

Additional List of Monomers and Additives Evaluated by the WG "Food Contact Materials" of the SCF During the 69th-70th Meetings (adopted during the SCF meeting of 12 and 13 June 1997)

1. During its 73rd meeting, the SCF was informed that, in principle, it was the Commission's intention to submit for adoption, at every meeting, a list of substances (monomers and additives) used in the manufacture of plastic materials and articles intended to come into contact with foodstuffs, evaluated or re-evaluated by the working group "Food Contact Materials (FCM)" of the SCF ("SCF-WG") between each Plenary session of the SCF.
2. This document contains the evaluations on monomers (Annex 2) and on additives (Annex 3) adopted by the SCF-WG "FCM" during the during the 69th (26-28 February 1997) and the 70th meetings (20-23 May 1997). The polymeric additives were excluded because they will be added in a specific report submitted later.
3. The substances are listed in alphabetical and PM/REF. N order and the allocation into the various SCF lists are summarized in Annexes 4 and 5. The column "EXPLANATION" gives, for the substances for which the SCF-WG changed a previous classification, a brief explanation for the reason for the change.
4. The SCF endorses the evaluations given by the SCF-WG during the above mentioned meetings. As a memo, the definition of the different lists established by the SCF is included in annex 1.
5. Because other additives are now under examination and will probably be evaluated in a few meetings, the Commission services intend to postpone the publication of the evaluations given in this document until the remaining substances have been evaluated. However the evaluations of this document will be communicated to the interested parties (governments, professional organizations etc.).
6. It has to be stressed that the SCF-WG classified these substances according to the general criteria described in the document CS/PM/2147 without any exception and that these general criteria have already been endorsed by the SCF in the past.

NOTA BENE

This is the first report distributed on Internet and therefore some changes have been made as regards the previous reports. In fact until now the reports did not contain any substance classified by the SCF-WG in SCF-lists 7-8-9, because the management of these lists was delegated to the SCF-WG.

To avoid any misunderstanding, for the first time this report contains all the substances classified by SCF into SCF-lists 0-6 and also the substances classified by the SCF-WG into lists 7-9.

It has been noted that the SCF-WG classified into SCF-lists 7-9 during the 69th and 70th meeting the following substances: 15030 (monomer) and 38565/47540/76665/83598 (additives).

The polymeric additives were excluded because they will be added in a specific report to be submitted later for the approval of the SCF. The current classification of these polymeric additives made by the SCF-WG during the 70th meeting (in meeting 69 no polymeric additive was examined) can be found in the minutes of these meetings, which will be issued only after confirmation of the SCF-WG (probably after the 15th October 1997).

ANNEX 1

DEFINITION OF THE SCF LISTS

Substances for which the committee was able to express an opinion

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, a temporary ADI (t-ADI), a MTDI, a PMTDI, a PTWI 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

Section A (for monomers)

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 B (only for monomers)

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.

Substances for which there were insufficient toxicological or technological data to enable the Committee to express an opinion

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 are not susceptible to be included in the Community lists, lacking the data requested by the Committee.

On the basis of the data lacking the waiting list is subdivided into:

List W7

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 W8

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

List W9

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).

Abbreviations

First part

ADI = Acceptable Daily Intake

MTDI = Maximum Tolerable Daily Intake

NS = Not specified

PMTDI = Provisional Maximum Tolerable Daily Intake

PTWI = Provisional Tolerable Weekly Intake

R = Restriction indicated. If not otherwise indicated R: x mg/kg means mg/kg of food or food simulant.

TDI = Tolerable Daily Intake

t-ADI = Temporary ADI

t-TDI = Temporary TDI

Second part

BIBRA = British Industrial Biological Research Association (UK)

CAS N. = Chemical Abstract Service Registry Number (USA)

CIVO-TNO = Central Institute for Nutrition and Food Research (NL)

EM = Electron microscopy

FAO = Food and Agriculture Organization (UN)

HRC = Huntingdon Research Centre (UK)

IARC = International Agency for Research on Cancer (F)

JECFA = Joint FAO/WHO Expert Committee on Food Additive (UN)

NTP = National Toxicology Program (USA)

RIVM = National Institute for Public Health and Environmental Protection (NL)

SCC = Scientific Committee for Cosmetology (EEC)

SCF = Scientific Committee for Food (EEC)

WHO = World Health Organisation (UN)

APPENDIX

DEADLINES FOR THE TRANSMISSION OF TOXICOLOGICAL DATA

List 9 - 1 year after the evaluation of SCF

List 8 - 1 year after the evaluation of SCF*

N.B. The deadlines for the transmission of the results of the tests requested are the same of those indicated for list 7.

List 7 - 1 year after the evaluation of SCF*

Data on:

- hydrolysis - 2 years after the evaluation of SCF
- mutagenesis - 2 years after the evaluation of SCF
- migration - 2 years after the evaluation of SCF

Studies:

- 28-days - 2 years after the evaluation of SCF

- 90-days - 2 years after the evaluation of SCF
- reproduction - 3 years after the evaluation of SCF
- teratogenesis - 3 years after the evaluation of SCF
- long term - 5 years after the evaluation of SCF

List 6 - 1 years after the evaluation of SCF*

N.B. The deadlines for the transmission of the results of the tests requested are the same of those indicated for list 7.

List 2 - For substances for which a temporary TDI (t-TDI) has been fixed, the data shall be transmitted as soon as possible.

* The dates labelled by an asterisk refer to the time inside which the Commission has to receive a letter where the interested person declares his/her intention to transmit the requested data and encloses, for example, copy of the contractual engagement with the laboratory (ies) of analysis

ANNEX 2

LIST OF MONOMERS EVALUATED IN THIS REPORT AND THEIR CLASSIFICATION

REF_N	CAS_N	NAME	SCFL	SCF_OP	EXPLANATION
11245	02156-97-0	ACRYLICACID, DODECYL ESTER	3	R: 0.05 mg/kg of food. Available: Migration data, 3 (negative) mutagenicity studies. (ISS/TNO SDS, March 1997 = CS/PM/2996/11245). Remark: Since high migration into fat has been demonstrated the WG recommends that the Commission take the necessary measures so that the restriction proposed is not exceeded.	Transferred from SCF List 8 to list 3 because new data were available.
12578	-	ALKYL(C1-C4)PHENOLS (consisting of a mixture of mono, di, tri and tetra alkyl substituted phenols and up to 2% phenol)	5	Substance which should not be used. Available: inadequate migration data, acute toxicity data on several components of mixture. Evaluation is not possible from the data provided. Sources for the mixture mentioned do not exclude presence of toxic components. Quantitative ranges are lacking for many substances. (RIVM/TNO SDS, February 1997 = CS/PM/2993/12578).	
13780	02425-79-8	1,4-BUTANEDIOL	4A	Genotoxic similar to glycidylethers.	Re-examined

		BIS(2,3-EPOXYPROPYL) ETHER		(CS/PM/2958).	because in the previous evaluation was classified on the basis of the similarity to the BADGE. The previous classification has been confirmed but the reason was changed from "similar to BADGE" into "similar to glycidylethers".
15030	00931-88-4	*CYCLOOCTENE	W7	<p>Available: inadequate migration data, three (negative) in vitro mutagenicity studies.</p> <p>Needed: Detailed information on the analytical method for the determination of cyclooctene in aqueous food simulants, particularly on establishment of detection limit, migration experiments should be carried with blends of polymer with maximum concentration of Vestenamer.</p> <p>(RIVM/TNO SDS, February 1997 = CS/PM/2529 REV II/15030).</p>	
15780	00111-90-0	DIETHYLENEGLYCOL MONOETHYL ETHER	2	<p>Group t-TDI : 0.05 mg/kg b.w. (with 16993=53765, 16996= 53820, 16999, 17002=53860, 30120, 48030).</p> <p>See references for 16996.</p>	Confirmed.
16690	01321-74-0	*DIVINYLBENZENE	6A	<p>R: not detectable in food.</p> <p>Available : Two (negative) Ames tests and a mouse inhalation study showing weak clastogenic activity.</p> <p>Needed: detailed description of analytical method to determine residual content.</p> <p>(RIVM/TNO SDS, January 1995 = CS/PM/2572).</p> <p>(ISS SDS, 1997 = CS/PM/2959/16690).</p>	Confirmed in list 6A but the data requested have been modified. See the SCF opinion.

				Remark: for the toxicity part (based on on very low migration) there is no need to ask for further data (awaiting the needed non-tox data to be listed in L4A).	
19990	00079-39-0	METHACRYLAMIDE	4A	<p>The classification is based on the decision made on the structurally related compound acrylamide classified in L4A and because it is not detected in food/food simulants.</p> <p>Available: migration data; Ames test; dominant lethal assay; 2 generation reproduction study; teratogenicity study in mice and three neurotoxicity studies.</p> <p>(RIVM/TNO SDS, November 1996 = CS/PM/2961).</p>	Transferred from L6A to 4A on the basis on the structurally related compound acrylamide, classified in L4A.

ANNEX 3

LIST OF ADDITIVES EVALUATED IN THIS REPORT AND THEIR CLASSIFICATION

REF_N	CAS_N	NAME	SCFL	SCF_OP	EXPLANATION
30120	00111-15-9	ACETIC ACID, 2-ETHOXYETHYL ESTER	3	R : 3 mg/kg of food based on the Group t-TDI: 0.05 mg/kg bw for ì16996.	Confirmed.
38565	90498-90-1	*3,9-BIS[2-(3-(tert.BUTYL-4-HYDROXY-5-METHYLPHENYL) PROPIONYLOXY)-tert.BUTYL]-2,4,8,10-TETRAOXASPIRO[5.5] UNDECANE	W7	<p>Available: Migration data, 3-month oral rat study; 3 (negative) in vitro mutagenicity studies, high bioaccumulation potential.</p> <p>Needed: data demonstrating absence of bioaccumulation in vivo especially in liver and fat.</p> <p>(RIVM SDS, = CS/PM/2994/38565).</p>	
39090	-	N,N-BIS(2-HYDROXYETHYL)ALKYL(C8-C18)AMINE	2	<p>Group t-TDI: 0.02 mg/kg b.w. (as "free" amine) (with 39120).</p> <p>See references for 39120.</p> <p>Needed: three in vitro mutagenicity studies according to guidelines on either PM/REF.No 39090 or 39120).</p> <p>RIVM SDS, September 1996 = CS/PM/2902).</p> <p>Remark: On the basis of the</p>	Confirmed but the needed data have been specified.

				available studies it remains included in the Group t-TDI pending the results of the required mutagenicity studies. If negative it will be classified in L3 with a restriction of 5 mg/kg of food.	
45450	68610-51-5	p-CRESOL-DICYCLOPENTADIENE -ISOBUTYLENE, COPOLYMER	3	R: 5 mg/kg of food. Available: Migration data; four (negative) in vitro mutagenicity studies; 28-day and 3-month oral rat studies; possible bioaccumulation potential. (RIVM/TNO SDS, May 1997 = CS/PM/2802 REV I/45450). Remark: Despite the indication of possible bioaccumulation (i.e. log Po/w >4) the WG finds the substance acceptable for the use as described under 3.1 of the document (eg. in ABS for freezers or very short contact).	Transferred from Scf list 7 into list 3 because new data were available.
47540	27458-90-8	*DI-tert.DODECYL DISULFIDE	W7	Available: Adequate migration data; three (negative) in vitro mutagenicity studies and a 4-week oral rat study on a closely related compound (di-tert-dodecyl pentasulfide). Needed: the information provided is insufficient to understand the procedure for the determination of the purity of the di-tert-dodecyl disulphide. Information on the method of quantification is missing. (RIVM/TNO SDS, December 1996= CS/PM/2964).	
48030	00112-34-5	DIETHYLENEGLYCOL MONOBUTYL ETHER	2	Group t-TDI: 0.05 mg/kg b.w. (with 15780=48050, 16993=53765, 16996=53820, 16999, 17002=53860, 30120, 48050). See references for 16996.	Confirmed.
48050	00111-90-0	DIETHYLENEGLYCOL MONOETHYL ETHER	2	Group t-TDI: 0.05 mg/kg b.w. (with 15780=48050; 16993=53765, 16996=53820, 16999, 17002=53860, 30120, 48030). See references for 16996.	Confirmed.

76665	?	*POLYCYCLOOCTENE	7	<p>Awaiting data on the monomer with PM/REF.No 15030).</p> <p>Needed: Migration of monomer from relevant plastic materials.</p> <p>(RIVM/TNO SDS, February 1997 = CS/PM/2995/76665).</p> <p>Remark: Migration of this polymeric additive is covered by the limit for global migration. No need for bioaccumulation data, since no effects were seen in the lymphonodes and Kupfer cells in the 90-day study.</p>
83598	181314-48-7	*REACTION PROD.OF 3-HYDROXY-5,7-DI-tert.BUTYLBENZOFURAN-2-ONE WITH O-XYLENE CONSISTING OF 5,7-DI-tert.BUTYL-3-(2,3-DIMETHYLPHENYL)-(3H)-BENZOFURAN-2-ONE AND 5-7-DI-tert.BUTYL-3-(3,4-DIMETHYLPHENYL)-(3H)-BENZOF.	W7	<p>Available: Adequate migration data, three (negative) in vitro mutagenicity studies; 90-day oral rat study (including examination of the activity of the peroxisome associated enzymes), metabolism studies (in vitro and in vivo) and an in vitro gene mutation assay in bacteria with the dimer; high bioaccumulation potential.</p> <p>Needed: data demonstrating the absence of bioaccumulation in vivo.</p> <p>(RIVM/TNO SDS, December 1996 = CS/PM/2965/83598).</p>

ANNEX 4

LIST OF MONOMERS EVALUATED IN THIS REPORT AND THEIR CLASSIFICATION

REF_N	CAS_N	NAME	SCF_L
11245	02156-97-0	ACRYLIC ACID, DODECYL ESTER	3
12578	-	ALKYL(C1-C4)PHENOLS (consisting of a mixture of mono, di, tri and tetra alkyl substituted phenols and up to 2% phenol)	5
13780	02425-79-8	1,4-BUTANEDIOL BIS(2,3-EPOXYPROPYL) ETHER	4A
15030	00931-88-4	*CYCLOOCTENE	W7
15780	00111-90-0	DIETHYLENEGLYCOL MONOETHYL ETHER	2
16690	01321-74-0	*DIVINYLBENZENE	6A
19990	00079-39-0	METHACRYLAMIDE	4A

ANNEX 5

LIST OF ADDITIVES EVALUATED IN THIS REPORT AND THEIR CLASSIFICATION

REF_N	CAS_N	NAME	SCF_L
30120	00111-15-9	ACETIC ACID, 2-ETHOXYETHYL ESTER	3
38565	90498-90-1	*3,9-BIS[2-(3-(tert.BUTYL-4-HYDROXY-5-METHYLPHENYL)PROPIONYLOXY)-tert.BUTYL]-2,4,8,10-TETRAOXASPIRO[5.5]UNDECANE	W7
39090	-	N,N-BIS(2-HYDROXYETHYL)ALKYL(C8-C18)AMINE	2
45450	68610-51-5	p-CRESOL-DICYCLOPENTADIENE-ISOBUTYLENE, COPOLYMER	3
47540	27458-90-8	*DI-tert.DODECYL DISULFIDE	W7
48030	00112-34-5	DIETHYLENEGLYCOL MONOBUTYL ETHER	2
48050	00111-90-0	DIETHYLENEGLYCOL MONOETHYL ETHER	2