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food — science and techniques

Reports of the Scientific Committee for Food

(Nineteenth series)

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FIRST ADDENDUM TO THE FIRST REPORT OF THE SCIENTIFIC COMMITTEE FOR FOOD ON CERTAIN MONOMERS AND OTHER STARTING SUBSTANCES TO BE USED IN THE MANUFACTURE OF PLASTIC MATERIALS INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

(Opinion expressed 28th November 1986)

TERM OF REFERENCE

To advise on the toxicological assessment of certain monomers and other starting substances migrating into food from plastic materials and articles intended to come into contact with foodstuffs.

BACKGROUND

The Scientific Committee for Food (" the Committee ") has already elaborated in the past a report on a list of monomers and other starting substances used in the manufacture of plastic materials and articles intended to come into contact with foodstuffs (hereinafter referred to as "monomers")(1). Subsequently the Commission of the European Communities has requested the Committee to complete a first addendum to the report evaluating a second group of monomers, listed in Annex IV. The Committee carried out this evaluation on the basis of the criteria previously established and repeated in the current review.
The Committee also considered the lists 6, 7, 8 and 9 require special attention and action by industry. A corrigendum to the first report is included in Annex V.

CURRENT REVIEW

1. The Committee was informed by the Commission that it is intended to regulate plastic materials and articles coming into contact with food by directives based on the principle of positive lists.

In elaborating its advice the Committee has taken into consideration its guidelines on the "Toxicological evaluation of a substance for materials and articles intended to come into contact with foodstuffs" (2). Each substance examined in this report was evaluated on the basis of information on its properties, on its use in plastic materials and articles and toxicity submitted to the Committee.

Unpublished data available to the Committee are listed among the references. (See Annex III).

2. In some cases the evaluation of the Committee differs from that of the Council of Europe (3), because new toxicological data have become available for some of the listed substances subsequent to the pubblication of the Council of Europe Report and because new scientific developments in toxicology, e.g. concerning genotoxicity, have been taken into consideration.

3. For the purposes of this Report the Committee endorsed the ADIs (Acceptable Daily Intake) for food additives established by JECFA (4) without necessarily reviewing the data base for the JECFA-decision because of the low level of intake likely to arise from the migration into food of the substances used in the manufacture of plastic materials and articles. In other cases the Committee referred to the ADIs it had established in previous reviews as published in its reports. ADIs relate to the total intake from food.

4. The Committee considered that many of the monomers which could migrate potentially from plastic materials and articles might also migrate from other materials, when present therein, into the same or other foods or might be ingested from other sources. The Committee established Tolerable Daily Intakes (TDI) where the data sufficed for this purpose and temporary TDI's (t-TDI), where additional data are required. In selecting this approach the Committee was aware that the available toxicological data were less extensive than in the case of food additives. Therefore, in establishing these TDIs a particularly cautious approach was chosen involving the choice of a larger safety factor than usual. The Committee emphasises however, that the procedure adopted for establishing TDIs for these migrants differs from the well known classical procedures for establishing ADIs. The TDIs need not be restricted in their applicability to substances used in plastic materials and articles. The TDIs are valid equally if these substances are used as components in the manufacture of any other groups of materials and articles for food packaging. If individual TDIs have been set for closely related substances these must be reduced proportionately when mixtures of these substances are used.

5. The Committee emphasises that, for toxicological reasons as well as for food hygiene, migration of such substances into foods from plastic materials and articles should be limited. The Committee

therefore recommended that the finished plastic materials and articles contain the lowest possible level of residual free monomer. (This may also avoid a situation in which most of a TDI is taken up by a substance approved for use in plastic materials and articles and thus bloking its use in other packaging materials and articles, where it might also be technologically required).

6. During its consideration of the available toxicological information the Committee noted that pratically no relevant information existed in many instances on the effects of individual substances concerning reproduction or on teratogenicity. Data on mutagenic potential were incomplete in several cases. These aspects could therefore not be considered in the present evaluation of such substances but may well be in future re-evalutions.

7. List 4 contains some substances for which sensitive methods of analysis have been developed and for which very low migration limits have been set. For the other substances on List 4 similar sensitive methods should be developed so that appropriate low migration limits could be defined. The Committee recognises that these substances are known to be toxic. They are, however, essential for polymer technology generally at present. The Committee recommends that appropriate sensitive methods of analysis should be developed within three years of publication of this report.

8. Conclusions on the toxicological assessment - with selected references - were prepared for those substances for which the Committee was able to express an opinion. These are listed in Annex III.

9. The Committee considered that substances in list 6 for which data are lacking or are insufficient were suspected of being toxic. The Committee recommends that information be supplied or that appropriate toxicological tests be made as soon as possible.

   Lists 7 and 8 also contain substances of concern due respectively to the incompleteness or absence of the available data.

10. The Committee recognises that priorities will have be set because of the large number of substances contained in list 6, 7 and 8 and the volume of experimental work that would be necessary to provide a basis for toxicological assessment of each substance mentioned. The criteria for setting these priorities should include, for example,

data on exposure (e.g. usage, extent of migration), availability of analytical methods, the toxicological and biochemical profile, and consideration of chemical structure in relation to toxicity (this last approach was used in preparing list 6). In setting priorities, the Committee recommends that the Commission obtain within 3 years the relevant data mentioned above and should invite industry and governments to provide information and assistance to enable the Committee to conclude its evaluation.

11. The Committee draws attention to the need for ensuring that in the manufacture of plastic materials and articles the requirements in the "guidelines" (2) concerning quality an specifications are followed. The Committee recommends the development of procedures to permit examination of plastic materials and articles with respect to compliance with the conclusions of this report.

12. Whenever acids, phenols or alcohols have been evaluated, the assessment also includes aluminium, ammonium, calcium, magnesium, potassium, sodium and zinc salts.

13. Substances for which the Committee was able to express an opinion are reported in Annex I. Substances for which there was insufficient toxicological or technological data to enable the Committee to express an opinion are reported in Annex II. Where CAS numbers are available these are specified to the left of the chemical name (some CAS numbers have an asterisk).

14. Where the required data are not specified in the lists and for new substances the information needed in general for assessment has been set out elsewhere by the Committee in its Guidelines (2), but will also depend on the migration data.

15. Annex I consists of the following 6 lists

List 0
Substances which may be used in the production of plastic materials and articles, e.g. food ingredients and certain substances knowm from the intermediate metabolism in man and for which and ADI need not be established.

List 1
Substances for which an ADI has been established by JECFA or this Committee.

List 2
Substances for which a TDI has been established by this Committee.

List 3
Substances for which an ADI or TDI could not be established, but where the continued 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,

List 4

Section A
Substances for which an ADI or TDI could not be established, but which could be used if the substance migrating into food is not detectable by an agreed sensitive method (see also para 7).

Section B
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 5
Reserved for substances which should not be used.

16. Annex II consists of the following 4 lists
List 6
Substances suspected of being toxic for which data are lacking or are insufficient. The Committee recommends that information be supplied or that appropriate toxicological tests be made as soon as possible.

List 7
Substances for which some toxicological data exist, but for which an ADI or TDI could not be established. The additional specified information should be furnished. The list will be reevaluated.

List 8
Substances for which no or only scanty and inadequate data were available.

List 9

Group of substances which could not be evaluated due to lack of specificity. These groups should be replaced by individual substances actually in use.

17. Annex III contains selected references for substances, for which the Committee was able to express an opinion.

REFERENCES

(1) Commission of the European Communities, Report of the Scientific Committee For Food (17th Series,1986).
(2) Commission of the European Communities, Report of the Scientific Committee For Food (3rd Series, 1977).
(3) Council of Europe Publication "Substances used in plastic materials coming into contact with food", 2nd Edition, Strasbourg 1982.
(4) JECFA = Joint FAO/WHO Expert Committee on Food Additives.

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ANNEX I

SUBSTANCES FOR WHICH THE COMMITTEE WAS ABLE TO EXPRESS AN OPINION

LIST 0

Substances which can be used in the production of plastic materials and articles, e.g. food ingredients and certain substances known from the intermediate metabolism in man.

9006-59-1	Albumin
106-31-0	Butyric anhydride

LIST 1

Substances for which an ADI has been established by JECFA or this Committee

65-85-0	Benzoic acid*	ADI=5 mg/kg b.w. (JECFA 17 M.)
123-62-6	Propionic anhydride	Group ADI=not specified; included in the ADI for propionic acid

---

* Substance already evaluated in the first Report under benzyl alcohol, list 1.

LIST 2

Substances for which a TDI has been established by this Committee

92-88-6	4.4'-Dihydroxybiphenyl	TDI= 0.1 mg/kg b.w.
99-96-7	p-Hydroxybenzoic acid	TDI= 10 mg/kg b.w.
111-66-0	1-Octene*	t-TDI= 0.25 mg/kg b.w.

---

* Substance already evaluated in the first Report, list 8.

LIST 3

Substances for which an ADI or TDI could not be established but where the continued use could be accepted

- Albumin, coagulated by formaldeyde

LIST 4

SECTION A

Substances for which an ADI or TDI could not be established but which could be used if the substance migrating into food is not detectable by an agreed sensitive method

1675-54-3	Bisphenol A, diglycidyl ether*
108-45-2	1,3-Phenylenediamine

SECTION B

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

---

* Substance already evaluated in the first report, list 6.

LIST 5

Reserved for substances which should not be used

ANNEX II

SUBSTANCES WITH INSUFFICIENT TOXICOLOGICAL OR TECHNOLOGICAL DATA FOR THE COMMITTEE TO EXPRESS AN OPINION

LIST 6

Substances suspected of being toxic for which data are lacking or are insufficient. The Committee recommends that information be supplied or that appropriate toxicological tests be made as soon as possible.

78-94-4	Methyl vinyl ketone
1484-13-5	N-vinyl carbazole

LIST 7

Substances for which some toxicological data exist, but for which an ADI or TDI could not be established. The additional specified information should be furnished.

40074-09-7 Acrylic acid, 2-sulfoethylester
Needed: hydrolysis data

2998-04-1 Adipic acid, diallyl ester*
Needed: hydrolysis data

112-30-1 1-Decanol
Needed: see 1st Report of the SCF on monomers, included in alcohols, aliphatic, saturated, monovalent, C4-C18.

1653-19-6 2,3-Dichloro-1,3-butadiene
Needed: migration data, mutagenicity studies, 90-day oral study. When data are avalaible, a decision concerning additional studies, e.g. for teratogenicity, will be taken.

11-40-0 Diethylentriamine
Not mutagenic in Ames test.
Needed: additional mutagenicity studies, 90-day oral study

1330-76-3 Maleic acid, diisooctyl ester
Needed: hydrolysis data

- Methacrylic acid, trismethylammoniummethylchloride ester
Needed: hydrolysis data, mutagenicity studies, 28-day oral study

10595-80-9 Methacrylic acid, 2-sulfoethyl ester
Needed: hydrolysis data

111-87-5 1-Octanol
See 1st Report of the SCF on monomers, included in

alcohols, aliphatic, saturated, monovalent, C4-C18

75-38-7 Vinylidene fluoride*
Needed: results from ongoing studies (1989), details from fertility and teratogenicity studies and oral 90-day study.

(*) Substances already evaluated in the first Report, list 7.

LIST 8

Substances for which no or only scanty and inadequate data were avalaible

15214-89-8	Acrylamidomethylpropanesulfonic acid
2960-44-6	Azelaic acid, bis(2-hydroxyethyl)ester
4422-35-1	1,3,5-Benzenetricarboxylic acid chloride
156-59-2	1,2-Dichloroethylene (cis)
75-00-3	Ethylchloride
-	Methacrylic acid, 1,3-butanediol monoester
513-35-9	3-Methyl-2-butene
814-78-8	Methyl isopropenyl ketone
4461-48-7	4-Methyl-2-pentene
-	Octyl vinyl ether
930-02-9	Stearyl vinyl ether
16646-44-9	Tetra(allyloxy)ethane
2867-48-3	N-vinyl-N-methylformamide
105-38-4	Vinylpropionate

LIST 9

Groups of substances which could not be evaluated due to lack of specificity. These groups should be replaced by individual substances actually in use.

- Acids aliphatic dicarboxylic, alcohols aliphatic monohydric esters
- Acids aliphatic monocarboxylic unsaturated, polypropyleneglycol esters
- Aldehydes (C4)
- Caprolactone, substituted
- Fumaric acid, alcohol polyhydric esters
- Itaconic acid, alcohols polyhydric (C1-C18) esters
- Maleic acid, alcohols aliphatic saturated (C1-C18) esters
- Phthalic acid, hydrogenated, substituted, endosubstituted and their halogenated derivatives
- Polyols derived from phenols and bisphenols, hydrogenated and/or condensed with epoxyalkanes and/or arylepoxyalkanes eventually halogenated, alcoxylated, aryloxylates
- Styrene substituted:
    - in the benzene group
    - in the vinyl group
    - by halogens (alpha or beta)
    - by alkyl groups (alpha)

ANNEX III

REFERENCES FOR THE SUBSTANCES LISTED IN LIST 1

See the references reported in list 1.

REFERENCES OF THE SUBSTANCES LISTED IN LIST 2

92-88-6	4.4'-Dihydroxybiphenyl	90-day oral study and limited mutagenicity studies enabled the establishment of a TDI at 0.1 mg/kg b.w. (RIVM Doc/Tox 300/495 June 1984)
99-96-7	p-Hydroxybenzoic acid	The value of the TDI is based upon the evaluation of the esters, JECFA 1973.
111-66-0	1-Octene	A 90-day oral rat study and mutagenicity studies enabled the establishment of a TDI of 0.25 mg/kg b.w. made temporary pending results of fertility and teratogenicity studies (CIVO rep V86.408/251091, 26 Sept. 1986). Substance already evaluated in the first report, list 8.

REFERENCES OF THE SUBSTANCES LISTED IN LIST 3

-	Albumin, coagulated by formaldeyde	Though albumin is a food component it has modified by formaldehyde which is already in List 3, first report

REFERENCES FOR THE SUBSTANCES LISTED IN LIST 4

SECTION A

1675-54-3	Bisphenol A, diglycidyl ether	Substance already evaluated in the first Report and classified in list 6. Additional data on mutagenicity and migration into alcoholic and aqueous solutions were submitted. These enabled the reclassification.
108-45-2	1,3-Phenylenediamine	Since the data on carcinogenicity by the oral route were inadequate and the substance demonstrated some genotoxic potential, it is only acceptable for use provided there is no detectable migration into food by an agreed sensitive method. If detectable, migration is shown to occur, then adequate oral carcinogenicity studies will be required.

ANNEX IV

LIST OF SUBSTANCES EVALUATED IN THIS REPORT AND THEIR CLASSIFICATION

-	Acids aliphatic dicarboxylic, alcohols aliphatic monohydric, esters	L9
-	Acids aliphatic monocarboxylic unsaturated, polypropyleneoxide esters	L9
15214-89-8	Acrylamidomethylpropanesulfonic acid	L8
40074-09-7	Acrylic acid, 2-sulfoethylester	L7
2998-04-1	Adipic acid, diallyl ester	L7 *
9048-46-8 and 9006-59-1	Albumin	L0
-	Albumin, coagulated by formaldehyde	L3
-	Aldehydes (C4)	L9
2960-44-6	Azelaic acid, bis(2-hydroxyethyl)ester	L8
4422-35-1	1,3,5-Benzenetricarboxylic acid chloride	L8
65-85-0	Benzoic acid	L1(5)* **
1675-54-3	Bisphenol A, diglycidyl ether	L4A*
106-31-0	Butyric anhydride	L0
-	Caprolactone, substituted	L9
112-30-1	1-Decanol	L7
1653-19-6	2,3-Dichloro-1,3-butadiene	L7
156-59-2	1,2-Dichloroethylene (cis)	L8
11-40-0	Diethylentriamine	L7
92-88-6	4,4'-Dihydroxybiphenyl	L2(0.1)**
75-00-3	Ethylchloride	L8
-	Fumaric acid, alcohol polyhydric esters	L9
99-96-7	p-Hydroxybenzoic acid	L2(10)**
-	Itaconic acid, alcohols polyhydric esters	L9
1330-76-3	Maleic acid, diisooctyl ester	L7
-	Maleic acid, alcohols aliphatic saturated(C1-C18)esters	L9
-	Methacrylic acid, 1,3-butanediol monoester	L8
10595-80-9	Methacrylic acid, 2-sulfoethyl ester	L7
-	Methacrylic acid, trismethylammonium ethanol ester chloride	L7
513-35-9	2-Methyl-2-butene	L8
814-78-8	Methyl isopropenyl ketone	L8
4461-48-7	4-Methyl-2-pentene	L8
78-94-4	Methyl vinyl ketone	L6

111-87-5	1-Octanol	L7
111-66-0	1-Octene	L2(0.25)* **
-	Octyl vinyl ether	L8
108-45-2	1,3-Phenylenediamine	L4A
-	Phthalic acid, hydrogenated, substituted, endosubstituted and their halogenated derivatives	L9
-	Polyols derived from phenols and bisphenols,hydrogenated and/or condensed with epoxyalkanes and/or arylepoxyalkanes eventually halogenated, alcoxylated, aryloxylates	L9
123-62-6	Propionic anhydride	L1(not specif.)
930-02-9	Stearyl vinyl ether	L8
-	Styrene substituted:	
	- in the benzene ring	L9
	- in the vinyl group	L9
	- by halogens (alpha or beta)	L9
	- by alkyl groups (alpha)	L9
16646-44-9	Tetra(allyloxy)ethane	L8
1484-13-5	N-vinyl carbazole	L6
75-38-7	Vinylidene fluoride	L7*
2867-48-3	N-vinyl-N-methylformamide	L8
105-38-4	Vinylpropionate	L8

---

* Substances already evaluated in the first Report.

** The number in the parentheses is expressed in mg/kg b.w.

ANNEX V

Corrigendum to the first report (17th Series of the SCF's reports)

Change the first report as follows:

- page 3, point 12

  Read the sentence as follows:
  "Whenever acids, phenols or alcohols have been evaluated, the assessment also includes aluminium, ammonium, calcium, magnesium, potassium, sodium and zinc salts."

- Page 4, point 15, list 3

  Add a second sentence after the first comma:
  "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."

- Page 10, list 2

  modify "Resin acids" into "Resin acids and rosin acids";

- Page 30, annex III

  add "(C9-C15)" after "Alcohols aliphatic monohydric saturated";

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The members are independent persons, highly-qualified in the fields associated with medicine, nutrition, toxicology, biology, chemistry, or other similar disciplines.

The present series relates to the opinions of the Committee on the toxicological assessment of certain monomers and other starting substances migrating into food from plastic materials and articles intended to come into contact with foodstuffs.

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