Opinion of the Scientific Committee on Food on an additional list of monomers and additives for food contact materials (adopted the 18 September 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
10060	ACETALDEHYDE	00075-07-0	2	Group TDI: 0.1 mg/kg b.w. (calculated as acetaldehyde (including 10060 and 23920) Toxicity profiles similar to methaldehyde. A 2-year oral rat study and a 3-generation oral rat study including teratogenicity with methaldehyde. The reports on nasal carcinogenicity after inhalation were considered without relevance for effects from oral intake of smaller doses. (Adopted at 113th SCF meeting) (17-18 September 1998).
11530	ACRYLIC ACID, 2-HYDROXYPROPYL ESTER	00999-61-1	7	Available: Calculation of worst case migration; Ames assay (negative); in vitro chromosomal aberration assay (positive); in vitro mammalian cell gene mutation assay (negative). Needed: In first instance, in vivo mouse bone marrow micronucleus assay or rodent bone marrow metaphase analysis assay. (RIVM/ISS/TNO SDS, January 1998 = CS/PM/3117/11530). (Adopted at 113th SCF meeting) (17-18 September 1998).
13180	BICYCLO(2.2.1)HEPT-2-ENE	00498-66-8	3	R: 0.05 mg/kg of food. Available: Adequate migration data; adequate Ames test (negative); adequate gene mutation assay in cultured mammalian cells (negative); inadequate chromosomal aberration assay in

				cultured mammalian cells; adequate chromosomal aberration assay in cultured mammalian cells (negative). (RIVM/ISS/TNO SDS, January 1998 = CS/PM/2851 REV. I/13180). (Adopted at 113th SCF meeting) (17-18 September 1998).
13545	1,1-BIS(4-HYDROXYPHENYL)-3,3,5-TRIMETHYLCYCLOHEXANE	129188-99-4	W7	Available: Adequate migration data; three (negative) mutagenicity studies; inadequate micronucleus assay; acute toxicity data; 3 months oral rat study (+ 4-week recovery period); one-generation reproduction rat study; teratogenicity oral rat study; log Po/w. Needed: In first instance, test for endocrine activity (such as in vitro test for binding to the oestrogen receptor). Remark: Reasoning for classifying in L7 is: there is a potential for accumulation and a potential for endocrine disrupter activity based on the structure of the substance as well as some effects seen in the animal experiments). (RIVM/TNO SDS, January 1998 = CS/PM/2644 REV. II/13545). (Adopted at 113th SCF meeting) (17-18 September 1998).
25840	1,1,1-TRIMETHYLOLPROPANE TRIMETHACRYLATE	03290-92-4	7	Available: Migration data; Ames assay (weakly positive); Ames assay (negative); in vitro chromosomal aberration assay (negative); in vitro mammalian cell gene mutation assay (negative); in vitro mammalian cell gene mutation assay (positive). Needed: in vivo mammalian bone marrow cytogenetic assay; in vivo UDS assay. (RIVM/DE SDS, February 1998 =CS/PM/3127/ 25840). (Adopted at 113th SCF meeting) (17-18 September 1998).
39815	9,9 BIS(METHOXYMETHYL)FLUORENE	182121-12-6	3	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). (Adopted at 113th SCF meeting) (17-18 September 1998).
40632	2-BUTYL-BENZO[d]ISOTHIAZOLIN-3-ONE	04299-07-4	W7	Available: Calculation of maximum migration assuming 100% migration of the additive over lifetime of the fcm; Ames/E.coli assay (negative); in vitro chromosomal aberrations assay in human lymphocytes (positive); in vitro mammalian cell gene mutation assay (negative); inadequate in vivo mouse micronucleus assay (negative); in vivo UDS assay (negative); 90-day oral rat study. Needed: analytical method for the determination of 2-butyl-benzo[d]isothiazolin-3-one in polymers such as PVC coatings, polyolefin and adhesives to enable future enforcement of restriction. Remark for Commission: No method of analysis is available for the enforcement of an SML. (RIVM/TNO SDS, December 1997 = CS/PM/3132/40632). (Adopted at 113th SCF meeting) (17-18 September 1998).
45450	P-CRESOL-DICYCLOPENTADIENE-ISOBUTYLENE, COPOLYMER	68610-51-5	L3	R = 0.05 mg/kg of food. Available: Migration data; four (negative) in vitro mutagenicity studies; 28-day and 3-month oral rat studies; possible bioaccumulation potential. Remark: The applicant did not demonstrate the absence of potential for bioaccumulation. Although the substance is insoluble in water and the log Po/w>6 (no reliable figure), it is unlikely that this substance accumulates, but no direct proof is given. The SCF concluded that due to its restricted use, the exposure will be minimal and therefore the question of potential bioaccumulation is not considered relevant. (Adopted at 113th SCF meeting) (17-18 September 1998).
49485	2,4-DIMETHYL-6-(1-METHYLPENTADECYL)-PHENOL	134701-20-5	3	R = 1 mg/kg of food. Available: Adequate migration data showing specific migration into aqueous food simulants is

				< 0.05 mg/kg food and into olive oil < 0.12-0.48 mg/kg food; three (negative) mutagenicity studies; 28-day oral rat study; 90-day oral rat study (relatively low NOAEL + effects still observed after the recovery period); log Po/w; ADME study. Remark: Based on the hepatotoxic effects observed in both the 28-day and 90-day oral rat studies which resulted in the same low NOAEL of 10 mg/kg b.w., the SCF used a safety factor of 500 and a 60 kg person to establish a restriction of 1 mg/kg of food. (RIVM SDS, February 1998 = CS/PM/2917 REV. I/49485). (Adopted at 113th SCF meeting) (17-18 September 1998).
54660	FATTY ACIDS OF COCONUT OIL, ESTERS WITH CHOLINE CHLORIDE	-	3	R : to be used at a maximum amount of 0.015 g/m^2 (150 ug/dm^2). Available: Method for determination of residual content; three (negative) mutagenicity studies (performed with lauroyl choline chloride); 28-day and 90-day oral rat studies (on coconut fatty acid esters of choline chloride, the largest component of which is lauric acid ester of choline chloride); bioaccumulation study (in Zebra fish). Remark: change name into 'Fatty acids of coconut oil, esters with choline chloride'. Remark: Given the physical/chemical data, there is no need for asking further data on possible accumulation. Remark: If hydrolysis data are provided (showing complete hydrolysis), then the restriction may be deleted. (RIVM/ISS/TNO SDS, April 1997 = CS/PM/2999/63400). REMARK for Commission: No method of analysis is available for the enforcement of an SML. (Adopted at 113th SCF meeting) (17-18 September 1998).
71635	PENTAERYTHRITOL DIOLEATE	25151-96-6	3	R: 0.05 mg/kg food. Available: migration data, 3 mutagenicity tests,

				not regarded as genotoxic. Remark: Since high migration into fat has been demonstrated, the SCF recommends that the Commission take the necessary measures, so that the restriction proposed is not exceeded. (RIVM SDS, October 1994= CS/PM/2465). (Adopted at 113th SCF meeting) (17-18 September 1998).
93120	THIODIPROPIONIC ACID, DIDODECYL ESTER	00123-28-4	3	Group R: 5 mg/kg of food (with thiodipropionic acid, dioctadecyl ester=93280) 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 limphoma cells (negative). Remark: Data insufficient for allocating a TDI (no reproduction study and no long-term study). The SCF 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). (Adopted at 113th SCF meeting) (17-18 September 1998).
93280	THIODIPROPIONIC ACID, DIOCTADECYL ESTER	00693-36-7	3	Group R: 5 mg/kg of food (with 93120= dilauryl thiodipropionate) based on data available for 93120. (Adopted at 113th SCF meeting) (17-18 September 1998).

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.