studies; 90-day oral rat study; Ames assay (negative); gene mutation assay in cultured mammalian cells (negative); two chromosomal aberration assays in cultured mammalian cells (one is positive and the other is inadequate). Needed: Micronucleus assay. (RIVM/TNO SDS, July 1997 = CS/PM/2220 REV.I/22360). (Adopted at 111th SCF meeting) (18-19 March 1998).

REF No.	NAME	CAS No.	SCF List	SCF Opinion
22390	2,6-NAPHTHALENE DICARBOXYLIC ACID, DIMETHYL ESTER	00840-65-3	7	R: 0.05 mg/kg of food. Available: Specific migration < 0.024 ppm into food; acute toxicity data; 90-day oral rat study; three (negative) in vitro mutagenicity studies; micronucleus assay (negative). Needed: Demonstration of hydrolysis according to the guidelines, otherwise give data to demonstrate the absence of potential for accumulation of the ester. (RIVM/TNO SDS, July 1997 = CS/PM/3085/22390). (Adopted at 111th SCF meeting) (18-19 March 1998).
22900	1-PENTENE	00109-67-1	7	Available: Migration data showing specific migration of 1-pentene <0.05 mg/kg in food; log Po/w; inadequate mouse lymphoma assay, 90-day oral rat study. Needed: Adequate mutagenicity studies according to SCF guidelines. (RIVM/TNO SDS, May 1996 = CS/PM/2855/22900). (Adopted at 111th SCF meeting) (18-19 March 1998).
23770	1,3-PROPANEDIOL	00504-63-2	3	R = 0.05 mg/kg of food. Available: Adequate migration data; Ames tests (negative); in vitro cytogenetic assay in Chinese hamster cells (positive); HPRT forward mutation assay in Chinese hamster cells (negative); mouse bone marrow micronucleus assay (negative); teratogenicity study (segment II). (RIVM/ISS/TNO SDS, August 1997 = CS/PM/3066/23770). (Adopted at 111th SCF meeting) (18-19 March 1998).

REF No.	NAME	CAS No.	SCF List	SCF Opinion
23920	PROPIONIC ACID, VINYL ESTER	00105-38-4	2	<p>Group-TDI = 0.1 mg/kg b.w. (included in the group-TDI of acetaldehyde).</p> <p>Available: Hydrolysis data for propionic acid vinylester, showing total (100% hydrolysis of the monomer in intestinal fluid, after 1hr at 37 °C, into propionic acid and acetaldehyde); calculation of (worst case) migration is <0.5 mg/kg food, assuming 100% migration of residual propionic acid vinylester from a typical dispersion film; a bacterial reversion assay (negative); a test for chromosomal aberrations in vitro (positive).</p> <p>Remark for the Commission: no method of analysis is available for the enforcement of an SML.</p> <p>(RIVM/ISS/TNO SDS, January 1997 = CS/PM/2909/23920).</p> <p>(Adopted at 111th SCF meeting) (18-19 March 1998).</p>
24760	STYRENESULPHONIC ACID	26914-43-2	3	<p>R = 0.05 mg/kg of food.</p> <p>Available: Adequate migration data in food simulants up to and including 175 °C; analytical method; four (negative) in vitro mutagenicity studies; acute toxicity; sensitisation study; eye irritation study.</p> <p>(RIVM/TNO SDS, August 1997 = CS/PM/2087 Rev I/24760).</p> <p>(Adopted at 111th SCF meeting) (18-19 March 1998).</p>
25080	1-TETRADECENE	01120-36-1	3	<p>R = 0.05 mg/kg of food.</p> <p>Available: Adequate migration data, showing specific migration of 1-tetradecene is < 0.05 mg/kg food; three (negative) mutagenicity studies.</p> <p>(RIVM/ISS/TNO SDS, January 1997 = CS/PM/2910/25080).</p> <p>(Adopted at 111th SCF meeting) (18-19 March 1998).</p>

REF No.	NAME	CAS No.	SCF List	SCF Opinion
25540	TRIMELLITIC ACID	00528-44-9	7	Available: migration data (exceeding 0.05 mg/kg of food); three (negative) mutagenicity studies; 30-day oral rat study. Needed: 90-day oral study. (TNO SDS, August 1997 = CS/PM/2825/25540). (RIVM SDS, July 1992 = CS/PM/1640). (Adopted at 111th SCF meeting) (18-19 March 1998).
25550	TRIMELLITIC ANHYDRIDE	00552-30-7	7	Available: Worst case calculation for high temperature application with polyamidimide coatings; migration data for application at temperatures up to 121°C with epoxy resins; six (negative) mutagenicity studies; acute toxicity; 90-day oral rat and dog studies; 14- day and 90-day inhalation studies in rats; teratogenicity studies in rats and guinea pigs. Needed: Covered by 25540. (TNO SDS, August 1997 = CS/PM/2826/25550). (RIVM SDS, July 1992 = CS/PM/1639). (Adopted at 111th SCF meeting) (18-19 March 1998).
30015	ACETIC ACID, 2-BUTOXYETHYL ESTER	00112-07-2	2	Group t-TDI : 0.05 mg/kg b.w. (with 15780=48050, 16993=53765, 16996=53820, 16999, 17002=53860, 30015, 30120, 30200, 48030). (Adopted at 111th SCF meeting) (18-19 March 1998).
30200	ACETIC ACID, 2-METHOXYETHYL ESTER	00110-49-6	2	Group t-TDI : 0.05 mg/kg b.w. (with 15780=48050, 16993=53765, 16996=53820, 16999, 17002=53860, 30015, 30120, 30200, 48030). (Adopted at 111th SCF meeting) (18-19 March 1998).

REF No.	NAME	CAS No.	SCF List	SCF Opinion
38810	BIS(2-6-DI-tert.BUTYL-4-METHYLPHENYL)PENTAERYTHRITOL DIPHOSPHITE (=Phosphorous acid, cyclic neopentetetrayl bis(2-6-di-tert-butyl-4-methylphenyl)ester	80693-00-1	3	R = 5 mg/kg of food (sum of phosphite and phosphate). Available: Adequate migration data of the additive from polypropylene into foods simulants; log Po/w; acute toxicity data; 28-day oral rat study; 90-day oral rat study; delayed neurotoxicity study; Ames assay (negative); in vitro chromosomal aberrations assay (negative); explanation of the petitioner concerning mutagenicity. No need for further studies on accumulation, because no toxic effects were observed upto the highest dose tested in the 90-day oral rat study (NOAEL = 2500 mg/kg b.w.). (RIVM/TNO SDS, September 1997 = CS/PM/2746 REV.I/38810). Remark for Commission: only migration data of the additive from polypropylene into food simulants are available. (Adopted at 111th SCF meeting) (18-19 March 1998).
39815	9,9-BIS(METHOXYMETHYL)FLUORENE	182121-12-6	3	R = 0,05 mg/kg of food Available: Maximum worst case migration is calculated to be 0.034 mg/kg; Ames assay (negative); in vitro chromosomal aberration assay (positive); in vitro mammalian cell gene mutation assay (negative); mouse bone marrow micronucleus assay (negative); rat bone marrow chromosome analysis (negative); in vivo UDS in rat liver (negative). (RIVM/ISS/UK SDS, October 1997 = CS/PM/3081/39815).
44080	CINNAMALDEHYDE	00104-55-2	8	(Adopted at 111th SCF meeting) (18-19 March 1998).

REF No.	NAME	CAS No.	SCF List	SCF Opinion
50080	DIOCTADECYL PENTAERYTHRITOL DIPHOSPHITE	03806-34-6	W7	<p>Available: Acute toxicity data; 90-day oral rat study (IBT study); 90-day oral dog study (IBT study); review of the IBT rat and dog studies; neurotoxicity study in the hen.</p> <p>Needed: Migration data (on the phosphite and phosphate); three in vitro mutagenicity studies and data to demonstrate the absence of potential for accumulation.</p> <p>(RIVM SDS, August 1996 = CS/PM/2903/50080). (Adopted at 111th SCF meeting) (18-19 March 1998).</p>
72800	PHOSPHORIC ACID, DIPHENYL 2-ETHYLHEXYL ESTER	01241-94-7	2	<p>TDI = 0.04 mg/kg b.w. (based on a 90-day study).</p> <p>The entire profile of this substance allows to allocate a TDI.</p> <p>Available: Acute toxicity data; two 90-day oral rat studies; inadequate 2-year oral rat and dog studies; one-generation reproduction study using rats; teratogenicity study; Ames assay (negative); gene mutation assay in mouse lymphoma cells (negative); in vivo bone marrow cytogenetic assay (negative); neurotoxicity study; peroxisome proliferation study.</p> <p>(RIVM SDS, June 1996 = CS/PM/2858/72800). Remark for Commission: no method of analysis is available for the enforcement of an SML. (Adopted at 111th SCF meeting) (18-19 March 1998).</p>

REF No.	NAME	CAS No.	SCF List	SCF Opinion
79550	POLYETHYLEN EGLYCOL 2,4,7,9- TETRAMETHY L-5-DECYN-4,7- DIOL ETHER	09014-85-1	7	Available: Incomplete thermographic test data of S-440, showing that a certain amount of unknown substances occurring from the additive remains in the PTFE coating; calculated worst case migration is 0.012 mg residue/dm ² from the final PTFE coating, assuming 100% migration of the solid residue of unknown composition; acute toxicity data; inadequate 28-day range-finding study with rats; inadequate 90-day oral rat study; inadequate one-generation reproduction study; three (negative) in vitro mutagenicity studies. Needed: In first instance, information on the nature of the residue. Remark: It is a processing agent intended to decompose, therefore the WG is not asking for an analytical method. (RIVM/TNO SDS, October 1996 = CS/PM/2906/79550). (Adopted at 111th SCF meeting) (18-19 March 1998).
83599	REACTION PRODUCTS OF OCTADECENOI C ACID, 2- MERCAPTOET HYL ESTER, WITH DICHLORODIM ETHYLSTANNA NE, SODIUM SULFIDE AND TRICHLOROME THYLSTANNA NE	68442-12-6	2	Group-TDI=0.003 mg/kg b.w. (as Sn) (with 49600 and 67520). Available: migration data from PVC; hydrolysis in gastric fluid; two bacterial reversion assays; a mouse bone marrow micronucleus assay; with methyltin compounds two bacterial reversion assays; a mammalian cell gene mutation assay; an in vitro chromosomal aberration assay; a mouse bone marrow micronucleus test; an in vivo/in vitro UDS in rat liver; acute toxicity data; a subacute oral rat study; 90-days oral rat studies on 3 representative mixtures of methyltin stabilisers, on methyltin chlorides and on mercaptoethyloctadecenoic. (RIVM/ISS/TNO October 1996,=CS/PM/2908) (Adopted at 111th SCF meeting) (18-19 March 1998).

REF No.	NAME	CAS No.	SCF List	SCF Opinion
93120	THIODIPROPIONIC ACID, DIDODECYL ESTER	00123-28-4	3	<p>Group R: 5 mg/kg of food (with thiodipropionic acid, dioctadecyl ester=93280)</p> <p>Available: Adequate migration data from PVC and ABS; acute toxicity data; 28-day oral rat study; 90-day oral rat study; inadequate data on long-term toxicity; three oral teratogenicity studies using mice, hamsters and rabbits; studies on absorption, distribution, metabolism and excretion; peroxisome proliferation study (this study deviated from the SCF guidelines on peroxisomal proliferation); two Ames assays (negative); in vitro chromosomal aberration assay (negative); gene mutation assay in mouse lymphoma cells (negative).</p> <p>Remark: Data insufficient for allocating a TDI (no reproduction study and no long-term study). The WG decided not to ask for a new peroxisome proliferation study, since the 90-day study showed only increased liver weights (no morphological changes) at very high doses (1000 mg/kg b.w.). In view of the structure of the compound and the metabolism data provided there is no need for demonstration of the absence of potential for accumulation. No need for a long-term toxicity study, since myocarditis was not seen after the recovery period of the 90-day study. (RIVM/TNO SDS, May 1996 = CS/PM/2862/93120).</p>
93760	TRIBUTYL ACETYL CITRATE	00077-90-7	7	<p>Available: Specific migration values in 3% acetic acid and olive oil ranging from 9.0-28.2 mg/6 dm²; 14-day oral range-finding study in rats; 90-day oral rat study; 2-generation reproduction study using rats; Ames assay (negative); two chromosomal aberration assays (negative); HGPRT assay (negative); mouse lymphoma assay (positive); metabolism study; skin and eye irritation studies (only summaries available); sensitisation study.</p> <p>Needed: In vivo UDS assay in rat liver. (RIVM/TNO SDS, June 1997 = CS/PM/2966 REV. I/93760). (Adopted at 111th SCF meeting) (18-19 March 1998).</p>

REF No.	NAME	CAS No.	SCF List	SCF Opinion
95600	1,1,3-TRIS(2-METHYL-4-HYDROXY-5-tert-BUTYLPHENYL) BUTANE	01843-03-4	7	<p>Available: Adequate migration data; acute toxicity data; inadequate 90-day oral dog study; inadequate 12-week oral rat study; 13-week oral rat study; three (negative) in vitro mutagenicity studies; excretion studies.</p> <p>Needed: Demonstration of the absence of potential for accumulation. (RIVM/TNO SDS, August 1996 = CS/PM/2905/95600). (Adopted at 111th SCF meeting) (18-19 March 1998).</p>

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 a TDI or a t-TDI has been established by this Committee.

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.

LIST 4 (for monomers)

Section 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.

Section 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 which 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.

Section 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.

Section 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.