EUROPEAN COMMISSION
DIRECTORATE-GENERAL XXIV
CONSUMER POLICY AND CONSUMER HEALTH PROTECTION
Directorate B - Scientific opinions on health matters
Unit B3 - Management of scientific committees II

SCIENTIFIC COMMITTEE ON FOOD

CS/PM/3295 final
18 June 99

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

(expressed on 17/6/1999)

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

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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.

The substances appearing in this table have been examined during the 78th meeting of the Working Group Food Contact Materials on 3-5 February 1999.

TABLE

REF. No.	NAME	CAS No.	SCF List	SCF ASSESSMENT
15030	CYCLOOCTENE	931-88-4	3	R = 0.05 mg/kg of food; only for aqueous foodstuffs. Available: migration data from polyoctenamer and from blends with polypropylene in aqueous food simulants; migration data from polyoctenamer in HB307; three negative mutagenicity studies performed with cyclooctene; acute toxicity data. (RIVM/TNO SDS, October 1998 = CS/PM/2529 REV. III/15030). (Adopted at 117th SCF meeting) (17 June 1999)
16390	2,2-DIMETHYL-1,3-PROPANEDIOL	126-30-7	3	R = 0.05 mg/kg of food. Available: information on identity; migration data with a coating made with 17% of the substance used as comonomer; analytical method; data on residual content (with 17% of the substance used as comonomer), and corresponding analytical method; 3 negative mutagenicity studies. (RIVM/FR SDS, December 1998 = CS/PM/3251/16390). Remark: petitioner has to clarify the 40% (weight) in the formulation. (Adopted at 117th SCF meeting) (17 June 1999)

REF. No.	NAME	CAS No.	SCF List	SCF ASSESSMENT
17392	FUMARIC ACID, DIISOPROPYL ESTER	7283-70-7	7	Available: 100% hydrolysis in intestinal fluid within 30-40 minutes to mono-isopropylester of fumaric acid and isopropanol. Needed: migration and toxicological data of fumaric acid, diisopropyl ester according to the guidelines. (RIVM/TNO SDS, January 1999 = CS/PM/3252/17392). (Adopted at 117th SCF meeting) (17 June 1999)
20590	METHACRYLIC ACID, 2,3-EPOXYPROPYL ESTER	106-91-2	4B	QM = 20 µg/6 dm^2. Available: adequate migration data from plastics showing hydrolysis in aqueous food simulant and residual content in coatings; gene mutation assay in bacteria (positive); chromosomal aberration assay in cultured mammalian cells (positive); two gene mutation assays in cultured mammalian cells (one weakly positive; one negative); two mouse bone marrow micronucleus assays (both negative; one assay has a limited protocol); 90-day rat inhalation study; teratogenicity study by inhalation in rabbits. (RIVM/DE/TNO SDS, October 1998 = CS/PM/3118 REV. I/20590). Remark for Commission: • Including the epoxide hydrolysis products is not needed if the restriction is on a QM basis. • If a future application is made for a higher restriction level, which could then permit use as an additive in PVC organosols, then chlorohydrin formation would need to be considered. (Adopted at 117th SCF meeting) (17 June 1999)
21970	N-METHYLOL METHACRYLAMIDE	923-02-4	7	Available: hydrolysis data; calculation of worst case migration assuming 100% migration of residual N-methylolmethacrylamide; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (positive); gene mutation assay in cultured mammalian cells (negative). Needed: data on the estimation of residual N-methylolacrylamide; assay for chromosomal damage in rodent bone marrow. (RIVM/DE SDS, February 1999 = CS/PM/3221 REV. I/21970). (Adopted at 117th SCF meeting) (17 June 1999)
22333	MONOCHLOROACETIC ACID	79-11-8	3	R = 0.05 mg/kg of food. Available: migration data in water; two gene mutation assays in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (equivocal); in vitro SCE assay (positive); sex-linked recessive lethal assay in Drosophila melanogaster (negative); 16-day oral mouse and rat studies; 90-day oral mouse and rat studies; 2-year oral mouse and rat studies. (RIVM/DE/TNO SDS, October 1998 = CS/PM/3065 REV. II/22333). (Adopted at 117th SCF meeting) (17 June 1999)
22900	1-PENTENE	109-67-1	7	Available: migration data showing specific migration of 1-pentene < 0.05 mg/kg in food; log Po/w; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); inadequate gene mutation assay in cultured mammalian cells; 90-day oral rat study. Needed: adequate gene mutation assay in cultured mammalian cells. (RIVM/TNO SDS, February 1999 = CS/PM/2855 REV. III/22900). (Adopted at 117th SCF meeting) (17 June 1999)

REF. No.	NAME	CAS No.	SCF List	SCF ASSESSMENT
25450	TRICYCLO(5,.2.1.$0^{2,6}$) DECANEDIMETHANOL	26896-48-0	7	Available: adequate information on the identity of the substance; incomplete specific migration data; three negative mutagenicity studies. Needed: specific migration or extraction tests with the highest percentage of the substance used in the coating; validation of the method; migration data in olive oil. (RIVM/FR SDS, February 1999 = CS/PM/3253 REV. I/25450). (Adopted at 117th SCF meeting) (17 June 1999)
25900	1,3,5-TRIOXANE	110-83-3	3	R = 0.05 mg/kg of food. Available: specific migration in water, 3% acetic acid, 15% ethanol and olive oil < 0.05 mg/kg into food; three gene mutation assays in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); two gene mutation assays in cultured mammalian cells ($TK^{+/-}$- study is positive at very high doses and HPRT-study is not accepted); in vivo micronucleus assay (negative); in vivo UDS assay (negative); induction of DNA single-strand breaks in vivo (positive); in vitro cell transformation assay (negative); acute toxicity data; 28-day oral rat study; 2-week inhalation rat study; 2 metabolism studies; skin/eye irritation studies; sensitisation studies. (RIVM/TNO SDS, September 1998 = CS/PM/2577 REV. I/25900). (Adopted at 117th SCF meeting) (17 June 1999)
35760	ANTIMONY TRIOXIDE	1309-64-4	7	Available: data on specific migration from PET; inadequately described test method; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (positive); gene mutation assay in cultured mammalian cells (negative); two micronucleus assays (negative; one assay with a single oral dose, the other assay with repeated oral doses); in vivo UDS assay (negative); 28-day oral range finding rat study; 90-day oral rat study. Needed: description of the technical function as " additive" ; confirmation that 350 mg/kg is the maximum amount used; adequately described method for the specific migration; method for the determination of antimony trioxide in the food contact material (residual content); if used in other polymers than PET: data on use and specific migration. (RIVM/DE SDS, February 1999 = CS/PM/3254 REV. I/35760). (Adopted at 117th SCF meeting) (17 June 1999)
73160	PHOSPHORIC ACID, MONO- AND DIESTERS WITH CETYL- AND STEARYL ALCOHOL	2958-09-0 3037-89-6 3539-43-3 2197-63-9	3	R = 0.05 mg/kg of food. Available: inadequate data on migration into aqueous simulants; inadequate hydrolysis data; three negative mutagenicity studies ; 14-day oral rat study ; 28-day oral rat study. (RIVM/DE SDS, January 1999 = CS/PM/2530 REV.I/73160). Remark: • there is no request for peroxisomal proliferation studies, due to the structure of the alkyl groups (natural origin, straight chain). Also no request for a neurotoxicity study. the substance does not occurr in food. (Adopted at 117th SCF meeting) (17 June 1999)

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.

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