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Commission of the European Communities

food—science and techniques

Reports of the Scientific Committee for Food

(Twenty-fifth series)



Report

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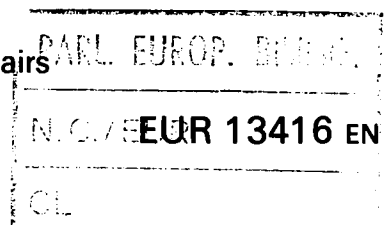
Reports of the Scientific Committee for Food

(Twenty-fifth series)

First series of food additives of various technological functions

(Opinion expressed on 18 May 1990)

Directorate-General
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Report of the Scientific Committee for Food on a First Series of Food Additives of Various Technological Functions

(Opinion expressed 18 May 1990)

Terms of Reference

To advise on the safety of a first series of additives not yet covered by current Community provisions and included in the categories in the framework directive on food additives ¹.

Background

The framework directive lists 24 categories of food additives falling within the scope of the directive (see Annex I).

Community provisions already exist for 7 of these 24 categories: colouring matters ², preservatives ³, antioxidants ⁴ and emulsifiers, stabilizers, thickeners and gelling agents ⁵.

The Committee has already advised on additives in these categories on several occasions, and these opinions have been published in the series of SCF reports:

Colouring matters: 27/6/75 (1st Series), 27/2/76 (2nd Series), 16/9/77 (4th Series), 23/3/79 (8th Series), 7/7/83 (14th Series) and 10/12/87 (21st Series).

Preservatives: 15/11/74 (1st Series), 2/4/76 (2nd Series), 20/10/77 (4th Series), 23/6/78 (6th Series), 31/10/79 (9th Series) and 15/1/81 (11th Series).

Antioxidants: 13/11/75 (1st Series), 2/7/76 (2nd Series), 24/6/77 (4th Series), 29/4/83 (14th Series) and 11/12/87 (22nd Series).

Emulsifiers etc: 30/11/78 (7th Series), 7/2/79 (8th Series), 12/6/81 (13th Series), 8/7/83 (15th series) and 11/11/88 (21st Series).

On 1st May 1978 (5th Series) the Committee advised on the specific use of a series of additives in **fine bakers wares**. In many cases, only temporary evaluations were made. For many of these additives a full evaluation is now included in this report.

In 1976 the Committee initially obtained data on "acids, bases and salts". During the process of evaluation other additives were also considered. The title was therefore changed to "Miscellaneous additives". This expression has, however, led to misunderstandings and has therefore been eliminated from this report.

In the intervening period additives belonging to a number of categories covered by the framework directive were allocated temporary EEC numbers in order to facilitate their identification on food labels⁶. The list provided useful information to the Committee on the number of substances included for evaluation.

With the adoption of the Single European Act it became increasingly necessary to prepare Community provisions for all remaining additives. The Commission services therefore requested industry to establish a complete inventory of all food additives in use in the Member States covered by all the categories listed in the framework directive.

Substances covered in this review

Although this review was intended to cover all remaining additives from the inventory falling within the categories listed in Annex I of the framework directive and not covered by the existing directives, some categories have been omitted from this report:

Sweeteners and modified starches have already been evaluated by the Committee in separate reports: 14/9/84 (16th Series), and 10/12/87 as well as 10/11/88, (21st Series) (sweeteners), 27/2/76 (2nd Series) and 12/6/81 (13th Series) (modified starches).

Glazing agents, flour treatment agents, bulking agents and a few other substances will be the subject of separate reports. The Committee also decided that the safety assessment of **enzymes** which are used both as processing aids and as food additives, as well as **novel foods**, require a special approach. They will therefore be evaluated later.

Furthermore, additives falling out of the scope of the directive, such as **processing aids and macro- and micro-nutrients**, have not been included in this report and will be dealt with separately.

In some cases a substance, or group of substances, has been included in this review although it was already included in existing directives. These are substances which have technological functions additional to those covered by the existing directives and are therefore included in this review (e.g. citric acid has antioxidant activity but may be also used as an acidifying agent).

The order in which most of the substances have been considered in this review is not based, as in other Committee reports, on technological function but on chemical relationships, as many of the substances have multiple technological applications. The summary table, on pp. 7-8, as well as the table of contents of Annex II on p.10, should enable the reader to locate comments on individual substances.

Principles used in the evaluation

In its 10th report the Committee laid down the guidelines for the safety assessment of food additives. The Commission document "Presentation of an application for assessment of a food additive prior to its authorization" ⁷ outlines the general procedures for the presentation of biological data and other relevant information.

The available data for many substances in this review are limited. Most of these substances are known to occur naturally in food and/or as intermediate metabolites and to have well established biological properties. Although *natural occurrence per se is not a guarantee of safety* to health, the Committee nevertheless considers further toxicological testing unnecessary as long as the uses are restricted to those indicated in this report. In some cases the Committee made its own review of the available toxicological data. In other cases it was satisfied with the summary information provided by the Commission, interested parties or other international review bodies, e.g. JECFA.

The Committee attaches great importance to the provision of information on the known uses of these additives. The reasons for the evaluations now established by the Committee may be gleaned from the background information collated in Annex II. Any new uses which could alter significantly the total intake of an additive will necessitate a new evaluation. The Committee recommends that any relevant Community legislation adopted in the future pay particular attention to this aspect.

In some cases, only one salt of a group relating to a single anion has been tested. Where appropriate, other ionizable salts of that anion have been included in the group ADI established for this anion.

The cations and anions evaluated in this manner have been listed in the summary table, pp. 7-8. It should be noted, however, that not all possible combinations of these ions have similar toxicological properties. Furthermore the Committee has only evaluated those substances specifically requested for use as food additives. Therefore only those combinations specifically mentioned in the summary table are to be considered acceptable under this evaluation procedure.

Unless otherwise specified, any ADI is expressed as relating to the named cation or anion

The Committee notes that the framework directive on food additives (art. 3.1) provides that individual conditions of use of food additives should be specified eventually, the extent of these provisions depending on the toxicological evaluation. The Committee supports these principles.

Although the Committee did not systematically assess the actual technological need for these additives, it deems it necessary nevertheless to specify on some occasions that certain additives should be restricted to particular food items. Thus whenever the expression "acceptable" is used it denotes an evaluation of the safety in use under the conditions specified.

The evaluations in this report only cover substances used with a satisfactory food quality specification.

Definition of terms used in this report

ADI (Acceptable Daily Intake) is the amount of a food additive, expressed on a mg/kg body weight basis, that can be ingested daily over a lifetime without incurring any appreciable health risk, and is based on an evaluation of available toxicological data.

ADI not specified is a term used when, on the basis of the available toxicological, biochemical and clinical data, the total daily intake of the substance, arising from its natural occurrence and/or its present use or uses in food at the levels necessary to achieve the desired technological effect, will not represent a hazard to health. For this reason, the establishment of a numerical limit for the ADI is not considered necessary for these substances.

It should be noted that any amount of such substances would not necessarily be toxicologically acceptable. Any additive allocated an "ADI not specified" must be used according to good manufacturing practice, i.e. it should be technologically efficacious, should be used at the lowest level necessary to achieve its technological effect, should not conceal inferior food quality or adulteration, and should not create a nutritional imbalance.

(Toxicologically) acceptable is an evaluation used in those cases where the Committee has not been able to allocate an ADI. If, however, the limited and defined use of the additive is judged to create no health problems, this specific use may be regarded as acceptable from a toxicological point of view.

Not (toxicologically) acceptable is a term used when a substance may be suspected of having undesirable health effects at the proposed level of use, or when the available data are inadequate to assess the safety in use.

(P)MTDI ((Provisional) maximum tolerable daily intake) is the terminology used by JECFA for some nutrients and contaminants without cumulative properties. Its value represents permissible human exposure as a result of the natural or accidental occurrence of the substance in food and in drinking water.

PTWI (Provisional tolerable weekly intake) is the terminology used by JECFA for food contaminants, such as heavy metals, with cumulative properties. Its value represents permissible human weekly exposure to those contaminants unavoidably associated with the consumption of otherwise wholesome and nutritious foods and drinking water.

The designations (P)MTDI and PTWI are normally used for unavoidable contaminants not acceptable as food additives. In this report, however, they have been used in some cases for food additives. In those circumstances it shall be understood that the substances specifically mentioned are acceptable as food additives as long as the total intake from all sources of the element in question lies within the specified limits.

References

1. Council Directive of 21 December 1988 on the approximation of the laws of the Member States concerning **food additives** authorized for use in foodstuffs intended for human consumption.
Directive 89/107/EEC O.J. L40 of 11.2.89, p.27
2. Council Directive of 23 October 1962 on the approximation of the rules of the Member States concerning the **colouring matters** authorised for use in foodstuffs intended for human consumption (amended 7 times).
Directive 62/23.10EEC O.J. N° 115 of 11.11.62, p.2645
3. Council Directive of 5 November 1963 on the approximation of the laws of the Member States concerning the **preservatives** authorised for use in foodstuffs intended for human consumption (amended 24 times).
Directive 64/54/EEC O.J. N° 12 of 27.1.64, p.161
4. Council Directive of 13 July 1970 on the approximation of the laws of the Member States concerning the **antioxidants** authorised for use in foodstuffs intended for human consumption (amended 7 times).
Directive 70/357/EEC O.J. L157 of 18.7.70, p.31
5. Council Directive of 18 June 1974 on the approximation of the laws of the Member States relating to **emulsifiers, stabilizers, thickeners and gelling agents** for use in foodstuffs (amended 4 times).
Directive 74/329/EEC O.J. L189 of 12.7.74, p.1
6. Commission Directive of 22 July 1983 introducing temporary measures for the designation of certain ingredients in the **labelling of foodstuffs** for sale to the ultimate consumer.
Directive 83/463/EEC O.J. L255 of 15.9.83, p.1
7. Presentation of an application for assessment of a food additive prior to its authorization (Catalogue number CB 57-89-370-EN-C (also available in DE and FR)

Introduction to the Summary Table of Evaluations

The table on pages 7 and 8 gives information on those substances included in the evaluations in Annex II. It is divided into two parts:

Part 1 (p. 7) summarizes in tabular form the majority of the substances. The first column lists the anions (vertical) and the most common cations (horizontal) included in the evaluations. The next column (vertical and horizontal) gives the evaluation allocated by the Scientific Committee for Food and the section in Annex II where the specific ion is evaluated. The remaining columns give the EEC numbers of the specific additives:

- Numbers with an "E" prefix refer to existing directives on food additives (refs. 2,3,4 and 5).
- Numbers without "E" refer to the temporary numbers allocated for labelling purposes (ref. 6).
- Numbers in round brackets "()" refer to substances with no EEC number, but where a number has been assigned by Codex in the International Numbering System (INS).
- Numbers marked with an asterisk "*" are the present, official numbers of these substances. The new, replacement number being allocated to them is indicated in square brackets "[]".
- No number: the specific substance is not included in the evaluation either because a technological need has not been established or because the substance is not commercially available.
- "+": no number p.t., but included in the evaluation.
- "-": not acceptable.

Part 2 (p. 8) lists other substances evaluated in this report.

Notes to the Summary Table

- 1 Large doses of magnesium ions cause diarrhoea and should be avoided.
- 2 For definition of ADI not specified, see p. 4.
- 3 Evaluation includes E262 sodium diacetate.
- 4 The use of ammonium chloride in large amounts in licorice products is currently under evaluation.
- 5 Evaluation includes 575 glucono-delta lactone.
- 6 Evaluation includes 370 1,4-heptonolactone.
- 7 Evaluation includes 529 calcium oxide.
- 8 Evaluation includes 530 magnesium oxide.
- 9 Evaluation includes 635 disodium 5'-ribonucleotides.
- 10 For food specially prepared for small children, only the L(+) isomer should be used.
- 11 Includes myristic, palmitic, stearic and oleic acid.
- 12 Evaluation includes 551 silicium dioxide.
- 13 For aluminium compounds see evaluation in part 2 of the summary table (p. 8).
- 14 DL-tartaric acid: not acceptable.
353 Metatartric acid: acceptable in wine up to 100 mg/l.

Summary Table of Evaluations (with reference to EEC numbers)
Part I

ANIONS	CATIONS	Acid (H ⁺)	Na ⁺	K ⁺	Ca ⁺⁺	Mg ⁺⁺ ¹	NH ₄ ⁺
	ADI with ref. to section in Annex II	Group ADI not specified ² (NS) (Section 1.1)					
Acetate ²	NS 1.3.4	E260	262 ³	E261	E263		(264)
Adipate	5 mg/kg bw 1.3.5	355	(356)	(357)			(359)
Carbonate	NS 1.3.1	E290	500	501	E170	504	503
Chloride	NS 1.3.1	507	Food ingredient	508	509	511	510 ⁴
Citrate	NS 1.3.6	E330	E331	E332	E333		380
Fumarate	6 mg/kg bw 1.3.5	297	(365)	(366)	(367)		
Gluconate ⁵	NS 1.3.6	574	576	577	578	(580)	
Glutamate	NS 2.1.2	620	621	622	623	625	624
Glycinate	NS 2.1.1	(640)	+	+	+		
Guanylate ⁹	NS 2.2	626	627	628	629		
Heptonate ⁶	Not acceptable 1.3.6	-	-	-	-	-	-
Hydroxide	Section 1		524	525	526 ⁷	528 ⁸	527
Inosinate ⁹	NS 2.2	630	631	632	633		
Lactate ¹⁰	NS 1.3.6	E270	E325	E326	E327	(329)	(328)
Malate	NS 1.3.6	296	350	351	352	+	
Fatty Acids ^{11, 13}	NS 1.3.4	570 *	E470	E470 *	E470 *	[470] 572 *	[470]
Phosphate, ortho ¹³	MTDI 70 mg/kg bw from all sources expressed as P 1.3.3	E338	E339	E340	E341	343	(342)
" , di + tri			E450 *	E450 *	(450)	(450)	
" , poly			[452] E450 *	[452] E450 *	[452] 544 *		545
Silicate ^{13, 12}	NS 1.3.2		550	(560)	552	553	
Succinate	NS 1.3.5	363					
Sulphate ¹³	NS 1.3.1	513	514	515	516	518	(517)
L(+)-Tartrate ¹³	30 mg/kg bw 1.3.6	E334	E335	E337	E336	354	

Summary Table of Evaluations

Part 2

EEC Number	Other Accepted Additives	Evaluation
520 521 522 523 (541) 554 555 556 558 559 573	Aluminium sulphate Aluminium sodium sulphate Aluminium potassium sulphate Aluminium ammonium sulphate Sodium aluminium phosphate, acid Sodium aluminium silicate Potassium aluminium silicate Calcium aluminium silicate Bentonite Aluminium silicate (kaolin) Aluminium salts of fatty acids	PTWI: 7 mg/kg bw expressed as Al from all sources (Section 1.1.2) When setting conditions of use for the accepted substances, intake from natural sources should be taken into account.
579 (585)	Ferrous gluconate Ferrous lactate	Acceptable as colour stabilizing agents in olives (Section 1.1.3)
(512)	Stannous chloride	Acceptable as colour stabilizing agent for white vegetables (canned and bottled) (Section 1.2.1)
519	Cupric sulphate	Acceptable as colour stabilizing agent in canned and bottled green beans and cucumbers (Section 1.2.2)
637	Ethyl maltol	ADI: 1 mg/kg bw (Section 4.4)
(387)	Oxystearin	ADI: 25 mg/kg bw (Section 4.1)
900	Dimethylpolysiloxane	ADI: 1.5 mg/kg bw (Section 4.2)
535 536	Sodium ferrocyanide Potassium ferrocyanide	ADI: 0.025 mg/kg bw (Section 4.3)
(946) (941) E290 (942) (945) (947)	Oxygen Nitrogen Carbon dioxide Nitrous oxide Hydrogen Argon	Toxicologically acceptable as packaging gases and propellants (Section 3)

Annex I

Categories of food additives

as listed in the Annex I of Directive 89/107/EEC of 21.12.88, OJ no L40, 11.2.89, p. 27, on the approximation of the laws of the member states concerning food additives authorized for use in foodstuffs intended for human consumption.

Colour
Preservative
Anti-oxidant
Emulsifier
Emulsifying salt
Thickener
Gelling agent
Stabilizer (1)
Flavour enhancer
Acid
Acidity regulator (2)
Anti-caking agent
Modified starch
Sweetener
Raising agent
Anti-foaming agent
Glazing agent (3)
Flour treatment agent
Firming agent
Humectant
Sequestrant (4)
Enzyme (4) (5)
Bulking agent
Propellent gas and packaging gas

(1) This category also comprises foam stabilizers.

(2) These can act as two-way acidity regulators.

(3) These substances include lubricants.

(4) Inclusion of these terms in this list is without prejudice to any future decision or mention thereof in the labelling of foodstuffs intended for the final consumer.

(5) Only those used as additives.

Annex II

to the Report of the Scientific Committee for Food on a First Series of Food Additives of Various Technological Functions

Evaluation of the Additives

Contents

1. Acids, bases and their salts

1.1 Cations

1.1.1 Ammonium, sodium, potassium, calcium, magnesium

1.1.2 Aluminium

1.1.3 Iron

1.2 Other compounds where use is restricted by the cation

1.2.1 Stannous chloride

1.2.2 Cupric sulphate

1.3 Anions (acids)

1.3.1 Chloride, sulphate, carbonate

1.3.2 Silicate and silicon dioxide

1.3.3 Orthophosphate, di-, tri- and polyphosphate

1.3.4 Monocarboxylic acids and their salts (acetate, fatty acids)

1.3.5 Dicarboxylic acids and their salts (succinate, adipate, fumarate)

1.3.6 Hydroxycarboxylic acids and their salts (lactate, citrate, malate, tartrate, gluconate, heptonate)

2. Amino acids and ribonucleotides

2.1 Amino acids

2.1.1 Glycine and its salts

2.1.2 L-Glutamic acid and its salts

2.1.3 L-Cysteine

2.2 5'-Ribonucleotides (inosinate, guanylate)

3. Packaging gases and propellants

3.1 Carbon dioxide, oxygen, nitrogen

3.2 Nitrous oxide

3.3 Hydrogen

3.4 Argon

4. Others

4.1 Oxystearin

4.2 Dimethylpolysiloxane

4.3 Potassium and sodium ferrocyanide

4.4 Ethylmaltol

1. Acids, bases and their salts

The evaluations of ionizable salts in this report have been based on the respective anions and cations listed below. The evaluation of specific salts may result in ADI's that differ from the general evaluation of the respective ions and such ADI's would supersede the general evaluations. Only those salts listed in the summary tables pp. 6-8 are included in the present evaluations. Other salts will need a separate individual assessment.

The ions contributed by mineral acids and bases (hydroxides), when used as acidity regulators according to GMP, cannot be distinguished toxicologically or analytically from the same ions already present in food from other sources. These contributions are therefore included in the evaluation of the respective anions and cations unless stated otherwise. Where appropriate, metal oxides have been included in the evaluation of the respective cations.

1.1 Cations

1.1.1 Ammonium, sodium, potassium, calcium, magnesium

These cations are natural constituents of man, animals and plants, and therefore occur in foodstuffs. They, together with certain anions, constitute the major electrolytes present in all biological materials. The Committee therefore established a **group ADI not specified** for these cations, although exhaustive systematic toxicological studies have not been carried out with the individual ions. No safety problems are likely to arise, provided the contributions from food intake do not disturb the homoeostatic mechanisms controlling the electrolyte balance of the body. For **magnesium**, large single doses taken in bulk are known to produce diarrhoea particularly in children, and should be avoided.

Calcium oxide and **magnesium oxide** are to be considered included in the group ADI of the ions

1.1.2 Aluminium

Intakes from foods containing aluminium-based food additives represent the major route of human exposure except for those individuals who regularly ingest medication containing aluminium. The toxicology of this cation was reviewed by JECFA and forms the basis of the evaluation. Recent estimates of intake range from about 2-6 mg/day for children and from 6-14 mg/day for teenagers and adults. Metabolic studies on selected aluminium compounds indicated poor absorption even at high levels of consumption and no significant accumulation in the short term. Absorbed aluminium deposits preferentially in the heart, spleen and bone marrow, without any associated histopathological lesions. Only individuals with chronic renal disease accumulate aluminium ions. There are no definite studies relating diet to a possible but unproven association between aluminium intake and neurological disorders such as Alzheimer's disease. The Committee agrees with the **PTWI for Al of 7 mg/kg body weight** established by JECFA for all intake sources. The aluminium salts considered acceptable as food additives by the Committee are listed in the summary table p.8.

Although there is reason to believe that only minute amounts of Al are likely to be absorbed from aluminium silicate, the Committee nevertheless considers that this contribution should be included in the PTWI for Al. If evidence of minute bioavailability is presented, the Committee would reconsider its position.

When setting conditions of use for aluminium salts, the intake from other food and drink sources should also be taken into account.

1.1.3 Iron

Iron is an essential nutrient and an unavoidable constituent of foods but may also be present as a contaminant. A considerable body of information about iron is available from biochemical, physiological, toxicological and epidemiological studies. Adequate guidelines for nutritional requirements for iron have been published. There is still some uncertainty with regard to the maximum level of iron that can be tolerated. The body has a considerable capacity to store iron, and chronic toxicity only occurs when stores become overloaded under certain pathological conditions. Normal individuals can tolerate 50 mg of iron/day (ferrous iron) for long periods without adverse effects. The Committee agrees with the JECFA which established a **PMTDI of 0.8 mg/kg body weight** calculated as Fe from all sources except for iron oxides used as colouring agents and iron supplements taken during pregnancy and lactation or for specific clinical requirements. The iron salts considered acceptable as food additives are listed in the summary table p 8.

1.2 Other compounds where use is restricted by the cation

1.2.1 Stannous chloride

This salt is used specifically for stabilizing the white colour of certain vegetable products (e.g. asparagus packed in glass jars) in amounts of up to 25 mg/kg. This use will contribute an intake of tin which lies well below the **PMTDI of 2 mg/kg body weight** established by JECFA. The Committee therefore accepts the continued use of stannous chloride for this purpose.

1.2.2 Cupric sulphate

This salt is used specifically for stabilizing the colour of canned green beans and cucumber salad. The possible intake from this use is unlikely to contribute significantly to the total dietary intake of copper and will lie well below the **PMTDI of 0.5 mg/kg body weight** calculated as Cu from all sources, established by JECFA. The Committee considers the continued use of cupric sulphate for this purpose as toxicologically acceptable at the technological levels proposed.

1.3 Anions (acids)

1.3.1 Chloride, sulphate, carbonate

These anions are natural constituents of man, animals and plants, and therefore occur in foodstuffs. They, together with certain cations constitute the major electrolytes present in all biological

materials. The Committee therefore established a **group ADI not specified** for these anions, although exhaustive systematic toxicological studies have not been carried out with these ions. No safety problems are likely to arise, provided the contributions from food do not disturb the homoeostatic mechanisms controlling the electrolyte balance of the body.

1.3.2 Silicate and silicon dioxide

The available data on orally administered silica and silicates, including amorphous silicon dioxide, appear to substantiate the biological inertness of those compounds. Any silicate absorbed is excreted by the kidneys without evidence of toxic accumulation in the body, except for the reported damage to dog kidney by magnesium trisilicate and sodium silicate. Methods for estimating silica in body tissues have been greatly improved in recent years, making some of the earlier data somewhat less valuable. A number of short-term studies in two species are available.

The effect on the kidney observed with magnesium trisilicate and sodium silicate in the dog was not observed in rats and chickens. There is also a wide experience with magnesium trisilicate as an antacid in man without any observed adverse effects. The Committee established a **group ADI not specified** for silicon dioxide and the silicates listed in the summary table, when used as anticaking agent. The use of aluminium silicates should be restricted to comply with the PTWI of aluminium (see section 1.1.2).

1.3.3 Orthophosphate, di-, tri- and polyphosphate.

Phosphate salts provide a metabolic source of the various cations and the phosphate anion. Of greatest concern is the toxicity arising from calcium, magnesium and phosphate imbalances in the diet. Ingested phosphate from food additive sources should be considered together with that from natural sources.

Polyphosphates are not absorbed to any significant extent as such, but only in the form of monophosphates, into which they are broken down in the intestine. Since the extent of hydrolysis is difficult to predict, the toxicological evaluation must be based on the assumption of complete conversion to monophosphate.

Phosphates are not mutagenic in a number of test systems. Teratogenic effects have not been observed in mammalian systems. Numerous animal studies have shown that excessive dietary phosphorus causes an increase in plasma P and a decrease in serum Ca. There is still uncertainty over the optimal Ca:P ratio and whether this is of any significance for the human dietary pattern.

The Committee agrees with the JECFA estimate of an **MTDI of 70 mg/kg body weight** for man, calculated as P, as the sum of phosphates naturally present in food and derived from additives in diets nutritionally adequate in respect of calcium. If the calcium intake were high, the intake of phosphate could be proportionally higher and the reverse relationship would also apply.

1.3.4 Monocarboxylic acids and their salts

Acetate: human studies determining the maximum metabolic load of acetate are not available. In evaluating the acceptance of acetates emphasis is placed on their established metabolic pathway and the consumption by man as normal constituents of the diet. The Committee established a **group ADI not specified** for acetate including diacetate.

Fatty acids: (myristic, stearic, palmitic, oleic acid) no exhaustive systematic toxicological studies have been carried out with these fatty acids. They are all constituents of biological fat and are therefore present in food generally. They are also produced during the metabolism of fats. The Committee established a **group ADI not specified** for the fatty acids and their salts listed in the summary table.

1.3.5 Dicarboxylic acids and their salts

Succinate: this anion occurs in nature and plays a role as an intermediate metabolite in the citric acid cycle. It also participates in the glucose and fatty acid synthesis. No systematic toxicological studies are available. However, in view of its role as an intermediate metabolite the Committee established a **group ADI not specified** for succinate.

Adipate: the evaluation was based on metabolic studies, acute, short-term and long-term toxicity studies, teratogenicity tests in 4 animal species, and mutagenicity studies. The Committee agrees with the **ADI of 5 mg/kg body weight** established by JECFA.

Fumarate: fumarates are normal components of intermediate metabolism. The testicular atrophy in rabbits reported after intraperitoneal administration of high doses was not seen after oral administration of doses as high as 6-9% in the diet of rabbits and other species. The Committee agrees with the **ADI of 6 mg/kg body weight** previously established by JECFA.

1.3.6 Hydroxycarboxylic acids

Lactate: in evaluating lactates emphasis is placed on the well-established metabolic pathways for the lactate anion in man after normal consumption. Lactate is an important intermediate of carbohydrate metabolism and a natural component of food. However, human studies determining the maximum load of lactate are not available. There is some evidence that babies in their first three months of life have difficulties in utilizing small amounts of DL- and D(-)-lactic acid. Adults metabolize D(-)-lactate without difficulty. The Committee agrees with the **group ADI not specified** established by JECFA. For food specially prepared for small children only the L(+) isomer should be used.

Citrate: in evaluating the acceptability of citrate emphasis is placed on the well-established role of citrate as an intermediate metabolite in the citric acid cycle and as a natural component of food. The Committee agrees with the **group ADI not specified** established by JECFA.

Malate: in evaluating the acceptance of malate emphasis is placed on the well-established metabolic pathway of this anion and the daily consumption of malate-containing food. The malate anion also occurs in D(+) and L(-) forms. The available evidence shows that D(+)-malate is metabolized without difficulty and there is no clear evidence for a need to distinguish between the enantiomers when malate is used in food. The Committee agrees with the **group ADI not specified** established by JECFA.

Tartrate: the long-term study in rats with L(+)-tartrate showed no adverse effects at the highest level tested. Tartrates have been used medicinally for long periods. The evaluation of L(+)-tartrate can therefore be based on experimental data, the metabolic inertness of tartrates and the fact that they are normal constituents of food. Monosodium-L(+)-tartrate also produced no adverse effects in long-term studies. The available data were inadequate to assess the safety of DL-tartrate. The Committee agrees with the **group ADI of 30 mg/kg body weight** established by JECFA for L(+) tartrate, while the DL-form is **not acceptable**.

Metatartaric acid: the Committee could not establish an ADI on the basis of the available data. It considered **acceptable**, however, the continued use in wine at a level up to 100 mg/l.

Gluconate and glucono-delta-lactone: consideration of these substances may be based on the metabolic evidence as intermediates of normal glucose metabolism in mammalian species. There is considerable experience with gluconates in man and animals. A single long-term test at one dose level showed no evidence of carcinogenicity for the lactone. Teratogenic tests have shown no abnormalities in 4 species. In view of their role in the glucose metabolism in mammals the Committee agrees with the **group ADI not specified** established by JECFA.

Heptonate and 1,4-heptonolactone: the Committee was unable to evaluate the safety in use of this anion in the absence of adequate data. It considered the use of heptonic acid and its salts as food additives **not acceptable**.

2. Amino acids and ribonucleotides

2.1 Amino acids

These substances are the essential constituents of proteins and are thus present in all foodstuffs containing proteins. Only the L-forms are physiologically important. The Committee considers the

use of L-amino-acids generally acceptable provided the addition to food does not give rise to a nutritional imbalance of the amino acids.

2.1.1 Glycine and its salts

The Committee reviewed the nutritional, biochemical and toxicological information on this non-essential amino acid. If used at levels corresponding to good manufacturing practice no nutritional or toxicological hazards arise to man. The Committee accepted the use of glycine as an acidity regulator, flavour modifier and humectant, but did not include its use as a sweetening agent in this evaluation.

2.1.2 L-Glutamic acid and its salts

L-Glutamic acid is a component of animal and plant proteins and represents some 20% of ingested protein. Glutamates are claimed to have a taste which is distinct from the basic four physiological tastes and which is recognised by many organisms. Bound glutamate is released during digestion and absorbed comparatively slowly. Infants, including prematures, have been shown to metabolize glutamate as efficiently as adults and therefore do not display any special susceptibility to elevated oral intakes of glutamate.

Acute, subchronic and chronic toxicity studies in mice, rats and dogs have shown no specific toxic effects due to monosodium glutamate (MSG). There was no evidence of carcinogenic or genotoxic potential. Numerous reproduction and teratology studies in mice, rats, rabbits and monkeys revealed no deleterious effects on the offspring.

Some investigations have demonstrated a strain-dependent but variable vulnerability of the developing mouse or rat central nervous system to high levels of glutamate alone or in combination with other amino acids following administration of massive doses. No brain lesions have occurred in numerous studies in the mouse, rat or hamster ingesting high doses of MSG in their diet.

Some of the acute human reactions, reported after ingestion of over 3g of glutamate per person, have also been observed with other foods not containing glutamates. No objective clinical measurements have been associated with the wide variety of symptoms described.

The Committee established a **group ADI not specified** on the basis of the data provided and in view of the large normal dietary intake of glutamates.

2.1.3 L-Cysteine

Both L-cysteine hydrochloride and the monohydrate have been used in bakery processes as dough improvers. L-cysteine is a non-essential amino acid, occurring in a wide variety of foods, especially cereals. The contribution to the total daily dietary intake from the use in bakery processes is insignificant. The Committee therefore considers its use as flour treatment **toxicologically acceptable**.

2.2 5'-Ribonucleotides

Inosinate and guanylate

These substances are widely distributed in all tissues of animals and plants. Their role in purine metabolism as well as their breakdown to uric acid and to allantoin (in the majority of mammals, but not man), is well substantiated. There are extensive biological data available including metabolic, short- and long-term studies in several species, as well as reproduction, teratology and mutagenicity studies. No evidence of carcinogenicity, of adverse effects on reproduction and of teratogenic or genotoxic potential has been observed.

Ingestion of large amounts by man can increase the serum uric acid level and urinary uric acid excretion. This is of importance only for people with gouty diathesis or those taking uric acid-retaining diuretics. The changes in dietary purine intake from the use of these substances as flavour modifiers are no greater than those due to variability in the consumption of the major dietary contributors of purines. The likely intake of these substances from their use as flavour modifiers varies from 10-30 mg/day compared with 400-600 mg/day contributed by the diet. The dietary treatment of gout or hyperuricaemia has been abandoned in favour of more efficient therapy by uricosoric agents. Based on this information, the Committee sees no reason for special warning labels in relation to gout. The Committee established a **group ADI not specified** for ribonucleotides when used as flavour modifiers at the levels proposed according to good manufacturing practice.

3. Packaging gases and propellants

3.1 Carbon dioxide, oxygen, nitrogen

Man is permanently exposed to these atmospheric gases. Additionally, carbon dioxide is a natural metabolite. Compared to this exposure, the intake from their use as packaging gases and propellants is insignificant. The establishment of ADI's for these compounds is unnecessary. The Committee considers these compounds **acceptable** as packaging gases and propellants provided they comply with a food grade specification.

3.2 Nitrous oxide

The pharmacological and pharmacokinetic properties of this gas are known from its wide and established use as an anaesthetic. Although no residue data are available, these are likely to be so low as to present no hazard to the consumer. The Committee considers the establishment of an ADI unnecessary and its use as packaging gas and propellant **acceptable**. The specification should exclude the presence of other oxides of nitrogen.



3.3 Hydrogen

Apart from drawing attention to its explosive properties the Committee considers the establishment of an ADI unnecessary. Its use as a packaging gas is toxicologically **acceptable** provided a food grade specification is available.

3.4 Argon

This rare gas is an elemental constituent of air. It is completely inert chemically. The Committee considers the establishment of an ADI unnecessary. Its use as a packaging gas and propellant is **toxicologically acceptable** provided a food grade specification is available.

4. Others

4.1 Oxystearin

The toxicological data on this substance include metabolic studies, acute, short-term and long-term toxicity studies in mice and rats. The Committee agrees with the evaluation of JECFA establishing an **ADI of 25 mg/kg body weight**.

4.2 Dimethylpolysiloxane

The available toxicological data include studies on the metabolism, acute, short-term and long-term toxicity and observations in man. A recent long-term feeding study in mice showed no evidence of absorption or carcinogenic potential. The Committee agrees with the **ADI of 1.5 mg/kg body weight** established by JECFA.

4.3 Sodium and potassium ferrocyanide

The Committee agrees with the **ADI of 0.025 mg/kg body weight** (calculated as sodium ferrocyanide) established by JECFA. When used as a processing aid in the production of wine only small residues are found, and only small technological levels are needed as anticaking agent in salt. Therefore the Committee has no objection, on toxicological grounds, to the continued use for these purposes.

4.4 Ethylmaltol

The available metabolic data point to rapid absorption, and rapid elimination as conjugate with sulphate or glucuronic acid. The various short-term studies showed no evidence of any serious target organ toxicity nor was there any evidence of interference with reproductive function or of foetal toxicity. Adequate long-term studies in the rat and dog exclude chronic toxicity and carcinogenic potential. Mutagenicity tests are also available. The Committee established an **ADI of 1 mg/kg body weight**.

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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.

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