codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 7 D **CX/FAC 03/8**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS
Thirty-fifth Session
Arusha, United Republic of Tanzania, 17 - 21 March 2003

COMMENTS SUBMITTED ON THE PROPOSED DRAFT AND DRAFT REVISIONS TO TABLE 1 OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES IN RESPONSE TO CL 2002/10-FAC AND CL 2002/44-FAC

The following comments have been received from Israël, USA, Poland, Canada, United Kingdom, IFU, IFAC, ISA, AMFEP, Marinalg International, European Community, ISDC, IBFAN, ISDI, CEFIC, OFCA:

ISRAËL:

CL 2002/44-FAC, October 2002, CX 4/30.2 : Request for Comments on the Proposed Draft and Draft Revisions to Table 1 of the Codex General Standard for Food Additives7j

In Appendix II , Provisions for Additives Scheduled for Discussion by the 35th CCFAC, Shellac is not included (this food additive is listed in Group V Priorities for discussion). Is it a simple omission or there are no provisions at step 3 or 6 for Shellac?

The maximum levels of use of several food additives having numerical ADI are still maintained at GMP level while point 60 of the 34th CCFAC Report specified that "Committee agreed to hold all GMP provisions for additives with numerical ADIs at Step 3 or 6 so that specific numerical levels of use could be provided before its 35th Session".
But perhaps such additional information will be provided later.

USA:

Numerical Maximum Use Levels for Additives assigned Numerical JECFA ADIs
The 34th CCFAC established a working principle that all food additives assigned a numerical ADI by JECFA should have a numerical limitation on their uses in the GSFA. The Committee agreed to hold all GMP provisions for additives assigned numerical ADIs so that specific numeric levels of use could be provided before its 35th Session. If this information was not provided by the 35th Session, the Committee agreed that these provisions would be deleted from the GSFA (ALINORM 03/12, para. 60). In general, the U.S. recognizes that this is a practical first approach when the Committee considers acceptable maximum use

levels for these additives, and that numerical maximum use levels can be useful to risk managers when considering whether there are any safety concerns with proposed additive uses. However, we urge the Committee to apply this principle pragmatically and not as an absolute requirement. We note that in some circumstances there are valid technical justifications based on the inherent properties of the additive or its intended conditions of use where it is either not practical or unnecessary to establish numerical additive maximum use levels to ensure safe conditions of use for an additive. We offer the following two examples to illustrate circumstances in which a pragmatic approach is recommended.

The first example involves the endorsement of maximum use levels for caramel colors III and IV (INS Nos. 150c and 150d). The 31st CCFAC made an explicit exception to this principle when it specifically endorsed GMP limitations for the use of caramel colors III and IV (ALINORM 99/12A, para. 42). This decision was based in part on the absence of requirements for the color intensity or content of the active coloring principle in the Codex specifications for the identity and purity for caramel colors III and IV and the variation in the amount of the active coloring principle in different preparations of these colors (See CX/FAC 99/6 Add. 1, comment from the Delegation of Japan). Therefore, in the absence of an identified safety concern, the Committee used a pragmatic approach and agreed that establishing numeric maximum levels for these two colors was unnecessary for ensuring the safety of consumers and impractical from a food technology standpoint because the level of caramel III or IV necessary to achieve the intended coloring effect depended in large part on the amount of coloring principle in each preparation of the color.

A second example involves the use of high intensity sweeteners. When considering the use of these sweeteners (e.g., acesulfame potassium (INS No. 950), aspartame (INS No. 951), sucralose (INS No. 956)), technological considerations limit the amount of the high intensity sweetener that can be added to foods should be taken into account. The GSFA food category system applies to all foods as marketed. Most of the food categories refer to finished foods that are consumed directly. However, tabletop sweeteners (food category 11.6) are not consumed directly. Rather, consumers use tabletop sweeteners by either sprinkling them onto or mixing them into foods and beverages, and they do so according to their own taste. Moreover, tabletop sweeteners are sold to the consumer in powder (packets and bulk), liquid and tablet form. Importantly, the use of high intensity sweeteners is technologically self-limiting. That is, adding too much of a tabletop sweetener results in a food or beverage that is unacceptably sweet or that has an unappealing flavor. As an outcome of this self-limiting effect, the level of consumption of any high intensity sweetener is limited.

Moreover, because of the highly intense sweetening effects of these substances (180 - 2000 times sweeter than sugar), only small quantities of tabletop sweetener are needed to achieve the desired level of sweetness for a food or beverage. For sucralose, which is approximately 600 times sweeter than sugar, tabletop formulations in packet and granular form contain only about 1% sucralose; bulking agents makes up the rest of the tabletop formulation. Thus, a half-gram serving of either the packet or granular formulation, equal in sweetness to one teaspoon of sugar, consists of about 5 milligrams of sucralose, which is about 83 micrograms of sucralose/kilogram of bodyweight for a 60 kilogram individual. JECFA has assigned sucralose an Acceptable Daily Intake (ADI) of 15 mg/kg bw/p/d.

When estimating daily intakes of high intensity sweeteners, even with highly conservative approaches based on the assumption that a single high intensity sweetener replaces all added sugar in the diet, it is generally not surprising to find that the resulting intake estimates are well below the ADI. An example of this is borne out by examination of actual post-marketing surveillance data for aspartame. Studies done in Canada, the U.S. and Brazil have shown that aspartame consumption is only a fraction of the Estimated Daily Intake (EDI) that, in turn, is less than the ADI for aspartame.

In sum, the U.S. generally supports the principle endorsed by the 34th CCFAC; however, we recommend that the CCFAC apply the principle pragmatically.

The 51st JECFA (1998) combined the specifications for tartaric, acetic and fatty acid esters of glycerol, mixed (INS 472f) with those of diacetyltartaric and fatty acid esters of glycerol (INS 472e). This change was endorsed by the 31st CCFAC (ALINORM 99/12A, para. 65 and App. VII) and subsequently adopted as

Advisory Specifications for the Identity and Purity of Food Additives by the 24th CAC (ALINORM 01/41, para. 137). As specifications no longer exist for tartaric, acetic and fatty acid esters of glycerol, mixed (472f), the ADI "not limited" was withdrawn at the 57th JECFA. The 34th CCFAC agreed (ALINORM 03/12, para. 20) that the listings for 472f should be deleted from the General Standard for Food Additives (GSFA) as this additive is now subsumed under 472e. Consequently, the United States proposes that :

i) The listings, whether adopted or under consideration, of INS 472f in Tables 1, 2 and 3 of the GSFA should be removed;

ii) The provisions for 472f that appear in Tables 1 and 2 of the draft GSFA should be combined with those for 472e currently in Tables 1 and 2;

iii) The provisions for the additives covered under INS 472e, should be maintained in draft status (step 3 and 6) until JECFA assigns a full ADI[1]; and

iv) "INS 472f – Tartaric, acetic, and fatty acid esters of glycerol (mixed)" should be included as a synonym in the heading for Diacetyltartaric and fatty acid esters of glycerol (INS 472e) in the GSFA.

B) The United States provides information on the use of the following additives for inclusion in the Draft General Standard for Food Additives (GSFA) and further consideration by the Committee:

i) Acetylated oxidized starch (INS 1451) as a stabilizer or thickener at the levels specified in the following food categories:

U.S. Food/Food Category	**Maximum Level**	**FCS No.[2]**
Foods in General	GMP	
Canned Field Corn and Canned Corn	GMP	04.2.2.4
Cured Pork Products	2%	08.2.1.1 (cured; in pieces/cuts) 08.2.1.2 (cured & dried; in pieces/cuts) 08.3.1.1 (cured; comminuted) 08.3.1.2 (cured & dried; comminuted)
Vanilla Powder and Vanilla-Vanillin Powder	GMP	12.2
Salad Dressings	GMP	12.6.1

ii) Curdlan (INS 424) as a formulation aid, processing aid, stabilizer, thickener, and texturizer in foods in general at GMP.

iii) Sodium sulfate (INS 514) for miscellaneous technical effects at the levels specified in the following food categories:

U.S. Food/Food Category	**Maximum Level**	**FCS No.[2]**
Chewing Gum Base	GMP (gum base basis)	05.3
Cake Mixes	1%	07.2.3

iv) Erythritol (INS 968) as a flavor enhancer, formulation aid, humectant, nutritive sweetener, stabilizer and thickener, sequestrant, and texturizer at the levels specified in the following food categories:

U.S. Food/Food Category	**Maximum Level**	**FCS No.[2]**
Dairy drinks (chocolate and flavored milks)	35,000 mg/kg	01.1.2
Bakery fillings (cream)	150,000 mg/kg	01.4.4 (not finished

[1] 472e was assigned a "temporary" ADI of 50 mg/kg bw by the 57th JECFA.
[2] Food Category System number (FCS No.) for the GSFA based the 34th CCFAC (CRD1, App. III).

U.S. Food/Food Category	Maximum Level	FCS No.[2]
		food)
Frozen dairy desserts (regular ice cream, soft serve, sorbet); Puddings (instant, phosphate set); Yogurt (regular and frozen)	100,000 mg/kg	01.7
Bakery fillings (pudding)	150,000 mg/kg	01.7 (not finished food)
Fat-based cream used in modified fat/calorie cookies, cakes and pastries	600,000 mg/kg	02.3
Bakery fillings (fruit)	150,000 mg/kg	04.1.2.11
Soft candies (plain chocolate, chocolate coated)	600,000 mg/kg	05.1.4
Soft candies (non-chocolate)	600,000 mg/kg	05.2
Hard candies (including pressed candy, mints, and cough drops)	990,000 mg/kg	05.2
Chewing gum	600,000 mg/kg	5.3
Cakes and cookies (regular and dietetic)	150,000 mg/kg	07.2.1
Bakery fillings (custard)	150,000 mg/kg	10.4 (not finished food)
Sugar substitutes (carrier)	1,000,000 mg/kg	11.6
Reduced- and low-calorie carbonated beverages	35,000 mg/kg	14.1.4.1
Reduced- and low-calorie non-carbonated beverages	35,000 mg/kg	14.1.4.2

v) Invertase from *Saccharomyces cerevisiae* as an enzyme catalyzing the hydrolysis of sucrose to glucose and fructose stabilizer or thickener at the levels specified in the following food categories:

U.S. Food/Food Category	Maximum Level	FCS No.[2]
Confectionary products	GMP	5.0
Artificial honey	GMP	11.4
Invert sugar	GMP	11.3

vi) β-carotene from *Blakeslea trispora* as a color in foods in general at GMP.

vii) D-tagatose as a bulk sweetener, humectant, texturizer, or stabilizer at the levels specified in the following food categories:

U.S. Food/Food Category	Maximum Level	FCS No.[2]
Light ice cream (ice milk), frozen milk dessert, low-fat and non-fat frozen yogurt and related frozen novelties	30,000 mg/kg	01.7
Regular and dietetic hard candies	150,000 mg/kg	05.2
Dietetic soft candies	100,000 mg/kg	05.2
Sugarless and sugar free chewing gum	60,000 mg/kg	05.3
Icings or glazes used on baked goods (cookies, pastries, brownies, and angel food, chiffon and pound cakes)	300,000 mg/kg	05.4
Ready-to-eat cereals	3 grams per serving = 100,000 mg/kg[3]	06.3
Low fat, reduced fat, diet, energy or nutrient fortified bars	100,000 mg/kg	13.5

[3] Assuming a 30 g serving size (21 CFR 101.12, Table 2), then : (3 g/30 g) x (1000 g/kg) x (1000 mg/g) = 100000 mg/kg

U.S. Food/Food Category	Maximum Level	FCS No.[2]
Diet and/or sugar free carbonated beverages	10,000 mg/kg	14.1.4.1
Ready-to-drink teas presweetened with low calorie sweeteners	10,000 mg/kg	14.1.4.2 for iced tea, 14.1.5 for hot tea
Powdered products prepared with milk	5 grams per serving = 21000 mg/kg[4]	16.0

viii) Diacetyltartaric and fatty acid esters of glycerol (INS 472e) as an emulsifier, flavor or adjuvant in the following food categories:

U.S. Food/Food Category	Maximum Level	FCS No.[2]
Dairy products analogs	GMP	01.3.2
Fats and oils	GMP	02.1
Rendered fats (animal)	GMP	02.1.3
Rendered poultry fat	GMP	02.1.3
Margarine	GMP	02.2.1.2
Fats and Oils	GMP	02.2.2
Fats and Oils	GMP	02.3
Fats and Oils	GMP	02.4
Confections and frostings	GMP	05.0
Baked goods	GMP	07.0
Raisin bread, rolls and buns	GMP	07.1.1
Whole wheat bread, rolls, and buns	GMP	07.1.1
Enriched bread, rolls and buns	GMP	07.1.1
Bread, rolls, and buns	GMP	07.1.1
Milk bread, rolls and buns	GMP	07.1.1
Baking mixes	GMP	07.2.3
Nonalcoholic beverages	GMP	14.1.4.1 for carbonated, 14.1.4.2 for non-carbonated

[4] Assume 240 mL serving, e.g. for a milkshake or cream-based soup (21 CFR 101.12, Table 2). Then: (5 g/240 mL) x (mL/g) x (1000 g/kg) x (1000 mg/g) = approx. 21000 mg/kg

POLAND:

According to Polish national regulations:

a) we propose to remove from the table following food additives which are forbidden to use in our country:
   - *Alitame*
   - *Ammonium Chloride*
   - *Azodicarbonamide*
   - *Benzoyl Peroxide*
   - *Castor Oil*
   - *Chlorine*
   - *Chlorine Dioxide*
   - *Curdlan*
   - *Dioctyl Sodium Sulfosuccinate*
   - *Erythritol*
   - *Ferric Ammonium Citrate*
   - *Formic Acid*
   - *Glucose Oxidase*
   - *Guaiac Resin*
   - *Isopropyl Citrates*
   - *Mineral Oil*
   - *Oxystearin*
   - *Bone Phosphate*
   - *Ammonium Phosphates*
   - *Salts of Myrystic, Palmitic And Stearic Acids (Nh4, Ca, K, Na)*
   - *Sodium Fumarate*
   - *Sodium Sorbate*
   - *Stannous Chloride*
   - *Stearyl Citrate*
   - *Sucralose*
   - *Sodium Thiosulphate*
   - *Potassium Sulphite*
   - *TBHQ*
   - *Thiodipropionates*
   - *Polyoxyethylene Stearates*
   - *Potassium Ascorbate*

b) the following substances are not recognised to be food additives in Poland:
   - *Bleached Starch*
   - *Acid Treated Starch*
   - *Dextrins, white and yellow*
   - *Roasted Starch*
   - *Enzyme Treated Starch*
   - *Alpha-amylase*
   - *Bromelain*
   - *Papain*
   - *Protease*

c) *Carotenes* (natural extracts) have the symbol E 160 ai (not E 160 aii), whereas *Beta-Carotene* (synthetic) has the symbol E 160 aii (not E 160 ai)

d) *Ethyl Maltol* and *Maltol* are flavouring substances

e) *Tannins (Tannic Acid)* are used only as clarification substances.

CANADA:

comments on Item 1, Part C:

Canada does not have the requested information for hydrogenated poly-1-decene (INS 907), calcium dihydrogen diphosphate (INS 450 vii), monomagnesium phosphate (INS 343i), sodium calcium polyphosphate (INS 452iii), trisodium diphosphate (INS 450ii), acetylated oxidized starch (INS 1451), alpha-cyclodextrin (INS 458), curdlan(INS 424), polyglycitol syrup (INS 964), sodium carboxy methyl cellulose, enzymatically hydrolyzed (INS 469), D-tagatose or erythritol, as they are not permitted additives in Canada.

Sodium sulfate is a permitted additive in Canada and is not used in any of the food categories listed in the Annex to Table 3.

Invertase is permitted for use in Canada in soft-centred and liquid-centred confections, and in unstandardized bakery foods at GMP levels.

Canada has no information on the levels and areas of use of ß-carotene from *Blakeslea trispora.*

Acetylated tartaric acid esters of mono-and diglycerides are permitted for use in Canada in bread (6,000 ppm of flour), unstandardized foods (GMP level), and infant formulas based on crystalline amino acids (240 ppm as consumed).

Canada supports the continued use of benzoates at 1000 mg/kg for Food Category Numbers 07.0 (bakery wares), 12.5 (soups and broths), 14.1.4 (beverages), 15.1 (snack foods) and 16.0 (mincemeat)(Paragraph 59 of 34th Report). Justification for this level of use can be found in a study by Cruess[5] and referenced in the CRC Handbook of Food Additives, 2nd Edition, Volume I. According to this study, optimum microbial inhibition at a pH of 3.5 to 4.0 requires 0.06 to 0.10% of sodium benzoate.

With regard to Paragraph 60, Canada does not agree that it is appropriate to eliminate GMP provisions for high intensity sweeteners in the table-top category (Food Category 11.6; “Table-top sweeteners, including those containing high-intensity sweeteners”) and assign finite levels of use to them, for the following reasons:

(1) The use of table-top sweeteners is in the home, institution or restaurant and does not involve the sale of foods already containing high-intensity sweeteners (i.e. as a food additive) and ultimately the use of these is in the hands of the consumer.

(2) The sweetness of Table-top sweeteners is usually based on a spoon-for-spoon equivalence or other measure of equivalence to sucrose and their use, based on a knowledge of such equivalence from label information, should allow their use at levels in food no greater than their regulated levels in food commodities as food additives.

(3) If maximum levels were to be placed on individual high-intensity sweeteners used in table-top preparations, the levels would depend on whether other high-intensity sweeteners are used in the preparation, the format of the table-top sweetener (i.e. a spoon-for-spoon equivalence preparation resembling sucrose, a concentrated drop-wise liquid preparation, a small tablet, etc.). It is inappropriate for regulators to regulate to the extent that flexibility is not offered to manufacturers to offer such sweeteners in a wide variety of possible formats.

[5] Cruess, W. V., 1932, *Ind. Eng. Chem., 24,* 648-649

With regard to the deletion of additives now listed at GMP for which finite ADIs exist, Canada agrees with the decisions reached at the 34th with the provisos that (1) the deletion only occur for Priority Additives under consideration at any given time (in this instance, the list entitled "Priority Additives for 35th CCFAC" appearing as Appendix I, CRD 1 in the *Report of the ad hoc Working Group on the Codex General Standard for Food Additives (GSFA)* emanating from the 34th Session); and that (2) if deleted, the entries be returned for consideration at the next session immediately after a member state is able to propose finite use levels to them.

With regard to the present list in Appendix I, to the extent possible, Canada has reviewed all GMP entries for the additives for which it proposed GMP entries of for which Canada was attributed responsibility on account of it having proposed GMP uses in "unstandardized foods." On this basis.....

- Carmines in "Margarine and similar products" (Category 02.2.1.2) may be deleted.
- Carotenes, vegetable in "Margarine and similar products" (Category 02.2.1.2) may be assigned a proposed use level of 26 mg/kg.
- Carotenes, vegetable in "Vegetables and seaweeds in vinegar, oil, brine or soy sauce" (Category 04.2.2.3) may be assigned a proposed use level of 1320 mg/kg (based on their use in Canada in pickles and relishes).
- Grape skin extract in "Margarine and similar products" (Category 02.2.1.2) may be deleted.
- Riboflavines in "Margarines and similar products" (Category 02.2.1.2) may be deleted.
- Sucralose in "Table-top sweeteners, including those containing high-intensity sweeteners" (Category 11.6) is proposed to retain its use level of GMP for the reasons cited in the discussion above.

UNITED KINGDOM:

Hydrogenated poly-1-decene.
At the 57th JECFA in 2001, Hydrogenated poly-1-decene, (INS 907) a revised specification was prepared and an ADI of 0-6 mg/kg bw. was allocated.
At the 34th CCFAC this was noted and any country where this food additive is permitted for use was requested to submit information on its use, including consumption by product category, for the additive to be included in the GSFA.

Hydrogenated poly-1-decene, (INS 907) has been permitted for use in Finland, both as a food additive and as a processing aid. Application for EU acceptance has been made, and the Scientific Committee on Food has also allocated an ADI of 0-6 mg/kg bw.

Justification and Technological need.
Mineral oil was formerly used in the European as a glazing agent for confectionery and dried fruit, and as a release agent for bread tins. Since its use was prohibited, less satisfactory alternatives, such as vegetable oils have been used, which often themselves develop stickiness in storage and use. There is, therefore, a need for an acceptable alternative to perform these functions.

Calculated intake
The following assumes that only hydrogenated poly-1-decene and no other glazing or release agent is used:

As a **food additive**, hydrogenated poly-1-decene is used as a glazing agent for certain gum and jelly sugar confectionery, and as a glazing (polishing agent or anti-blocking agent) for the dried fruits currants, raisins and sultanas. Up to 2000 mg hydrogenated poly-1-decene /kg of food product are used in these applications, (similar to the use of mineral hydrocarbon oil for these uses outside the European Union).

The mean consumption[1] of dried fruit 2.7 g per day (97.5th percentile 25.2 g per day) and of all gum and jelly confectionery, glazed or not, is about 3.6 g per day, (97.5th percentile, 50.4). At the maximum usage rate of glazing agent of 2000 mg/kg food product, the daily intake of hydrogenated poly-1-decene from these sources can be calculated to be not more than 12.7 mg/person/day. (128 g/person/day at the 97.5th percentile). **Hydrogenated poly-1-decene is also used as a component of chewing gum, at an inclusion rate of up to 2% by weight.**

As a **processing aid,** hydrogenated poly-1-decene is used as a release agent on tins for bread baking and as a dough mixer blade lubricant. In a study on mineral oil as a release agent, an oil residue of 410 mg/kg bread was shown. At an average daily consumption[1] of 110 g bread, (268 g at the 97.5th percentile) the intake of hydrogenated poly-1-decene is 45 mg/person/day (109 mg/person/day at the 97.5th percentile.)

Other processing aid uses with minor carry over are as an anti dusting agent in the drying of confectionery moulding starch, (giving a carry over not exceeding 4 mg per kg of finished confectionery, which is negligible in this context). Also at a 2% incorporation as a plasticizer in polystyrene, polyethylene and polypropylene. Assume 1 mg/person per day.

The two major food additive and processing aid applications combined thus can give rise to a daily intake of **60 mg/person/day**. (240mg/person/day at the 97.5th percentile. It is unlikely that persons will consume each of the food products at the 97.5th percentile, so this is probably a considerable over statement)

[1] Based on UK figures

Summary

	Mean Food Consumption (g/day)	97.5th percentile Food consumption (g/day)	Mean hp-1-d intake (mg/person/day)	97.5th percentile intake (mg/person/day)
Food product				
Dried fruit	2.7	25.2	5.4*	50.4*
Confectionery	3.6	78	7.3*	78*
Bread release	111	268	45	109
Other applications	-	-	1	1

Total daily intake	**60mg/person/day**	**240mg/person/day**
ADI 0-6mg/kg bw		
For a 60 kg adult,	360 mg/person/ day	
	*Basis 2000 mg hydrogenated poly-1-decene added/kg finished food	

IFU:

The global fruit juice industry, represented by our Federation in the *ad hoc Intergovernmental Task Force on Fruit and Vegetable Juices*, is investing considerable efforts to keep fruit and vegetable juices and related products as natural as possible. Beyond other facts this results in a very short list of additives in the existing Draft Codex General Standard for Fruit Juices and Nectars at step 3, which should reflect also in Table 1 and 2 of the GSFA.

Even when taking into consideration, that the elaboration of the Standards by the Task Force is only at step 3, there are no substantial changes to be expected after the last meeting of the Drafting Group in October 2002. We therefore present to you our position regarding the following food categories:

14.1.2 Fruit and vegetable juices
14.1.2.1 Canned or bottled (pasteurised) fruit juice
14.1.2.2 Canned or bottled (pasteurised) vegetable juice
14.1.2.3 Concentrates (liquid or solid) for fruit juice
14.1.2.4 Concentrates (liquid or solid) for vegetable juice

14.1.3 Fruit and Vegetable Nectars
14.1.3.1 Canned or bottled (pasteurised) fruit nectar
14.1.3.2 Canned or bottled (pasteurised) vegetable nectar
14.1.3.3 Concentrates (liquid or solid) for fruit nectar
14.1.3.4 Concentrates (liquid or solid) for vegetable nectar

We have divided the list of additives into two tables:

A. This list contains all the additives, which are foreseen in some or all of the above mentioned food categories, including the max. use level and in some cases the restrictions explained in foot notes.
B. This list contains all the additives, which are not foreseen to be allowed at all in the above mentioned food categories, and the these food categories should therefore be removed from the list of these additives.

Recommendation:

In order to avoid wrong decisions for the time being, we propose not to forward any of the above mentioned food categories of the additives on table A. and B. to a higher step of the Codex Procedure until the

Standards on Fruit and Vegetable Juices and Nectars are finalized and ready for adoption by the Codex Commission at step 8.

Source Data and Recommendations of the CCFAC/GSFA Quality Control Group

Recommendation:

The same conclusions as for Table 1 (see above) are also valid for Appendix III to CL 2002/ 44-FAC.

A: Additives, in which the allowed max. level and the foodc ategories have to be modified as follows:

INS	Name of the Additive	Max. Level	Food Categories, in which the additive is foreseen by the ad hoc Codex Task Force on Fruit and Vegetable Juices
300	Ascorbic Acid	GMP	14.1.2; 14.1.3
951	Aspartame	600 mg/l	14.1.3.1; 14.1.3.3
210 - 213	Benzoic Acid and its salts	1'000 mg/l [1)]	14.1.2 [2)]; 14.1.3 [2)]
302	Calcium Ascorbate	GMP	14.1.2; 14.1.3
330	Citric Acid	3'000 mg/l 5'000 mg/l	14.1.2.1 [2)]; 14.1.2.2; 14.1.2.3 [2)]; 14.1.2.4; 14.1.3
952	Cyclamates	400 mg/l	14.1.3.1; 14.1.3.3
296	Malic Acid	GMP 3'000 mg/l	14.1.2.1 [3)] 14.1.2.2; 14.1.2.4; 14.1.3.2; 14.1.3.4
440	Pectins	3'000 mg/l	14.1.2.1 [4)];14.1.2.2 [5)]; 14.1.2.3 [4)]; 14.1.2.4 [5)]; 14.1.3.1 [4)]; 14.1.3.2 [5)]; 14.1.3.3 [4)]; 14.1.3.4 [5)]
954	Saccharin and its salts	80 mg/l	14.1.3.1; 14.1.3.3
451i	Sodium Tripolyphosphate [8)]	1'000 mg/l	14.1.2; 14.1.3
303	Potassium Ascorbate	GMP	14.1.2; 14.1.3

302	Sodium Ascorbate	GMP	14.1.2; 14.1.3
200 - 203	Sorbic Acid and its salts	1’000 mg/l [6)]	14.1.2 [2)]; 14.1.3 [2)]
955	Sucralose	300 mg/l	14.1.3.1; 14.1.3.3
220 – 225 227 – 228 539	Sulphites	50 mg/l [7)]	14.1.2; 14.1.3
334	Tartaric Acid	4’000 mg/l GMP	14.1.2.1 [9)] ; 14.1.2.3 [9)]; 14.1.3.1; 14.1.3.3 14.1.2.2; 14.1.2.4; 14.1.3.2; 14.1.3.4

1) Singly or in combination with Sorbic Acid and its salts
2) Subject to national legislation of the importing country
3) For Pineapple juice only
4) For cloudy juices and nectars only
5) For mixtures with fruit juices and nectars only
6) Singly or in combination with Benzoic acid and its salts
7) As residual SO_2
8) Only to enhance effectiveness of Benzoates and Sorbates
9) For Grape Juice only

B: Additives in the GSFA which do not comply with the Additive Provisions foreseen by the ad hoc Codex Task Force on Fruit and Vegetable Juices in the following Food Categories:

INS	Name of the Additive	Not foreseen by the ad hoc Codex Task Force on Fruit and Vegetable Juices, to be removed from the following Food Categories in the GSFA:
950	Acesulfame Potassium	14.1.2.1; 14.1.2.2; 14.1.2.3; 14.1.2.4
1422	Acetylated Distarch Adipate	14.1.2.1; 14.1.2.3
1414	Acetylated Distarch Phosphate	14.1.2.1; 14.1.2.3
1401	Acid Treated Starch	14.1.2.1; 14.1.2.3
406	Agar	14.1.2.1; 14.1.2.3; 14.1.3.1; 14.1.3.3
400	Alginic Acid	14.1.2.1
1402	Alkaline Treated Starch	14.1.2.1; 14.1.2.3
129	Allura Red AC	14.1.2.3
1100	Alpha-Amylase (Asp.Oryzae)	14.1.2.1
123	Amaranth	14.1.2.3
160b	Annatto Extracts	14.1.2.1; 14.1.2.3; 14.1.3.1
122	Azorubine	14.1.2.1; 14.1.2.2
162	Beet Red	14.1.2.1; 14.1.3.1
1403	Bleached Starch	14.1.2.1; 14.1.2.3
133	Brilliant Blue FCF	14.1.2.3
556	Calcium Aluminium Silicate	14.1.2.1
170i	Calcium Carbonate	14.1.2.1
509	Calcium Chloride	14.1.2.1
161g	Canthaxanthin	14.1.2.1; 14.1.3.1; 14.1.3.3
150a	Caramel Colour Class I	14.1.2.3
150b	Caramel Colour Class II	14.1.2.3
150c	Caramel Colour Class III	14.1.2; 14.1.2.3*; 14.1.3.2*; 14.1.3.4*
150d	Caramel Colour Class IV	14.1.2; 14.1.2.3*; 14.1.3.2*; 14.1.3.4*
120	Carmines	14.1.2.1; 14.1.3.1
903	Carnauba Wax	14.1.2.1
410	Carob Bean Gum	14.1.2.1; 14.1.2.3; 14.1.3.1; 14.1.3.3
160aii	Carotenes Vegetable	14.1.2; 14.1.3.2; 14.1.3.3; 14.1.3.4
160ai,e,f	Carotenoids	14.1.2.1; 14.1.2.3; 14.1.3.2; 14.1.3.4
407	Carrageenan	14.1.2.1; 14.1.2.3; 14.1.3.1; 14.1.3.3
140	Chlorophylls	14.1.2.1; 14.1.3.1
141i	Chlorophylls, Copper Complexes	14.1.2.1; 14.1.3.1; 14.1.3.2; 14.1.3.4
100i	Curcumin	14.1.2.1; 14.1.3.1
1400	Dextrins, White and Yellow, Roasted Starch	14.1.2.1; 14.1.2.3
472e	Diacetyltartaric and Fatty Acid Esters of Glycerol	14.1.2.2; 14.1.2.4
1412	Distarch Phosphate	14.1.2.1; 14.1.2.3
1405	Enzyme Treated Starch	14.1.2.1; 14.1.2.3
315	Erythorbic Acid	14.1.2.1; 14.1.3.1
968	Erythritol	14.1.2.1; 14.1.2.3
127	Erythrosine	14.1.2.3

INS	Name of the Additive	Not foreseen by the ad hoc Codex Task Force on Fruit and Vegetable Juices, to be removed from the following Food Categories in the GSFA:
418	Gellan Gum	14.1.2.1; 14.1.2.3; 14.1.3.1; 14.1.3.3
163ii	Grape Skin Extract	14.1.3.2; 14.1.3.4
412	Guar Gum	14.1.2.1; 14.1.2.3; 14.1.3.1; 14.1.3.3
414	Gum Arabic	14.1.2.1; 14.1.2.3; 14.1.3.1; 14.1.3.3
214,216,218	Hydroxybenzoates, p-	14.1.2; 14.1.3
1442	Hydroxypropyl Distarch Phosphate	14.1.2.1; 14.1.3.1
1440	Hydroxypropyl Starch	14.1.2.1; 14.1.2.3
132	Indigotine	14.1.2.3
172i,ii,iii	Iron Oxydes	14.1.3.2; 14.1.3.4
953	Isomalt	14.1.2.1 ; 14.1.2.3 ; 14.1.3.1 ; 14.1.3.3
416	Karaya Gum	14.1.2.1; 14.1.2.3; 14.1.3.1; 14.1.3.3
425	Konjac Flour	14.1.2.1; 14.1.2.3; 14.1.3.1; 14.1.3.3
427b	Lactic and Fatty Acid Esters of Glycerol	14.1.2.3
965	Maltitol and Maltitol Syrup	14.1.2.1; 14.1.2.3
460i	Microcrystalline Cellulose	14.1.2.1; 14.1.2.3; 14.1.3.1; 14.1.3.3
1410	Monostarch Phosphate	14.1.2.1; 14.1.2.3
942	Nitrous Oxide	14.1.2.1; 14.1.2.3
1404	Oxidized Starch	14.1.2.1; 14.1.2.3
1413	Phosphated Distarch Phosphate	14.1.2.1; 14.1.2.3
900a	Polydimethylsiloxane**	14.1.2; 14.1.3
124	Ponceau 4R	14.1.2.1; 14.1.2.2
402	Potassium Alginate	14.1.2.1
460ii	Powdered Cellulose	14.1.2.1; 14.1.2.3; 14.1.3.1; 14.1.3.3
407a	Processed Eucheuma Seaweed	14.1.2.1; 14.1.2.3; 14.1.3.1; 14.1.3.3
1520	Propylene Glycol	14.1.3.1
405	Propylene Glycol Alginate	14.1.2.1; 14.1.2.3; 14.1.3.1; 14.1.3.3
1101i	Protease (A. Oryzae Var.)	14.1.2.1
101i	Riboflavines	14.1.2.1; 14.1.2.3; 14.1.3.1; 14.1.3.2; 14.1.3.4
401	Sodium Alginate	14.1.2.1; 14.1.2.3; 14.1.3.1; 14.1.3.3
466	Sodium Carboxymethyl Cellulose	14.1.2.1; 14.1.2.3; 14.1.3.1; 14.1.3.3
316	Sodium Erythorbate	14.1.2.1; 14.1.3.1
200 - 203	Sorbates	14.1.2.1; 14.1.2.2; 14.1.2.3; 14.1.2.4; 14.1.3.1; 14.1.3.2; 14.1.3.3; 14.1.3.4
420	Sorbitol	14.1.2.1: 14.1.2.3
512	Stannous Chloride	14.1.2.1
1420	Starch Acetate	14.1.2.1; 14.1.3.1
1450	Starch Sodium Octenyl Succinate	14.1.2.1; 14.1.3.1
110	Sunset Yellow FCF	14.1.2.1; 14.1.2.2; 14.1.2.3
417	Tara Gum	14.1.2.1; 14.1.2.3; 14.1.3.1; 14.1.3.3
102	Tartrazine	14.1.2.1; 14.1.2.2; 14.1.2.3
957	Thaumatin	14.1.2.1
413	Tragacanth Gum	14.1.2.1; 14.1.2.3; 14.1.3.1; 14.1.3.3

INS	Name of the Additive	Not foreseen by the ad hoc Codex Task Force on Fruit and Vegetable Juices, to be removed from the following Food Categories in the GSFA:
415	Xanthan Gum	14.1.2.1; 14.1.2.3; 14.1.3.1; 14.1.3.3

* Already at step 8
** Is considered as a Processing Aid and has therefore to be removed from the list of additives

IFAC:

The International Food Additives Council (IFAC) is an international association specifically devoted to serving the unique needs of producers of high purity substances used as food additives. IFAC is recognized as a Non Government Organization (NGO) within the Codex Alimentarius Food Standards Programme.

IFAC is responding to the request for data that can be used to establish maximum use levels for food additives, having numerical ADI's which are listed in the GFSA for use at GMPs, and requesting that tabletop sweeteners only be regulated by GMP limitations.

Recommended use levels for the aspartame categories requested are provided below. This information is based on current levels of use in the listed products and the amounts used in similar products.

ASPARTAME 951

01.3.2	Beverages whiteners	wet 6000 mg/L; dry 20,000 mg/kg
01.4.1	Pasteurized cream	wet 6000 mg/L; dry 20,000 mg/kg
01.4.2	Sterilized, UHT, whipping or whipped, and reduced fat creams	wet 6000 mg/L; dry 20,000 mg/kg
01.4.3	Clotted cream	wet 6000 mg/L; dry 20,000 mg/kg
01.5.1	Milk powder and cream powder (plain)	5000 mg/kg
01.5.3	Milk and cream (blend) powder (plain and flavoured)	5000 mg/kg
01.6.1	Unripened cheese	1000 mg/kg
02.3	Fat Emulsions other than food category 02.2, including mixed and/or flavoured products based on fat emulsions	1000 mg/kg
04.1.2.1	Frozen fruit	2000 mg/kg
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other Hot cereal and grain beverages, excluding cocoa	5000 mg/kg

IFAC is concerned about setting use levels for tabletop sweeteners, category 11.6. Such information is currently requested for acesulfame potassium, alitame, cyclamates and sucralose. A GSFA draft specifies a level of 1000 mg/kg for aspartame and a level of 4545 mg/kg for saccharin in category 11.6. Sweetener use in tabletop products should only be limited by GMPs.

The concentration of sweeteners, as consumed, can vary widely depending upon the type of product in which they are used (e.g., ice tea or sprinkled on fruit or cereal). The use of a mg/kg limitation would only lead to confusion in the marketplace because the regulation could be interpreted on an as-is basis. Tabletop sweeteners should be regulated only with GMP limitations because they are not consumed on an as-is basis, but are used by consumers with a variety of taste preferences in a variety of products. Sweeteners generally do not have instructions for use but are self limiting in nature.

In addition, tabletop sweeteners are available in powder (packets and bulk), liquid and tablet form. Limitations for tabletop sweeteners, other than GMP limitations, serve no useful purpose, do not serve a public health purpose and may lead to unnecessary confusion by governments as well as in the marketplace.

ISA (The International Sweeteners Association)**:**

The International Sweeteners Association represents producers of high intensity sweeteners as well as food products and drinks that contain them. The ISA has Non-Governmental Observer Status with Codex Alimentarius. In this capacity, we would like to request that **tabletop sweeteners be regulated by GMP** limitations and propose some maximum levels for sweeteners having an **ADI.**

1. Cat. 11.6. All sweeteners used in tabletop products should be regulated at GMP

Reasons for this request:

a. Sweeteners are particularly **self-limiting** in this application;

b. Tabletop sweeteners being **sold to the ultimate consumers**, it is the latter who determine the amount consumed;

c. additionally, **"use levels" refer to the food as consumed** and tabletop sweeteners are only consumed in conjunction with other foods (coffee, etc).

d. real intake data (see Renwick A. "Intake of sweeteners) do show **no evidence of exceeding the ADI.**

2. Maximum use levels

In response to your request for data that can be used to establish maximum use levels for food additives having a numerical ADI which are listed in the GFSA for use at GMP, we are listing proposed maximum levels for acesulfame K and aspartame.
This information is based on current levels of use in the listed products and the amounts used in similar products.

Acesulfame K 950

01.2 Fermented and renneted milk products... 500mg/kg

01.3.2 Beverage whiteners wet 2.000 mg/kg dry 10.000 mg/kg

01.4 Cream... 1.000mg/kg

01.5.1 We propose to replace this listing by

01.5 Milk powder and cream powder and powder analogues (plain) 3.000 mg/kg

National approvals in several countries include analogues and blended products (e.g. USA: "dry bases for dairy product analogues,
GMP, 21cfr § 172.800) or include these in more general approvals for food use

01.6.1 Unripened cheese) 500 mg/kg

02.3 Fats emulsion... 1.000 mg/kg

04.1.2.10 Fermented fruit products 500 mg/kg

04.2.2.7 Fermented vegetable… 500 mg/kg

07.1 Bread.. 1.000 mg/kg

09.4 Fully preserved… fish... 600 mg/kg

12.2 Herbs, spices, seasonings 2.000 mg/kg

12.3 Vinegars 2.000 mg/kg

14.1.5 Coffee…600mg/kg ready-to-drink/3.500 mg/kg concentrates

14.2.1,14.2.2, 14.2.3, 14.2.4, 14.2.5, 14.2.6.1 and 14.2.6.2 ***Alcoholic beverages: We propose to simplify the standard and to use a single category : 14.2*** *Alcoholic beverages*
350 mg/kg

2.2. ASPARTAME 951

01.3.2 Beverages whiteners wet 6000mg/L; dry 20,000mg/kg
01.4.1 Pasteurized cream wet 6000mg/L; dry 20,000mg/kg
01.4.2 Sterilized, UHT, whipping or whipped, and reduced fat creams
wet 6000mg/L; dry 20,000mg/kg
01.4.3 Clotted cream wet 6000mg/L; dry 20.000mg/kg
01.5.1 Milk Powder and cream powder (plain) 5.000mg/kg
01.5.3 Milk and cream (blend) powder (plain and flavoured)
5.000mg/kg
01.6.1 Unripened cheese 1.000mg/kg
02.3 Fat emulsions other than food category 02.2,
including mixed and/or flavoured products based on fat emulsions
1.000mg/kg
04.1.2.1 Frozen Fruit 2.000mg/kg
14.1.5 Coffee, coffee substitutes, tea herbal infusions, and
other hot cereal and grain beverages, excluding cocoa
5.000mg/kg

Should a dual listing (wet vs dry products) not be considered feasible, we should like to propose to list the lower value with a footnote for clarification (e.g for Acesulfame K in 01.3.2: “except10.000 mg/kg for use in powdered products” and for 14.1.5: “except 3.500 mg/kg for use in concentrates”

AMFEP (Association of Manufacturers and Formulators of Enzyme Products):

Enzyme entries in GSFA

In Appendix I we note the following enzyme entries:

page 15-16
Alpha-amylase (A. oryzae var) INS 1100
as adjuvant, enzyme, flour treatment agent
GMP at step 6 in all 8 categories except flour and starches at step 8 (1999).

Alpha-amylase (B. subtilis) INS 1100 NEW
as enzyme, flour treatment agent
GMP at step 3 in 1 category.

Alpha-amylase (carbohydrase) (B. licheniformis) INS 1100 NEW
as enzyme, flour treatment agent
GMP at step 3 in 1 category.

page 44
Bromelain INS 1101iii
as flavour enhancer, flour treatment agent, stabilizer, thickener
GMP at step 6 in 2 categories.

page 110
Glucose oxidase (A. niger var) INS 1102
as antioxidant, preservative, stabilizer

780 mg/kg at step 3 flours and starches NEW
GMP at step 6 for grape wines.

page 137
Lysozyme hydrochloride INS 1105
as preservative
GMP at step 8 (1999) for ripened cheese
500 mg/kg at step 6 for cider and perry, grape wines.

page 156
Papain INS 1101 ii
as flavour enhancer, flour treatment agent, stabilizer
1000 mg/kg at step 6 for whole, broken or flaked grain, including rice
GMP at step 6 for flours and starches, fresh meat, poultry, and game, whole pieces or cuts, grape wines.

page 187
Protease (A. oryzae var) INS 1101 i
as enzyme, flavour enhancer, flour treatment agent, glazing agent
GMP at step 6 except for flours and starches at step 8 (1999).

Enzymes are included in the GSFA to the extent that individual member states have considered them as having a use as food additives.
We have often argued that only the use of invertase as a stabiliser and lysozyme as a preservative can be considered as food additive uses of enzymes. Apart from these two specific applications, all the enzymes listed in the GSFA are only used as processing aids and therefore should be removed from the GSFA. This also applies to any other applications of invertase and lysozyme than those mentioned.

However, we realise that to achieve this objective it will first be necessary to finalise the ongoing discussions in CCFAC and reach consensus on the general status for processing aids in Codex.
The case for flour treatment agents is different because they may only formally be considered as food additives when flour is (somewhat arbitrarily) considered as a food.

Having thus acquiesced on the listing of enzymes in the GSFA for the time being, we nevertheless must object to the addition of NEW entries of enzymes to the GSFA. This applies to alpha-amylase from B. subtilis and B. licheniformis as well as glucose oxidase.

GMP as use level for all enzymes

We also note that since no enzyme has been allocated a numerical ADI by JECFA, the use level should be GMP for all enzymes. We refer to CX/FAC 03/6 para 83 b for recent support of this view as a matter of policy.
We must therefore object to the numerical use levels for glucose oxidase for flours and starches (780 mg/kg), and more so since it is NEW on the list , and for lysozyme hydrochloride for cider and perry, grape wines (500 mg/kg), and for papain for whole, broken or flaked grain, including rice (1000 mg/kg).

Functional classes for enzymes

The functional classes used are, as admitted in the document, not consistent. We believe a choice should be made between either the common class of “enzyme” for all enzymes or individual established functional classes like antioxidant and preservative. The class “adjuvant” seems particularly strange in a food context.

Priorities on enzymes

Having read the document we are uncertain whether or not some at least of the high priority additives in group I-III will be discussed in CCFAC35, or if the discussion will be limited to groups IV and V. Only alpha-amylase, lysozyme-HCl and protease (A. oryzae var) are listed and they are all in group I.

Miscellaneous

Finally you may want to note that the numbers of appendices II and III have been switched in the "body" part of the document.

MARINALG INTERNATIONAL:

Carrageenan/PES

During its fifty-seventh meeting (Rome – June 2001), the JECFA recommended an Acceptable Daily Intake of « non specified » for both carrageenan and PES. Following this recommendation, we are proposing to harmonize the functions and maximum levels for these two additives in the revised Table 1 as follows :

Function Cat No.

01.1.1 This category is not further broken down for PES but is for carrageenan. Furthermore the entire category is GMP for PES while the subcategories for carrageenan have maximum levels of 10,000 and 8,000 mg/kg as maximum levels. We suggest that carrageenan be treated the same as PES.

01.4.1 This category is GMP for PES but is 500mg/kg for carrageenan. We suggest that carrageenan be treated the same as PES.

04.2.2.7 This category is present at GMP for carrageenan but is missing from PES. We suggest this category be added to PES at GMP.

06.4.1 This category is present at GMP for carrageenan but is missing from PES. We suggest this category be added to PES at GMP.

09.2.2 This category is GMP for PES but is 5,000mg/kg for carrageenan.We suggest that carrageenan be treated the same as PES.

09.2.4 This category is 4008 not subdivided for PES but is subdivided into 09.2.4.1, 09.2.4.2 and 09.4.3 for carrageenan. The maximum level is GMP for both. We suggest the subdivision of this category be removed from carrageenan

11.4 This category is GMP for PES and is 5,000mg/kg for carrageenan. We suggest that carrageenan be treated the same as PES.

14.1.2.1 This category is GMP for PES and is 3,000mg/kg for carrageenan. We suggest that carrageenan be treated the same as PES

14.1.3.3 This category is GMP for PES and is 1,000mg/kg for carrageenan. We suggest that carrageenan be treated the same as PES.

Alginates

In the category 01.4.1 – Pasteurized cream (plain) - A maximum level of 100 mg/kg is indicated. We believe that it is a typing error. Indeed the maximum level previously recommended was 1000 mg/kg.

EUROPEAN COMMUNITY:

1. The European Community has examined the Group IV and Group V food additives listed in revised Table 1 of the draft Codex General Standard for Food (GSFA)(Appendix I) that are to be discussed in the *ad hoc* GSFA working group in March 2003. The European Community would like to make the following general and specific remarks.

GENERAL COMMENTS

1. The European Community would like to reiterate several general comments made during the 34th CCFAC.

2. The European Community attempts to minimise the use of food additives to those that are technologically necessary and to limit their use to a level as low as possible.

3. Accordingly the European Community is of the opinion that the Draft General Standard on Food Additives (GSFA) generally allows too many additives in too many food products. The Codex Committee for Food Additives and Contaminants should make a close scrutiny of the Draft General Standard on Food Additives (GSFA) and should

– re-examine which additives are technologically necessary in the individual foodstuffs,

– question levels which are very high (see examples in specific comments on the priority list),

– compare the standards accepted by the Codex Commodity Committees to those in the draft GSFA in order to avoid contradictions.

4. The EC is aware that differences exist in the production processes and storage conditions employed around the world. The same phenomenon can be observed when it comes to food patterns and the taste and colour preferences of individual countries. These differences must be taken into account when evaluating the technological need for food additives in the Draft General Standard on Food Additives (GSFA).

5. However, the EC suggests that instead of automatically adopting the highest reported use level of each additive as the maximum use level, as is now being done, the lowest reported use level should be adopted by the Codex Committee on Food Additives and Contaminants. This has been discussed in great length at earlier sessions of the Committee.

6. If the principle for setting levels of use in Codex had been chosen to be the lowest level, the possibilities of exceeding the ADI would had been reduced. If a Member State, in submitting proper documentation, can justify a need for higher use levels, this should be taken into account. If proper documentation can not be provided, the entry is to be deleted from the GSFA. This approach will ensure that additives are only used in applications where the technological need is justified and in quantities that are not exceeding the amounts sufficient to fulfil this need.

Additives in unprocessed or fresh food

7. The European Community is of the opinion that unprocessed foods or fresh food such as: fresh fruit and vegetables (food categories 04.1.1 and 04.2.1), frozen fruit and vegetables (food categories 04.1.2.1 and 04.2.2.1), fresh meat and fish (food categories 08.1 and 09.1) and fresh eggs (food category 10.1) should not contain additives.

8. This is because the use of additives in these products will in many cases mislead the consumers on the quality of the foodstuff. Any exemption should be justified as a technical necessity. The Codex Committee on Food Additives and Contaminants has already accepted some exemptions following proper documentation. However, the technological need for the majority of the suggested additives in the GSFA for unprocessed foods or fresh food seems unjustified and should be deleted, if documentation is not presented to the Committee.

Additives in infant formulae, follow-on formulae, and weaning foods

9. Infant formulae, follow-on formulae, and weaning foods are full-meal foodstuffs in the sense that they constitute most if not all the nutrition provided to an infant. For this reason it is imperative that this food only contains additives that are technologically justified or even indispensable. If considered necessary they should only be authorised in the minimal amounts necessary to obtain the desired effect.

10. In particular the European Community does not support the use of colouring agents or sweeteners in infant formulae, follow-on formulae and weaning foods.

Use of colouring agents

11. According to the draft GSFA, colours are proposed for a significant number of food groups. In some cases the use of colours can mislead consumers and many consumers find colours superfluous as additives in food. For this reason the European Community believes that colours should be used in a restrictive manner. In particular no colours should be used in (grape) wine, unprocessed food and infant formulae, follow-on formulae and weaning foods.

Preservatives

12. Draft General Standard on Food Additives (GSFA) proposes the use of preservatives in a broad variety of foodstuffs. Moreover some of the levels proposed are quite high. This is especially true if it is taken into account that there is no provision that excludes the use of similar preservatives like sorbates, benzoates and p-hydroxybenzoates in the same product. A provision that limits the use of several preservatives with overlapping technological effects in the same product is recommended.

13. The use of preservatives in fresh or unprocessed food is misleading to consumers since a foodstuff can not both be fresh or unprocessed and at the same time preserved.

Use of additives with quantitative/numerical ADI under GMP

14. The European Community considers that additives having a quantitative/numerical acceptable daily intake (ADI) should not be allowed to be used according to Good Manufacturing Practice (GMP) in the GSFA. When additives are used according to GMP it is not possible to conduct reliable intake-studies in order to evaluate whether or not the ADI has been exceeded. For this reason the European Community suggests that the GMP status for all additives having a quantitative ADI is re-evaluated. This process has already started at the last CCFAC meeting.

SPECIFIC COMMENTS

1. ALUMINIUM AMMONIUM SULPHATE

INS: 523 Function: Firming Agent, Raising Agent, Stabiliser

Many new uses are proposed for this food additive. The European Community would like to hear the technological justification for these uses. Furthermore, numerical use levels should be proposed instead of GMP, as this additive is included in the provisional tolerable weekly intake for aluminium from all sources (7 mg/kg b.w).

2. ASCORBYL ESTERS

INS: 304 Function: Antioxidant

No specific comment.

3. BEESWAX, WHITE AND YELLOW

INS: 901 Function: Bulking agent, glazing agent, release agent, stabiliser

The use of beeswax in decorations (05.4) with the level of 4000 mg/kg was adopted at step 8 by the 24th CAC. The EC therefore questions the need for higher level for the same use.

The use of beeswax is proposed in water-based flavoured drinks (14.1.4.). If the presence of beeswax in these drinks results from a carry over from flavourings a note should be added to clarify this. However, the proposed level seems high for a carry over, therefore, this use should be justified.

4. BENZOATES

INS: 210, 211, 212, 213 Function: Preservative

04.1.2.4 Canned or bottled (pasteurised) fruit

It is considered that adequate pasteurisation of these products in sealed containers is sufficient to ensure an acceptable shelf life. Consequently the EC considers it necessary to thoroughly review this listing, especially its technical necessity.

04.2.2.4 Canned or bottled (pasteurised) or retort pouch vegetables

Benzoates are not allowed according to European Community legislation in canned or bottled (pasteurised) or retort pouch vegetables. It is considered that adequate pasteurisation or of these products in sealed containers or pouches is sufficient to ensure an acceptable shelf life. Consequently the EC considers it necessary to thoroughly review this listing, especially its technical necessity.

07.0 bakery wares

The low water activity of bakery wares (07.0) has a preserving effect towards bacteria eliminating the need for benzoates. Since bakery wares are consumed daily in significant quantities there is a possibility of exceeding ADI (5 mg/kg) when benzoates are used at 1000 mg/kg in these kind of foods. Consequently the EC considers it necessary to reconsider the technical necessity of the use in bakery wares.

08.3.1.2 Cured (including salted) and dried non-heat treated processed comminuted meat, poultry, and game products

For these products preservative treatment is necessary on the surface only. This should be done according to Good Manufacturing Practice (GMP).

12.5 Soups and broths

For soups and broths it should be specified that the use of benzoates is only for liquid products as there is no need to use this preservative in dried products.

14.1.1.2 Table waters and soda waters

There is no technical need for the use of benzoates. The EC considers that this listing is a mistake. It should be deleted.

14.1.2.1 Canned or bottled pasteurised fruit juice, 14.1.2.2 canned or bottled pasteurised vegetable juice, 14.1.2.3. concentrate (liquid or solid) for fruit juice, 14.1.2.4. concentrate (liquid or solid) for vegetable juice, 14.1.3.1 canned or bottled pasteurised fruit nectar, 14.1.3.2 canned or bottled pasteurised vegetable nectar, 14.1.3.3. concentrate (liquid or solid) for fruit nectar and 14.1.3.4. concentrate (liquid or solid) for vegetable nectar

It is considered that adequate pasteurisation of these products in sealed containers is sufficient to ensure an acceptable shelf life. Consequently the EC considers it necessary to thoroughly review this listing, especially its technical necessity. Moreover these proposals are not in line with the Codex Draft Standards for Fruit and Vegetable Juices and Nectars according to which antioxidants and preservatives may only be used in accordance with national legislation.

14.1.4 Water based flavoured drinks, including “sport” or “electrolyte” drinks and pasteurised drinks

Taking into account that beverages are often the major contributors to the intake of additive, the proposed level of 1000 mg is too high. Consequently the EC considers it necessary to thoroughly review the level proposed, especially its technical necessity.

14.2.5 Mead

The use of benzoates in mead seems unjustified since the low pH value and the alcohol content of the product inhibits the growth of bacteria. Therefore it is suggested to delete the application of benzoates in mead.

16.0 Composite foods (e.g., casseroles, meat pies, mincemeat) - foods that could not be placed in categories 01 – 15

It seems unnecessary to allow the use of 1000 mg/kg of benzoates in all composite products. Consequently the EC considers it necessary to thoroughly review the level proposed and to identify more precisely in which foodstuffs of this group preservatives are technically indispensable.

5. BHA

INS: 320 Function: Antioxidant

BHT

INS: 321 Function: Antioxidant

For several categories of desserts (01.7, 04.1.2.9, 06.5, 10.4) 2 mg/kg of BHA is proposed. It should be verified that this is not covered by carry over from ingredients.

There is no need to use additives in dried pasta. Therefore, the entry for category 6.4.2 should be removed.

In addition, BHA and BHT are proposed for use in many categories where technological justification should be provided e.g. whole, broken or flaked grain (06.1), breakfast cereals (06.3), fresh meat (08.1), frozen fish fillets (09.2.1), in other sugars (11.2), yeast (12.8) and water-based flavoured drinks (14.1.4). Furthermore, the levels proposed for fat based-desserts (02.4) and edible ices (03.0) should be verified.

6. BRILLIANT BLUE FCF

INS: 133 Function: Colour

Generally the use of brilliant blue FCF is proposed for a too large variety of products. It should be considered that colours could also deceive the consumer.

For instance the use of brilliant blue FCF in lard, tallow, fish oil (02.1.3), butter and concentrated butter (02.2.1.1), margarine (02.2.1.2) and bread and bakery wares (07.1) has a bleaching effect on the natural yellow colour of these foodstuffs. The resulting white colour serves no purpose in enhancing the safety or nutritional value of the foodstuffs. Consequently, these uses should be deleted.

Moreover the use in cocoa products and chocolate products (05.1), fully preserved fish (09.4), beer and malt beverages (14.2.1) and composite foods (16.0) can be questioned and the levels proposed for soups and broths (12.5 - 300 mg/kg) and for smoked, fish (09.2.5 – 500 mg) are too high.

Consequently the EC considers it necessary to thoroughly review this listing, especially in relation to technological need.

7. CANDELILLA WAX

INS/E: 902 Function: Bulking Agent, Carrier Solvent, Glazing Agent, Release Agent

The use of candelilla wax is proposed in water-based flavoured drinks (14.1.4.). If the presence of candelilla wax in these drinks results from a carry over from flavourings a note should be added to clarify this.

8. CARMINES

INS: 120 Function: Colour

JECFA has set ADI for carmines of 0-5 mg/kg bodyweight. In view of this ADI the use of carmines is proposed for too many products. The use of carmines in the following products should be technologically justified at the same time it should be demonstrated that the consumer is not mislead: unripened cheese (1.6.1), total ripened cheese (1.6.2.1), fats and oils (2.1), fat emulsions mainly of type water-in-oil (2.2), surface-treated fresh fruit (04.1.1.2), surface-treated fresh vegetables (04.2.1.2), cocoa products and

chocolate products (05.1), dried pastas and noodles and like products (06.4.2), pre-cooked pastas and noodles and like products (06.4.3), bread and ordinary bakery ware (07.1), fresh meat (08.1), fresh fish (09.1.1), fresh eggs (10.1), canned or bottled fruit juice (14.1.2.1), canned or bottled fruit nectar (14.1.3.1), beer and malt beverages (14.2.1), grape wines (14.2.3.). Alternatively these uses have to be deleted.

Furthermore, a numerical use level should be proposed instead of GMP, as carmines have a numerical ADI.

Consequently the EC considers it necessary to thoroughly review this listing, especially its technical necessity.

9. CARNAUBA WAX

INS: 903 Function: Anticaking Agent, Adjuvant, Bulking Agent, Carrier Solvent, Glazing Agent, Release Agent

No specific comment.

10. CAROTENES, VEGETABLE

INS: 160a ii, E 160a Function: Colour

Generally the use of carotenes is proposed for too many products. It should be considered that colours could also deceive the consumer. Especially the proposed use in canned or bottled (pasteurised) fruit and vegetable juices and nectars (14.1.2.1 – 14.1.3.4) should be justified. The use in many other products e.g. cocoa products and chocolate products including imitations and chocolate substitutes (05.1), fresh eggs (10.1), beer and malt beverages (14.2.1) or wine in general (14.2.3) seems to be not only unjustified but rather intended to deceive the consumer. Furthermore, the use is proposed in dietetic foods for special medical purposes for infants and young children (13.3.2), which for the EC is not acceptable. Consequently the EC considers it necessary to thoroughly review the listings for carotenes and to especially question the necessity for use.

11. CASTOR OIL

INS:1503 Function: Anticaking Agent, Carrier Solvent, Glazing Agent, Release Agent

The Codex Standards proposes the use of castor oil in cocoa products and chocolate products including imitations and chocolate substitutes, confectionery including hard and soft candy, nougat, etc., chewing gum, decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces, food supplements, water-based flavoured drinks, including "sport" or "electrolyte" drinks and particulated drinks. This should be justified.

12. CHLOROPHYLLS, COPPER COMPLEXES

INS: 141i, 141ii Function: Colour

Generally the use of chlorophylls is proposed for too many products. It should be considered that colours could also deceive the consumer. Especially the proposed use in canned or bottled (pasteurised) fruit and vegetable juices and nectars (14.1.2.1 – 14.1.3.4) should be justified. The use in many other products e.g.

surface treated fresh fruits (04.1.1.2), cocoa products and chocolate products including imitations and chocolate substitutes (05.1), fresh eggs (10.1), dried pastas and noodles (06.4.2) or wine in general (14.2.3) seems to be not only unjustified but rather intended to deceive the consumer. Consequently the EC considers it necessary to thoroughly review this listing and to especially question the necessity.

13. DIACETYLTARTARIC AND FATTY ACID ESTERS OF GLYCEROL

INS: 472e Function: Emulsifier, Sequestrant, Stabiliser

At its 57th meeting, JECFA recommended a temporary ADI of 50 mg/kg b.w. to diacetyltartaric and fatty acid esters of glycerol. JECFA will consider this additive next time in its 61. meeting in June 2003. The EC suggests that the proposed uses would be discussed only pending the final conclusion of JECFA.

14. GRAPE SKIN EXTRACT

INS: 163ii Function: Colour

Generally the use of colours should be carefully considered as colours could also deceive the consumer. The use in many products e.g. fresh eggs (10.1), canned or bottled vegetable nectars (14.1.3.2) and grape wines (14.2.3) seems to be not only unjustified but also rather intended to deceive the consumer. Consequently the EC considers it necessary to thoroughly review this listing and to especially question the necessity.

15. HYDROXYBENZOATES, p-

Ethyl p-hydroxybenzoate INS: 214, Propyl p-hydroxybenzoate INS: 216, Methyl p-hydroxybenzoate INS: 218 Function: Preservative

The use of preservatives in fresh or unprocessed food is misleading to consumers since a foodstuff can not both be fresh or unprocessed and at the same time preserved. Therefore, the use of p-hydroxybenzoate in e.g. surface-treated fresh fruit (04.1.1.2), peeled or cut fresh fruit (04.1.1.3), surface-treated fresh vegetables (04.2.1.2), peeled, cut or shredded vegetables (04.2.1.2) should be omitted from the GSFA.

04.1.2.1 Frozen fruit

The low water activity of frozen fruit ensures preservation. For this reason this entry should be deleted.

04.1.2.4 Canned or bottled (pasteurised) fruit

European Community legislation does not allow the use of p-hydroxybenzoates in canned or bottled fruit. It is considered that adequate pasteurisation of these products in sealed containers is sufficient to ensure an acceptable shelf life. Consequently the EC considers it necessary to thoroughly review this listing, especially its technical necessity.

04.2.2.4 Canned or bottled (pasteurised) or retort pouch vegetables

The use of p-hydroxybenzoic acid in canned or bottled (pasteurised) or retort pouch vegetables is not allowed according to European Community legislation. It is considered that adequate pasteurisation of these products in sealed containers or pouches is sufficient to ensure an acceptable shelf life. Consequently the EC considers it necessary to thoroughly review this listing, especially its technical necessity.

05.1.1 Cocoa mixes (powders and syrups)

The low water activity of cocoa mixes ensures preservation of the product. For this reason this entry should be deleted.

08.3.1.2 Cured (including salted) and dried non-heat treated processed comminuted meat, poultry, and game products

For these products preservative treatment is necessary on the surface only. This should be done according to GMP.

11.2 Other sugars and syrups (e.g. brown sugar, maple syrup)

There is no technical need for the use of p-hydroxybenzoates in sugar and other products with a low content of free water. The EC considers that this listing is a mistake. It should be deleted.

12.5 Soups and broths

The use of p-hydroxybenzoic acid in soups and broths should be limited to those that cannot be adequately preserved with other methods. For this reason dried products and those that are heat-treated in the canning procedure should be excluded.

14.1.2. Fruit and vegetable juices to 14.1.3.4 Concentrate (liquid or solid) for vegetable nectar

According to European Community legislation p-hydroxybenzoates are not allowed in fruit or vegetable juices, nectars or concentrates to prepare them. In particular for pasteurised products it is considered that adequate heat treatment or of these products in sealed containers is sufficient to ensure an acceptable shelf life. Consequently the EC considers it necessary to thoroughly review this listing, especially its technical necessity.

14.1.4 Water based flavoured drinks, including “sport” or “electrolyte” drinks and pasteurised drinks

Taking into account that beverages are often the major contributors to the intake of additive, the proposed level of 1000 mg is too high. Consequently the EC considers it necessary to thoroughly review the level proposed, especially its technical necessity.

14.2.1 Beer and malt beverages

The use of p-hydroxybenzoates is proposed for so called coolers covered by several categories (14.2.1, 14.2.3, 14.2.6.2). As there is a new category 14.2.7 for aromatized alcoholic beverages, these uses should be transferred to this category. Consequently, no p-hydrozybenzoates are needed in beer (14.2.1), wines (14.2.3.) or spirituous beverages (14.2.6).

15.1 Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes) and 15.2 Processed nuts, including covered nuts and nut mixtures (with e.g., dried fruit)

The low water activity of these products ensures preservation. For this reason this two entries should be deleted.

16.0 Composite foods (e.g., casseroles, meat pies, mincemeat) - foods that could not be placed in categories 01 – 15

It seems unnecessary to allow the use of 1000 mg/kg of p-hydroxybenzoic acid in all composite products. Consequently the EC considers it necessary to thoroughly review the level proposed and to identify more precisely in which foodstuffs of this group preservatives are technically indispensable.

16. MINERAL OIL

INS: 905a Function: Adjuvant, Antioxidant, Glazing Agent, Humectant, Release Agent

In 1995, JECFA revised its 'Mineral Oil' specification and divided it into two groups: High viscosity and Medium-low viscosity, class I, class II and class III.

Mineral Oil (High viscosity) INS 905a, was given an ADI of 0-20 mg /kg in 1995.

Mineral Oil (Medium- and low viscosity, class I) INS 905a, was given a temporary ADI of 0-1 mg /kg in 1995 but this was revised in 2002 to ADI 0-10 mg/kg.

Mineral Oil (Medium- and low viscosity, class II) INS 905a, was given a temporary ADI of 0-0.1 mg /kg in 1995.

Mineral Oil (Medium- and low viscosity, class III) INS 905a, was given a temporary ADI of 0-0.1 mg /kg in 1995.

Considering that only additives evaluated by JECFA and allocated a full ADI should be included in the GSFA, the EC would like to propose that only Mineral oil (high viscosity) and Mineral oil (Medium- and low viscosity, class I) be retained in the GSFA.

17. NISIN

INS: 234 Function: Preservative

In the European Community there is generally a cautious use of this preservative in foodstuffs. For this reason the technological need for nisin is only recognised in three food groups. In ripened cheese (01.6.1) and processed cheese (01.6.4) nisin is allowed at 12.5 mg/kg, in clotted cream and mascarpone at 10 mg/kg and in semolina and tapioca puddings is allowed at 3 mg/kg.

When comparing the applications for nisin within the Community to the suggestions of the GSFA a significant number of these suggestions seem unjustified. Furthermore the suggested use levels at 250 mg/kg in processed cheese (01.6.4) and fine bakery wares (07.2) are high. The ADI assigned to nisin by JECFA is 33.000 IU. For an adult this means that ADI is exceeded after consuming 200 grams of processed cheese or fine bakery ware. On the basis of this, the EC also questions the new entries proposed at step 3 for dairy products (01.0) and meat and meat products (08.0).

The use of nisin at GMP in canned vegetables (04.2.2.4) and ready-to-eat soups and broths (12.5.1) not only seems technologically unnecessary since the products can be pasteurised, but also not recommended considering the low ADI of nisin.

Consequently the EC considers it necessary to thoroughly review this listing, especially its technical necessity.

18. PHOSPHATIDIC ACID, AMMONIUM SALT

INS: 442 Function: Emulsifier, Stabiliser

The levels of 5000 mg/kg in dairy-based desserts (0.1.7) and 7500 mg/kg in edible ices (03.0) are unnecessarily high. The use of phosphatidic acid in dairy-based drinks (01.1.2), cream (plain – 01.4) and bread and rolls (07.1.1) at GMP seems technologically unjustified and should be deleted. Consequently the EC considers it necessary to thoroughly review the levels proposed.

19. POLYSORBATES

Polyoxyethylene (20) Sorbitan Monolaurate INS: 432 Polyoxyethylene (20) Sorbitan Monooleate INS: 433 Polyoxyethylene (20) Sorbitan Monopalmitate INS: 434 Polyoxyethylene (20) Sorbitan Monostearate INS: 435 Polyoxyethylene (20) Sorbitan Tristearate INS: 436

Function: Antifoaming Agent, Adjuvant, Emulsifier, Foaming Agent, Flour Treatment Agent, Stabilizer

Polysorbates are in the GSFA proposed for a broad variety of foodstuffs at high use levels when it is considered that the ADI assigned to polysorbates by JECFA is 25 mg/kg b.w.. For example the proposed use level of polysorbates in processed meat (08.2) is 10000 mg/kg which means that after consuming 150 g of processed meat an adult consumer will have exceeded the ADI.

In order to avoid ADI concerns the suggested uses of polysorbates must be reviewed. The technological need for polysorbates in the following products seems unjustified: unripened cheese (01.6.1), fat emulsions mainly of type water-in-oil (02.2), surface-treated fresh fruit (04.1.1.2), cocoa mixes (05.1.1), dried pastas and noodles and like products (06.4.2), pre-cooked pastas and noodles and like products (06.4.3), batters (06.6), processed meat (08.2), processed comminuted meat (08.3), edible casings (08.4), salt (12.1), herbs, spices, seasonings (12.2), non-emulsified sauce (12.6.2), clear sauces (12.6.4), yeast and like products (12.8), carbonated drinks (14.1.4.1), non-carbonated drinks (14.1.4.2) and composite foods (16.0).

20. RIBOFLAVINES

Riboflavin 5'-Phosphate, Sodium INS: 101i Riboflavin 5'-Phosphate INS: 101ii

Function: Colour

The technical need for using colour in foodstuffs like fats and oils essentially free from water (02.1), surface-treated fresh fruit (04.1.1.2), surface-treated fresh vegetable (04.2.1.2), bread and ordinary bakery wares (07.1), meat and meat products (08.0), other sugars (11.2), fruit juice and nectar (14.1.2.1, 14.1.2.2, 14.1.3.1), vegetable nectar (14.1.3.2, 14.1.3.4), grape wine (14.2.3) and composite foods (16.0) could deceive the consumer and seems unjustified. These entries should therefore be deleted.

21. SHELLAC

INS: 904 Function: Bulking Agent, Glazing Agent, Release Agent

No specific comment.

22. SODIUM ALUMINIUM PHOSPHATES

Sodium Aluminium Phosphate-Acidic INS: 541i Sodium Aluminium Phosphate-Basic INS: 541ii

Function: Acidity Regulator, Emulsifier, Raising Agent, Stabiliser, Thickener

The tolerable weekly intake of aluminium is 7 mg/kg bodyweight equal to approximately 70 mg/day aluminium (originating from all sources) for an adult. Given the low tolerable weekly intake of aluminium and considering that other aluminium compounds are also suggested for use as additives (Aluminium

Ammonium Sulphate, Aluminium Silicate, Calcium Aluminium Silicate) the number of suggested applications for sodium aluminium phosphates seems exaggerated and the use levels far too high. If 45000 mg/kg sodium aluminium phosphate is allowed in flours and starches (06.2) the tolerable weekly intake will be exceeded for an adult consumer after the indigestion of 55 grams of flour or starch.

It is difficult to believe that sodium aluminium phosphates when used as an acidity regulator, stabiliser or thickener can not be substituted by other additives to obtain the same technological effects.

The European Community allows sodium aluminium phosphates as an emulsifier and raising agent. However, the application is limited to a few products that are not consumed in significant quantities. Furthermore the maximum use level allowed is 1000 mg/kg. It is suggested that the Committee employ the same type of precautionary measures.

Consequently the EC considers it necessary to thoroughly review the entire listing of sodium aluminium phosphates, especially its technical necessity.

23. SORBITAN ESTERS OF FATTY ACIDS

Sorbitan Monostearate INS: 491, Sorbitan Tristearate INS: 492, Sorbitan Monolaurate INS: 493 Sorbitan Monooleate INS: 494, Sorbitan Monopalmitate INS: 495

Function: Emulsifier, Stabiliser

Generally the use of sorbitan esters of fatty acids is proposed for a large variety of products and in a number of the suggested applications for sorbitan esters of fatty acids the additive seems to be technically irrelevant. Examples are: fats and oils essentially free from water (02.1), surface-treated fresh fruit (04.1.1.2), fruit preparations (04.1.2.8), dried vegetables (04.2.2.2), non-emulsified sauces (12.6.2) and wines (14.2.3).

Consequently the EC also considers the following levels as too high: 1200 mg/kg for edible ices, including sherbet and sorbet (03.0) and 20 000 mg/kg for confectionery (05.0).

For that reason a significant number of entries should be lowered in level or be deleted from the table in order to avoid ADI concerns. Apart from those mentioned above the following entries should also be discussed in this light: dairy-based drinks (01.1.2), fruit fillings (04.1.2.11), dried pastas and noodles and like products (06.4.2), pre-cooked pastas and noodles and like products (06.4.3), ordinary bakery ware (07.1), edible casings (08.4), egg products (10.2) and mixes for soups and broths (12.5.2). Furthermore, a numerical use level should be proposed instead of GMP, as sorbitan esters have a numerical ADI.

24. SUCRALOSE

INS: 955 Function: Sweetener

There is no technical need to use sucralose in whole and broken, or flaked grain, including rice (06.1), flours and starches (06.2) and grape wines (14.2.3). The EC considers that these listing are mistakes and should be deleted. In EC legislation intense sweeteners are only permitted in energy-reduced or no added sugar varieties for the majority of foodstuffs.

25. SUCROGLYCERIDES

INS: 474 Function: Emulsifier, Stabiliser, Thickener

The technical necessity for this additive in fine bakery wares (07.2) should be justified.

26. SULPHITES

Sulphur dioxide INS:220, Sodium sulphite INS:221, Sodium hydrogen sulphite INS:222, Sodium metasulphite INS:223, Potassium metabisulphite INS:224, Potassium sulphite INS:225, Calcium hydrogen sulphite INS:227, Potassium bisulphite INS:228, Sodium thiosulphite INS:539

Function: Acidity regulator, adjuvant, bleaching agent (not to flour), flour treatment agent, firming agent, preservative, sequestrant, stabiliser

In general, the draft Codex standard allows the use of sulphites in a broad variety of foodstuffs and for uses where the technological necessity hasn't been proven. In addition, certain proposed use levels seem much too high and higher than really necessary. Consequently, the ADI allocated for sulphites (0.7 mg/kg b.w) is likely to be exceeded by most population groups.

01.2.12 Fermented milks (plain), heat treated after fermentation

Note 12 indicates that the additive is contained in fermented milk as a carry over from flavouring substances. This is not in line with the fact that the product is " plain". Therefore, this entry should be deleted.

01.6.4 Plain processed cheeses

For this proposed use technological need should be verified and whether the presence of sulphites in these products is due to carry over. If that would be the case, this entry could be deleted.

01.7 Dairy based desserts (e.g. ice cream, ice milk, pudding, fruit or flavoured yoghurt)

Technological need should be verified especially in the products preserved by freezing (ice cream, ice milk). For fruit or flavoured yoghurts note 88 (for the fruits) and note 12 (for flavourings) should be added.

03.0 Edible ices, including sherbet and sorbet

These products are preserved by freezing, therefore carry over for certain ingredients should be sufficient.

04.1.1.2 Surface-treated fresh fruit

The use of food additives should be as limited as possible in unprocessed foodstuffs. In addition, technological need has not been demonstrated for all the fruits. Therefore, if there is any fruit where the use of sulphites is indispensable, this should be specified in a note.

04.1.2.1 Frozen fruit

Since these products are preserved by freezing, this entry should be deleted. In addition, the corresponding commodity standard does not contain the use of sulphites.

04.1.2.2 Dried fruit

The proposed maximum level (3000 mg/kg) seems very high and could be modified according the fruit: only for certain fruits such as dried apricots, peaches, grapes, prunes and figs. It is necessary to restrict the use of

sulphites in this category because it is a significant source for exceeding the ADI, especially for young children.

It should be noted that corresponding Codex commodity standards contain the following uses:

- Dried apricots: 2000 mg/kg
- Dried, grated coconut: 50 mg/kg
- Raisins (only to bleached raisins) : 1500 mg/kg

04.1.2.5 Jams, jellies and marmalades, 04.1.2.6 Fruit based spreads (e.g. chutney) excluding products of food category 04.1.2.5

The proposed maximum level (3000 mg/kg) seems very high and is not necessary from the technical point of view in all the products (for example Codex standard for chutney does not contain the use of this additive) if good manufacturing practices are followed. Therefore, the EC proposes the level of 100 mg/kg.

04.1.2.8.Fruit preparations including pulp, purees, fruit toppings and coconut milk, 04.1.2.9 Fruit based desserts, including fruit flavoured water-based desserts

The use levels of 3000 and 750 mg/kg are excessive from the technological point of view and public health point of view in products that are often consumed by young children. There is a risk that ADI will be exceeded. In addition, it should be verified whether carry over from fruit preparations is sufficient.

04.1.2.12 Cooked or fried fruit

A numerical use level should be proposed instead of GMP, as sulphites have a numerical ADI. In addition, these products would be consumed by young children.

04.2.1.3 Peeled, cut or shredded vegetables, nuts and seeds

Proposed use level (500 mg/kg) is too high and technological need is proven only for white vegetables and potatoes. A note to restrict the use to this effect should be added.

04.2.2.1 Frozen vegetables

Proposed use level (750 mg/kg) is too high. In addition, as the purpose is to stabilise the white colour, the authorisation should be restricted to white vegetables and potatoes.

Commodity standards do not contain these uses, except in quick frozen French-fried potatoes (50 mg/kg).

04.2.2.2 Dried vegetables, seaweeds, nuts and seeds

The proposed use level can lead to exceeding the ADI (for example potato puree consumed by children). Therefore, the EC would propose to replace the level with 500 mg/kg.

04.2.2.4 Canned or bottled or retort pouch vegetables

It is important to restrict the use level of products that are consumed in big quantities (risk of exceeding the ADI) and that undergo heat treatment. Therefore, the EC would propose the level of 50 mg/kg.

04.2.2.5 Vegetables, nut and seed and spreads

The use level of 500 mg/kg that was proposed in earlier version of GSFA, seemed sufficient from the technological point of view.

04.2.2.7 Fermented vegetable products, 04.2.2.8 Cooked or fried vegetables and seaweeds

The proposed use levels are high, therefore the technological need should be verified especially as these products can be consumed in great quantities leading to a risk of exceeding the ADI.

05.1.1 Cocoa mixes (powders and syrups)

Sulphites are not authorised in the corresponding Codex standard. Therefore, the Codex Committee on Cocoa Products and Chocolate should verify the technological need for this use.

05.1.2 Cocoa based spreads, including fillings

The use level of 2000 mg/kg seems very high. Therefore, the technological need should be verified for this product that is often consumed by children. The EC would propose the level of 100 mg/kg.

05.1.3 Cocoa and chocolate products, 05.1.4 Imitation chocolate, chocolate substitute products

For these categories, carry over from ingredients (such as raisins) should be sufficient.

05.2 Confectionery, 05.3 Chewing gum

The technological need does not apply in all the categories, therefore, it should be verified whether carry over is sufficient. In addition, the proposed use levels are very high.

06.1 Whole, broken or flaked grain including rice

The proposed use with the level of 400 mg/kg should be justified in a large food category (consumed in great quantities daily in most countries).

06.2 Flours and starches

The proposed use level is too high compared to the technological need and is not necessary in flour.

06.4.2 Pre-cooked or dried pasta and noodles and like products

There is no need to use additives in dried pasta. Therefore, the entry for category 6.4.2 should be removed.

07.1.1 Breads and rolls, 07.1.3 Other ordinary bakery wares, 07.1.4 Bread type products

Authorisation of sulphites in common bakery products is not technologically justified and should only concern certain special products if there are specific needs. In the current proposal, the proposed use levels of bread are much too high for a commodity that is a very important part of the diet in some countries and is consumer on a regular, often daily, basis.

7.2 Fine bakery wares

The proposed use level is high. Therefore, the level should be verified to correspond to the technological effect desired.

09.4 Fully preserved, including canned or fermented fish and fish products including molluscs, crustaceans and echinoderms

In the case of preserved products, the technological need for sulphites doesn’t seem justified.

11.1 White and semi-white sugar, fructose, glucose, xylose, sugar solutions and syrups, inverted sugars

The proposed use level seems very high. In addition, there doesn't seem to be technological need for use level higher than foreseen for category 11.2 (40 mg/kg). The coherence with the corresponding Commodity standards should be verified.

12.1 Salt

The technological need of sulphites in salt has to be justified.

12.5 Soups and broths

The proposed use level of 1000 mg/kg would lead to exceeding the ADI. Addition of sulphites in the final product is not necessary; carry over from the ingredients is sufficient. Therefore, this entry should be deleted.

12.6 Sauces and like products

It should be verified whether addition of sulphites to the final product is necessary or whether carry over from ingredients is sufficient.

14.1.2.1 Canned and bottled fruit juice, 14.1.2.2 Canned and bottled vegetable juice

The proposed uses are too high and the technological need has not been demonstrated for all fruit juice. Only lemon juice, lime juice and grape juice need addition of sulphites.

14.1.4.1 Carbonated drinks, 14.1.4.2 Non carbonated drinks

The use levels (115 and 250 mg/kg) seem high. It should be verified whether carry over is sufficient.

14.2 Alcoholic beverages

For the use of sulphites in wine, the EC would propose to distinguish between different types of wine for which the technological need is different (see annex that contains the regulation in the EC).

15.1 Snacks potato, cereal, flour and starch based

The proposed use level of 200 mg/kg seems excessive.

15.2 Processed nuts, including covered nuts and nut mixtures

Proposed use level (500mg/kg) seems high. It should be verified that carry over is not sufficient.

16.0 Composite foods

For composite foods, carry over should be sufficient.

27. TANNIC ACID (TANNINS, FOOD GRADE)

INS: 181 Function: Colour

The JECFA evaluation with the result ADI "not specified" is only valid for "use as a filtering aid where the application of good manufacturing practice ensures that it is removed from food after use." In the view of the European Community, it is not valid for the use of tannic acid as a colouring agent. The listing should therefore be deleted.

TBHQ

INS: 319 Function: Antioxidant

For sweetened condensed milk (01.3.3) it is proposed that 200 mg/kg of TBHQ would be present as a carry over from ingredient (note 88) in the product. This does not seem correct, therefore, the entry should be justified.

TBHQ is proposed for use in fats and oils (02.0). However, the use in butter (2.2.1.1) should be excluded.

In addition, TBHQ is proposed for use in categories where technological justification should be provided e.g. fresh meat (08.1) and water-based flavoured drinks (14.1.4). It should also be verified whether note 15 (fat or oil basis) should be added to categories on dairy-based desserts (01.7) and bakery products (07.1.1, 07.1.2, 07.1.3, 07.1.4).

SO2 limits in wine
European Community Regulations

Still wines		
		Residual sugar ≥ à 5g/l
1) Red wine (REC n° 1493/1999 annex V A.)	160 mg/l	210 mg/l
White wine and rosé wine (REC n° 1493/1999 annex V A.)	210 mg/l	260 mg/l
2) Quality white wines psr REC n° 1493/1999 annex V A. point 2 b) REC n°1622/2000 annex XII a)	300 mg/l	
3) Table wines REC n°1622/2000 annexe XII a)	Total alcoholic strength by volume > 15% vol and residual sugar > 45g/l	
	300 mg/l	
4) Quality white wines psr REC n° 1493/1999 annex V A. point 2, d) REC n°1622/2000 annex XII b)	400 mg/l	

LIQUEUR WINE		
		Sugar content
REC n° 1493/1999 annex V J. point7 :		> 5 g/l
Liqueur wine and quality liqueur wine psr	150 mg/l	200 mg/l

Sparkling wine	
Sparkling wine (REC n°1493/1999 annex V H. point11 d)	235 mg/l
Quality sparkling wine (REC n°1493/1999 annex V I. point5)	185 mg/l
Quality sparkling wine psr (RCE n° 1493/1999 annex VI K. point7)	185 mg/l

ISDC: (The International Soft Drinks Council)

The International Soft Drinks Council (ISDC) is pleased to provide comments on the Proposed Draft and Draft Revisions to Table 1 of the Codex General Standard for Food Additives. We request that this letter and the attachment be made a working paper for the next CCFAC meeting.

At the 34th Session of the Codex Committee on Food Additives and Contaminants, comments were made concerning the technological need of the proposed maximum level of 1,000 mg/kg benzoates in Category 14.1.4 (water-based flavored drinks, including "sport" and "electrolyte" drinks and particulated drinks). The ISDC wishes to provide a technological need statement in support of the maximum level of 1,000 mg/kg (attached).

We would like to highlight that the use of benzoates, just like other food additives, is governed by Good Manufacturing Practices (GMPs) which means that the lowest levels will be used in every beverage to achieve the desired effect. As described in the attached document, there are several factors that must be considered when selecting the appropriate use level in a beverage. This results in varying use levels around the world. Different production environments and climatic conditions require a greater need for benzoates in some countries or regions. Further, the intake data show that the ADI is not exceeded in countries even at the maximum level of 1,000 mg/kg in soft drinks in countries with the highest consumption.

We urge that CCFAC consider the needs of the developing countries and all Codex regions when setting maximum levels for food additives. It should be recognized that the technological need may differ from one country to another. In addition, developing countries face a number of problems in assuring the quality and safety of foods for their domestic markets and for export. In many cases the level of equipment available, and prevailing weather conditions in developing countries, located mainly in tropical or semi-tropical areas, and other factors require use of accepted food preservatives at a level that may not be needed in state-of-the-art equipped plants in temperate, developed countries.
If using acceptable GMPs results in products with levels of benzoates at or below the proposed Codex limit of 1,000 mg/kg, and food intake data show that the ADI is not exceeded, then there should not be any objection to the use of benzoates at acceptable levels needed to assure adequate preservation of safe and affordable drink products. We believe that the maximum level that is technologically supported is 1,000 mg/kg in Category 14.1.4. In addition, close to 50 countries in five Codex regions permit 1,000 mg/kg in this category.

TECHNOLOGICAL NEED FOR BENZOATES IN THE CODEX FOOD CATEGORY 14.1.4: WATER-BASED FLAVORED DRINKS, INCLUDING "SPORT" OR "ELECTROLYTE" DRINKS (NOV/2002)

Growth of spoilage microorganisms in water-based drinks, including "sport" or "electrolyte" drinks, hereinafter referred to as soft drinks, may result in a variety of undesirable effects, including off-taste, off-odor, scum, and sedimentation (1). Gas formation because of microbial activity as well as changes in beverage color and clarity may also be noted (2). The growth of the majority of these organisms may be controlled by the addition of benzoic acid or its salts (benzoates). Benzoates are the preservatives of choice for soft drink manufacturers.

Natural occurrence

Benzoic acid occurs naturally in a number of foods including cranberries, prunes, cinnamon, cloves, green gage plums, huckleberries, raspberries, currants and others (4, 9). The keeping quality of these foods and their juices results from their benzoic acid content (4, 11).

Contaminating microorganisms

Several types of microorganisms may contaminate beverages. Most cases of microbial spoilage of carbonated soft drinks have been caused by yeast (1, 2). Included among beverage spoilage organisms are

the acid-tolerant bacteria such as *Lactobacillus* and *Acetobacter* (3). In non-carbonated drinks, molds are often a problem as well (4).

Beverage susceptibility

The major factors influencing yeast growth are beverage composition, pH, degree of carbonation and preservative concentration in the beverage (2). A few carbonated beverages, such as sugar-sweetened cola-type beverages, are adequately preserved by the anti-microbial properties of beverage acidity and high carbonation. However, the majority of beverages do support the growth of microorganisms. In this respect, non-carbonated beverages, fountain syrups, fruit drinks and cider provide an environment in which yeast, molds and bacteria can grow readily (5). Benzoates can provide the necessary stabilization for carbonated as well as non-carbonated soft drinks (1).

Role of sanitation in processing

There is no substitute for proper sanitation. Preservatives, including benzoates, can prevent growth of microorganisms but only when the microorganisms are initially present in relatively low numbers. Preservatives will inhibit microbial spoilage but cannot prevent spoilage if there is a high level of contamination in the manufacturing environment, equipment, or ingredients (6-8).

Despite the most rigorous execution of the best sanitation action standards, some number of microorganisms will be introduced into the product due to their prevalence in ingredients and the environment. It is important to note that beverage ingredients and the processing environment are not sterile and, therefore, it is not uncommon for low numbers of microorganisms to be carried into the beverage. A single microorganism entering into a beverage can result in spoilage if preservative agents are not present to inhibit the growth of that organism. Microorganisms may originate from prior contamination of ingredients such as water, syrup, or juice, or they might come from the production environment by exposure to air (e.g., dust particles or aerosols) or during processing (e.g., containers).

Role of benzoic acid and its salts in beverages

The potential for contamination makes it necessary to add preservatives like benzoates to susceptible beverages to control microbial growth. These beverages are often products that are not treated by heat or other processing means to destroy microorganisms (5). Benzoates provide a cost-effective and a safe way to preserve beverages enabling lower prices for consumers.

Benzoates have a long history of safe use as preservatives in foods (1, 2, 4-7, 9, 10). They are particularly well suited for use in soft drinks, such as carbonated and still beverages, or fruit juices (4). When either benzoic acid or benzoate salts are added to an aqueous solution (beverage), some fraction of the total amount added will convert to an inactive form (dissociated) and some portion will convert to the active form (undissociated) resulting in a state of equilibrium between the two forms. The ratio of active form to total amount of added preservative that results as a consequence of this equilibrium state is largely determined by pH. It is the undissociated molecule of benzoic acid that is responsible for antimicrobial activity.

Benzoic acid is least active in neutral medium, and its preservative effect is increased considerably with decreasing pH. For example, reducing the pH of the drink from 4.5 to 3.0 can result in a 3-fold increase in benzoic acid activity (4). This is due to the fact that more undissociated benzoic acid exists at lower pH. At pH 4.5, only 33% exists as the undissociated acid but, at pH 3.0, as much as 94% of the benzoic acid exists as the undissociated acid.

Benzoic acid inhibits the growth of microorganisms. Benzoic acid interrupts many enzymatic processes in microorganisms at concentrations that retard the growth rate. In addition, benzoic acid may cause a microorganism to die by altering the cell's membrane permeability so that a microorganism cannot maintain cellular activity for growth and reproduction (21).

Benzoic acid is effective against yeasts and molds. In addition, benzoic acid also inhibits the growth of bacterial pathogens, such as *Vibrio parahaemolyticus*, *Staphylococcus aureus*, *Bacillus cereus*, and *Listeria*

monocytogenes (24). Common soft drink spoilage bacteria, namely *Acetobacter* and lactobacilli, are also inhibited by benzoic acid.

In beverages with a relatively high pH, concentrations must be increased to compensate for the reduced activity. At pH 3.5-4.0, 600-1,000 mg/kg (ppm) is required to prevent growth of fermentative organisms (10, 12). Further, because some spoilage fungi (yeast and mold) possess a natural tolerance to benzoic acid, it is necessary to employ concentrations of benzoic acid or benzoate salts that provide for a 500 ppm concentration of the active form of the preservative that is required to avoid spoilage. In order to achieve a concentration of 500 ppm of the active form, it usually is necessary to add more than 500 ppm of the acid or salt to the beverage to compensate for the amount of nonactive form of the preservative that develops upon equilibrium.

The inhibitory concentration of benzoic acid at pH less than 5.0 against most yeasts ranges from 20 to 700 ppm, for molds it is 20 to 2,000 ppm (25). A few fungal species possess mechanisms of resistance to weak acid preservatives, the most notable being the yeast *Zygosaccharomyces bailii* (23). Minimum inhibitory concentrations (MIC) for some of the bacteria, yeasts, and fungi involved in beverage spoilage are given in Table 1 and Table 2 (21-23).

Use of benzoic acid and its salts

Benzoic acid is usually added to beverages as the sodium, potassium, or calcium salt. This is because benzoic acid has low solubility in aqueous solutions (the sodium salt is approximately 180 times more soluble in water than the acid) (11).

Some types of soft drinks do not require the use of benzoic acid and others require differing levels depending on taste characteristics and inherent microbiological stability of the particular product. Beverage carbonation and pH are significant controlling factors in determining optimum preservative concentration, however the presence of nutrients (juice, vitamins, etc.), the nature of acidulants, essential oils, sweeteners, and stabilizers must also be considered (2). Furthermore, some soft drinks may undergo additional processing (for example syrup pasteurization) reducing the need for preservatives. Beverages that do not contain preservatives are thermally processed and then filled either hot or aseptically. However, this is not always practical.

A recent trend to bring more beverages to the market with a higher pH (approaching 4.6) has a measurable impact on the use of benzoate salts in soft drinks as described above. At pH 4.4, the amount of active preservative present is only 275 ppm when 1,000 ppm of sodium benzoate is added.

There are a number of variables to consider when formulating soft drinks, such as how carbon dioxide, benzoate, nutrient concentrations, and pH taken together influence the growth of microorganisms. Benzoates also may be used in combination with other preservatives such as potassium sorbate or esters of para-hydroxybenzoic acid (9-10). One also must consider the economics, climate, and technology available in a country when deciding on the use of preservatives. Therefore, use levels of benzoates may vary among different countries or regions and higher preservative concentrations may be required to produce microbiologically stable beverages. In any case, only the level that is needed to stabilize the beverage formulation is used according to the Good Manufacturing Practices (GMPs).

Safety evaluations of benzoic acid

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has evaluated benzoic acid and its salts several times and found them to be acceptable for use in foods. The latest full review was conducted in 1997 (14). JECFA established an Acceptable Daily Intake (ADI) of 0-5 mg/kg body weight/day based on a four generation feeding study in rats. In this study the diet contained 1% benzoic acid, equivalent to 500 mg/kg body weight, as the maximum level and no harmful effects were observed on growth, fertility, lactation and life span. The post mortem examinations showed no abnormalities. Sodium benzoate also has been tested in human volunteers in early 1900's. The Referee Board of Consulting Scientific Experts of the U.S. Department of Agriculture concluded that sodium benzoate was "not injurious to health" even in large doses (up to 4,000 milligrams per day) mixed with the food (26, 27).

JECFA also reviewed the biochemistry of benzoic acid. It is rapidly absorbed, and rapidly and completely excreted in the urine. Accumulation into the body does not occur.

In addition, benzoates have been safely used in foods close to hundred years.

Intake of benzoic acid and its salts

Intake data show that the ADI is not exceeded even when using 1,000 ppm as a maximum limit for soft drinks. In 1998, JECFA evaluated intake data from nine countries and concluded that in none of these countries did the intake exceed the ADI, including the United States where the intake was calculated using the maximum use level of 1,000 ppm which is the legal limit (15). Since the JECFA evaluation, additional intake studies have been conducted in Brazil, Japan, Norway, and the U.S.

Examination of a new 14-day intake study conducted in the U.S. in 1999 shows that the ADI is still not exceeded over a 14-day period which JECFA states is indicative of long-term exposure (16). The maximum level used in the calculations was 1,000 ppm in soft drinks. Results of the intake surveys in Brazil (17) and Japan (18) also show that the ADI is not exceeded. The maximum permitted levels in soft drinks were 500 ppm in Brazil and 600 ppm in Japan. Careful examination of the intake study conducted in Norway in 1998 shows that the ADI is not being exceeded at the 95th percentile even when performing the calculations at levels of benzoate as high as 931 ppm, the highest level measured in a juice-containing soft drink (19).

Countries that permit the use of Benzoic Acid and its salts in soft drinks

Close to 50 countries in five Codex regions permit benzoic acid and its salts in soft drinks at levels of 1,000 ppm or greater (see Table 3). These include the United States, Canada and Mexico who are members of the North American Free Trade Agreement.

Conclusion

Benzoates have many of the properties of an ideal preservative. Its addition at a level inhibitory for many microorganisms does not or only slightly affect product flavor or taste. Use levels of benzoates vary depending on the beverage type, level of carbonation, taste characteristics, package type, and the inherent microbiological stability of a particular product. Different production environments, climatic conditions (temperate or tropical), access to heat processing and hot or aseptic filling, transportation conditions, and access to refrigeration also contribute to the need for varying use levels around the world. The use of benzoates is governed by GMPs regardless of the maximum permitted level, and only the amount necessary is used to preserve the product. Due to the above, GMPs may vary among countries.

The use of benzoates in soft drinks benefits the consumer and society in general (6). Using benzoates in beverages lengthens the shelf-life and minimizes unnecessary food losses caused by microbial contamination and growth. Also, the addition of preservatives like benzoates is required so that beverages can be transported safely over long distances making them available to a larger number of consumers (20). In many instances, processed beverages are the safest sources of liquids for people living in areas with lack of access to potable water. Use of benzoates and other preservatives also minimizes economic loss for the consumer and enhances convenience due to the reduced likelihood that the products will deteriorate and be discarded (6). Possible public health hazards and food losses also are minimized (6). Safe beverages can be offered at more affordable prices due to the cost-effectiveness of benzoates.

Thus, the use of benzoates protects beverage quality and minimizes possible public health hazards due to yeast, molds and bacteria. Its use is advantageous to the consumer and society for reasons of both safety and economy. Because of this, the use of benzoates in soft drink manufacture is technologically justified.

RECOMMENDATION

We recommend that CCFAC endorse the maximum use of benzoates at a level of 1,000 mg/kg in food category 14.1.4 (water-based flavored drinks, including “sports” and “electrolyte” drinks) for the following reasons:

a) Because intake data show that the ADI is not exceeded even at a maximum level of 1,000 ppm in soft drinks in highest consuming countries;

b) Because manufacturers should have flexibility in choosing formulations and ingredient levels that suit the technological requirements of a beverage medium when appropriate quality and safety rules are met; and

c) Because different production environments and climatic conditions require a greater need for benzoates; and

d) Because the use of benzoates, just like other food additives, is governed by Good Manufacturing Practices which means that the lowest levels will be used in every beverage to achieve the desired effect.

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Table 1: Antimicrobial Spectrum of Benzoic Acid Against Selected Bacteria, Yeasts, and Fungi (21-23)

Microorganisms	**pH**	**MIC (ppm)** [a]
Bacteria		
Escherichia coli	5.2-5.6	50-120
Lactobacillus sp.	4.3-6.0	300-1,800
Yeasts		
Sporogenic yeasts	2.6-4.5	20-200
Asporogenic yeasts	4.0-5.0	70-150
Debaryomyces hansenii	4.8	500
Pichia membranefaciens		700
Rhodotorula sp.		100-200
Saccharomyces bayanus	4.0	330
Torulopsis sp.		200-500
Zygosaccharomyces bailii	4.8	4,500
Zygosaccharomyces rouxii	4.8	1,000
Candida krusei		300-700
Fungi		
Aspergillus sp	3.0-5.0	20-300
Aspergillus niger	5.0	2,000
Byssochamys nivea	3.3	500
Penicillium sp.	2.6-5.0	30-280
Penicillium citrinum	5.0	2,000
Cladosporium herbarum	5.1	100
Mucor racemosus	5.0	30-120
Rhizopus nigricans	5.0	30-120

[a]Minimum inhibitory concentration in µg/ml (ppm)

Table 2: Minimum Inhibitory Concentrations of Benzoic Acid for Yeasts (21-23)

Isolate[b]	MIC (ppm)
Kloeckera apiculata	188
Saccharomyces cerevisiae	170-450
Zygosaccharomyces bailii	600-1,300
Hansenula anomala	223
Kluveromyces fragilis	173
Saccharomyces ludwigii	500-600

[b] Most were isolated from spoiled foods that had contained preservative.

Table 3: Countries that permit 1,000 ppm in soft drinks in various Codex regions (based on industry data)

Country	Maximum level of benzoic acid and its salts in water-based flavored beverages expressed as benzoic acid (mg/kg)	Comments
AFRICA		
Benin	1000	
Burkina Faso	1000	
Burundi	1000	
Cameroon	1000	
Cape Verdi	1000	
Central African Republic	1000	
Chad	1000	
Congo, Democratic Reupblic of	1000	
Congo, Republic of	1000	
Cote d'Ivoire	1000	
Equatorial Guinea	1000	
Gabon	1000	
Gambia	1000	
Guinea	1000	
Guinea Bissau	1000	
Kenya	1000	the unity principle applies
Liberia	1000	
Niger	1000	
Nigeria	1000	interim, the unity principle applies
Rwanda	1000	
Sierra Leone	1000	
Tanzania	1000	
Togo	1000	
Zambia	1000	the unity principle applies
ASIA		
China	1000 in juice-containing drinks	
Pakistan	1000	
Philippines	1000	the unity principle applies
Vietnam	1000	
LATIN-AMERICA AND THE CARIBBEAN		
Chile	1000	
Colombia	1000	
Dominican Republic	1000	
Ecuador	1000	
El Salvador	1000	
Guatemala	1000	
Honduras	1000	
Jamaica	1000	
Mexico	1000	

Nicaragua	1000	
Panama	1000	
Peru	GMP	
Trinidad and Tobago	1000	
NEAR EAST		
Bahrain	1000	
Saudi Arabia	1000	
Syria	1000	
Yemen	1000	
NORTH AMERICA		
Canada	1000	
U.S.A.	1000	

ISDI: (International Special Dietary Foods Industries)

Draft revisions to Table 1 of the Codex General Standard for Food Additives Answer to CL 2002/44

Additive usage already in member country legislation and/or Codex Standards

ISDI comments are based on provisions already existing in different legislations. ISDI has considered each additive one by one and only for the category 13 (dietetic products). Each request refers to a national legislation or to provisions adopted in Commodity Standards, which should be transferred into GSFA. The mentioned legislations are: Infant formula (CODEX STAN 72-1981), Follow-up formula (CODEX STAN 156-1987), Canned baby foods (CODEX STAN 73-1981), Processed cereal-based foods for infants and young children (CODEX STAN 74-1981), EU Directives 94/35/EC on sweeteners for use in foodstuffs, 94/36/EC on colours for use in foodstuffs, 95/2/EC on food additives other than colours and sweeteners and the US legislation.

Colours and sweeteners in foods for infants and young children

At Codex Committee on Nutrition and Food for Special Dietary Uses, a working group chaired by Switzerland, which ISDI is part of, is reviewing the additive provisions for infant formula and processed cereal-based foods. As agreed by **all** the members of the working group, there is no need for the use of colours and sweeteners in foods intended for infants and young children **in good health**. Therefore all colours and sweeteners should be deleted for categories 13.1 and 13.2.

On another hand ISDI requests some colours (INS 140, 160aii, 162 and 163ii) be authorised in FSMPs for the older infants & young children (individuals above one year of age) as their senses of taste and smell develop. Indeed, the mixture of amino acids, vitamin, mineral complex, unusual fats or fatty acids etc. give a non-attractive colour to the FSMP product. Furthermore, the link between visual appearance and taste is well known: if a product looks better the patient perceives that the product tastes better. Non compliance with the dietary regimen provided by these specialised foods may result in malnutrition, illness or rapid degeneration of the patient. FSMP manufacturers wish to add colours to these mixtures which would help dietary compliance.

For the same reasons, i.e. to improve dietary compliance, ISDI wishes that some sweeteners (INS 950, 951, 954, 955, 967) be allowed in FSMPs for the older infants & young children in order to mask the unpleasant taste of certain FSMPs mixtures in cases where additional sweetness from sugar is not appropriate because of:

Osmolality: the addition of sugar increases the osmolality of the product which is not desirable in products for patients known to be at risk of diarrhoea.

Volume: Sugar or other natural sweetening ingredients will greatly increase the bulk of a product and thus require much increased volumes of a product to be consumed to meet the dietary requirements. This may reduce patient compliance.

Effect: Natural sweeteners e.g. sugar, dried glucose syrup, maltodextrin on their own cannot mask the unpleasant and bitter taste of many synthetic ingredients such as amino acids.

Contraindications: the inclusion of high levels of sugars in products for young children is discouraged to avoid dental caries and may be contraindicated for some special diets e.g. energy-restricted.

Natural sweetening agents (e.g. sugar, glucose syrups) are used wherever possible, sweeteners are used only when absolutely necessary.

ISDI comments on Table 1 Additives of the General Standard for Food Additives
CL 2002/44-FAC Appendix I

Remark: all levels are expressed as mg of additive per kg of the product as consumed.

ACESULFAME POTASSIUM: INS 950

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	450		Agree, EU Directive	6
13.3.2	450		for infants over 1 year Opinion of the EU Scientific Committee for Food Mar. 2000	6
13.4	450		Agree, EU Directive	6
13.5	500 1000		Agree with 1000mg/kg EU Directive	6 3
13.6	2000		Agree, EU Directive	6

ACETIC ACID, GLACIAL: INS 260 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.2.	5000		REQUESTED at GMP EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	

ACETIC AND FATTY ACID ESTERS OF GLYCEROL: INS 472a (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.2	5000		Agree, EU Directive	6
13.3.2			REQUESTED at 5000mg/kg EU Directive	

ACETYLATED DISTARCH ADIPATE: INS 1422 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1.1	GMP		-	3
13.1.2	25000		Level in accordance with Codex Standard 156-1987 Singly or in combination in hydrolysed protein and/or amino acid acid-based follow-on formulae only Singly or in combination for soy based products	6
13.2	60000		Agree, Codex Stan 73-1981	6
13.3.2			REQUESTED at 60000mg/kg EU Directive	

ACETYLATED DISTARCH PHOSPHATE: INS 1414 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	25000		Agree Codex Stan 72-1981. Singly or in combination, 500mg/kg for soy based formulae only 2500mg/kg for hydrolysed protein and/or amino acid-based infant formulae only	6
13.2	60000		Agree, Codex Stand 73-1981	6
13.3.2			REQUESTED at 60000mg/kg	

ACID TREATED STARCH: INS 1401 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		-	3

AGAR: INS 406 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		-	6
13.2	GMP		-	6

ALGINIC ACID: INS 400 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1.1	300		-	6
13.2	5000		Agree, EU Directive:500 mg/kg	6
13.3.2			REQUESTED at 5000 mg/kg	

ALITAME: INS 956

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.5	300		-	6

ALKALIN TREATED STARCH: INS 1402 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		-	3

ALLURA RED AC: INS 129

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	50		Agree, EU Directive	6
13.4	50		Agree, EU Directive	6
13.5	300		-	6
13.6	300		Agree, EU Directive	6

ALPHA-AMYLASE (ASPERGILLUS ORYZAE): INS 1100 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		Not appropriate, should be in	6

			a separate list of processing aids	
13.2	GMP		Not appropriate, should be in a separate list of processing aids	6

AMMONIUM ALGINATE: INS 403 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	300		-	6
13.2	5000		-	6

AMMONIUM CARBONATE: INS 503i (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.2	GMP		Agree, Codex Stan 74-1991 & EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	

AMMONIUM HYDROGEN CARBONATE: INS 503ii (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.2	GMP		Agree, Codex Stan 74-1991 & EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	

ANNATTO EXTRACTS: INS 160b

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.6	GMP		-	6

ASCORBIC ACID: INS 300 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1.2	50		Agree, Codex Stand 156-1987	6
13.2	3000		REQUESTED at 500mg/kg Codex Stan 74-1991&73-1981	6
13.3.2			REQUESTED at 500 mg/kg	

ASCORBYL ESTERS: INS 304 and 305

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	50	As ascorbyl stearate	Remove Note, should include ascorbyl palmitate (INS 304)	Adopted
13.2	50	As ascorbyl stearate		Adopted
13.3.1	100	As ascorbyl stearate		Adopted
13.3.2	100	As ascorbyl stearate		Adopted
13.4	GMP	As ascorbyl stearate	Agree, EU Directive. Remove note	3
13.5	GMP	As ascorbyl stearate		3
13.6	500	As ascorbyl stearate	REQUESTED at GMP EU Directive. Remove note	6

ASPARTAME: INS 951

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3	800		REQUESTED at 1000mg/kg EU Directive, should be category 13.3.1	6
13.3.2	1000		Agree, for infants over 1 year	3
13.4	800 1000		Agree with 800, EU Directive	6 3
13.5	2000		Agree, EU Directive:1700mg/kg	6
13.6	5500		Agree, EU Directive	6

AZORUBINE: INS 122

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	50		Agree, EU Directive	6
13.4	50		Agree, EU Directive	6
13.5	300		Agree	6
13.6	300		Agree, EU Directive	6

BEESWAX, WHITE AND YELLOW: INS 901 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.6	GMP			Adopted

BEET RED: INS 162 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1			REQUESTED at GMP EU Directive	
13.3.2			REQUESTED at 20mg/kg for infants over one year Opinion of the EU Scientific Committee for Food Dec. 1996	
13.4			REQUESTED at GMP EU Directive	
13.5			REQUESTED at GMP EU Directive	
13.6			REQUESTED at GMP EU Directive	

BENZOATES: INS 210, 211, 212, 213

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	1500	As benzoic acid		Adopted
13.4	1500	As benzoic acid		Adopted
13.5	2000	As benzoic acid		Adopted
13.6	2000	As benzoic acid	Agree, EU Directive	8/5

BHA: Butylated Hydroxyanisole: INS 320

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.6	400		Agree, U Directive	6

BHT: Butylated Hydroxytoluene: INS 321

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.6	400		Agree, EU Directive	6

BLEACHED STARCH: INS 1403 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		-	3

BRILLIANT BLACK PN: INS 151

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	50		Agree, EU Directive	6
13.4	50		Agree, EU Directive	6
13.5	300		Agree	6
13.6	300		Agree, EU Directive	6

BRILLIANT BLUE FCF: INS 133

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	50		Agree, EU Directive	6
13.4	50		Agree, EU Directive	6
13.5	300		Agree	6
13.6	300		Agree, EU Directive	6

BROWN HT: INS 155

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	50		Agree, EU Directive	6
13.4	50		Agree, EU Directive	6
13.5	300		Agree	6
13.6	300		Agree, EU Directive	6

CALCIUM ACETATE: INS 263 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.2	GMP		Agree, EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	

CALCIUM ALGINATE: INS 404 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1.1	300		-	6
13.2	5000		Agree EU Directive: 500 mg/kg	6
13.3.2			REQUESTED at 5000 mg/kg EU Directive	

CALCIUM ASCORBATE: INS 302 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step

13.1.2	50		Agree, Codex Stand 156-1987	6
13.2	3000		Agree, Directive: 200 mg/kg	6
13.3.2			REQUESTED at 3000 mg/kg	

CALCIUM CARBONATE: INS 170i (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		-	6
13.2	GMP		Agree, Codex Standards 73-1981 & 74-1981& EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	

CALCIUM CITRATE: INS 333 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1.1	GMP		-	6
13.2	GMP		Agree, EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	

CALCIUM HYDROXIDE: INS 526 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		Agree, Codex Stand 72-1981 & 156-1987	6
13.2	GMP		Agree, EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	

CALCIUM LACTATE: INS 327 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.2	GMP		Agree, EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	

CANDELILLA WAX : INS 902

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.6	GMP			Adopted

CARAMEL COLOUR, CLASS III: 150c

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	GMP			Adopted
13.4	GMP			Adopted
13.5	GMP			Adopted
13.6	GMP			Adopted

CARAMEL COLOUR, CLASS IV: E150d

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	GMP			Adopted
13.4	GMP			Adopted
13.5	GMP			Adopted
13.6	GMP			Adopted

CARBON DIOXIDE: INS 290 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP	Use as packing gaz	Agree	3
13.2	GMP	Use as packing gaz	Agree	3

CARMINES: INS 120

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	50		Agree, EU Directive	6
13.4	50		Agree, EU Directive	6
13.5	300		-	6
13.6	300		Agree, EU Directive	6

CARNAUBA WAX: INS 9032

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.6	GMP			Adopted

CAROB BEAN GUM: INS 410 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1.1	2000		Agree, Codex Stan 72-1981: 1000 mg/kg	6
13.1.2	1000		Agree, EU Directive	6
13.2	20000		Agree, EU Directive	6
13.3.2			REQUESTED at 10000 mg/kg EU Directive	

CAROTENES, VEGETABLE : INS 160aii

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	GMP		Agree, EU Directive	6
13.3.2	30		Agree for infants over one year Opinion of the EU Scientific Committee for food Dec. 1996	3
13.4	GMP		Agree, EU Directive	6
13.5	GMP		Agree, EU Directive	6
13.6	GMP		Agree, EU Directive	6

CAROTENOIDS: INS 160ai, 160f, 160e

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	50		Agree, EU Directive	6

13.3.2	50		DELETION REQUESTED	6
13.4	50		Agree, EU Directive	6
13.5	300		Agree, EU Directive	6
13.6	300		Agree, EU Directive	6

CARRAGEENAN: INS 407 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1.1	3000		Agree, in US and Canadian Legislation	6
13.1.2	1000		Agree, Codex Stan 156-1987	6
13.2	GMP		-	6
13.3.2			REQUESTED at 300mg/kg EU Directive	

CASTOR OIL: INS 1503

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.6	GMP		-	6

CHLOROPHYLLS: INS 140 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.2			REQUESTED at 20mg/kg for infants over one year Opinion of the EU Scientific Committee for Food Dec 1996	

CHLOROPHYLLS, COPPER COMPLEXES: INS 141i, 141ii

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	GMP		Agree, EU Directive	6
13.3.2	GMP		DELETION REQUESTED	6
13.4	GMP		Agree, EU Directive	6
13.5	GMP		Agree, EU Directive	6
13.6	GMP		Agree, EU Directive	6

CITRIC ACID: INS 330 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		Agree, Codex Stand 72-1981 & 156-1987	6
13.2	25000		REQUESTED at GMP EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	6

CITRIC AND FATTY ACID ESTERS OF GLYCEROL: INS 472c (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	7500		Agree at 7500mg/kg for formulae sold as powder REQUESTED at 9000mg/l for	3

			formulae soled as liquid , when contains partially hydrolysed proteins, peptides, or amino acids EU Directive	
13.2	5000		Agree, EU Directive	6
13.3.2			REQUESTED at 7500mg/kg for formulae sold as powder REQUESTED at 9000mg/l for formulae sold as liquid Pending amendment of EU Directive (SCF Opinion Sept 2002)	

CURCUMIN: INS 100i

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	50		Agree, EU Directive	6
13.4	50		Agree, EU Directive	6
13.5	300		-	6
13.6	300		Agree, EU Directive	6

CYCLAMATES: INS 952

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3	1300 1600	As cyclamic acid	DELETION REQUESTED	6 3
13.3.1	1600 1300	As cyclamic acid	Requested at 400mg/kg EU Directive	6 3
13.3.2	1600 1300	As cyclamic acid	DELETION REQUESTED	6 3
13.4	1300		EU Directive: 400mg/kg	6
13.5	1300		REQUESTED at 16000 mg/kg EU Directive	6
13.6	1250		EU Directive: 500mg/kg	6

DEXTRINS, WHITE AND YELLOW , ROASTED STARCH: INS 1400 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		-	3

DELTA-TOCOPHEROLS: INS 309

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1			REQUESTED at 10mg/kg EU Directive	
13.2			REQUESTED at 100mg/kg EU Directive	
13.3.1			REQUESTED at GMP EU Directive	
13.3.2			REQUESTED at 100mg/kg EU Directive	
13.4			REQUESTED at GMP EU Directive	

13.5			REQUESTED at GMP EU Directive	
13.6			REQUESTED at GMP EU Directive	

DIACETYLTARTARIC AND FATTY ACID ESTERS OF GLYCEROL: INS 472e

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		Agree, affirmed GRAS status in USA	6
13.3.1	GMP		Agree, EU Directive	6
13.3.2			REQUESTED at GMP affirmed GRAS status in USA	
13.4	GMP		Agree, EU Directive	6
13.5	GMP		Agree, EU Directive	6
13.6	GMP		Agree, EU Directive	6

DISTARCH PHOSPHATE: INS 1412 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	25000		Agree Codex Stan 72-1981: 500mg/kg for soy based formulae 2500mg/kg for hydrolysed protein and/or amino acid-based infant formulae only	6
13.2	60000		Agree, Codex Stan 73-1981	6
13.3.2			REQUESTED at 60000mg/kg	

EDTA'S: INS 385, 386

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.6	150			Adopted

ENZYME TREATED STARCH: INS 1405 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		-	3

ERYTHROSINE: INS 127

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.6	300		-	6

FAST GREEN FCF: INS 143

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.6	GMP		-	6

GALLATE, PROPYL: INS 310

Cat	Levels (mg/kg)	Note	ISDI comment	Step

13.6	150			Adopted

GAMMA-TOCOPHEROLS: INS 308

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1			REQUESTED at 10mg/kg EU Directive	
13.2			REQUESTED at 100mg/kg EU Directive	
13.3.1			REQUESTED at GMP EU Directive	
13.3.2			REQUESTED at 100mg/kg EU Directive	
13.4			REQUESTED at GMP EU Directive	
13.5			REQUESTED at GMP EU Directive	
13.6			REQUESTED at GMP EU Directive	

GELLAN GUM: INS 418 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		-	6
13.2	GMP		-	6

GLUCONO DELTA-LACTONE: INS 575 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.2	5000		Agree, EU Directive	3
13.3.2			REQUESTED at 5000mg/kg EU Directive	

GRAPE SKIN EXTRACT: INS 163ii

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	GMP		Agree, EU Directive	6
13.3.2			REQUESTED at 20mg/kg for infants over one year Opinion of the EU Scientific Committee for Food December 1996	
13.4	GMP		Agree, EU Directive	6
13.5	GMP		Agree, EU Directive	6
13.6	GMP		Agree, EU Directive	6

GUAR GUM: INS 412 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	1000	For use in special formula at 10000 mg/kg	Agree, EU Directive Remove note see 13.3.2	6
13.2	20000		Agree, EU Directive	6
13.3.2			REQUESTED at 10000 mg/kg EU Directive	

GUM ARABIC: INS 414 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	10000	Carry over from nutrient preparations	Agree, EU Directive: 10 mg/kg	6
13.2	20000		Agree, EU Directive Gluten free cereal-based foods	6
13.3.2			REQUESTED at 20000 mg/kg EU Directive	

HYDROCHLORIC ACID: INS 507 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.2	GMP		Agree, EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	

HYDROXYBENZOATES,p-: INS 214, 216, 218

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.6	2000	As p-hydroxybenzoic acid	Agree, EU Directive	3

HYDROXYPROPYL DISTARCH PHOSPHAT: INS 1442 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		-	3

HYDROXYPROPYL STARCH: INS 1440 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1.1	25000		Agree, Codex Stan 72-1981. In hydrolysed protein and/or amino acid acid-based infant formulae	6
13.1	GMP		-	3
13.2	60000		Agree, Codex Stan 73-1981	6
13.3.2			REQUESTED at 60000 mg/kg	

INDIGOTINE: INS 132

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	50		Agree, EU Directive	6
13.4	50		Agree, EU Directive	6
13.5	300		-	6
13.6	300		Agree, EU Directive	6

IRON OXIDES: INS 172i, 172ii, 172iii

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	GMP		Agree, EU Directive	6
13.4	GMP		Agree, EU Directive	6
13.5	GMP		-	6
13.6	GMP		Agree, EU Directive	6

ISOMALT: INS 953 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		DELETION REQUESTED	6
13.1	100 000		DELETION REQUESTED	3
13.2	GMP		DELETION REQUESTED	6
13.2	100 000		DELETION REQUESTED	3

KARAYA GUM: INS 416 (in Table 3))

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		-	6
13.2	GMP		-	6

KONJAC FLOUR: INS 425 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		-	6
13.2	GMP		-	6

LACTIC ACID (L-, D-and DL-): INS 270 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		Agree , Codex Stan 72-1981& EU Directive Form L(+) only	6
13.2	15000		REQUESTED at GMP Form L(+) only, EU Directive	6
13.3.2			REQUESTED at GMP Form L(+) only, EU Directive	

LACTIC AND FATTY ACID ESTERS OF GLYCEROL: INS 472b (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.2	5000		Agree, EU Directive	6
13.3.2			REQUESTED at 5000 mg/kg EU Directive	

LACTITOL: INS 966 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		DELETION REQUESTED	6
13.2	GMP		DELETION REQUESTED	6

LECITHIN: INS 322 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	5000		Agree Codex Stan 72-1981 & 156-	6

			1987	
13.2	15000		Agree, Codex Stan 74-1981	6
13.3.2			REQUESTED at 15000 mg/kg	

MAGNESIUM CARBONATE: INS 504i (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.2	GMP		-	6

MAGNESIUM CHLORIDE: INS 511 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1.1	GMP		-	6

MAGNESIUM OXIDE: INS 530 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		-	6

MALIC ACID (DL-): INS 296 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.2	GMP		Agree EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	

MALTITOL AND MALTITOL SYRUP: INS 965 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		DELETION REQUESTED	6
13.2	GMP		DELETION REQUESTED	6

MANNITOL: INS 421 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		Agree, EU Directive As a carrier for Vitamin B12 B12/mannitol=1000	6
13.2	GMP		Agree, EU Directive As a carrier of Vitamin B12 B12/mannitol=1000	6
13.3.2			REQUESTED As a carrier of Vitamin B12 B12/mannitol=1000	

MICROCRYSTALLINE CELLULOSE: INS 460i (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		-	6
13.2	GMP		-	6

MINERAL OIL: INS 905a

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.6	6000		-	6

MONO-AND DIGLYCERIDES: INS 471 (In Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	5000		REQUESTED at 4000 mg/kg, EU Directive	6
13.2	15000		Agree, Codex Stan74-1981	6
13.3.2			REQUESTED at 5000 mg/kg EU Directive	

MONOSTARCH PHOSPHATE: INS 1410 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		-	3
13.2	50000		Agree, EU Directive	6
13.3.2			REQUESTED at 50000 mg/kg EU Directive	

NITROGEN: INS 941 (Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP	Use as packing gas	Agree	3
13.2	GMP	Use as packing gas	Agree	3

NITROUS OXIDE: INS 942 (Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		-	6
13.2	GMP		-	6

OXIDIZED STARCH : INS 1404 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		-	3
13.2	50000		Agree, EU Directive	6
13.3.2			REQUESTED at 50000 mg/kg EU Directive	

OXYSTEARIN: INS 387

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.6	GMP		-	6

PECTINS (AMIDATED AND NON-AMIDATED): INS 440 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	10000		Agree, EU Directive	6
13.2	20000		Agree, EU Directive	6
13.3.2			REQUESTED at 10000 g/kg EU Directive	

PHOSPHATED DISTARCH PHOSPHATE : INS 1413 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1.1	60000		Codex Stan 72-1981: 500mg/kg for soy based formulae only 2500mg/kg for hydrolysed protein and/or amino acid-based infant formulae only	6
13.1.2	25000		Agree Codex Stan 156-1987 for hydrolysed protein and/or amino acid-based infant formulae only	6
13.2	60000		Agree Codex Stan 73-1981 – EU Directive:50000 mg/kg	6
13.3.2			REQUESTED at 60000 mg/kg	

PHOSPHATES: INS 338, 339i, 339ii, 339iii, 340i, 340ii, 340iii, 341i, 341ii, 341iii, 342i, 342ii, 343ii, 343iii, 450i, 450iii, 450v, 450vi, 451i, 451ii, 452i, 452ii, 452iv, 452v, 542

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.0	2200		DELETION REQUESTED	6
13.1	2200	As phosphorus	REQUESTED at GMP EU Directive In conformity with the limits set for P in composition criteria	6
13.2	2200	As phosphorus	Agree, EU Directive	6
13.3.1	2200	As phosphorus	REQUESTED at 5000mg/kg EU Directive	6
13.3.2	2200	As phosphorus	REQUESTED at GMP EU Directive	6
13.4	2200	As phosphorus	REQUESTED at 5000mg/kg EU Directive	6
13.5	2200	As phosphorus	-	6
13.6	2200	As phosphorus	REQUESTED at GMP EU Directive	6

POLYDIMETHYLSILOXANE: INS 900a

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.0	50		DELETION REQUESTED for 13.1 and 13.2 and 13.2.2	6

POLYGLYCEROL ESTERS OF FATTY ACIDS : INS 475

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	5000		Agree, EU Directive	6
13.4	5000		Agree, EU Directive	6
13.6	GMP		Agree, EU Directive	6

POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID: INS 476

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3	5000		-	6
13.4	5000		-	6

POLYSORBATES: INS 432, 433, 434, 435, 436

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	1000		Agree, EU Directive	6
13.4	1000		Agree, EU Directive	6
13.5	360mg/dose		-	6
13.6	790	Level based on the maximum recommended daily dose of 475 mg/dose, assuming one 600 mg tablet is consumed per day	REQUESTED at GMP EU Directive	6

POLYVINYLPYRRODIDONE: INS 1201

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.6	GMP			Adopted

PONCEAU 4R: INS 124

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	50		Agree, EU Directive	6
13.3.2	50		DELETION REQUESTED	6
13.4	50		Agree, EU Directive	6
13.5	300		-	6
13.6	300		Agree, EU Directive	6

POTASSIUM ACETATE: INS 261 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.2	GMP		Agree, EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	

POTASSIUM ALGINATE: INS 402 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1.1	300		-	6
13.2	5000		Agree, EU Directive: 500mg/kg	6
13.3.2			REQUESTED at 500 mg/kg EU Directive	

POTASSIUM ASCORBATE: INS 303 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1.2	50		-	6
13.2	500	As the acid	Agree, Codex Stan 72-1981	6

POTASSIUM CARBONATE: INS 501i (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		Agree, Codex Stan 72-1981&156-1978	6
13.2	GMP		Agree, Codex Stan 73-1981 & EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	

POTASSIUM CHLORIDE: INS 508 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1.1	GMP		-	6

POTASSIUM DIHYDROGEN CITRATE: INS 332i (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		REQUESTED at 2 mg/kg, EU Directive	6
13.2	GMP		Agree, EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	

POTASSIUM HYDROGEN CARBONATE: INS 501ii (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		Agree, Codex Stand 72-1981&156-1987 & EU Directive	6
13.2	GMP		Agree, Codex Stan 74-1981&73-1981	6
13.3.2			REQUESTED at GMP EU Directive	

POTASSIUM HYDROXIDE: INS 525 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		Agree, Codex Stan 72-1981&156-1987	6
13.2	GMP		Agree, EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	

POTASSIUM LACTATE: INS 326 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.2	GMP		Agree, EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	

POWDERED CELLULOSE: INS 460ii (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		-	6
13.2	GMP		-	6

PROCESSED EUCHEUMA SEAWEED: INS 407a (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	1000		-	6
13.2	GMP		-	3

PROPYLENE GLYCOL: INS 1520

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.6	2000		REQUESTED at GMP US legislation	3

PROPYLENE GLYCOL ALGINATE: INS 405

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP	Except for use in special formula at 200 mg/kg	DELETION REQUESTED	3
13.2	GMP		DELETION REQUESTED	3
13.3.1	1200		Agree, EU Directive	6
13.3.2	200		Agree, EU Directive	6
13.4	1200		Agree, EU Directive	6
13.6	1000		Agree, EU Directive	6

PROPYLENE GLYCOL ESTERS OF FATTY ACIDS: INS 477

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	5000			Adopted
13.4	5000			Adopted

QUINOLINE YELLOW: INS 104

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	50		Agree, EU Directive	6
13.4	50		Agree, EU Directive	6
13.5	300		Agree	6
13.6	300		Agree, EU Directive	6

RIBOFLAVINES: INS 101i, 101ii

Cat	Levels (mg/kg)	Note	ISDI comment	Step

13.3.1	GMP		Agree, EU Directive	6
13.4	GMP		Agree, EU Directive	6
13.5	GMP		Agree	6
13.6	GMP		Agree, EU Directive	6

SACCHARIN: INS 954

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	300		Agree, EU Directive: 200mg/kg	6
13.3.2	300		REQUESTED at 200 mg/kg for infants over 1 year Opinion of the EU Scientific Committee for Food June 1995	6
13.4	300		Agree, EU Directive: 240mg/kg	6
13.5	500		Agree, EU Directive: 170 mg/kg	6
13.6	1200		Agree, EU Directive	6

SHELLAC: INS 904

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.6	GMP	Surface treatment		Adopted

SILICON DIOXIDE (AMORPHOUS): INS 551 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	10000	Carryover from nutrient preparations	Agree, EU Directive	6
13.2	10000	Idem	Agree, EU Directive	6
13.3.2		idem	REQUESTED at 10000 mg/kg	6

SODIUM ACETATE: INS 262i (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.2	GMP		Agree, EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	

SODIUM ALGINATE: INS 401 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1.1	1000	For use in special formula only	Delete, see below 13.3.2	3
13.1	300		-	6
13.2	5000		EU Directive: 500 mg/kg	6
13.3.2			REQUESTED at 1000mg/kg EU Directive	

SODIUM ASCORBATE: INS 301 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1		Carryover from nutrient preparations	REQUESTED at 75 mg/kg EU Directive-	
13.1.2	50	Carryover from nutrient preparations	REQUESTED at 75 mg/kg EU Directive-	6
13.2	3000		REQUESTED at 500 mg/kg Codex Stan 74-1981	6
13.3.2			REQUESTED at 3000 mg/kg	

SODIUM CARBONATE: INS 500i (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		Agree, Codex Stan 72-1981 & 156-1987	6
13.2	GMP		Agree, Codex Stan 73-1981 & EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	

SODIUM CARBOXYMETHYL CELLULOSE: INS 466 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP	For use in special formula at 10000mg/kg	DELETION REQUESTED	3
13.2	GMP		DELETION REQUESTED	3
13.3.2			REQUESTED at 10000 mg/kg EU Directive	

SODIUM DIACETATE: INS 262ii

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.2	GMP		Agree, EU Directive	6

SODIUM DIHYDROGEN CITRATE: INS 331i (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		REQUESTED at 2mg/kg, EU Directivee	6
13.1	2000		Agree	3
13.2	GMP		Agree, EU Directive	6
13.2	5000		Requested at GMP	3
13.3.2			REQUESTED at GMP EU Directive	

SODIUM HYDROGEN CARBONATE: INS 500ii (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		Agree, Codex Stan 72-1981&156-1987	6
13.2	GMP		Agree, Codex Stan 73-1981&74-1981 & EU Directive	6
13.3.2			REQUESTED at GMP	

			EU Directive	

SODIUM HYDROXIDE: INS 524 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		Agree, Codex Stan 72-1981&156-1987	6
13.2	GMP		Agree, EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	

SODIUM LACTATE: INS 325 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	
13.2	GMP		Agree, EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	

SORBATES: INS 200, 201, 202, 203

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	1500	As sorbic acid	Agree, EU Directive	6
13.4	1500	As sorbic acid	Agree, EU Directive	6
13.5	2000	As sorbic acid	-	6
13.6	2000	As sorbic acid	Agree, EU Directive	6

SORBITAN ESTERS OF FATTY ACIDS: INS 491, 492, 493, 494, 495

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	5000		Agree, EU Directive	6
13.4	5000		Agree, EU Directive	6
13.5	GMP		-	6
13.6	GMP		Agree, EU Directive	6

SORBITOL (INCLUDING SORBITOL SYRUP): INS 420 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		DELETION REQUESTED	6
13.2	GMP		DELETION REQUESTED	6

STARCH ACETATE: INS 1420, 1421 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		-	3
13.2	50000		Agree, EU Directive	6
13.3.2			REQUESTED at 50000 mg/kg EU Directive	

STARCH SODIUM OCTENYL SUCCINATE: INS 1450 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP	Except for use in special formula at 20,000mmg/kg	-	3
13.2	50000		Agree, EU Directive	6

13.3.2			REQUESTED at 20000 mg/kg EU Directive	

STEAROYL-2-LACTYLATES: INS 481i, 482i

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	2000		Agree, EU Directive	6
13.4	2000		Agree, EU Directive	6

SUCRALOSE: INS 955

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	400		Agree, EU Directives	6
13.3.2	400		Agree, for infants over 1 year Opinion of the EU Scientific Committee for Food Sept. 2000	6
13.4	1250		Agree, US legislation	6
13.5	800		Agree, EU Directives	6
13.6	2400		Agree, EU Directives	3

SUCROGLYCERIDES: INS 474

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	5000		Agree, EU Directive6	6
13.4	5000		Agree, EU Directive	6
13.6	GMP		Agree, EU Directive	6

SUCROSE ESTERS OF FATTY ACIDS: INS 473

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	5000		EU Directive: 120mg/kg	6
13.2	5000		-	6
13.3.1	5000		Agree, EU Directive	6
13.3.2	5000		-	6
13.4	5000		Agree, EU Directive	6
13.6	GMP		Agree, EU Directive	6

SUNSET YELLOW FCF: INS 110

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	50		Agree, EU Directive	6
13.4	50		Agree, EU Directive	6
13.5	300		Agree	6
13.6	300		Agree, EU Directive	6

TARA GUM: INS 417 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	1000		-	6
13.2	GMP		-	6

TARTRATES: INS 334, 335i, 335ii, 336i, 336ii, 337

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.2	5000	As tartaric acid	Agree, EU Directive	6
13.3.1	GMP	As tartaric acid	Agree, EU Directive	3
13.3.2	GMP	As tartaric acid	REQUESTED at 5000 mg/kg EU Directive	3
13.4	GMP	As tartaric acid	Agree, EU Directive	3
13.6	GMP	As tartaric acid	Agree, EU Directive	3

TARTRAZINE: INS 102

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.3.1	50		Agree, EU Directive	6
13.4	50		Agree, EU Directive	6
13.5	300		-	6
13.6	300		Agree, EU Directive	6

THAUMATIN: INS 957

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.2	GMP		DELETION REQUESTED	3

TOCOPHEROLS: INS 306, 307

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	30		REQUESTED at 10 mg/kg, Codex Stand 156-1987&EU Directive	6
13.2	1000		Requested at 100 mg/kg, Codex Stand 73-1981 and EU Directive	6
13.3.1			REQUESTED at GMP EU Directive	
13.3.2	1000		REQUESTED at 100 mg/kg, EU Directive	6
13.4	GMP		Agree, EU Directive	3
13.5	GMP		Agree, EU Directive	3
13.6	GMP		Agree, EU Directive	3

TRIPOTASSIUM CITRATE: INS 332ii (Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step

13.1	GMP		REQUESTED at 2 mg/kg EU Directive	6
13.2	GMP		Agree, EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	

TRISODIUM CITRATE: INS 331iii (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		Agree, Codex Stan 72-1981&156-1987	6
13.2	5000		REQUESTED at GMP EU Directive	6
13.3.2			REQUESTED at GMP EU Directive	

XANTHAN GUM: INS 415 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP	Except for special formula at 1200 mg/kg	Remove note, see 13.3.2	6
13.2	20000		Agree, EU Directive	6
13.3.2			REQUESTED at 1200 mg/kg EU Directive	

XYLITOL: INS 967 (in Table 3)

Cat	Levels (mg/kg)	Note	ISDI comment	Step
13.1	GMP		DELETION REQUESTED	6
13.2	GMP		DELETION REQUESTED	6
13.3.2			REQUESTED at 20000 mg/kg for infants over one year	

CEFIC:

Cat. 11.6. All sweeteners used in tabletop products should be regulated at GMP

Reasons for this request:
a. sweeteners are particularly self-limiting in this application;
b. table-top sweeteners being sold to the ultimate consumers, it is the latter who determine the amount actually consumed; additionally "use levels" refer to the *food as consumed* ***and table-top sweeteners are only consumed in conjunction with another food (coffee etc.) and as the use level is at discretion of the final user, it does not make sense to define numerical use levels in table-top formulations.***
c. among the existing ***real*** *intake data (see Renwick A. "Intake of sweeteners") there is no evidence of exceeding the ADI.*

1. **Maximum Levels**

In response to your request for data that can be used to establish maximum use levels for food additives having a numerical ADI which are listed in the GFSA for use at GMP, we are listing proposed maximum levels for acesulfame K.

Acesulfame K 950

Not all changes proposed by the ISA in former submissions were incorporated into the current Draft GSFA, including some proposals for replacement of "GMP" by numerical levels. These are listed again below.

Evaluation of listed use levels for acesulfame K showed that they sometimes exceed the case of need. Therefore we propose levels reflecting the case of need as demonstrated in practical applications. This applies especially for several product categories for which "GMP" is listed.

For milk and cream powders and their analogues the present listing does not fully reflect existing national authorizations. The more general category proposed with replacement for "GMP" by a numerical level.

The following changes are proposed:

01.2 Fermented and renneted milk products... 500mg/kg
01.3.2 Beverage whiteners' 2.000 mg/kg liquid/10.000 mg/kg dry
01.4 Cream... 1.000mg/kg
01.5.1 It is proposed to replace this listing by
01.5 Milk powder and cream powder and powder analogues (plain)
3.000 mg/kg
National approvals in several countries include analogues and blended products (e.g. USA: "dry bases for dairy product analogues, GMP, 21cfr § 172.800) or include these in more general approvals for food use

01.6.1 UnripeNed cheese) 500 mg/kg
02.3 Fats emulsion... 1.000 mg/kg
04.1.2.10 Fermented fruit products 500 mg/kg
04.2.2.7 Fermented vegetable… 500 mg/kg
07.1 Bread.. 1.000 mg/kg
09.4 Fully preserved… fish... 600 mg/kg
12.2 Herbs, spices, seasonings 2.000 mg/kg
12.3 Vinegars 2.000 mg/kg
14.1.5 Coffee…600mg/kg ready-to-drink/3.500 mg/kg concentrates

14.2.1, 14.2.2, 14.2.3, 14.2.4, 14.2.5, 14.2.6.1 and 14.2.6.2 ***Alcoholic beverages: It is proposed to simplify the standard and to use one only category***

14.2 Alcoholic beverages ***350 mg/kg***

Should a dual listing as proposed not be considered feasible we propose listing of the lower value and clarification by respective footnotes, e.g. for Acesulfame K to 01.3.2: "except10.000 mg/kg for use in powdered products" and to 14.1.5: "except 3.500 mg/kg for use in concentrates" or "for products from concentrates when diluted to instruction".

IBFAN:

Appendix II

p. 26 we support that infant formulae and follow-on formulae have been stroke out.
p.17 We question the need for vegetable carotenes as coloring agent (p.17) in dietetic foods for special medical purposes intended for infants and young children – we request to strike them out for infants with special medical needs as they are not allowed for healthy children
p.23 We question the need for chlorophyll's, copper complexes as coloring agents in dietetic foods for special medical purposes intended for infants and young children – we request to strike them out for infants with special medical needs as they are not allowed for healthy children
As infants and young children needing special medical food should at least have the same reduced contact to food additives as "normal" children, colors should not be used to mislead the parents on the content of the product

General comments

Additives in infant formulae, follow-on formulae, and weaning foods

Infant formulae, follow-on formulae, and weaning foods are full-meal foodstuffs in the sense that they can constitute most if not all the nutrition provided to an infant not being breastfeed or only partially breastfeed. For this reason it is imperative that this food only contains additives that are indispensable and they should only be authorized in the minimal amounts necessary to obtain the desired effect.
IBFAN does not support the use of coloring agents or sweeteners in infant formulae, follow-on formulae and complementary foods **nor in food for special medical purposes for infants and young children,** if this category is maintained, as this infants and young children need as a result of their special medical situation to be even brought less in contact with food additives, colors or artificial sweeteners.

OFCA: (organization des fabricants de produits cellulosiques alimentaires)

OFCA, the "Organisation des Fabricants de produits Cellulosiques Alimentaires" represents the manufacturers of food grade cellulose derivatives in the European Union. OFCA has a recognised NGO status for the meetings of the Codex Committee on Food Additives and Contaminants.

With reference to the allocation of an ADI "not specified" for INS 468, croslinked sodium carboxymethyl cellulose (attachment 1) it has become opportune to include INS 468 in the Draft General Standard for Food Additives (GSFA). This product is applied (EU, USA) as desintegrant.

OFCA would like to request you to include INS 468 in Table 3 to the Draft GSFA. with the objective to recognise the use of this additive.

If needed OFCA will be at your disposal for further clarification during the next working group meeting during the 35th CCFAC Meeting in Arusha, Tanzania.