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(20th series)

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SECOND 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 (19th Series of the SCF's reports)

(Opinion expressed 10th December 1987)

TERMS 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 (1) and a first addendum to the first report (2) on a list of monomers and other starting substances (hereinafter referred to as "monomers") used in the manufacture of plastic materials and articles intended to come into contact with foodstuffs (see also the definition of plastic materials and articles in the Directive 82/711/EEC)(3). Subsequently the Commission of the European Communities has requested the Committee to complete a second addendum to the report evaluating a third 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.

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" ("Guidelines")(4). 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 of 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 Unpublished data available to the Committee are listed among the references (see Annex III).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 (5), because new toxicological data have become available for some of the listed substances subsequent to the publication 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 (6) 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 should be related 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 in many instances it did not meet present requirements (e.g. reproduction, teratogenicity or mutagenicity data were incomplete or lacking).

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" (4) 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 in "Guidelines" by this Committee and other international bodies, e.g. OECD. The extent to which substances migrate into foods will determine the amount and type of toxicity data which may be required.

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 or temporary 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 (under press).
(3) Official Journal of the European Communities, N. L 297 p.26
(4) Commission of the European Communities, Report of the Scientific Committee For Food (3rd Series, 1977).
(5) Council of Europe Publication "Substances used in plastic materials coming into contact with food", 2nd Edition, Strasbourg 1982.
(6) 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 O

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.

6915-15-7 Malic acid

LIST 1

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

LIST 2

Substances for which a TDI or temporary TDI has been established by this Committee

2998-08-5	Acrylic acid, sec.butyl ester	Group t-TDI: 0.1 mg/Kg b.w. Needed: hydrolysis data.
1663-39-4	Acrylic acid, tert.butyl ester	" "
4655-34-9	Methacrylic acid, isopropylester	Group t-TDI: 0.1 mg/Kg b.w. Needed: hydrolysys data.
2998-18-7	Methacrylic acid, sec. butyl ester	" "
585-07-9	Methacrylic acid, tert.butyl ester	" "

LIST 3

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

11132-73-3	Lignocellulose
630-08-0	Carbon monoxide

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

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

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.

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.

2156-96-9 Acrylic acid, decyl ester
Needed: hydrolysis data.

29590-42-9 Acrylic acid, isooctyl ester
Needed: hydrolysis data.

2499-59-4 Acrylic acid, n-octyl ester
Needed: hydrolysis data.

937-41-7 Acrylic acid, phenyl ester
Needed: hydrolysis data.

150-13-0 para-Aminobenzoic acid
Known: metabolism in man, mutagenicity studies negative (IARC, 1978).
Needed: migration data, 28-day oral study

1675-54-3 2,2-Bis(4-hydroxyphenyl)propane diglycidylether
Needed: hydrolysis data.

14861-06-4 Crotonic acid, vinyl ester
Needed: hydrolysis data.

38775-37-0 Hexamethylenediamine azelate
Needed: hydrolysis data.

3179-47-3 Methacrylic acid, decyl ester
Needed: hydrolysis data.

28675-80-1 Methacrylic acid, isooctyl ester
Needed: hydrolysis data.

2157-01-9 Methacrylic acid, n.octyl ester
Needed: hydrolysis data.

75-38-7 Vinylidene fluoride

Still needed: results from a major program sponsored by the world vinylidene fluoride producers is ongoing and results avalaible 1989 (cited from Solvay, undated).

LIST 8

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

91355-90-7	Acrylic acid, cyclohexylaminoethanol ester
44992-01-0	Acrylic acid, trimethylammonium ethanol ester, chloride
1477-55-0	1,3-Benzenedimethanamine
539-48-0	1,4-Benzenedimethanamine
615-67-8	Chlorohydroquinone
57981-99-4	Chlorohydroquinone diacetate
105-08-8	1,4-Cyclohexanedimethanol
3749-77-7	4,4'-Dicarboxy diphenoxy butane
3753-05-7	4,4'-Dicarboxy diphenoxy ethane
2215-89-6	4,4'-Dicarboxy diphenyl ether
80-07-9	4,4'-Dicarboxy diphenyl sulfone
2664-63-3	4,4'-Dihydroxy diphenyl sulfide
1965-09-9	4,4'-Dihydroxy diphenyl ether
- -	Methacrylic acid, cyclohexylaminoethanol ester
10595-80-9	Methacrylic acid, 2-sulfoethyl ester and sodium salt
95-71-6	Methyl hydroquinone
717-27-1	Methyl hydroquinone diacetate
1141-38-4	2,6-Naphthalene dicarboxylic acid
930-02-9	Octadecyl vinyl ether
1079-21-6	Phenyl hydroquinone
58244-28-3	Phenyl hydroquinone diacetate

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.

- Acrylamide, N-methylol and ethers
- Acrylic acid, ether alcohol esters
- Acrylic acid, etheralcohols aliph. monohydric sat.(C1-C21) esters
- Methacrylamide, N-methylol and ethers
- Methacrylic acid, etheralcohols aliph. monohydric sat. (C1-C21) esters
- Methacrylic acid, ether alcohol ester
- Methoxymethylacrylamide, ethers
- Perfluoroalkyl (C1-C3) vinyl ethers
- Phenols and bisphenol alkoxylated or hydrogenated

ANNEX III

REFERENCES OF THE SUBSTANCES LISTED IN LIST 0

6915-15-7	Malic acid	Occurs naturally in foods, metabolism known, JECFA ADI 100 for D-form. ADI not specified for L+ form

REFERENCES OF THE SUBSTANCES LISTED IN LIST 2

2998-08-5 1663-39-4 4655-34-9	Acrylic acid, sec.butyl ester Acrylic acid, tert.butyl ester Methacrylic acid, isopropylester	See the references included in the report on monomers (17th Series, 1986) Needed: hydrolysis data.
2998-18-7 585-07-9	Methacrylic acid, sec.butyl ester Methacrylic acid, tert.butyl ester	See the references included in the report on monomers (17th Series, 1986) Needed: hydrolysis data.

REFERENCES OF THE SUBSTANCES LISTED IN LIST 3

11132-73-3	Lignocellulose	Natural, non digestible fibre.
630-08-0	Carbon monoxide	low migration

ANNEX IV

LIST OF SUBSTANCES EVALUATED IN THIS REPORT AND THEIR CLASSIFICATION

91355-90-7	Acrylic acid, cyclohexylaminoethanol ester	L8
2156-96-9	Acrylic acid, decyl ester	L7
29590-42-9	Acrylic acid, isooctyl ester	L7
2499-59-4	Acrylic acid, n-octyl ester	L7
937-41-7	Acrylic acid, phenyl ester	L7
2998-08-5	Acrylic acid, sec.butyl ester	L2
1663-39-4	Acrylic acid, tert.butyl ester	L2
44992-01-0	Acrylic acid trimethylammonium ethanol ester, chloride	L8
- -	Acrylamide, N-methylol and ethers	L9
- -	Acrylic acid, ether alcohols ester	L9
- -	Acrylic acid, etheralcohols aliph. monohydric sat.(C1-C21) esters	L9
*150-13-0	para.Aminobenzoic acid	L7
1477-55-0	1,3-Benzenedimethanamine	L8
539-48-0	1,4-Benzenedimethanamine	L8
1675-54-3	2,2-Bis (4-hydroxyphenyl) propane diglycidylether	L7
630-08-0	Carbon monoxide	L3
615-67-8	Chlorohydroquinone	L8
57981-99-4	Chlorohydroquinone diacetate	L8
14861-06-4	Crotonic acid, vinyl ester	L7
105-08-8	1,4-Cyclohexanedimethanol	L8
3749-77-7	4,4'-Dicarboxy diphenoxy butane	L8
3753-05-7	4,4'-Dicarboxy diphenoxy ethane	L8
2215-89-6	4,4'-Dicarboxy diphenyl ether	L8
80-07-9	4,4'-Dicarboxy diphenyl sulfone	L8
1965-09-9	4,4'-Dihydroxy diphenyl ether	L8
2664-63-3	4,4'-Dihydroxy diphenyl sulfide	L8
38775-37-0	Hexamethylenediamine azelate	L7
11132-73-3	Lignocellulose	L3
6915-15-7	Malic acid	L0
- -	Methacrylamide, N-methylol and ethers	L9
- -	Methacrylic acid, cyclohexylaminoethanol ester	L8
3179-47-3	Methacrylic acid, decyl ester	L7
- -	Methacrylic acid, etheralcohols aliph. monohydric sat. (C1-C21) esters	L9
- -	Methacrylic acid, ether alcohol ester	L9
28675-80-1	Methacrylic acid, isooctyl ester	L7
4655-34-9	Methacrylic acid, isopropylester	L2
2157-01-9	Methacrylic acid. n.octyl ester	L7
2998-18-7	Methacrylic acid, sec.butyl ester	L2
10595-80-9	Methacrylic acid, 2-sulfoethyl ester and sodium salt	L8
585-07-9	Methacrylic acid, tert.butyl ester	L2
- -	Methoxymethylacrylamide, ethers	L9
95-71-6	Methyl hydroquinone	L8
717-27-1	Methyl hydroquinone diacetate	L8
1141-38-4	2,6-Naphthalene dicarboxylic acid	L8
930-02-9	Octadecyl vinyl ether	L8

- -	Perfluoroalkyl (C1-C3) vinyl ethers	L9
- -	Phenols and bisphenol alkoxylated or hydrogenated	L9
1079-21-6	Phenyl hydroquinone	L8
58244-28-3	Phenyl hydroquinone diacetate	L8
75-38-7	Vinylidene fluoride	L7

OPINION OF THE SCIENTIFIC COMMITTEE FOR FOOD ON NITROSAMINES IN BABIES DUMMIES AND TEATS

(Opinion expressed 10 December 1987)

TERMS OF REFERENCE

To give an opinion on the health hazards arising from the presence of nitrosatable amines and nitrosamines in babies dummies and teats in the light of the potential migration during the use of the products.

DISCUSSION

In recent years the formation of carcinogenic volatile nitrosamines during the manufacture of rubber products has been reported. In the case of rubber dummies and teats these nitrosamines derive from the accelerators and stabilizers added during the manufacturing process. Accelerators may release secondary amines which are subsequently nitrosated by ambient NOx or through transnitrosation from nitrosamines used as retarders. Following extraction with dichloromethane or artificial saliva the following volatile nitrosamines were identified: N-nitrosodimethylamine, N-nitrosodiethylamine, N-nitrosodibutylamine, N-nitrosopiperidine and N-nitrosomorpholine; among the non-volatile nitrosamines were found N-nitrosodibenzylamine, N-nitrosodicyclohexylamine, N-nitrosoethylphenylamine and N-nitrosomethylphenylamine.

In the case of some rubber dummies and teats migration is considerable. Differences in migration figures are due to the extraction methods used, the dichloromethane extraction being generally greater than salivary extraction. Early analytical data revealed migration ranging from less than 10 up to 2900 micrograms/kg of rubber, more recent results varied from 16-380 micrograms/kg as a result of the reformulation of products by the rubber manufacturers. Migration diminishes during repeated use but there is continued further migration of nitrosamines into the milk. Even repeated boiling either before first use or during use does not exclude continued migration of amounts of nitrosamines which may be toxicologically significant. In addition in some circumstances (eg. in hospitals) babies are exposed more frequently to fresh nipples.

Because nitrosatable substances can also migrate from rubber nipples and can be nitrosated possibly in the infant stomach, it is considered advisable to reduce the amounts of nitrosatable substances which may be extracted from nipples. Earlier results ranged from 1 to several 1000 micrograms/kg rubber, more recent results showed values ranging from 10-230 micrograms/kg even after repeated sterilisation in boiling water.

The Committee considered the problem of the proven carcinogenicity for many animal species of most of the volatile nitrosamines detected. It regretted the lack of information concerning the analytical capabilities for detecting non-volatiles nitrosamines as well as the lack of toxicity data on those substances which have been identified. The amounts of nitrosamines formed *in vivo* from ingested nitrosatable substances are most likely to be far less than is suggested by *in*

vitro studies and may not exceed 10% of what is formed *in vitro*. In addition some of the components in baby food may inhibit the *in vivo* formation of nitrosamines. Neverthless the large amounts of nitrosatable substances that have been detected in migration tests would suggest that it may be prudent to apply a limitation also to these substances.

The manufacturing practice at the production plant is of paramount importance for the potential production and subsequent migration of nitrosamines from conventional rubber products. The Committee was unable to obtain accurate technological information which might help in explaning the differences in levels of nitrosamines in various products. However, a few possibilities for decreasing the amounts of nitrosamines and nitrosatable substances suggest themselves. They include a reduction as far as technologically practicable in the use of accelerators, the substitution of nitrosatable by non-nitrosatable accelerators and retarders or by those forming non-carcinogenic nitrosamines and the control of indoor atmospheric concentrations of nitrogen oxides. Silicon rubbers do not usually give rise to migration of nitrosamines but these products may become cross-contaminated unless appropriate manufacturing practices are maintained. The ability of manufacturers to reduce the nitrosamine content of dummies and teats is reflected in the low migration figures obtained from products tested more recently. Several laboratories have shown absence of migration using a method with a detection limit of 10 ppb and a few in some circumstances, of 1 ppb. Detection limits of nitrosatable substances vary for different laboratories from 20 to 200 ppb. However, the reproducibility and repeatibility of these analytical results has not be considered.

CONCLUSIONS AND RECOMMENDATIONS

The Committee recommends that the use of nitrosatable amines, amides and related substances should be kept to the lowest possible level in rubber dummies and teats or nitrosatable accelerators and retarders should be replaced by non-nitrosatable products or those not giving rise to carcinogenic nitrosamines.

The manufacture of rubber dummies and teats should be kept separate from the production of other rubber products to avoid cross-contamination with nitrosamines.

Since rubber dummies and teats may represent a major source of exposure to nitrosamines and nitrosatable substances for babies and in the light of the fact that high quality products may be manufactured with low migration levels, it is recommended to keep the amounts of nitrosamines and nitrosatable subetances migrating from such rubber articles below the detection limit of agreed appropriate sensitive methods.

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The Scientific Committee for Food was established by Commission Decision 74/234/EEC of 16 April 1974 (OJ L 136, 20.5.1974, p. 1) to advise the Commission on any problem relating to the protection of the health and safety of persons arising from the consumption of food, and in particular the composition of food, processes which are liable to modify food, the use of food additives and other processing aids as well as the presence of contaminants.

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:

(i) certain monomers and other starting substances to be used in the manufacture of plastic materials and articles intended to come into contact with foodstuffs;

(ii) nitrosamines in babies dummies and teats.