EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C3 - Management of scientific committees II; scientific co-operation and networks

SCIENTIFIC COMMITTEE ON FOOD

SCF/CS/PM/GEN/M83
13 November 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)

Rue de la Loi 200, B-1049 Bruxelles/Wetstraat 200, B-1049 Brussel - Belgium - Office: BE232 - 6/37.
Telephone: direct line (+32-2) 295.81.10 / 296.48.70, exchange 299.11.11. Fax: (+32-2) 299.48.91
Telex: COMEU B 21877. Telegraphic address: COMEUR Brussels.
http://europa.eu.int/comm/food/fs/sc/scf/index_en.html

Opinion of the Scientific Committee on Food on the11th additional list of monomers and additives for food contact materials

(expressed on 19 October 2000)

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 No.), Chemical Abstract Number (CAS No.) 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_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
12976	BIS (HYDROXYPHENYL) METHANE BIS (2,3-EPOXYPROPYL) ETHER	39817-09-9 (mixture)	7	Available: migration data of bis(2,3-epoxypropyl)ether (BFDGE) < 0.05 mg/kg food when used as a cross-linker in thermoset coatings and 1-5 mg/kg food into fat simulant (oily foods) when used as an additive in PVC organosols; gene mutation assay in bacteria (positive; performed with bisphenol F diglycidyl ether); chromosomal aberration assay in cultured mammalian cells (positive; performed with bisphenol F diglycidyl ether); micronucleus assay (negative; performed with bisphenol F diglycidyl ether); 14-day oral rat study (performed with bisphenol F diglycidyl ether); 90-day oral rat study (performed with bisphenol F diglycidyl ether); gene mutation assay in bacteria (positive; performed with bisphenol F/epichlorohydrin epoxy resin, containing ca. 75% BFDGE); 2-year dermal carcinogenicity study (performed with bisphenol F/epichlorohydrin epoxy resin, containing ca. 75% BFDGE). Needed: • Migration of BFDGE and its reaction products (hydrolysed and chlorinated adducts) from well-characterised samples in food simulants and in various foodstuffs; • Information on the foodstuffs in respect to the amount and physical conditions of fat present; • Data on the amount of BFDGE in the recipe and the actual amount of BFDGE and reaction products in the final article; • In first instance ADME study and DNA binding study. Remark: The data requested should be provided within 3 years. RIVM/UK SDS, April 2000 = CS/PM/3402 REV. I/12976. Statement on novolac glycidyl ethers (NOGES): NOGES are polyepoxides (n>2) which may give rise to a broader scope of cross-linking reactions than bisepoxides like BFDGE, BADGE and BADGE oligomers. Therefore any of these bisepoxides cannot be considered as worst case test compounds. Remark: on the question of the Commission (i.e. request for risk assessment on BFDGE) the SCF confirms the statement, on NOGE, as made in December 1999. Request for NOGES: • non-toxicity data according to the guidelines on polymeric additives

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
				(see Annex 2 of "Note for Guidance" updated to 23-02-1999) of typical coatings (epoxy and organosol) before and after curing of the coating; • migration data from well characterised samples in food simulants and in various foods in conformance to requested data for BFDGE; • 3 mutagenicity studies on the more representative migration fraction having a Mw less than 1000 D. Remark: The data requested should be provided within 1 year. (Adopted at the 123rd SCF meeting, 19 October 2000)
13545	1,1-BIS(4-HYDROXY-PHENYL)-3,3,5-TRIMETHYL CYCLOHEXANE	129188-99-4	7	Available: specific migration data < 0.05 mg/kg food; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative); micronucleus assay (negative); acute toxicity data; 90-day oral rat study; reproduction study; teratogenicity study; scientific statement provided by the applicant. Needed: test for endocrine activity in accordance with US-EPA tiered approach. RIVM/TNO SDS, February 2000 = CS/PM/2644 REV.III/13545. (Adopted at the 123rd SCF meeting, 19 October 2000)
13810	1,4-BUTANEDIOL FORMAL	505-65-7	3	R = 0.05 mg/kg of food. Available: calculated (worst case) migration is < 0.05 mg/kg of food; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (positive); gene mutation assay in cultured mammalian cells (negative); micronucleus assay (negative); in vivo UDS assay (negative) RIVM/ISS/TNO SDS, January 2000 = CS/PM/2853 REV.I/13810. Remark for Commission: only a method for the residual quantity in the finished product (FP) is available. A QMA is proposed. (Adopted at the 123rd SCF meeting, 19 October 2000)
14800	2-BUTENOIC ACID (crotonic acid)	3724-65-0	7	Available: information on the use of the substance; analytical method, properly described for the determination of the substance in the PVC emulsion stabiliser; two gene mutation assays in bacteria (data inadequate for evaluation); gene mutation assay in cultured mammalian cells (negative); micronucleus assay (negative). Needed: adequate gene mutation assay in bacteria in accordance with the SCF guidelines. RIVM/FR SDS, April 2000 = CS/PM/3357 REV. II/14800. (Adopted at the 123rd SCF meeting, 19 October 2000)
21520	METHALLYLSULFONIC ACID, SODIUM SALT	1561-92-8	3	R = 5 mg/kg of food. Available: migration data in water, 3% acetic acid, 15% ethanol and sunflower oil from a latex coated paper; sufficiently described analytical method for the determination of the specific migration; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative); 90-day oral rat study. RIVM/DE SDS, January 2000 = CS/PM/3079 REV.I/21520. Remark: since the substance is very soluble in water and has no lipophilic structural elements, the absence of accumulation can be expected. No additional data concerning the absence of accumulation are requested. (Adopted at the 123rd SCF meeting, 19 October 2000)
21640	2-METHYL-1,3-	78-79-5	4A	N.D.

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
	BUTADIENE			Available: calculated worst case migration is 0.0001-0.3 mg/kg food; log Po/w; three gene mutation assays in bacteria (one limited, one negative (publication) and one negative (publication; tested with metabolites); chromosomal aberration assay in cultured mammalian cells (negative); in vivo chromosomal aberration assay by inhalation route (positive); mouse peripheral blood micronucleus assay (positive; only summary available); rat lung fibroblast micronucleus assay (negative; only summary available); chronic toxicity study (by inhalation) in rats and mice; chronic oncogenicity study (by inhalation) in mice; carcinogenicity study (by inhalation) in rats. RIVM/UK/TNO SDS, October 1999 = CS/PM/3351/21640. Remark for Commission: no method of analysis is available. However, the CEN-method for butadiene can be adapted. (Adopted at the 123rd SCF meeting, 19 October 2000)
21765	4,4'-METHYLENEBIS(3-CHLORO-2,6-DIETHYL-ANILINE	106246-33-7	3	R = 0.05 mg/kg of food. Available: residual content; calculation of worst case migration < 0.05 mg/kg food; log Po/w; two gene mutation assays in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); micronucleus assay (negative); in vivo UDS assay (negative). RIVM/IT/UK SDS, April 2000 = CS/PM/3413/21765. Remark for Commission: only a method for the residual quantity in the finished product (FP) is available. A QMA is proposed. (Adopted at the 123rd SCF meeting, 19 October 2000)
22778	4,4'-OXYDIBENZENE-SULFONYL AZIDE	7456-68-0	3	R = 0.05 mg/kg of food. Available: specific migration of the reaction by-product 4,4'-oxy-dibenzenesulfonamide is less than 3.4 ug/kg; analytical method for the determination of 4,4'-oxydibenzenesulfonyl azide in PP; residual content of 4,4'-oxydibenzenesulfonyl azide in PP is not detectable or less than 31 ug/kg PP, which results in a worst case migration of 0.3 ug/kg; log Po/w; gene mutation assay in bacteria (positive); gene mutation assay in cultured mammalian cells (negative); micronucleus assay (negative); subacute (4-week) oral toxicity study in rats; acute oral toxicity study in rats; acute dermal toxicity study in New Zealand White rabbits. RIVM/UK/TNO SDS, April 2000 = CS/PM/3410/22778. Remark for Commission: only a method for the residual quantity in the finished product (FP) is available. A QMA is proposed. (Adopted at the 123rd SCF meeting, 19 October 2000)
25380	TRIALKYL ACETIC ACID (C7-C17), VINYL ESTERS	26544-09-2	3	R = 0.05 mg/kg of food. Available: 40% hydrolysis determined in simulated saliva only; residual content is 11.72 ug/g polymer, resulting in a worst case migration of 40 ug/kg; log Po/w; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative); acute toxicity data; skin/eye irritation data; sensitisation data; 13-week toxicity study (by inhalation) in rats. RIVM/TNO SDS, January 2000 = CS/PM/3385/25830. Remark for Commission: only a method for the residual quantity in thin films is available. A QMA is proposed. (Adopted at the 123rd SCF meeting, 19 October 2000)

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
65768/65770	2-MERCAPTO-BENZOTHIAZOLE	149-30-4	-	Statement on 2-Mercaptobenzothiazole (MBT) The Committee has received a request to comment on the safety of the proposed CEN extraction limit[1] for MBT from rubber materials used for soothers and teats. • Considering that on the basis of well-conducted genotoxicity studies the previously expressed concern of possible carcinogenic effects related to the migration of low amounts of MBT from finished products can now be discounted. • Considering that based on the limit of 8 mg MBT/kg rubber extracted over 24 hours as proposed by CEN, a worst case exposure to MBT was calculated not to exceed 22 ug/kg b.w. for a baby weighing 2 kg, fed 8 times a day using a new teat of 5 g at each occasion and • In view of the existing toxicological studies, albeit insufficient for establishing a TDI, which show a NOAEL of 94 mg/kg b.w. from a 90-day oral mouse study leading to a margin of safety of around 4200, The Committee concludes that the potential oral exposure to MBT resulting from materials in compliance with the proposed CEN limit of 8 mg/kg rubber extracted over a 24 hour period does not constitute a health hazard. However, the Committee is aware that MBT has been reported, primarily in occupational settings, to induce sensitisation after dermal contact. As this issue is not related to food safety it is considered to be outside the remit of the Committee. Therefore the SCF recommends that the Commission seeks appropriate advice to consider whether direct contact exposure to MBT, through teats and soothers, constitutes a sensitisation hazard. Available: inadequate migration data and worst case calculations; gene mutation assays in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (positive); gene mutation assays in cultured mammalian cells (one assay negative and one assay weakly positive); SCE assay in vitro (positive); mouse bone marrow micronucleus assay (negative); in vivo rat liver UDS assay (negative); limited in vivo DNA binding assay (negative); three 16-day oral mouse and rat studies (one inadequate); two 90-day oral mouse and rat studies; 2 carcinogenicity studies (mouse and rat); two teratogenicity studies (rat); metabolism study; skin and eye irritation studies; sensitisation study; human data concerning sensitisation. RIVM/DK/ISS/TNO SDS, March 2000 = CS/PM/3224 A+B REV.IV/65768/65770. (Adopted at the 123rd SCF meeting, 19 October 2000)
72081/10	PETROLEUM HYDROCARBON RESINS (HYDROGENATED)	88526-47-0	7	Available: molecular weights and molecular weight distribution curve; residual amounts of monomers, hydrogenated monomers and catalysts; data on global migration; gene mutation assay in bacteria (negative; performed with the hydrogenated hydrocarbon resin (Arkon M-90)); chromosomal aberration assay in cultured mammalian cells (negative; performed with the hydrogenated hydrocarbon resin (Arkon M-90)); gene mutation assay in cultured mammalian cells (negative; performed with the hydrogenated hydrocarbon resin (Arkon M-90)); 90-day oral rat study including an in utero phase (performed with Arkon M-90); 90-day inhalation study with decalin, one of the hydrocarbon impurities of Arkon M-90, in dogs, rats and mice. Needed: given the high migration to be expected in fatty food, in first instance reduction of the residues of the hydrogenated monomers and unpolymerisable components (by technical processing e.g. by steam stripping). RIVM/DE SDS, May 2000 = CS/PM/3082 REV. III/72081/10.

[1] Reference: CEN TC 252.

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
				(Adopted at the 123rd SCF meeting, 19 October 2000)

Previous opinions adopted by the SCF in the area of Food Contact Materials containing lists of assessments of substances (status up to October 1999)

The 42nd Series of Reports of the SCF (Compilation of the evaluations of the Scientific Committee for Food on certain monomers and additives used in the manufacture of plastics materials intended to come into contact with foodstuffs expressed until 21st March 1997, ISBN 92-828-5886-3) contains the compilation of the SCF opinions on Food Contact Materials for the period 1974 (the beginning of the existence of the Committee) to March 1997.

Following this date, the Committee has evaluated or re-evaluated a number of substances. All these opinions have been published on the Internet at the webpages of the Committee (http://europa.eu.int/comm/food/fs/sc/scf/index_en.html):

- Opinion on the 10th additional list of monomers and additives for food contact materials (29 substances) (expressed on 22 June 2000)
- Opinion on the 9th additional list of monomers and additives for food contact materials (4 substances) (expressed on 22 June 2000)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (10 substances) (expressed on 2 December 1999)
- Statement on the use of Novolac glycidyl ethers (NOGE) as additives in food contact materials Minutes of the 119th meeting of the SCF (1st/2nd December 1999)
- Statement on a recent survey on Bisphenol A diglycidyl ether (BADGE) and Bisphenol F diglycidyl ether (BFDGE) in canned food. Minutes of the 119th meeting of the SCF (1st/2nd December 1999)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (9 substances) (expressed on 23 September 1999)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (11 substances) (expressed on 17 June 1999)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (6 substances) (expressed on 24 March 1999)
- Opinion on Bisphenol A dyglicidyl ether (expressed on 24 March 1999)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (23 substances) (expressed on 10 December 98)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (13 substances) (expressed on 17 September 1998)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (37 substances) (expressed on 19 March 1998)
- Additional list of monomers and additives evaluated by the WG "Food Contact Materials" of the SCF during the 69th-70th meetings. (16 substances) (adopted during the SCF meeting of 12 and 13 June 1997). Also appearing in the Forty-third series of Reports of the Scientific Committee for Food, ISBN 92-828-5887-1)

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.

****