

COMMISSION OF THE EUROPEAN COMMUNITIES

REPORTS
OF THE SCIENTIFIC COMMITTEE
FOR FOOD

Fifth series

1978

CORRIGENDUM

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Page 5 is to be replaced by the following text:

Composition of the Scientific Committee for Food

Messrs P. Elias
F. Fairweather
R. Franck
H. Gounelle de Pontanel
L. Gatti
F. Hill
A. Lafontaine
P. Marquardt (vice-chairman)
A. Mariani
E. Poulsen (vice-chairman)
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R. Truhaut (chairman)
G.J. Van Esch
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ELEMENTS OF INFORMATION GIVEN TO THE COMMISSION ON THE USE
OF ADDITIVES FOR WHICH NO ACCEPTABLE DAILY INTAKE HAS BEEN
ALLOCATED

(16 March 1978)

The Scientific Committee for Food was asked by the Commission to state its attitude to the use of food additives for which it had been unable to allocate an Acceptable Daily Intake.

The Committee defined its position in the following way:

"The Committee emphasizes that where it does not lay down any acceptable daily intake for an additive which it considers acceptable, this is because it agrees that use of that additive does not raise any health problem".

REPORT OF THE SCIENTIFIC COMMITTEE FOR FOOD ON THE PROVISIONS RELATING TO ADDITIVES AND PROCESSING AIDS IN THE DRAFT PROPOSAL FOR A COUNCIL DIRECTIVE CONCERNING THE APPROXIMATION OF THE LAWS OF MEMBER STATES RELATING TO FINE BAKERS' WARES, RUSKS, PASTRIES AND BISCUITS

(Opinion expressed 1st May 1978)

TERMS OF REFERENCE

To give an opinion on the acceptability, from the point of view of the health of the consumer, of the additives and processing aids which have been requested for inclusion in a proposal for a Council Directive on "fine bakers' wares".

CONCLUSIONS

1. A substance is classed "acceptable" when the available toxicological data is adequate and when the potential daily intake of the substance from "fine bakers' wares" is not too large a proportion of the ADI. This classification does not necessarily imply that the Committee endorses the levels of use submitted nor the need for the wide variety of additives and processing aids.
2. The Committee accepts, on a provisional basis, ADIs established by JECFA.
3. The advice of the Committee applies to products not intended specifically for young infants and other critical population groups.
4. The advice of the Committee on individual substances (in the Annex) is given on the understanding that it may need to be revised as Community legislation is developed (e.g. by the elaboration of rules on conditions of use of food additives, or by the elaboration of comprehensive lists of other classes of food additives).

DISCUSSION

1. The Commission estimates that the future Directive will apply to some 5,000 products that may potentially be traded between the Member States. The Committee is informed that Member States will not be prevented from allowing the marketing, in their own countries, of other products that do not comply with every provision in the Proposed Directive. Such products will of course have to comply with national legislation and any requirements of other Community legislation, such as that on various food additives and on some food ingredients (e.g. cocoa, chocolate, honey and sugars).
2. The Committee considers that, in principle, it should only give a definitive opinion on a particular additive as part of a comprehensive assessment of that class of additive. However, many classes of additives and processing aids have not yet been studied in this way at Community level, although most of them, i.e. acids/bases/salts, solvents, flavours and enzymes, are due to be assessed in the near future. In these circumstances and at the request of the Commission the Committee is prepared to give a provisional opinion, on the understanding that this opinion may need to be revised as such Community legislation is developed or reviewed. It is to be understood that additives should always comply with an adequate specification.

The Committee recognizes that these products are not intended specifically for young infants or other critical population groups. It wishes to draw attention to the special needs of these critical groups for which the use and the levels of additives and processing aids listed in this directive may be unsuitable.

3. Until now, the Committee, in dealing with additives, has not usually made recommendations concerning their acceptability in specific foods or groups of foods. The Committee stresses the importance of implementing the provisions, which are in all Directives on food additives adopted at Community level, requiring that conditions of use of additives should be determined. Only if this is done can assessments be made of potential intakes of additives, and indications obtained on whether or not ADIs are likely to be exceeded. The Committee emphasizes that the allocation of maximum levels of additives where this is necessary, amongst the various foods with the objective of not exceeding the ADI must not be regarded as a purely arithmetical exercise, but as a matter involving scientific

judgement. The Committee recommends that from the point of view of safety-in-use it should be associated with this work.

4. The Committee's approach to the assessment of the acceptability of an additive or processing aid in "fine bakers' wares" has been to establish for the purpose of this exercise, the acceptable daily intake (ADI) of each substance, and to ascertain that the potential daily intake of the substance from "fine bakers' wares" was not too large a proportion of this ADI.

ESTABLISHMENT OF ADIs

5. The Committee has set out its concept of ADI in its Report on Colours (Opinion, 27 June 1975). The ADI represents an estimate of the average daily intake of a substance, which, taken throughout the human life span, would not result in any obvious harm to human health. The Committee emphasizes that an ADI is intended as a guide and has a safety margin such that there need be no undue concern where, in the expert judgement of the Committee it is occasionally or slightly exceeded (see also paragraph 3).

For reasons given in paragraph 2 and below, the Committee has established its own ADIs for relatively few of the additives and processing aids in the Proposed Directive on Fine Bakers' Wares. For the remainder, the Committee, in order to expedite consideration of the Proposed Directive has been prepared to accept the latest assessments of JECFA* on a provisional basis.

6. Many of the additives and processing aids listed in the draft Proposed Directive are already controlled by Community legislation. Directives on colours, preservatives, antioxidants and emulsifiers, stabilisers, thickening and gelling agents have been in existence for some time and were based on advice from our predecessors, the Scientific Commission. Since the adoption of these Directives, ADIs have been established by this Committee for colours and propyl gallate; and this Committee has endorsed the approach of JECFA in its recommendations on pectin, guar gum, carrageenan (furcellaran), parahydroxybenzoates and propionates.
7. The draft Proposed Directive includes certain emulsifiers (sorbitan and polyoxyethylene sorbitan esters of fatty acids) which are on Annex II of the Directive on emulsifiers, stabilisers, thickening and gelling agents. Annex II substances are being reviewed by the Commission and the Committee, and the Committee was advised by the Commission that in the meantime it would be inappropriate to give advice on these substances.
8. For the remainder (and majority) of additives and processing aids the Committee was prepared to accept, on a provisional basis, ADIs established by JECFA where these were available. For those substances which did not have a JECFA assessment, the Committee made its own evaluation on the basis of information which was provided to it. These substances were L-cysteine, succinic acid, acid sodium aluminium phosphate, polyglycerol esters of dimerised fatty acids of soya bean oil, oxidatively polymerized soya bean oil, certain natural waxes and stearyl tartrate. These evaluations by the Committee relate only to the particular use listed in the Annex.
9. The draft Directive, as presented to the Committee, permits additives that are not specifically named "which are the residues of the treatment of the raw materials from which fine bakers' wares are made and where qualitative and quantitative presence conforms to the requirement of the legislation of the Member State in which such fine bakers' wares are to be sold". The Committee is unable to express any opinion on such un-named residues. Similarly the Committee notes that flavours are not listed individually thus it is unable to give advice on their acceptability.
10. In summary, therefore, for some additives and processing aids ADIs have previously been established by this Committee or have been established during this review of "fine bakers' wares". For the remainder of the named additives and processing aids the Committee has agreed to accept, provisionally, ADIs established by JECFA. The Committee could not establish ADIs for un-named additives and processing aids and was advised that it would be inappropriate at present for it to give advice on 'Annex II emulsifiers'.

*Joint FAO/WHO Expert Committee on Food Additives

ESTIMATION OF POTENTIAL DAILY INTAKES

11. The potential daily intake of an additive or processing aid from its use in "fine bakers' wares" has been obtained by multiplying the average quantity of "fine bakers' wares" estimated to be consumed per person per day, by the maximum level of the additive or processing aid. The Committee was provided with some information on the consumption levels in the Community of products controlled by the Proposed Directive. The highest average consumption of such products in the Community appears to be about 45-50 g per person per day (assumed to be about 40 g on a dry matter basis) including about 20 g of "biscuits". This is no more than about 3 per cent by weight of the total average food in the diet (1500 g per person per day) and furthermore the Committee estimates this percentage is unlikely to rise to more than about 12 per cent for a consumer with a higher than average appetite for such items.
12. The maximum levels for the additives and processing aids in the Proposed Directive have been put forward by the Commission after discussion with Member States and Industry as the levels to be found in the product. In some cases the Committee requested and was provided with further information by the Commission. The Committee was aware that several approaches exist to the problem, each of which has its inherent difficulties. The Committee was also informed that in some Member States the government authorities had developed detailed procedures for estimating potential daily intake of additives from all foodstuffs. The Committee was of the opinion that were a similar exercise to be pursued by the Commission it would be found that lower levels of additives in "fine bakers' wares" might be proposed at Community level. The Committee is also aware of international cooperation in this area. The Committee emphasizes that its use of any of these levels for estimating potential daily intakes does not imply its endorsement of those levels nor of the need for the wide variety of additives and processing aids.
13. It should be stressed that it has only been possible to calculate potential daily intakes of additives from "fine bakers' wares" in an arbitrary manner. It is certain that not all additives will be present in any single product nor the maximum level found in each product.

ASSESSMENT OF TOXICOLOGICAL ACCEPTABILITY

14. The Committee's assessment of the toxicological acceptability of each of the additives and processing aids at the levels in the draft Proposed Directive on "fine bakers' wares" has been based on a comparison of the acceptable daily intake (paragraphs 5-10) with its potential daily intake (paragraphs 11-13) estimated from "fine bakers' wares". The Committee's assessments are in terms of "acceptable" or "not possible".
15. Taking into consideration the following points:
 - (a) fine bakers' wares represent, on average, some 3 per cent of the total diet;
 - (b) at most only about 50 per cent of the total diet would be likely to contain an additive;
 - (c) not all additives will be present in any single fine bakers' wares product nor the maximum level present in every product;

the Committee's opinion is that it would not be unreasonable to allow about 10 per cent of the ADI of a food additive to be allocated to intake from fine bakers' wares. Additives or processing aids that are within or do not greatly exceed this criterion are considered by the Committee to be toxicologically "acceptable" on a provisional basis.

16. The Committee's assessments "not possible" arise for one of two reasons. In some cases there is a lack of toxicological information. These assessments could be reviewed if data are submitted. In many other instances these assessments arise because, though toxicological information is available, the Committee considers that the intake of the additive or processing aid from "fine bakers' wares" could be too high in relation to the estimated ADI, bearing in mind the possibility of the widespread use of the additive or processing aid in other foods. The approach the Committee has had to adopt in order to come to a decision (paragraph 13) makes it likely that more precise information on the extent of the use of such additives in "fine bakers' wares" and in other foods will permit a revised toxicological assessment.

17. The Committee has already indicated (paragraphs 7-9) that it is unable to give advice on a number of additives and processing aids (e.g. flavours and Annex II emulsifiers). Additionally, the Committee has not reconsidered colours in this Review. Colouring matters were not listed individually, neither were any maximum limits supplied. The Committee was therefore unable to give any advice on the acceptability or otherwise of colouring matters other than that contained in its Reports on the subject. The Committee stresses that for certain colouring matters a low acceptable daily intake has been established. The use in fine bakers' wares of such colouring matters should be examined very carefully in order to avoid possible exclusion from other relevant uses. The Committee also draws attention to the need to observe the restrictions on use in foods recommended in its Reports.
18. The Committee's assessments are summarised in the Annex to this Report, which tabulates for each additive or processing aid the information used in reaching its decisions, together with comments where appropriate.

A. PRESERVATIVES

| EEC No | Substance | Acceptable Intake ⁽²⁾ (mg/adult/day) | Maximum level in Fine Bakers' Wares to be proposed in Draft Directive (g/kg/dry matter)(1.1) | Average Daily Intake from Fine Bakers' Wares based on previous column (mg/adult/day) | Toxicological Assessment and Comments |
|-----------------------------|---|--|--|--|--|
| E200 to E203 | Sorbic acid and its sodium, potassium and calcium salts, expressed as sorbic acid. | 1500 as total sorbate, expressed as sorbic acid. JECFA | 2(1.3) | 40 | <u>ACCEPTABLE</u> : assumes 20 g intake (dry matter) i.e. biscuits excluded. |
| | Sorboyl palmitate, expressed as sorbic acid. | ADI not fixed, insufficient data, not available commercially SCF/JECFA | 2(1.2, 1.3) | 40 | <u>NOT POSSIBLE</u> : results of <u>in vivo</u> hydrolysis study required and results from short-term study desirable assumes 20 g intake of yeast raised products |
| E280 to E283 | Propionic acid and its sodium, potassium and calcium salts, expressed as propionic acid. | Not specified. SCF(3)/JECFA | 5(1.3) | 100 | <u>ACCEPTABLE</u> : (see comment on E200) |
| E210 to E213 | Benzoic acid and its sodium, potassium and calcium salts, expressed as benzoic acid. | 300 as total benzoate, expressed as benzoic acid. JECFA | 0.5 | 20 | <u>ACCEPTABLE</u> : |
| E214 to E219 | Ethyl, propyl and methyl p-hydroxybenzoates and their sodium derivatives (expressed as acid). | 600 as sum of esters: SCF(3)/JECFA | 0.5 (as p-hydroxybenzoic acid) | 24 (as ethyl p-hydroxybenzoates) | <u>ACCEPTABLE</u> : |
| E220 to E224 and E226, E227 | Sulphur dioxide, sodium sulphite, sodium hydrogen sulphite, sodium metabisulphite, potassium metabisulphite; calcium sulphite, calcium hydrogen sulphite. | 42 as sulphur dioxide. JECFA | 0.05 Separately or together, calculated as sulphur dioxide. | 2 | <u>ACCEPTABLE</u> : but the Directive should emphasise that the sulphur dioxide is present only as a result of carry-over from food ingredients e.g. sugars, jams, dried fruits etc. (see also section B). |

B. DOUGH TREATMENT AGENTS

| EEC No | Substance | Acceptable Intake (2) (mg/adult/day) | Maximum level in Fine Bakers' Wares to be proposed in Draft Directive (g/kg/dry matter) | Average Daily Intake from Fine Bakers' Wares based on previous column (mg/adult/day) | Toxicological Assessment and Comments |
|--------------------------------------|---|---|---|--|--|
| E220 E221 E223 E224 E226 | Sulphur dioxide Sodium sulphite Sodium metabisulphite Potassium metabisulphite Calcium sulphite v | } } 42 as sulphur dioxide } JECFA) (Although JECFA did not consider use as a dough treatment agent) | 0.01 as sulphur dioxide | Negligible | <u>ACCEPTABLE</u> : Negligible residue of sulphur dioxide remains in the final product after the normal use level of about 0.2 g/kg flour, according to information received. |
| - | L-Cysteine (hydrochloride or hydrochloride monohydrate). | Not assessed by JECFA | Nil as cysteine in final product | Nil as added cysteine (residue after treatment is cystine) | <u>ACCEPTABLE</u> : on the basis of detailed toxicological information studied by the Committee. Committee was informed that residues after treatment with cysteine at 0.1 g/kg were negligible. |
| E300 | L-Ascorbic acid | Acceptable at 0-200 mg/kg flour JECFA | Use level, 0.15 Residual level after baking, nil. | Nil | <u>ACCEPTABLE</u> : (see also Section C). |

C. ANTIOXIDANTS

| EEC No | Substance | Acceptable Intake ⁽²⁾ (mg/adult/day) | Maximum level in Fine Bakers' Wares to be proposed in Draft Directive (g/kg dry matter) | Average Daily Intake from Fine Bakers' Wares based on previous column (mg/adult/day) | Toxicological Assessment and Comments |
|------------------|--|---|---|--|---------------------------------------|
| E300 to E302 | L-ascorbic acid and its sodium and calcium salts | 900 as total ascorbic acid from all sources JECFA | 1 | 40 | <u>ACCEPTABLE:</u> |
| E304 | 6-palmityl-L-ascorbic acid (ascorbyl palmitate) | 75 (as sum of ascorbyl palmitate and ascorbyl stearate). JECFA | 0.5 of fat content, singly or in combination | 2 (assumes 10% fat content) | <u>ACCEPTABLE:</u> |
| E306 to E309 | Tocopherol-rich extracts of natural origin, synthetic α -tocopherol, synthetic δ -tocopherol, synthetic γ -tocopherol | 120 total tocopherols expressed as α -tocopherol. JECFA | | | <u>ACCEPTABLE:</u> |
| E311, E312, E310 | Octyl gallate, dodecyl gallate, and propyl gallate | 12 as sum of gallates SCF(4) | 0.3 | 1 separately or together, assuming about 10% fat content | <u>ACCEPTABLE:</u> |
| E320 E321 | Butylated hydroxyanisole Butylated hydroxytoluene |)30 as sum of both) (temporary) JECFA | | | <u>ACCEPTABLE:</u> |

D. ACIDS, BASES AND SALTS

| EEC N° | Substance | Acceptable Intake ⁽²⁾ (mg/adult/day) | Maximum level in Fine Bakers' Wares to be proposed in Draft Directive (g/kg dry matter) | Average Daily Intake from Fine Bakers' Wares based on previous column (mg/adult/day) | Toxicological Assessment and Comments |
|---------------------------------|--|--|---|--|--|
| E260 to E263 and sodium acetate | Acetic acid and its potassium, sodium and calcium salts | Not specified (sodium diacetate 900) JECFA | 10 (20 in snack products) | 400 | <u>ACCEPTABLE:</u> |
| E270 E325 to E327 | Lactic acid and its sodium, potassium and calcium salts | L & DL, not specified (but D - not to be used in foods for young infants) JECFA | 5 | 200 | <u>ACCEPTABLE:</u> |
| E330 to E333 | Citric acid and its sodium, potassium and calcium salts | Not specified JECFA | 15 | 600 | <u>ACCEPTABLE:</u> |
| E334 to E336 E337 | Tartaric acid and its sodium and potassium salts. Sodium potassium tartrate. | 1800 as total L-tartaric acid from all sources. JECFA | 20 | 400 | <u>ACCEPTABLE:</u> Widely used and present in food, therefore desirable to restrict potential intake to lowest value technologically possible. Committee informed that main use in Fine Bakers' Wares is as chemical raising agents (see comment on glucose delta lactone) |
| - | Malic acid and its sodium, potassium and calcium salts expressed as malic acid | L & DL, not specified (but D not to be used in foods for young infants) JECFA | 15 | 600 | <u>ACCEPTABLE:</u> |
| - | Fumaric acid | 360 JECFA | 20 | 800 | <u>NOT POSSIBLE:</u> Potential intake might be high in relation to ADI. Could be |

D. ACIDS, BASES AND SALTS - continued

| EEC No | Substance | Acceptable Intake ⁽²⁾ (mg/adult/day) | Maximum level in Fine Bakers' Wares to be proposed in Draft Directive (g/kg dry matter) | Average Daily Intake from Fine Bakers' Wares based on previous column (mg/adult/day) | Toxicological Assessment and Comments |
|-------------|--|--|---|--|--|
| | | | | | considered for use in specific (named) applications |
| - | Calcium chloride | Not specified JECFA | 5 | 20 (5) | <u>ACCEPTABLE</u> : |
| - | Sodium hydroxide | Not specified JECFA | 0.5 | 2 (5) | <u>ACCEPTABLE</u> : requested for use on bretzels and also as a diluent for colours |
| - | Calcium hydroxide | Not specified JECFA | 0.5 | 2 (5) | <u>ACCEPTABLE</u> : requested as whipping aid for egg albumen |
| - - - | Calcium sulphate Ammonium chloride Ammonium sulphate | Not specified Not assessed Not assessed JECFA | 5 | 100 | <u>ACCEPTABLE</u> : in context of the requested use as a yeast improver (assumes intake of 20 g yeast raised products) |
| - | Silicic acid and its calcium, sodium, aluminium and magnesium salts and their compounds. | Not specified (magnesium silicates, including talc) JECFA | 0.2 | 8 | <u>ACCEPTABLE</u> : requested as anti-caking/free flow agents |
| - | Magnesium oxide | Not specified JECFA | 1 | 40 | - ditto - |
| - | Magnesium, calcium and aluminium stearates | Not specified JECFA | 1 | 40 | - ditto - |
| - | Succinic acid | Not assessed | 15 | 600 | <u>NOT POSSIBLE</u> : Toxicological information on this substance required. |

D. ACIDS, BASES AND SALTS - continued

| EEC No | Substance | Acceptable Intake (2) (mg/adult/day) | Maximum level in Fine Bakers' Wares to be proposed in Draft Directive (g/kg dry matter) | Average Daily Intake from Fine Bakers' Wares based on previous column (mg/adult/day)p | Toxicological Assessment and Comments |
|----------------------|---|--|---|---|---|
| - | Glucono-delta-lactone (D-glucono-1, 5-lactone) | 3000 total gluconates, expressed as gluconic acid JECFA | 20 | 400 (as chemical raising agent) | <u>ACCEPTABLE</u> : Committee informed that main use in food is as chemical raising agent in Fine Bakers' Wares (assumes 20 g intake of chemically raised products) |
| - | Acid aluminium sodium phosphate | 600 (temporary) SCF | 30 | 600 (165 as P) | <u>NOT POSSIBLE</u> : Potential might be high in relation to ADI. Could be considered for use in specific (named) applications. |
| E341 (a) E341 (b) | Mono calcium ortho-phosphate (ACP) dicalcium ortho-phosphate | 4200 as total P from all sources JECFA | 20 (total) | 400 (106 as P) | <u>ACCEPTABLE</u> : (see comment on glucono-delta-lactone) |
| E341 (c) | Tricalcium ortho phosphate | | | | <u>ACCEPTABLE</u> : (as an anti-caking agent) |
| E450 | Acid sodium pyrophosphate (ASP) | 4200 as total P from all sources JECFA | 20 | 400 (112 as P) | <u>ACCEPTABLE</u> : (see comment on glucono delta lactone) |
| | Sodium and potassium polyphosphates (other than ASP) | | 1 | 40 (12 as P) | <u>ACCEPTABLE</u> : in fruit fillings and decorations |
| - | Carbonic acid and its sodium, potassium, calcium and ammonium salts | Not specified JECFA | 20 | 400 | <u>ACCEPTABLE</u> : (see comment on glucono-delta-lactone) |
| | Magnesium carbonate | | | | <u>ACCEPTABLE</u> : requested as anti-caking/free flow agent. |

E. EMULSIFIERS, STABILISERS, THICKENERS & GELLING AGENTS

| EEC No | Substance | Acceptable Intake (2) (mg/adult/day) | Maximum level in Fine Bakers' Wares to be proposed in Draft Directive (g/kg dry matter) | Average Daily Intake from Fine Bakers' Wares based on previous column (mg/adult/day) | Toxicological Assessment and Comments |
|--------------|--|---|---|--|--|
| - | Modified starches | Mostly not specified JECFA - but see also SCF Report, certain modified starches restricted to 3.5% or 5% for infant food SCF(4) | 300 | 12000 | <u>ACCEPTABLE:</u> In accordance with SCF Report |
| E322 | Lecithins | Not specified JECFA | 30 | 1200 | <u>ACCEPTABLE:</u> |
| E400 to E403 | Alginic acid and its sodium, potassium, ammonium and calcium salts (6) | 3000 as alginic acid JECFA | 10 | 400 | <u>ACCEPTABLE:</u> |
| E405 | 1,2-Propylene glycol alginate (6) | 1500 JECFA | 10 | 400 (100 as propylene glycol and 300 as alginic acid) | <u>NOT POSSIBLE:</u> More precise information required on total intake of propylene glycol |
| E406 | Agar (6) | Not specified JECFA | 10 | 400 | <u>ACCEPTABLE:</u> |
| E407 E408 | Carrageenan (syn. Carrageen) (6) Furcellaran (6) | 4500 as sum of both SCF(8)/JECFA | 10 | 400 | <u>ACCEPTABLE:</u> |
| E410 | Locust bean gum (syn carob gum) (6) | Not specified (temporary) JECFA | 10 | 400 | <u>ACCEPTABLE:</u> |
| E412 | Guar gum (syn.guar flour) (6) | Not specified SCF(8)/JECFA | 10 | 400 | <u>ACCEPTABLE:</u> |
| E413 | Tragacanth (6) | Not allocatable on data available JECFA | 10 | 400 | <u>NOT POSSIBLE:</u> |

E. EMULSIFIERS, STABILISERS, THICKENERS & GELLING AGENTS - continued

| EEC No | Substance | Acceptable Intake ⁽²⁾ (mg/adult/day) | Maximum level in Fine Bakers' Wares to be proposed in Draft Directive (g/kg dry matter) | Average Daily Intake from Fine Bakers' Wares based on previous column (mg/adult/day) | Toxicological Assessment and Comments |
|--------------------------------------|--|--|---|--|--|
| E414 | Acacia (syn. gum arabic)(6) | Not specified JECFA | 10 | 400 | <u>ACCEPTABLE:</u> |
| E440 | Pectins | Amidated 1500 (temporary) Non-amidated; not specified SCF(8)/JECFA | 30 | 1200 | <u>ACCEPTABLE:</u> (non-amidated) <u>NOT POSSIBLE:</u> (amidated) More precise information needed on intake from Fine Bakers' Wares. |
| E460 | Microcrystalline cellulose (7) | Not specified (includes also powdered cellulose) JECFA | 5 | 200 | <u>ACCEPTABLE:</u> |
| E461 E463 E464 E465 E466 | Methyl Cellulose Hydroxypropyl cellulose Hydroxypropyl methyl-cellulose Methylethylcellulose Carboxymethylcellulose (syn. sodium carboxymethylcellulose) (7) | } } 1500 as sum of } cellulose derivatives } JECFA | 10 | 400 | <u>NOT POSSIBLE:</u> More precise information needed on total intake from all foods. |
| E470 | Sodium, potassium and calcium salts of fatty acids | Myristates, stearates and palmitates - not specified, as anti-caking agents JECFA | 15 of flour in Dutch rusks; 5 dry matter other products | 200 | <u>ACCEPTABLE:</u> |
| E471 | Mono- and di-glycerides of fatty acids | Not specified JECFA | 30 | 1200 | <u>ACCEPTABLE:</u> |

E. EMULSIFIERS, STABILISERS, THICKENERS & GELLING AGENTS - continued

| EEC No | Substance | Acceptable Intake ⁽²⁾ (mg/adult/day) | Maximum level in Fine Bakers' Wares to be proposed in Draft Directive (g/kg dry matter) | Average Daily Intake from Fine Bakers' Wares based on previous column (mg/adult/day) | Toxicological Assessment and Comments |
|--------------|--|---|---|--|---|
| E472 | Esters of mono and di-glycerides of food fatty acids with: (a) acetic acid (b) lactic acid (c) citric acid (d) tartaric acid (e) diacetyltartaric acid (-) mixed acetic/tartaric acids |)) Not specified) SCF/JECFA SCF 3000 SCF/JECFA Not specified SCF/JECFA | 30 | 1200 | <u>ACCEPTABLE:</u> However, see note on E334 relating to use of tartaric acid. <u>NOT POSSIBLE:</u> More precise information needed on total intake from all food <u>ACCEPTABLE:</u> See note on E334 as above. |
| E475 | Polyglycerol esters of fatty acids | 1500 JECFA | 10 | 400 | <u>NOT POSSIBLE:</u> May be desirable to restrict use to specific (named) applications. |
| E477 | Propylene glycol esters of fatty acids | 1500 as propylene glycol JECFA | 10 | 400 (90 as propylene glycol) | <u>NOT POSSIBLE:</u> (see E405) |
| E481 E482 | Sodium stearoyl 2-lactylate) Calcium stearoyl 2-lactylate) | 1200 as sum of both JECFA | 5 | 100 | <u>ACCEPTABLE:</u> principal use yeast based products assumes intake of 20g yeast based products) |
| E483 | Stearyl tartrate | 1200 SCF | 3 | 60 | <u>ACCEPTABLE:</u> (see comment on E481/E482) |
| "Annex II" | Sorbitan monopalmitate, monostearate and tristearate Polyoxyethylene(20)Sorbitan monolaurate, monopalmitate monostearate, tristearate and mono-oleate | | | | Review of Annex II Emulsifiers in progress |

F. RELEASE AGENTS

| EEC N° | Substance | Acceptable Intake (2) (mg/adult/day) | Maximum level in Fine Bakers' Wares to be proposed in Draft Directive (g/kg dry matter) | Average Daily Intake from Fine Bakers' Wares based on previous column (mg/adult/day) | Toxicological Assessment and Comments |
|------------------------|---|---|---|--|---|
| "Annex II" Emulsifiers | Polyglycerol esters of polycondensed fatty acids of castor oil. | 450 JECFA | 0.12 | 5 | <u>ACCEPTABLE:</u> |
| | Polyglycerol esters of dimerised fatty acids of soya bean oil. | Not assessed by JECFA | 0.12 | 5 | <u>ACCEPTABLE:</u> |
| | Oxidatively polymerised soya bean oil. | Not assessed by JECFA | 0.04 | 2 | <u>ACCEPTABLE:</u> |
| | Natural waxes of vegetable or animal origin: Reeswax, carnauba, spermaceti) | Not assessed by JECFA | 1 | 40 | <u>ACCEPTABLE:</u> |
| | Candellila wax | | | | <u>NOT POSSIBLE:</u> |
| | Liquid paraffin (pharmaceutical quality) | Not specified for food grade mineral oil and liquid petrolatum. | 1 | 40 | <u>ACCEPTABLE:</u> |
| | Edible oils and fats, including those esterified | Not assessed by JECFA | 1 | 40 | <u>ACCEPTABLE:</u> Esterified products to be limited to glycerides of edible fat-forming straight-chain fatty acids |

G. SOLVENTS

| EEC No | Substance | Acceptable Intake ⁽²⁾ (mg/adult/day) | Maximum level in Fine Bakers' Wares to be proposed in Draft Directive (g/kg dry matter) | Average Daily Intake from Fine Bakers' Wares based on previous column (mg/adult/day) | Toxicological Assessment and Comments |
|---|--|--|---|--|--|
| - | Propylene glycol (1,2-propanediol) | 1500 (to include contribution from esters) JECFA | 20 | 800 (plus 190 from esters) | <u>NOT POSSIBLE:</u> (see E405): Acceptable as diluent for colours, antioxidants, flavours with minimal residues. |
| - | Isopropyl alcohol | Temporary acceptance in accord with good manufacturing practice i.e. minimal residue in food. JECFA | 10 | 400 | <u>NOT POSSIBLE:</u> (see comment on propylene glycol) |
| E420 | Sorbitol | Not specified JECFA | 50 | 2000 | <u>ACCEPTABLE:</u> |
| E421 | Mannitol (D-) | 3000 temporary JECFA | 50 | 2000 | <u>NOT POSSIBLE:</u> |
| E422 | Glycerol | Not specified JECFA | 50 | 2000 | <u>ACCEPTABLE:</u> |
| H. CORRECTORS AND ENHANCERS OF FLAVOUR | | | | | |
| - | Glutamic acid and its sodium and potassium salts | 7200 total glutamate expressed as glutamic acid (but not for infants younger than 12 weeks). JECFA | 5 | 200 | <u>ACCEPTABLE:</u> |
| - | Guanylic acid and its sodium and potassium salts | Disodium (and calcium) guanylate - not specified JECFA | 0.5 | 20 | <u>ACCEPTABLE:</u> |
| - | Inosinic acid and its sodium and potassium salts | Disodium and calcium inosinate-not specified JECFA | 0.5 | 20 | <u>ACCEPTABLE:</u> |
| | Maltol | ADI withdrawn JECFA | 0.25 | 10 | <u>NOT POSSIBLE:</u> |
| | Ethyl maltol | 120 JECFA | 0.25 | 10 | <u>ACCEPTABLE :</u> |

I. TECHNICAL ADJUVANTS

| EEC N° | Substance | Acceptable Intake (2) (mg/adult/day) | Maximum level of Fine Bakers' Wares to be proposed in Draft Directive (g/kg dry matter) | Average Daily Intake from Fine Bakers' Wares based on previous column (mg/adult/day) | Toxicological Assessment and Comments |
|--------|---|---|---|--|--|
| - | Enzymes (amylases, proteases, glucose oxidases, pentosanases, invertases) | JECFA list given "not specified" classification | 0.2 | 8 | JECFA list <u>ACCEPTABLE</u> : |
| E290 | Carbon dioxide | Not assessed by JECFA | | negligible | <u>ACCEPTABLE</u> : |
| - | Nitrogen | Not assessed by JECFA | | negligible | <u>ACCEPTABLE</u> : |
| - | Nitrous oxide | Not assessed by JECFA | 1 vol N ₂ O to 1 vol cream | 100 ml N ₂ O | <u>ACCEPTABLE</u> : for requested use as propellant/whipping aid for cream |

NOTES

- 1.1 The use of several of these preservatives in combination shall be authorised only in quantities such that the sum of the percentages to which these quantities correspond in relation to the authorised maximum content for each of them does not exceed the figure 100.
- 1.2 Solely for dough.
- 1.3 Not authorised in products with a water content of less than 8%.
2. Acceptable Intake = Acceptable Daily Intake X 60 (adult body weight taken as 60 kg)
JECFA = ADI established by JECFA up to and including 21st Report.
SCF = ADI established by Scientific Committee for Food.
3. Office for Official Publications of the European Communities (8801/7290).
4. Office for Official publications of the European Communities (8843/7525).
5. The intake has been considered to be 1/10th that of Fine Bakers' Wares in general.
6. E400-E414: 10 g/kg singly or in combination.
7. E460-E466: 10 g/kg singly or in combination.
8. In press.

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The Scientific Committee for Food was established by Commission Decision 74/234/EEC of 16 April 1974 (OJ No. L 136 of 20.5.1974 page 1) to advise it 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 opinions on the elements of information given to the Commission on the use of additives for which no Acceptable Daily Intake has been allocated and the provisions relating to additives and processing aids in the draft proposal for a Council Directive concerning the approximation of the laws of Member States relating to Fine Bakers' Wares, Rusks, Pastries and Biscuits.

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