

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
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ORGANIZATION



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Agenda Item 7 (d)

CX/FAC 04/36/9

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-sixth Session

Rotterdam, The Netherlands, 22 -26 March 2004

PROPOSED DRAFT AND DRAFT REVISIONS TO TABLE 1 OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES

COMMENTS AT STEPS 3 AND 6

The following comments have been received from: Australia, Brazil, El Salvador, Italy, Spain, European Community, IFAC, IFU, IPPA, ISDC, ISDI, and OIV
in response to CL 2003/34-FAC

AUSTRALIA:

Comment 1:

Australia makes the following comments on the request: CL 2003/34-FAC - REMINDER to CL 2003/13-FAC Part B - Request for Comments and Information: Draft (Step 6) and Proposed Draft (Step 3) Revisions to the Codex General Standard for Food Additives (GSFA) (ALINORM 03/12-App. III and CL 2002/44-FAC).

The 34th Session of the CCFAC agreed to hold food additive provisions with specific numeric levels at steps 3 and 6 and to request additional information, including technological need and justification for their use at the 35th Session. The Committee noted the absence of the data required to implement revisions to Table 1 of the Standard, and decided to request additional comments on CL 2002/44-FAC by circular letter for further consideration at its 36th Session.

Australia commented on this item previously for the 34th Session. Furthermore, Australia is fully supportive of the measures and decisions taken by the Committee at the 35th Session to resolve some of the more contentious issues in relation to additive permissions and levels in the GSFA. In this regard we support the re-installation of the Quality Control Group with expanded responsibilities to examine technical justification and make recommendations for maximum levels of use in the GSFA (list of priority additives already sent to QC group members - USA, Australia, Morocco, South Africa, Tanzania, Thailand and EC). The work of this group should largely cover previous requests for information on Group IV and V food additives listed in revised Table 1 of the draft GSFA (Appendix I). Australia has prepared a summary of permissions in Australia and New Zealand to help facilitate this work.

Australia also supported the establishment of and is a member of a Working Group to review the Preamble to the GSFA, develop an accompanying document for the GSFA to describe technical procedures used by CCFAC in development of the GSFA and review policy for selecting maximum levels of use for inclusion in the GSFA. Australia would like to reiterate the following general comments:

1. Australia attempts to minimise the use of food additives to as low a level as possible, taking into account safe levels of use and technological necessity to perform a technological function in the final food. Differences exist in the food patterns, taste and colour preferences of individual countries, and production processes and storage conditions employed around the world, and these differences must be taken into account when evaluating the technological justification for food additives in the GSFA.
2. Accordingly, Australia continues to support the adoption of the highest reported safe use level of each additive as the maximum use level within the food category described, noting that maximum levels are by definition safe use levels and should not exceed the ADI (upper bound of safe use). Adoption of this approach will ensure that maximum levels for additives are reasonably achievable for the majority of member countries, continue to promote innovation in the food industry and facilitate international trade.
3. Australia continues to support the reporting by a Member State of the use of an additive as *prima facie* evidence of the technological need for the use of an additive. Australia continues to support the two-member country rule to indicate that a food additive is traded internationally.
4. Australia does not support the proposal to amend section 1.1 of the Preamble to include a reference to "additives considered to be technologically necessary or which are widely permitted for use in food" as set out in the Procedural Manual (page 84, 12th ed.). The term "widely permitted" is vague and not defined.
5. Australia supports the recommendation to revise the Preamble of the GSFA to clarify the relationship between the food additive provisions in the GSFA and in the Codex Commodity Standards. Australia continues to support the agreed upon policy of moving away from vertical (recipe based) standards which establish restrictive positive lists and have been shown to be largely ineffective, in favour of horizontal, less prescriptive and inclusive standards.
6. Australia believes that the terms "technological need" and "technological justification" are used interchangeably in comments on the GSFA that leads to confusion, especially in relation to the roles of Codex Commodity Committees and CCFAC. Some consideration should be given by the Committee to defining what is meant by "technological need" and "technological justification".
7. Australia believes that the GSFA takes into account that additives are used in standardised and/or non-standardised foods and that once complete it will be inclusive and provide users with an up to date synopsis reflective of all food uses.

Comment 2:

Australia proposes new entries into Tables 1 and 2 of the GSFA for the flavour enhancer and sweetener neotame. The proposed use levels for neotame are listed for Tables 1 and 2 of the GSFA in the attached document and reflect the levels necessary for the additive to perform its specified technological function in the foods for which it is proposed.

It should also be noted that some levels proposed for neotame are at GMP and this is consistent with the policy agreed to at the 35th CCFAC for some additives with numerical ADIs on a case-by-case basis.

PROPOSED USE LEVELS

NEOTAME

Neotame INS: 961

Function: Flavor Enhancer, Sweetener

Food Cat. No.	Food Category	Max Level	Comments
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	20 mg/kg	
01.2	Fermented and renneted milk products (plain), excluding food category 01.1.2 (dairy-based drinks)	65 mg/kg	
01.3.2	Beverage whiteners	GMP	
01.4.1	Pasteurized cream	GMP	
01.4.2	Sterilized, UHT, whipping or whipped creams, and reduced fat creams	GMP	
01.4.3	Clotted cream	GMP	
01.4.4	Cream analogues	33 mg/kg	
01.5.1	Milk powder and cream powder (plain)	GMP	
01.5.2	Milk and cream powder analogues	65 mg/kg	
01.6.1	Unripened cheese	33 mg/kg	
01.6.5	Cheese analogues	33 mg/kg	
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	100 mg/kg	
02.3	Fat emulsions other than food category 02.2, including mixed and/or flavoured products based on fat emulsions	10 mg/kg	
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	100 mg/kg	
03.0	Edible ices, including sherbet and sorbet	100 mg/kg	
04.1.2.1	Frozen fruit	100 mg/kg	
04.1.2.2	Dried fruit	100 mg/kg	
04.1.2.3	Fruit in vinegar, oil, or brine	10 mg/kg	
04.1.2.4	Canned or bottled (pasteurized) fruit	33 mg/kg	
04.1.2.5	Jams, jellies and marmalades	33 mg/kg	
04.1.2.6	Fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	65 mg/kg	
04.1.2.7	Candied fruit	65 mg/kg	
04.1.2.8	Fruit preparations, including pulp, purees, fruit toppings and coconut milk	100 mg/kg	
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	100 mg/kg	
04.1.2.10	Fermented fruit products	65 mg/kg	
04.1.2.11	Fruit fillings for pastries	100 mg/kg	
04.1.2.12	Cooked or fried fruit	65 mg/kg	

Food Cat. No.	Food Category	Max Level	Comments
04.2.2.1	Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes [(including soybeans)], and aloe vera), seaweeds, and nuts and seeds	33 mg/kg	
04.2.2.2	Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes [(including soybeans)], and aloe vera), seaweeds, and nuts and seeds	33 mg/kg	
04.2.2.3	Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes [(including soybeans)], and aloe vera) and seaweeds in vinegar, oil, brine, or soy sauce	10 mg/kg	
04.2.2.4	Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes [(including soybeans)], and aloe vera), and seaweeds	33 mg/kg	
04.2.2.5	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes [(including soybeans)], and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)	33 mg/kg	
04.2.2.6	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes [(including soybeans)], and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5	33 mg/kg	
04.2.2.7	Fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes [(including soybeans)], and aloe vera), and seaweed products	33 mg/kg	
04.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes [(including soybeans)], and aloe vera), and seaweeds	33 mg/kg	
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	100 mg/kg	
05.1.2	Cocoa mixes (syrups)	33 mg/kg	
05.1.3	Cocoa-based spreads, including fillings	100 mg/kg	
05.1.4	Cocoa and chocolate products	80 mg/kg	
05.1.5	Imitation chocolate, chocolate substitute products	100 mg/kg	
05.2	Confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	330 mg/kg	
05.3	Chewing gum	330 mg/kg	
05.4	Decorations (e.g., for fine bakery wares), toppings (nonfruit) and sweet sauces	33 mg/kg	
06.3	Breakfast cereals, including rolled oats	80 mg/kg	
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	33 mg/kg	
07.1	Bread and ordinary bakery wares	70 mg/kg	
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	80 mg/kg	
08.2	Processed meat, poultry, and game products in whole pieces or cuts	10 mg/kg	
08.3	Processed comminuted meat, poultry, and game products	10 mg/kg	
09.2	Processed fish and fish products, including mollusks, crustaceans, and echinoderms	10 mg/kg	
09.3	Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	10 mg/kg	

Food Cat. No.	Food Category	Max Level	Comments
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09.4	Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	10 mg/kg	
10.2.3	Dried and/or heat coagulated egg products	33 mg/kg	
10.4	Egg-based desserts (e.g., custard)	33 mg/kg	
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	100 mg/kg	
11.6	Table-top sweeteners, including those containing high intensity sweeteners	GMP	
12.2	Herbs, spices, seasonings (including salt substitutes), and condiments (e.g., seasoning for instant noodles)	65 mg/kg	
12.3	Vinegars	12 mg/kg	
12.4	Mustards	12 mg/kg	
12.5	Soups and broths	20 mg/kg	
12.6.1	Emulsified sauces (e.g., mayonnaise, salad dressing)	65 mg/kg	
12.6.2	Non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)	65 mg/kg	
12.6.3	Mixes for sauces and gravies	12 mg/kg	
12.6.4	Clear sauces (e.g., soy sauce, fish sauce)	12 mg/kg	
12.7	Salads (e.g., macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based spreads of food categories 04.2.2.5 and 05.1.3	33 mg/kg	
13.3	Dietetic foods intended for special medical purposes, including those for infants and young children	25 mg/kg	
13.3.1	Dietetic foods for special medical purposes intended for adults	33 mg/kg	
13.4	Dietetic formulae for slimming purposes and weight reduction	33 mg/kg	
13.5	Dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4	65 mg/kg	
13.6	Food supplements	90 mg/kg	
14.1.2	Fruit and vegetable juices	65 mg/kg	
14.1.3	Fruit and vegetable nectars	65 mg/kg	
14.1.4	Water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulated drinks	33 mg/kg	
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	50 mg/kg	
14.2.1	Beer and malt beverages	20 mg/kg	
14.2.2	Cider and perry	20 mg/kg	
14.2.4	Wines (other than grape)	23 mg/kg	
14.2.5	Mead	23 mg/kg	
14.2.6	Distilled spirituous beverages containing more than 15% alcohol	23 mg/kg	
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	33 mg/kg	
15.0	Ready-to-eat savouries	16 mg/kg	

BRAZIL:

Brazil comment: The Brazilian comments to the CL 2002/44 have already been sent .They were included in the room document # 7 (CRD n° 7) at the 35th CCFAC.

Furthermore, Brazil requests **that the food additives listed below be** included in the food sub-category 07.1.6. Mixes for bread and ordinary bakery wares (Includes all the mixes containing the dry ingredients to which wet ingredients (e.g. water, milk, oil, butter, eggs) are added to prepare a dough for baked goods from categories 07.1.1. to 07.1.5. Examples included: french bread mix, tin bread mix, pannetone mix, ciabatta mix, among others).

Function	INS	Food Additive	Maximum Level (mg/kg)	CFCS
Firming agent, raising agent, stabilizer	523	ALUMINIUM AMMONIUM SULPHATE	10000	07.1.6
Antioxidant	304	ASCORBYL ESTERS	1000	07.1.6
Preservative	210, 211, 212, 213	BENZOATES	1000	07.1.6
Antioxidant	320	BHA	200	07.1.6
Antioxidant	321	BHT	100	07.1.6
Colour	160aii	CAROTENES, VEGETABLE	GMP	07.1.6
Colour	100i	CURCUMIN	200	07.1.6

EL SALVADOR:

This is to inform you that in the city of San Salvador, El Salvador C.A., in the installations of the National Board of Science and Technology “Consejo Nacional de Ciencia y Tecnologia – CONACYT”, the session of the CODEX Subcommittee on Food Additives and Contaminants, having as its object the analyzing and interpreting of the contents of the document Appendix III “Proposed Draft (Step 2) and Draft (Step 6) Revisions to Table 1 of the Codex General Standard for Food Additives” to be found in Alinorm 03/12, was held as requested in CL 2003/34 – FAC. The analyzing was carried out with representatives of the following sectors: the academic, government and industrial sectors and a consumer protection body.

This analysis resulted in two comments which were based on the consensus arrived at by the Subcommittee and of which it was considered important that they be submitted. These comments read as follows:

1. That the food additives mentioned in appendix III, should, whenever possible, contain the value of the Acceptable Daily Intake expressed as “mg / Kg Bodyweight”. Reference JECFA appendix IV of Alinorm 03/12 A.
2. That in the food additives referred to in Appendix III, reference should be made to the official method of analysis, for example for Aluminium Ammonium Sulphate .INS: 523 ref. for the method.

We take our leave with best regards, giving you the assurance that we will always be willing to furnish any further information you may require.

ITALY:

We have examined the food additives listed in revised Table 1 of the draft Codex General Standard for Food Additives (Appendix 1 of GSFA), and would like to reiterate comments already submitted for the 35th Session of CCFAC in response to CL 2002/10-FAC and CL 2002/44-FAC.

We are of the opinion that the draft of the GSFA allows too many additives in fresh and dried pasta.

We deem that there is no “*technological justification and need*” for the admission of a so relevant amount of additives.

This principle, that has been recalled in the document CX/FAC 03/6, was firstly affirmed during the 9th Session of the CAC (1972) where an advisory text of General Principles for the use of Food Additives (ALINORM 72/35, para. 295) was adopted and ultimately (25th CCFAC – 1993) modified agreeing to a number of recommendations for revising the Proposed Draft Preamble of the GSFA, including the addition of a new section on technological need and justification.

The Preamble was modified to establish that the “*The use of food additives is justified only when such use has an advantage, do not present a hazard to health to the consumer, does not mislead the consumer and serves one or more of the purposes set out from (a) through (d) from the Codex General Principles for the Use of Additives, and only where these objectives cannot be achieved by other means which are economically and technologically practicable*”.

The said “(a) through (d)” purposes are the following: “

- a) *to preserve the nutritional quality of the food; (...);*
- b) *to provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;*
- c) *to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not so change the nature, substance or quality of the food as to deceive the consumer;*
- d) *to provide aids in the manufacture, processing, preparation, treatment, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these additives”.*

Notwithstanding the above mentioned principles, a great amount of additives has been included in the Table 1 of the GSFA for the pasta category (84 additives for dried pastas and 41 additives for fresh pastas), which technological or sensorial needs can be fulfilled by using natural ingredients or very few additives in the case of fresh pasta.

The incoherence of the draft of the Table 1 of the GSFA with its general principles is even manifest if we read the **paragraph 55 of the ALINORM 03/12, where, with reference to the categorisation system, it is clearly stated that “*there would be few, if any, additives needed in the dried pasta and noodle category*”.**

The main problem, indeed, is probably given by the **categorisation system** set out by the 34th CCFAC which, revising the 06.4 food category, established that pastas and noodles should figure in the same category, despite the Italian delegation, together with the E.U. representatives, more than once raised its concerns about the proposed categorisation system which does not take into consideration that **pasta and noodles are two completely different products, with different technological needs.**

As a consequence of this, all the additives probably needed for the manufacture, processing, preparation, treatment, transport or storage of noodles, have been lent to pasta without any significant “*technological need and justification* and with the realistic risk of misleading the consumer.

For all the above mentioned reasons, we are of the opinion that:

- a) food category 06.4 should be further revised by separating pasta from noodles and distinguishing “fresh” from “dry” pasta;
- b) there is no need to use additives in dry pasta. Therefore the entry for category 06.4.2 should be removed from all additives;
- c) most of the additives proposed for fresh pasta should be removed following the indications of the attached table.

PROPOSED ADDITIVES	06.4.1 <i>Fresh pastas and noodles and like products</i>	06.4.2 <i>Dried pastas and noodles and like products</i>	COMMENTS
<u>ACESULFAME POTASSIUM</u> (INS: 950); Function: Flavour enhancer, Sweetener		1000 mg/kg	TO BE REMOVED 6.4.2
<u>ACETIC ACID, GLACIAL</u> (INS:260); Function Acidity Regulator, Preservative		GMP	TO BE REMOVED 6.4.2
<u>ADIPATES</u> Adipic Acid (INS: 355) - Potassium Adipate (INS: 357) – Sodium Adipate (INS:356) – Ammonium Adipate (INS: 359); Function: Acidity Regulator, Firming Agent, Raising Agent		1000 mg/kg	TO BE REMOVED 6.4.2
<u>ALGINIC ACID</u> (INS: 400); Function: Bulking Agent, Emulsifier, Stabilizer, Thickener	GMP	GMP	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>AMARANTH</u> (INS: 123); Function: Colour		100mg/kg	TO BE REMOVED 6.4.2
<u>AMMONIUM ALGINATE</u> (INS: 403); Function: Emulsifier, Thickener, Stabilizer		GMP	TO BE REMOVED 6.4.2
<u>ASCORBIC ACID</u> INS (:300); Function: Antioxidant, Colour retention agent)	200mg/kg	200mg/kg	TO BE REMOVED 6.4.2
<u>BEET RED</u> (INS: 162); Function: Colour		GMP	TO BE REMOVED 6.4.2
<u>CALCIUM ALGINATE</u> (INS: 404); Function: Antifoaming Agent, Emulsifier, Stabilizer, Thickener		GMP	TO BE REMOVED 6.4.2
<u>CALCIUM ASCORBATE</u> (INS: 302); Function: Antioxidant	200mg/kg	200mg/kg	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>CALCIUM CARBONATE</u> (INS: 170i); Function: Anticaking Agent, Acidity Regulator, Colour, Emulsifier, Stabilizer	10.000mg/kg	10.000mg/kg	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>CALCIUM PROPINATE</u> (INS: 282); Function: Preservative	200mg/kg	200mg/kg	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>CALCIUM SULPHATE</u> (INS: 516); Function: Acidity Regulator, Bulking Agent, Firming Agent, Flour Treatment Agent, Sequestrant, Stabilizer; Thickener		5000mg/kg	TO BE REMOVED 6.4.2
<u>CANTHAXANTHIN</u> (INS: 161g); Function: Colour		GMP	TO BE REMOVED 6.4.2
<u>CARAMEL COLOUR, CLASS II</u> Caramel Colour, Class II-caustic sulphate process (INS: 150b); Function: Colour		GMP	TO BE REMOVED 6.4.2
<u>CARAMEL COLOUR, CLASS III</u> Caramel Colour, Class III – Ammonia Process (INS: 150c); Function: Colour		GMP	TO BE REMOVED 6.4.2

PROPOSED ADDITIVES	06.4.1 <i>Fresh pastas and noodles and like products</i>	06.4.2 <i>Dried pastas and noodles and like products</i>	COMMENTS
<u>CARAMEL COLOUR, CLASS IV</u> Caramel Colour, Class IV- Ammonia Sulphite Process (INS: 150d); Function: Colour		GMP	TO BE REMOVED 6.4.2
<u>CARBON DIOXIDE</u> (INS: 290); Function: Adjuvant, Carbonating Agent, Packing Gas	GMP		TO BE REMOVED 6.4.1
<u>CARMINES</u> (INS: 120); Function: Colour		100mg/kg	TO BE REMOVED 6.4.2
<u>CAROB BEAN GUM</u> (INS: 410); Function: Emulsifier, Stabilizer, Thickener	GMP	GMP	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>CAROTENES, VEGETABLE</u> Carotenes, Natural Extracts, (Vegetable) (INS: 160aii); Function: Colour		GMP	TO BE REMOVED 6.4.2
<u>CARRAGEENAN</u> (INS: 407); Function: Emulsifier, Filler, Stabilizer, Thickener	GMP	8330mg/kg	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>CHLOROPHYLLS</u> (INS: 140); Function: Colour		GMP	TO BE REMOVED 6.4.2
<u>CHLOROPHYLLS, COPPER, COMPLEXES</u> (INS: 141i) Chlorophyllin Copper Complex, Sodium and Potassium Salts (INS: 141ii); Function: Colour		GMP	TO BE REMOVED 6.4.2
<u>CURCUMIN</u> (INS: 100i); Function: Colour		500mg/kg	TO BE REMOVED 6.4.2
<u>DIACETYLTARTARIC AND FATTY ACID ESTERS OF GLYCEROL</u> (INS: 472e); Function: Emulsifier, Sequestrant, Stabilizer		10.000mg/kg	TO BE REMOVED 6.4.2
<u>DISODIUM GUANYLATE, 5' –</u> (INS: 627); Function: Flavour Enhancer		GMP	TO BE REMOVED 6.4.2
<u>DISODIUM INOSINATE, 5' –</u> (INS: 631); Function: Flavour Enhancer		GMP	TO BE REMOVED 6.4.2
<u>DISODIUM RIBONUCLEOTIDES, 5' –</u> (INS: 635); Function: Flavour Enhancer		GMP	TO BE REMOVED 6.4.2
<u>FAST GREEN FCF</u> (INS: 143); Function: Colour		100mg/kg	TO BE REMOVED 6.4.2
<u>FUMARIC ACID</u> (INS: 297); Function: Acidity Regulator, Stabilizer	GMP	GMP	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>GALLATE PROPYL</u> (INS: 310); Function: Antioxidant		200mg/kg	TO BE REMOVED 6.4.2
<u>GELLAN GUM</u> (INS: 418); Function: Stabilizer, Thickener	GMP	GMP	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2

PROPOSED ADDITIVES	06.4.1 <i>Fresh pastas and noodles and like products</i>	06.4.2 <i>Dried pastas and noodles and like products</i>	COMMENTS
<u>GLUCONO DELTA – LACTONE</u> (INS: 575); Function: Acidity Regulator, Raising Agent	GMP		
<u>GLYCEROL</u> (INS: 422); Function Emulsifier, Humectant,	GMP		TO BE REMOVED 6.4.1
<u>GUAR GUM</u> (INS: 412); Function: Bulking Agent, Emulsifier, Stabilizer, Thickener	GMP	GMP	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>GUM ARABIC</u> (INS: 414); Function: Bulking Agent, Emulsifier, Filler, Stabilizer, Thickener	GMP	GMP	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>KARAYA GUM</u> (INS: 416); Function: Bulking Agent, Emulsifier, Stabilizer, Thickener	GMP	GMP	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>KONJAC FLOUR</u> (INS: 425); Function: Emulsifier, Stabilizer, Thickener	GMP	10.000mg/kg	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>LACTIC ACID (L-, D- AND DL-)</u> (INS: 270); Function: Acidity Regulator	GMP	GMP	TO BE REMOVED 6.4.2
<u>LACTITOL</u> (INS: 966); Function: Bulking Agent, Emulsifier, Stabilizer, Sweetener, Thickener		GMP	TO BE REMOVED 6.4.2
<u>LECITHIN</u> (INS: 322); Function: Antioxidant, Emulsifier, Stabilizer	GMP	5000mg/kg	TO BE REMOVED 6.4.2
<u>MALIC ACID (DL-)</u> (INS: 296); Function: Acidity Regulator, Sequestrant		GMP	TO BE REMOVED 6.4.2
<u>MALTITOL and MALTITOL SYRUP</u> (INS: 965); Function: Bulking Agent, Emulsifier, Stabilizer, Sweetener, Thickener		GMP	TO BE REMOVED 6.4.2
<u>MANNITOL</u> (INS: 421); Function: Anticaking Agent, Bulking Agent, Emulsifier, Stabilizer, Sweetener, Thickener		GMP	TO BE REMOVED 6.4.2
<u>MICROCRYSTALLINE CELLULOSE</u> (INS: 460i); Function: Anticaking Agent, Bulking Agent, Emulsifier, Foaming Agent, Stabilizer, Thickener	GMP	GMP	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>MONO – AND DIGLYCERIDES</u> (INS: 471); Function: Antifoaming Agent, Bulking Agent, Emulsifier, Stabilizer, Thickener	GMP	30.000mg/kg	TO BE REMOVED 6.4.2
<u>MONOSODIUM GLUTAMATE</u> (INS: 621); Function: Flavour Enhancer		GMP	TO BE REMOVED 6.4.2
<u>NITROUS OXIDE</u> (INS: 942); Function: Propellant		GMP	TO BE REMOVED 6.4.2
<u>PECTINS (AMIDATED AND NON AMIDATED)</u> (INS: 440); Function: Emulsifier, Stabilizer, Thickener	GMP	GMP	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2

PROPOSED ADDITIVES	06.4.1 <i>Fresh pastas and noodles and like products</i>	06.4.2 <i>Dried pastas and noodles and like products</i>	COMMENTS
<u>PHOSPHATED DISTARCH PHOSPHATE</u> (INS: 1413); Function: Bulking Agent, Emulsifier, Stabilizer, Thickener	200mg/kg	200mg/kg	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>POLYGLYCEROL ESTERS OF FATTY ACIDS</u> (INS: 475); Function: Adjuvant, Crystallization Inhibitor, Emulsifier, Stabilizer, Thickener		20.000mg/kg	TO BE REMOVED 6.4.2
<u>POLYSORBATES</u> Polyoxyethylene (20) Sorbitan Monolaurate (INS: 432) Polyoxyethylene (20) Sorbitan Monopalmitate (INS: 434) Polyoxyethylene (20) Sorbitan Tristearate (INS: 436) Polyoxyethylene (20) Sorbitan Monooleate (INS: 433) Polyoxyethylene (20) Sorbitan Stearate (INS: 435) Function: Antifoaming Agent, Adjuvant, Emulsifier, Foaming Agent, Flour Treatment Agent, Stabilizer		5000mg/kg	TO BE REMOVED 6.4.2
<u>POTASSIUM ALGINATE</u> (INS: 402); Function: Emulsifier, Stabilizer, Thickener		GMP	TO BE REMOVED 6.4.2
<u>POTASSIUM CARBONATE</u> (INS: 501i); Function: Acidity Regulator, Stabilizer	GMP	2600mg/kg	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>POTASSIUM CHLORIDE</u> (INS: 508); Function: Stabilizer, Thickener		GMP	TO BE REMOVED 6.4.2
<u>PROCESSED EUCHEUMA SEAWEED</u> (INS: 407a); Function: Stabilizer, Thickener		8330mg/kg	TO BE REMOVED 6.4.2
<u>PROPYLENE GLYCOL</u> (INS: 1520); Function: Anticaking Agent, Adjuvant, Antifoaming Agent, Carrier Solvent, Emulsifier, Flour Trt Agt., Humectant, Stabilizer, Thickener.	20.000mg/kg		TO BE REMOVED 6.4.1
<u>PROPYLENE GLYCOL ALGINATE</u> (INS: 405); Function: Adjuvant, Bulking Agent, Emulsifier, Stabilizer, Thickener.	10.000mg/kg	1000mg/kg	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>RIBOFLAVINES</u> Riboflavin 5'-Phosphate, Sodium (INS: 101i) Riboflavin 5'-Phosphate (INS: 101ii) Function: Colour		GMP	TO BE REMOVED 6.4.2 TO BE REMOVED 6.4.3
<u>SALTS OF MYRISTIC, PALMITIC & STEARIC ACIDS (NH₄, Ca, K, Na)</u> (INS: 470); Function: Anticaking Agent, Emulsifier, Stabilizer		GMP	TO BE REMOVED 6.4.2
<u>SODIUM ACETATE</u> (INS: 262i); Function: Acidity Regulator, Preservative, Sequestrant	GMP	6000mg/kg	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2

PROPOSED ADDITIVES	06.4.1 <i>Fresh pastas and noodles and like products</i>	06.4.2 <i>Dried pastas and noodles and like products</i>	COMMENTS
<u>SODIUM ALGINATE</u> (INS: 401); Function: Bulking Agent, Emulsifier, Stabilizer, Thickener	GMP	GMP	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>SODIUM ASCORBATE</u> (INS: 301); Function: Antioxidant, Colour Retention Agent	200mg/kg	200mg/kg	TO BE REMOVED 6.4.2
<u>SODIUM CARBONATE</u> (INS: 500i); Function: Anticaking Agent, Acidity Regulator, Raising Agent, Stabilizer	GMP	2600mg/kg	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>SODIUM CARBOXYMETHYL CELLULOSE</u> (INS: 466); Function: Bulking Agent, Emulsifier, Stabilizer, Thickener	50.000mg/kg	GMP – 50.000mg/kg	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>SODIUM DIACETATE</u> (INS: 262ii); Function: Acidity Regulator, Preservative, Sequestrant		3000mg/kg	TO BE REMOVED 6.4.2
<u>SODIUM GLUCONATE</u> (INS: 576); Function: Sequestrant		GMP	TO BE REMOVED 6.4.2
<u>SODIUM HYDROGEN CARBONATE</u> (INS: 500ii); Function: Acidity Regulator, Anticaking Agent, Raising Agent, Stabilizer	GMP	GMP	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>SODIUM LACTATE</u> (INS: 325); Function: Acidity Regulator, Antioxidant, Bulking Agent, Emulsifier, Humectant, Stabilizer, Thickener	2400mg/kg	2400mg/kg	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>SODIUM MALATE</u> (INS: 350ii); Function: Acidity Regulator, Humectant	GMP		TO BE REMOVED 6.4.1
<u>SORBATES</u> Sorbic Acid (INS: 200) Potassium Sorbate (INS: 202) Sodium Sorbate (INS: 201) Calcium Sorbate (INS 203) Function: Antioxidant, Preservative, Stabilizer		2000mg/kg	TO BE REMOVED 6.4.2
<u>SORBITAN ESTERS OF FATTY ACIDS</u> Sorbitan Monostearate (INS: 491) Sorbitan Monolaurate (INS: 493) Sorbitan Monopalmitate (INS: 495) Sorbitan Tristearate (INS: 492) Sorbitan Monooleate (INS: 494) Function: Emulsifier, Stabilizer		5000mg/kg	TO BE REMOVED 6.4.2
<u>SORBITOL (INCLUDING SORBITOL SYRUP)</u> (INS: 420); Function: Bulking Agent, Emulsifier, Humectant, Sequestrant, Stabilizer, Sweetener, Thickener	35.000mg/kg	GMP	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>STEAROYL-2-LACTYLATES</u> Sodium Stearoyl Lactylate (INS: 481i) Calcium Stearoyl Lactylate (INS: 482i); Function: Emulsifier, Stabilizer, Thickener		4500mg/kg	TO BE REMOVED 6.4.2

PROPOSED ADDITIVES	06.4.1 <i>Fresh pastas and noodles and like products</i>	06.4.2 <i>Dried pastas and noodles and like products</i>	COMMENTS
<u>SUCROSE ESTERS OF FATTY ACIDS</u> (INS: 473); Function: Adjuvant, Emulsifiers, Stabilizer, Thickener	2000mg/kg	2000mg/kg	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>SUNSET YELLOW FCF</u> (INS: 110); Function: Colour		300mg/kg	TO BE REMOVED 6.4.2
<u>TARA GUM</u> (INS: 417); Function: Stabilizer, Thickener		GMP	TO BE REMOVED 6.4.2
<u>TARTRATES</u> Tartaric Acid (L(+)-) (INS: 334) Disodium Tartrate (INS: 335ii) Dipotassium Tartrate (INS: 336ii) Monosodium Tartrate (INS: 335i) Monopotassium Tartrate (INS: 336i) Potassium Sodium Tartrate (INS: 337) Function: Anticaking Agent, Acidity Regulator, Adjuvant, Antioxidant, Bulking Agent, Emulsifier, Flour Trt Agt., Humectant, Preservative, Raising Agent, Sequestrant, Stabilizer, Thickener.	GMP		
<u>TARTRAZINE</u> (INS: 102); Function: Colour		300mg/kg	TO BE REMOVED 6.4.2
<u>TOCOPHEROLS</u> Mixed Tocopherols Concentrate (INS: 306) Alpha-Tocopherol (INS: 307) Function: Antioxidant		GMP	TO BE REMOVED 6.4.2
<u>TRAGACANTH GUM</u> (INS: 413); Function: Bulking Agent, Emulsifier, Stabilizer, Thickener	GMP	GMP	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>XANTHAN GUM</u> (INS: 415); Function: Stabilizer, Thickener	10.000mg/kg	4000mg/kg	TO BE REMOVED 6.4.1 TO BE REMOVED 6.4.2
<u>XYLITOL</u> (INS: 967); Function: Bulking Agent, Emulsifier, Humectant, Stabilizer, Sweetener, Thickener		GMP	TO BE REMOVED 6.4.2

SPAIN:

We would like to reiterate some of the comments already submitted in 2003. However, in order to make a greater contribution to the elaboration of the General Standard for Food Additives, a detailed study has been carried out in respect of all the additives included in Table ONE,

INS 950 Acesulphame potassium

Since this sweetener has been assigned a numerical ADI, it should not appear at Good Manufacturing Practice level in various food categories.

Given the proposed numerous uses it should not appear in category 16.

INS 260 Acetic acid, glacial

In respect of categories 04.2.1 and 08.1.1, the use of additives should not be permitted.

INS 355-359 Adipates

The proposed use in the entire category 02.1 is not technologically justified. The Good Manufacturing Practice level in category 14.2.1 should be replaced by a maximum level. In category 16.0 its use should not appear at all.

INS 406 Agar

The proposed use in category 06.4.1 is not justified. The same applies for category 08.1, which should carry note 53.

INS 956 Alitame

Since this sweetener has been assigned a numerical ADI, it should not appear at Good Manufacturing Practice level in various food categories.

INS 129 Allura red

The uses proposed at Good Manufacturing Practice level and which are not coatings, must be replaced by maximum levels (categories 02.1.3; 02.2.1.2 and 14.2.1). The necessity for it not being placed in category 05.1 Cocoa and Chocolate should be considered.

It should not appear in category 16.

INS 559 Aluminium Silicate

The same comments as for INS 523.

INS 510 Ammonium Chloride

The proposed use in category 08.1 is not technologically justified. This category, being fresh meat, should not carry any additive whatsoever. There exists, moreover, a contradiction between the assigned function: flour treatment agent and the proposed applications.

INS 160 b Annatto Extract

Due to the low ADI assigned to it, the Good Manufacturing Practice level cannot be used for this additive (categories 04.1.2.4; 04.1.2.6; 05.1.1.; 05.1.3; 07.1; 11.3; 11.4; 13.6; 14.1.2.1; 14.1.2.3; 14.1.3.1 and 14.2.3.3), maximum levels should be used. Given the large number of proposed uses, it makes no sense to include category 16.0, which should be deleted.

Categories 05.1.4; 07.1; 14.1.2.1; 14.1.2.3; 14.1.3.1 and 14.2.3 should not contain colours, since these may mislead concerning the nature of the product.

INS 951 Aspartame

Since this colour has been assigned a numerical ADI, it should not appear at Good Manufacturing Practice level in various food categories (01.3.2; 01.4.1; 01.4.2; 01.4.3; 01.5.1; 01.5.3; 01.6.1; 02.3; 04.1.2.1; 09.4; 12.3 and 14.1.5).

INS 122 Azorubine

The proposed Good Manufacturing Practice levels in categories 14.1.2.1 and 14.1.2.2 should be replaced by numerical values. Moreover, it should be questioned whether the use of colours in these two categories is justified. The same argument can be used for their use in categories 05.1 and 16.0, which categories should be eliminated.

INS 162 Beet Red

The use of a colour in category 06.1 is not justified.

INS 151 Brilliant Black PN

Categories 05.1 and 16.0 should be excluded from the use of colours.

INS 155 Brown HT

The proposed use in category 05.1.4 can be misleading. Category 16.0 should be excluded.

- INS 556 Calcium Aluminium Silicate
We find no technological justification for its use in categories 14.1.2.1 and 14.2.3 and for the G.M.P. level of use.
- INS 170 i) Calcium Carbonate
Its use in category 06.2, accompanied by note 57, is not easy to comprehend.
- INS 509 Calcium Chloride
Category 08.1.1 should not contain any additive.
- INS 526 Calcium Hydroxide
No additive whatsoever should be used in category 08.1.1.
- INS 529 Calcium Oxide
The same comments as for additive INS 526.
- INS 282 Calcium Propionate
The use of preservatives in category 06.4.1 may mask non-hygienic practices and is not justified in category 06.4.2.
- INS 516 Calcium Sulphate
Its use in category 06.2 accompanied by note 57 is not easy to comprehend.
- INS 161 g Canthaxanthin
An additive with so low an ADI, cannot be justified with so wide a use and, therefore, never at G.M.P. level, and neither in category 16.
Moreover, the use of colours in categories such as 05.1; 08.1.1; 14.1.2.1; 14.2 and 14.2.3 is not justified.
- INS 100i Curcumin
Categories 05.1.4; 07.1.1 and 14.1.2.1 should not contain colours. The G.M.P. levels should be replaced by maximum levels. Category 16.0 should be withdrawn.
- INS 627 Disodium Guanylate
- INS 621i Disodium Inosinate
Category 08.1 should not contain any additive.
- INS 127 Erythrosine
Due to the low ADI assigned to this additive, it can never be used at GMP level (categories 02.1.3; 02.2.1.2 and 14.2.7), should be replaced by maximum levels. Given the large number of proposed uses, it makes no sense to include category 16.0, which category should be eliminated.
- INS 418 Gellan Gum
Categories 06.4.1; 08.1 and 09.1 should not contain additives or be accompanied by note 16.
- INS 422 Glycerol
Category 06.4.1 should not contain this additive.
- INS 414 Gum Arabic
We have found no technological justification for the inclusion of category 06.4.1.
- INS 1440 Hydroxypropyl Starch
In category 13.1.1 this should be specified in the type of infant formulae to which it would be added, according to Codex Stan 72-1981.

INS 132 Indigotine

In categories 02.1.3 and 02.2.1.2 appearing at GMP levels, these should be replaced by numerical levels, given the fact that this additive has been assigned an ADI. Its use in these categories is not justified and neither is such use justified in category 16.0 which would make the use of colours general.

Categories 05.1.4; 06.3; 07.0 and 11.6 should not contain colours either since such use would be too wide in these categories, and this is not technologically justified.

INS 172 i and 172 ii Iron Oxide, BlackIron Oxide, Yellow

Categories 01.6.1 and 01.6.3 should not contain colours, and neither should category 16.0, which would make the use of colours general.

INS 953 Isomalt

This should not be used in categories 13.1 and 13.2, where at the proposed numerical level it would have a laxative effect with an intake by the baby of 200 ml milk.

It should not be used in liquid foods such as those appearing in 14.1.2.1; 14.1.2.3; 14.1.3.1 and 14.1.3.3, given its laxative effect, which is increased by intake in liquid form.

INS 416 Karaya Gum

In categories 01.1.1; 02.1; 08.1; 13.1 and 13.2 the use of a thickener is not justified.

INS 421 Konjac Flour

In categories 01.1.1; 08.1; 13.1 and 13.2 the use of this additive is not justified.

INS 966 Lactitol

This additive should not be used in categories 13.1 and 13.2 due to its laxative effect, which is increased by intake in liquid form due to a greater osmotic pressure.

Its use in categories 08.1 and 09.1 should be accompanied by note 16.

INS 511 Magnesium Chloride

The proposed use in category 08.1.1 should be accompanied by note 16. In category 13.1.1. the use of magnesium salts does not seem appropriate.

INS 296 Malic acid (DL)

Its use in category 04.2.1 is not justified. It should be withdrawn.

INS 965 Maltitol and Maltitol Syrup

This should not be used in categories 13.1 and 13.2 due to its laxative effect, which is increased by intake in liquid form due to a greater osmotic pressure.

Its use in categories 08.1 and 09.1 should be accompanied by note 16.

Its use in categories 14.1.2.1 and 14.1.2.3 should not be contemplated, due to its laxative effect.

INS 421 Mannitol

This should not be used in categories 13.1 and 13.2 due to its laxative effect, which is increased by intake in liquid form due to a greater osmotic pressure.

Its use in categories 08.1 and 09.1 should be accompanied by note 16.

INS 460 i Microcrystalline Cellulose

Its use in categories 13.1 and 13.2 is not justified.

INS 624 Monoammonium Glutamate

Its use in category 08.1 should not be contemplated.

- INS 621 Monosodium Glutamate
Category 08.1 should not be included.
- INS 251 Sodium Nitrate
This should not be used in categories 08.1; 09.2.1 and 09.3, since this is not technologically justified.
- INS 249 Potassium Nitrite
Its use in categories 08.1 and 09.2.4.1 is not technologically justified.
- INS 1101 II) Papain
The use of a flavour enhancer, stabilizer and flour treatment agent is not justified in category 08.1.1, which should not contain any additives since these are fresh products.
- INS 440 Pectins
Its use in categories 04.2.1.2 and 08.1 is not justified.
- INS 338 422 Phosphates
In general terms, the levels appearing in the Standard for these additives seem too high in some categories and could exceed the assigned ADI, which is coming from all sources. They should be revised.
Categories 08.1.1; 09.1.1; 14.1.2 and 16.0 should not appear.
- INS 900a Polydimethylsiloxane
Its use at GMP level in category 08.1.1. should be eliminated.
The proposed levels in categories such as 03.0; 08.2; 08.3; 09.2 and 14.1.5 are too high and are not technologically justified. These levels should be re-examined in general since this is an additive with a low ADI.
- INS 475 Polyglycerol Esters of Fatty Acids
The inclusion of categories 06.1; 06.2; 08.0; 09.0 and 16.0 is not technologically justified and these should be eliminated.
- INS 476 Polyglycerol Esters of Interesterified Ricinoleic Acid
In fresh product categories, such as 08.0 and 09.0 the use of additives is not justified and it has no technological effect.
- INS 124 Ponceau 4R
Its use at GMP level in categories 14.1.2.1 and 14.1.2.2 should be eliminated. Category 16.0 should not be included, since this makes the use of colours general.
- INS 508 Potassium Chloride
Its use at GMP level in category 08.1.1 is not justified.
- INS 525 Potassium Hydroxide
Its use in category 08.1.1 does not seem justified.
- INS 405 Propylene Glycol Alginate
It should be removed from categories 13.1 and 13.2.
Its use in categories 12.5; 14.1.2.1; 14.1.2.3; 14.1.3.1; 14.1.3.3 and 14.1.5 should be re-examined and in some cases the GMP should be replaced by numerical values.
In other categories, such as 02.1; 08.3 and 08.4, it should be eliminated.

- INS 104 Quinoline Yellow
No colours should be used in category 05.1.4, and neither should category 16.0 be included, since this makes the use of colours general.
- INS 128 Red 2G
The GMP level appearing in categories 14.2.6 and 14.2.7 should be replaced by numerical values.
- INS 551 Silicon Dioxide (Amorphous)
This should never be used in category 06.2; its use would not be justified.
- INS 501 i Sodium Carbonate
Its use in categories 02.1; 06.2 and 08.1 does not seem technologically justified and should be eliminated.
- INS 466 Sodium Carboxymethyl Cellulose
Categories 01.1.1; 08.1.1; 14.1.2.1; 14.1.2.3; 14.1.3.1 and 14.1.3.3 should not be included. If inclusion of category 08.1.1 is contemplated, it should be accompanied by note 16.
- INS 576 Sodium Gluconate
Inclusion of its use in category 09.1 is not technologically justified.
- INS 500 ii Sodium Bicarbonate
Its use in categories 06.2 and 08.1.1 does not seem technologically justified and should be eliminated.
- INS 524 Sodium Hydroxide
Its use in category 08.1.1 does not seem justified.
- INS 500 iii Sodium Sesquicarbonate
The inclusion of categories 02.1 and 08.1.1 does not seem technologically justified.
- INS 200 and 202 Sorbates
Categories 04.1.1 and 04.1.2.1 should not be included, and neither should 05.1.1 and 05.1.4. Categories 06.2 and 14.1.1.2 should not contain preservatives either.
Inclusion in category 16.0 would make the use of these additives general.
- INS 420 Sorbitol and Sorbitol Syrup
These should not be used in categories 13.1 and 13.2 since its laxative effect, which is increased by the liquid form of the infant formulae, renders this additive unsuitable for babies.
For the same reason, because of its laxative effect, it should not be used in liquid foodstuffs, such as those included under categories 14.1.2.1 and 14.1.2.3.
- INS 512 Stannous Chloride
Its use in category 14.1.4 does not seem justified and would increase the intake of Tin.
- INS 481i and 482 i Stearoyl-2-Lactylates
Cannot be included in category 16.0, since this makes the use of these additives general.
- INS 473 Sucrose Esters of Fatty Acids
The GMP level in categories 01.4.2; 01.4.4; 07.1; 09.4 and 13.6 should be replaced, since this is an additive with a fixed ADI.
Category 16.0 should not be included, since it would make the use of this additive general.

INS 110 Sunset Yellow FCF

The G.M.P. levels appearing in categories 02.1.3 and 02.2.1.2 should be replaced by numerical values, since this is an additive with a numerical ADI.

In categories 14.1.2.1 and 14.1.2.2 the use of colours is not justified, and neither is this justified in category 05.1.4.

The use of colours in so broad a category as category 07.0 should be reconsidered.

Category 16.0 should not be included, since this would lead to a wider use of colours. In other foodstuffs the carry-over principle should be applied.

INS 417 Tara Gum

Its use in categories 02.1; 06.1; 08.1 and 13.1 should be reconsidered, the need is not justified.

INS 334-337 Tartrates

Their use in categories 06.2 and 08.0 should be reconsidered. Category 16.0 should not be included since this would lead to a wider use.

INS 102 Tartrazine

The G.M.P. level in categories 02.1.3 and 02.2.1.2 should be replaced by numerical values, given the fact that this is an additive with a numerical ADI.

Its use in categories 14.1.2.1; 14.1.2.2 and 14.2.1 is not justified and should be reconsidered.

Category 16.0 should be excluded, since this would wrongly complicate the use of colours.

INS 957 Thaumatococin

The use of sweeteners in category 13.2 should not be admitted.

INS 415 Xanthan Gum

Category 08.1 should be accompanied by footnote 16.

INS 967 Xylitol

It should not be used in categories 13.1 and 13.2 because of its laxative effect, which is increased by intake in liquid form, due to a greater osmotic pressure.

EUROPEAN COMMUNITY:

The European Community would like to submit the following comments to CL 2003/34-FAC. These comments update the comments already submitted for the 35th session of the CCFAC (EC comments on CL 2002/44 FAC).

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 2004. 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 have 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 numerical ADI

14. In line with the conclusions reached at the 34th session of the CCFAC and re-confirmed at the 35th session, the European Community considers that additives assigned a numerical acceptable daily intake (ADI) by JECFA should be assigned numerical maximum levels of use in the GSFA. If these 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 numerical ADI is re-evaluated. This process has already started at the 34th session of the CCFAC.

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, in line with point 14 of the general comments, 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. ANNATO EXTRACTS

At its 61st meeting, JECFA examined 6 Annatto extracts (B to G). For 4 of these extracts, temporary ADIs were established. For the two remaining extracts, no ADI could be established since no data on toxicity were available. The Committee requested additional information to clarify the role that the non-pigment components play in the expression of the differences in toxicity of the extracts. In addition the Committee requested data on reproductive toxicity of an extract that contains norbixin.

Therefore, the European Community would like to suggest that the discussion on the proposed uses for Annatto extracts are postponed until a full characterization and evaluation of the whole group of Annatto extracts is available.

3. ASCORBYL ESTERS

INS: 304 Function: Antioxidant

No specific comment.

4. 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.

5. 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 in table and soda waters. The use of benzoates could mask unhygienic practices in these drinks. Therefore, 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 particulated 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. The use of benzoates could mask unhygienic practices in these foods. 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.

6. 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.

Note 15 should also be added for margarine and similar products (02.2.1.2).

7. 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.

8. 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.

9. 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 misled: 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.

10. CARNAUBA WAX

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

Carnauba wax has been assigned a numerical ADI of 7 mg/kg bodyweight by JECFA. In line with point 14 of the general comments, the EC proposes that the GMP level is replaced by numerical levels for the following food categories:

Surface-treated fresh fruit (04.1.1.2), processed fruit (04.1.2) and surface-treated fresh vegetables (04.2.1.2): 200 mg/kg

Cocoa and chocolate products (05.1.4), imitation chocolate and confectionery other than food categories 05.1, 05.3 and 05.4 (05.2): 500 mg/kg

Bakery wares (07.0): 200 mg/kg

Food supplements (13.6): 200 mg/kg

Coffee, coffee substitutes, tea (14.1.5): 200 mg/kg

Ready-to-eat savouries (15.0): 200 mg/kg

The GMP level should be reviewed for the remaining food categories, i.e. sauces (12.6) and canned or bottled fruit juice (14.1.2.1).

The maximum level proposed for the use of carnauba wax as carrier in water-based flavoured drinks, 200 mg/kg, is too high and should be reduced.

11. 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), bread-type products (07.1.4), 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.

12. 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.

13. 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), bread-type products (07.1.4), 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.

14. DIACETYLTARTARIC AND FATTY ACID ESTERS OF GLYCEROL

INS: 472e Function: Emulsifier, Sequestrant, Stabiliser

At its 61st meeting, JECFA has established an ADI of 0-50 mg/kg b.w. for diacetyltartaric and fatty acid esters of glycerol. In line with point 14 of the general comments, numerical use levels should be proposed instead of GMP. Furthermore, in view of the ADI and the many uses that are already foreseen for this additive, the new uses proposed should be justified. In particular the levels proposed for the food categories of edible ices (03.0), bakery wares (07.0) and snacks (15.1) are very high.

15. 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.

16. 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-hydroxybenzoates 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.

17. 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.

18. 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.

19. 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), vegetables (04.2.2.3) 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.

20. 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).

21. 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.

22. SHELLAC

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

No specific comment.

23. 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.

24. 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.

25. SUCRALOSE

INS: 955 Function: Sweetener

There is no technical need to use sucralose in frozen and dried fruit (04.1.2.1 and 04.1.2.2). The EC considers that these listings should be deleted. In EC legislation intense sweeteners are only permitted in energy-reduced or no added sugar varieties for the majority of foodstuffs.

26. SUCROGLYCERIDES

INS: 474 Function: Emulsifier, Stabiliser, Thickener

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

27. SULPHITES

Sulphur dioxide INS:220, Sodium sulphite INS:221, Sodium hydrogen sulphite INS:222, Sodium metabisulphite 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.

01.6.4 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.

04.2.1.3 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 puree 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.

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 consumed 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.

28. 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 ≥ 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 > 5 g/l
REC n° 1493/1999 annex V J. point7 : 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	

IFAC (The International Food Additives Council):

The International Food Additives Council (IFAC) requests that the attached list of food additives be added to the General Standard for Food Additives.

Food Additives for Addition to the Codex General Standard for Food Additives (GSFA)**Submitted by:****International Food Additives Council****5775 Peachtree Dunwoody Road****Bldg. G – Suite 500****Atlanta, Georgia 30342****November 24, 2003**

AMMONIUM HYDROXIDE Function: Food Category No. 13.6	INS: 527 ACIDITY REGULATOR Food Category Needed Food Supplements	Maximum Level 5,000 mg/kg
CALCIUM CARBONATE Function:	INS: 170i ANTICAKING AGENT, ACIDITY REGULATOR, COLOR, EMULSIFIER, STABILIZER	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 35,000 mg/kg
CALCIUM SULPHATE Function:	INS: 516 ACIDITY REGULATOR, BULKING AGENT, FIRMING AGENT, SEQUESTRANT, STABILIZER, THICKENER	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 35,000 mg/kg
CARAMEL COLOUR, CLASS 1 Function:	INS: 150a COLOUR	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 35,000 mg/kg
CARAMEL COLOUR, CLASS II Function:	INS: 510b COLOUR	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 35,000 mg/kg
CHLOROPHYLLS Function:	INS: 140 COLOUR	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 25,000 mg/kg
ETHYLCELLULOSE Function:	INS: 462 BINDER, FILM COATING, SEALING AGENT, SURFACE-FINISHING AGENT, GLAZING AGENT	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 20,000 mg/kg

GLYCEROL Function:	INS: 422 EMULSIFIER, HUMECTANT, STABILIZER, THICKENER	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 25,000 mg/kg
HYDROXYPROPYL CELLULOSE Function:	INS: 463 BINDER, FILM COATING, SEALING AGENT, SURFACE-FINISHING AGENT, GLAZING AGENT	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 5,000 mg/kg
HYDROXYPROPYL METHYLCELLULOSE Function:	INS: 464 BINDER, FILM COATING, SEALING AGENT, SURFACE-FINISHING AGENT, GLAZING AGENT	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 40,000 mg/kg
LECITHIN Function:	INS: 322 EMULSIFIER, STABILIZER	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 10,000 mg/kg
METHANOL Function:	INS: NONE EXTRACTION SOLVENT	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 2,000 mg/kg
METHYL CELLULOSE Function:	INS: 416 BINDER, FILM COATING, SEALING AGENT, SURFACE-FINISHING AGENT, GLAZING AGENT	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 91,000 mg/kg
N-BUTYL ALCOHOL Function:	INS: NONE EXTRACTION SOLVENT	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 15,000 mg/kg
OLEIC ACID Function:	INS: NONE EMULSIFIER, PLASTICIZER, STABILIZER	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 5,000 mg/kg
POLYDEXTROSE Function:	INS: 1200 BULKING AGENT, GLAZING AGENT	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 30,000 mg/kg

POLYVINYL ALCOHOL Function:	INS: TO BE ASSIGNED COATING, BINDER, SEALING AGENT, SURFACE-FINISHING AGENT	
Food Category No. 1.7	Food Category Needed Dairy-based desserts	Maximum Level 2,000 mg/kg
5.1.4	Cocoa and chocolate products	15,000 mg/kg
6.3	Breakfast cereals, including rolled oats	5,000 mg/kg
13.6	Food Supplements	45,000 mg/kg
15.2	Processed nuts, including coated nuts and nut mixtures	15,000 mg/kg
POTASSIUM ALUMINOSILICATE Function:	INS: 555 ANTICAKING AGENT	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 10,000 mg/kg
SODIUM CARBOXYMETHYL CELLULOSE Function:	INS: 466 BINDER, FILM COATING, SEALING AGENT, SURFACE-FINISHING AGENT, GLAZING AGENT	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 50,000 mg/kg
SODIUM DIHYDROGEN CITRATE Function:	INS: 331i ACIDITY REGULATOR	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 5,000 mg/kg
STEARIC ACID Function:	INS: None EMULSIFIER, STABILIZER	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 5,000 mg/kg
TALC Function:	INS: 553iii ANTICAKING AGENT	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 20,000 mg/kg
TITANIUM DIOXIDE Function:	INS: 171 COLOUR	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 50,000 mg/kg
TRIACETIN Function:	INS: 1518 PLASTICIZER, EMULSIFIER	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 10,000 mg/kg
XANTHAN GUM Function:	INS: 415 STABILIZER, THICKENER	
Food Category No. 13.6	Food Category Needed Food Supplements	Maximum Level 1,000 mg/kg

IFU (International Federation of Fruit Juice Producers):

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 7, which should reflect also in Table 1 and 2 of the GSFA. It is absolutely necessary, that there is consistency between the additive list in a commodity standard and the list of additives in the GSFA.

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
 - 14.1.2.3 Concentrates (liquid or solid) for fruit juice
- 14.1.3 Fruit and Vegetable Nectars
 - 14.1.3.1 Canned or bottled (pasteurised) fruit nectar
 - 14.1.3.3 Concentrates (liquid or solid) for fruit nectar

In the Annex of this letter you will find two lists, which contain the following information:

- A. This list contains all the additives, which are foreseen in the Codex Standard for Fruit Juices and Nectars for 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 in the Codex Standard on Fruit Juices and Nectars and these additives should therefore be removed in the GSFA from the above mentioned food categories.

We kindly request you to take into consideration the above mentioned requests. Of course we are prepared to submit further information if needed before or also during the meeting of the Working Group on Friday, 19 March 2004.

A: Additives, in which the allowed max. level and the food categories 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
290	Carbon Dioxide	GMP	14.1.2.1; 14.1.2.3; 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

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
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 SO₂
- 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

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:
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
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
418	Gellan Gum	14.1.2.1; 14.1.2.3; 14.1.3.1; 14.1.3.3
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
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
25 INS	Phosphates	14.1.2
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

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:
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	Thaumatococin	14.1.2.1
413	Tragacanth Gum	14.1.2.1; 14.1.2.3; 14.1.3.1; 14.1.3.3
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

IPPA (International Pectin Producers Association):

We note that, in line with the Draft Codex Standard for Vegetable Juices and Nectars, which has a restricted list of permitted additives, the entries in the Annex to Table 3 have been changed to cover 14.1.2 Fruit and vegetable juices and 14.1.3 Fruit and vegetable nectars, thus including both fruit and vegetable products of this type.

As pectins are listed as permitted stabilisers in the Commodity Standards for all these products, we wish to confirm that a corresponding change will be made to the entry for pectins in Table 1 of the standard, so that the entries for 14.1.2.1, 14.1.2.3, 14.1.3.1, and 14.1.3.3 are replaced by entries for 14.1.2 and 14.1.3 respectively, at the level of 3000 mg/kg as approved in the proposed Commodity Standards.

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

^aMinimum inhibitory concentration in µg/ml (ppm)

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

Isolate ^b	MIC (ppm)
<i>Kloeckera apiculata</i>	188
<i>Saccharomyces cerevisiae</i>	170-450
<i>Zygosaccharomyces bailii</i>	600-1,300
<i>Hansenula anomala</i>	223
<i>Kluveromyces fragilis</i>	173
<i>Saccharomyces ludwigii</i>	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 Republic 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	

Country	Maximum level of benzoic acid and its salts in water-based flavored beverages expressed as benzoic acid (mg/kg)	Comments
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):

Among the priority additives to be discussed at the next session of CCFAC (listed in CL 2002/44 Appendix II), ISDI brings herewith the justification for the use at certain levels of additives in Foods for Special Medical Purposes as described in category 13.3 of the Food Category System.

INS	Food cat No	Max level	ADI	Source	Step	Proposed numerical level / Justification
120 Carmines	13.3.1	50mg/kg	0-5 mg/kg bw	EU (6), ISDI (3)	6	The unusual ingredients in FSMPs often give an unpleasant colour to the product so the addition of colour improves visual aspect and taste perception and therefore dietary compliance. 50mg/kg as consumed equates to current level of use in FSMPs and the amount needed to achieve the required technological effect.
160a(ii) Carotenes vegetable	13.3.1	GMP 30mg/kg	Acceptable	EU(6), ISDI(3)	6	The unusual ingredients in FSMPs often give an unpleasant colour to the product. Addition of colour improves visual aspect and taste perception and therefore dietary compliance. Level : For young children over one year based on the Opinion of the EU Scientific Committee for Food, Dec.1996 on colours in FSMPs.
	13.3.2	30 mg/kg		ISDI (3)	3	The mixture of amino acids, vitamin, mineral complex, unusual fats or fatty acids etc. give an unpleasant colour to the FSMP product so the addition of colour improves visual aspect and taste perception and therefore dietary compliance. Level: For young children over one year Opinion of the EU Scientific Committee for Food, Dec.1996
141i, 141ii Chlorophylls, copper complex	13.3	GMP 20mg/kg	141i not limited 141 ii 0-15 mg/kg bw	EU&SAfrica (6), ISDI (3)	6	The unusual ingredients in FSMPs often give an unpleasant colour to the product so the addition of colour improves visual aspect and taste perception and therefore dietary compliance. Level : For young children over one year based on the Opinion of the EU Scientific Committee for Food, Dec.1996 on colours in FSMPs
472e Diacetyltartaric and fatty acid esters of glycerol	13.3.1	GMP 400mg/kg	0-50 mg/kg bw	EU(6), ISDI(3)	6	The unusual ingredients in FSMPs(eg amino acids, combination of oils) require a robust emulsifier such as E472e to provide stable emulsions to enhance product acceptability and hence patient compliance. Level: 400mg/kg as consumed represents current level of use in FSMPs and the amount needed to achieve the required technological effect.
163ii Grape skin extract	13.3.1	GMP 20mg/kg	0-2.5 mg/kg bw	EU(6), ISDI(3)	6	The unusual ingredients in FSMPs often give an unpleasant colour to the product so the addition of colour improves visual aspect and taste perception and therefore dietary compliance. Level : based on Opinion of the EU Scientific Committee for Food, Dec.1996 .
	13.3.2	GMP 20mg/kg				The mixture of amino acids, vitamin, mineral complex, unusual fats or fatty acids etc. give an unpleasant colour to the product so the addition of colour improves visual aspect and taste perception and therefore dietary compliance. Level: For young children over one year based on the Opinion of the EU Scientific Committee for Food, Dec.1996.
955, Sucralose	13.3.	400 mg/kg	0-15 mg/kg bw	ISA(6), ISDI(3)	6	This intense sweetener, unlike aspartame, is stable to high temperature processing (such as that required for sterile FSMP products) and a wide pH range and has a nutritional composition which renders it suitable for for all disease applications including PKU.

OIV (Office international de la vigne et du vin/ International bureau for wines and vineyards)

OIV (International bureau for wines and vineyards)

The OIV is endeavouring to set out the recommendations and conditions for the use of oenological treatments necessary to produce and presn moved to the more general category « alcoholic beverages » (14.2) or suggested for transference grape-derived wines (category 14.2.3) and limiting the use of technologically unjustifiable adjuncts.

The OIV, having taken part in the Drafting Committee's work, gives its full support to the proposals to distinguish clearly between grape-derived wines (14.2.3.) and the other categories of alcoholic beverages, specifically by establishing the new category 14.2.7. for all flavoured beverages. These pending modifications have already been included in document CL 2002/44, and a good many thickeners, sweeteners and colouring agents (agar, aspartame, carrageenan, cyclamates, mineral oil, saccharine, tartrazine,...) have already been excluded from grape-derived wines on the drafters' own initiative. There still remain certain additives that the OIV would suggest removing from the GSFA, as being unessential to making products that are sound, reliable and true to tradition, and which could be confusing to consumers. Likewise, certain elements that play only a secondary technological role have no reason to figure in the GSFA.

Furthermore, certain additives have beer into this category, which includes the sub-category « grape-derived wines » (14.2.3). Still with the aim of limiting the use of additives, the OIV proposes that the additives indicated in 14.2 should be specified for each of the sub-categories where technological necessity is claimed.

Finally, the OIV emphasizes that « the CCFAC has taken note of the concerns expressed by the OIV on the overuse of additives in category 14.2.3 and has decided to submit those misgivings for scrutiny by the working committee at the thirty-fifth session of the CCFAC » (alinorm 03/12 § 63).

1 – Specific comments on the CCFAC 35 priority list

Group I

Caramel Colour Class III

Caramel Colour Class IV

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
CARAMEL COLOUR CLASS III	CARAMEL III	colorant	150c	14.2.3.3	Fortified Grape Wines	GMP		8
CARAMEL COLOUR CLASS IV	CARAMEL IV	colorant	150d	14.2.3.3	Fortified Grape Wines	GMP		8

Adding caramel to colour certain botrytised sweet wines (14.2.3.3.) is generally accepted practice. For caramels III and IV, however, which have an ADI of 200 mg/kg pc, the OIV has undertaken to examine them so as to establish a numerically quantified dosage.

Dimethyl dicarbonate

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
DIMETHYL DICARBONATE	DICARBONATE DE DIMETHYLE	conservateur	242	14.2.3.	Grape Wines	200	18	6

In 1999, the OIV requested and obtained from the Commission (Alinorm 99/37 § 107) the removal of this additive from the GSFA so that its qualified experts might study it. Now the addition of dimethyl dicarbonate to wine in order to get microbiological stability in bottled wine containing fermentescible sugars is an oenological practice approved by the OIV (Resolution oeno 5/2001). The dose used must not go beyond 200 mg of dimethyl dicarbonate per litre. The OIV favours its use in stage 8.

Ferrocyanides

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
FERROCYANIDES	FERROCYANURES	antiagglomérant	535/536/538	14.2.3.	Grape Wines	GMP	24	6

The ferrocyanides in category 14.2.3 of Alinorm 01/12a Appendix III, brought forward to stage 6 by the 49th session of the executive Committee, are no longer found in document CL 2002/44.

The addition of potassium ferrocyanide to wine to lower its content in certain heavy metals is an œnological practice approved by the OIV (Resolution oeno 16/1970).

The OIV has put on its agenda the establishment of a residual limit based on the ADI set by the JECFA at 0.025 mg/kg pc. The OIV recommends maintaining the use of ferrocyanides in stage 6 for category 14.2.3. pending determination of this limit.

Lysozyme

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
LYSOZYME HYDROCHLORIDE	LYSOZYME	agent de conservation	1105	14.2.3.	Grape Wines	500		6

The addition of a lysozyme to wine in order to control the growth and activity of the bacteria responsible for malolactic fermentation is an œnological practice approved by the OIV (Resolution oeno 10/1997). Experimentation has shown that the maximum dose of 500 mg/l suffices to control the growth and activity of the bacteria responsible for malolactic fermentation. The OIV favours its use in stage 8.

Polyvinylpyrrolidone

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
POLYVINYLPYRROLIDONE	POLYVINYLPYRROLIDONE	raffermissant, stabilisant	1201	14.2.3	Grape Wines	60	36	6

Only the addition of polyvinylpyrrolidone (PVPP) (INS 1202) to wine in order to lower tannin content, etc. is an œnological practice approved by the OIV (Resolution oeno 5/1987). The PVPP dose used must not surpass 800 mg/l.

As was accepted by the Commission in 1999 (Alinorm 99/37 § 107), the OIV recommends removal of polyvinylpyrrolidone (INS 1201) for category 14.2.3. The OIV suggests the inclusion of polyvinylpyrrolidone (INS 1202) in the GSFA for category 14.2.3 in stage 3 at a dose limited to 800 mg/l.

Protease

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
PROTEASE (ASP. ORYZ. VAR.)	PROTEASE	exalteur d'arôme stabilisant attendrisseur	1101i	14.2.3.	Grape Wines	GMP		6

Enzymatic preparations are technological aids in wine-making that are inscribed in the Catalogue of technological aids sanctioned by the Codex Alimentarius. Therefore, the OIV recommends that protease should be taken off the GSFA for category 14.2.3.

Group IIIEDTAs

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
ETHYLENE DIAMINE TETRA ACETATE	EDTAs	antioxydant conservateur	385/386	14.2	alcoholic beverages	25	21	6

As indicated by the OIV in 2001 when approving the use of EDTA in stage 8 for category 14.2 (Alinorm 01/41 § 113), the OIV recommends that this additive should be specified for the sub-categories where it is of technological interest and should be excluded from category 14.2.3. (grape-derived wines).

Group IVSulphites

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
SULPHITES (CALCIUM HYDROGEN SULPHITE) (POTASSIUM BISULPHITE) (POTASSIUM METABISULPHITE) (POTASSIUM SULPHITE) (SODIUM HYDROGEN SULFITE) (SODIUM METABISULPHITE) (SODIUM SULPHITE) (SODIUM THIOSULPHATE) (SULPHUR DIOXYDE)	SULFITES (SULFITE ACIDE DE CALCIUM) (BISULFITE DE POTASSIUM) (METABISULFITE DE POTASSIUM) (SULFITE DE POTASSIUM) (SULFITE ACIDE DE SODIUM) (METABISULFITE DE SODIUM) (SULFITE DE SODIUM) (THIOSULFATE DE SODIUM) (ANHYDRIDE SULFUREUX)	agent de conservation antioxygène	227 228 224 225 222 223 221 539 220	14.2	Alcoholic beverages	350	44/103	6

The addition of sulphur dioxide to wine as an antiseptic against diseases arising from the development of microbes is an OIV-sanctioned œnological practice (Resolution oeno 16/1970). Total sulphur dioxide content (residual limit) at the time the wine is offered for sale must comply with the following limits :

150 mg/l for red wines containing at most 4 g/l of reducing agents

200 mg/l for white and rosé wines containing at most 4 g/l of reducing agents

300 mg/l for red, white, and rosé wines containing more than 4 g/l of reducing agents

400 mg/l for certain special sweet white wines

Group VHydroxybenzoates

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
HYDROXYBENZOATES, p-	p-HYDROXYBENZOATE	agent de conservation	214,216,218	14.2.3.	Grape Wines	1000 - 50	27 / 6	6

In the previous version (Alinorm 01/12A appendix IV) hydroxybenzoate content was fixed for category 14.2.3. at a limit of 1000 mg/kg, with the specification in note 96: "for use in cooler-type products only". As a result of the new system of food categories that has been set up, the OIV recommends removal of hydroxybenzoates for category 14.2.3 and their maintenance in the new category 14.2.7 that includes "coolers". (Proposal in compliance with the recommendations of the Working committee on quality control - CL 2002/44 Annexe II)

Carmines

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
CARMINES	CARMINS	colorant	120	14.2.3.1.	Still Grape Wines	GMP 200	96	6
CARMINES	CARMINS	colorant	120	14.2.3.2.	Sparkling and semi-sparkling Grape Wines	GMP 200	96	6
CARMINES	CARMINS	colorant	120	14.2.3.3.	Fortified and Liquor Grape Wines	GMP 200		6

The OIV recommends elimination of this colouring agent for category 14.2.3. Moreover, in the previous version (Alinorm 01/12A appendix IV) the admissible level of carmines was set for category 14.2.3. with the specification in note 96: "for use in cooler-type products only". As a result of the new system of food categories that has been established, the OIV recommends removal of carmines for categories 14.2.3.1, 14.2.3.2 and 14.2.3.3 and their maintenance in the new category 14.2.7 that includes les "coolers".

Carotenes, Vegetable

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
CAROTENES, VEGETABLE	CAROTENE EXTRAITS NATURELS	colorant	160aii	14.2.3.2.	Sparkling and semi-sparkling Grape Wines	GMP		6
CAROTENES, VEGETABLE	CAROTENE EXTRAITS NATURELS	colorant	160aii	14.2.3.1.	Still Grape Wines	GMP		3
CAROTENES, VEGETABLE	CAROTENE EXTRAITS NATURELS	colorant	160aii	14.2.3.3.	Fortified Grape Wines	GMP		3

The OIV recommends withdrawal of carotenes as a colouring agent for categories 14.2.3.1, 14.2.3.2 and 14.2.3.3 and their maintenance in the new category 14.2.7 .

Grape Skin Extract

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
GRAPE SKIN EXTRACT	EXTRAITS DE PEAU DE RAISIN	colorant	163i	14.2.3.2.	Sparkling and semi-sparkling Grape Wines	GMP		6
GRAPE SKIN EXTRACT	EXTRAITS DE PEAU DE RAISIN	colorant	163i	14.2.3.3.	Fortified and Liquor Grape Wines	GMP		6

The OIV recommends removal of Grape skin extracts as a colouring agent for categories 14.2.3.2 and 14.2.3.3 and their maintenance in the new category 14.2.7 . The OIV is therefore unfavourable to the recommendation of the Working committee on quality control, which suggests lumping everything together in category 14.2. In addition, the original source is the EU, which also recommends removal from category 14.2.3.

Riboflavines

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
RIBOFLAVINES	RIBOFLAVINE	colorant	101i	14.2.3.4.3	Still Fortified Grape Wines	GMP		6
RIBOFLAVINES	RIBOFLAVINE	colorant	101i	14.2.3.2.	Sparkling and semi-sparkling Grape Wines	GMP		6

The OIV recommends striking riboflavins as colouring agents from categories 14.2.3.2 and 14.2.3.3 and their maintenance in the new category 14.2.7 . Moreover, an original source is the EU, which also recommends their elimination from category 14.2.3.

Sorbitan Esters of Fatty Acids

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
SORBITAN ESTERS OF FATTY ACIDS	SORBITANE (MONOSTEARATE, TRISTEARATE, MONOLAURATE, MONOOLEATE, MONOPALMITATE)	émulsifiant	491/492/493/494/495	14.2.3	Grape Wines	GMP		6

Sorbitans are technological aids in wine-making (anti-foaming agents) listed in the Catalogue of technological aids sanctioned by the Codex Alimentarius. Therefore, the OIV recommends their withdrawal from the GSFA for category 14.2.3.

Sucralose

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
SUCRALOSE	SUCRALOSE	édulcorant	955	14.2	Alcoholic beverages	700		6

OIV recommends that sucralose should be specified as a sweetener for the sub-categories of category 14.2, where, unlike category in 14.2.3, they are technologically justified..

Tannic Acid

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
TANNIC ACID (TANNINS, FOOD GRADE)	TANINS DE QUALITE ALIMENTAIRE	colorant émulsifiant stabilisant	181	14.2.3.	Grape Wines	3000		3 6

Adding tannins to wine to further the decanting of new wines by the partial precipitation of excessive proteic matter and to facilitate their fining is an œnological practice approved by the OIV (Resolution oeno 16/1970). Tannins are used to promote clarification of musts and wines. They must not modify the wines' fragrances or colour. (Resolutions oeno 12/2002).

A study of the sources shows that a limit of 3000 mg/kg was proposed by the USA for category 14.2.3, but also that the limit initially proposed was 150 mg/kg for the whole of category 14.2.

Consultation of the USA wine-making regulations (CFR 27 §24.247) shows that “tannins” are used "to clarify or to adjust tannin content of wine". It is specified that "the residual amount of tannin shall not exceed 800 mg/l in white wine and 3000 mg/l in red wine. Only tannin which does not impart colour may be used in the cellar treatment of wine. Total tannin shall not be increased by more than 150 mg/l by the addition of tannic acid". There thus seems to be some confusion between the limit on the amount that can be added (150 mg/l) and the total residual tannin content, limited in the USA to 3000 mg/l.

The OIV recommends that for category 14.2.3 the GSFA should retain the use limit and that a note should be inserted in the “comments” column indicating: "only tannin which does not impart colour may be used to clarify grape wine".

Group VI

Acesulfame Potassium

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
ACESULFAME POTASSIUM	ACESULFAME POTASSIUM	édulcorant	950	14.2.3.	Grape Wines	350 GMP		6

The OIV recommends the elimination of this sweetener from category 14.2.3.

Carotenoids

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
CAROTENOIDS	CAROTENOIDES	colorant	160ai, e, f	14.2.3.2.	Sparkling and semi-sparkling Grape Wines	GMP		6

The OIV recommends that carotenoids should be withdrawn as colouring agents for category 14.2.3.2 and maintained in the new category 14.2.7 .

Ethyl maltol

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
ETHYL MALTOL	ETHYL-MALTOL	exalteur d'arôme	637	14.2.3.	Grape Wines	100	93	6

The OIV sanctions the use of this additive with the restriction stated in the commentary, which excludes wine products derived from *Vitis vinifera*.

Phosphates

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
PHOSPHATES	PHOSPHATES	émulsifiant anti-agglomérant agent de rétention de l'eau	542	14.2.3.	Grape Wines	- 440	33	6

In the previous version (Alinorm 01/12A Appendix IV) phosphates were suggested in note 96 "for use in cooler-type products only". As a result of the new system of food categories that has been set up, The OIV recommends that phosphates should be struck from category 14.2.3 and maintained in the new category 14.2.7 which includes "coolers".

Polyglycerol Esters of Fatty AcidsPolyglycerol Esters of interesterified ricinoleic acid

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
POLYGLYCEROL ESTERS OF FATTY ACIDS	ESTERS POLYGLYCEROLIQUES D'ACIDES GRAS	émulsifiant	475	14.2.3.	Grape Wines	500		6
POLYGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	ESTERS POLYGLYCEROLIQUES DE L'ACIDE RICINOLEIQUE INTERESTERIFIE	émulsifiant	476	14.2.3.	Grape Wines	1000		6

Polyglycerol esters are technological aids in wine-making (anti-foaming agents) listed in the Catalogue of technological aids sanctioned by the Codex Alimentarius. Therefore, the OIV recommends their removal from the GSFA for category 14.2.3.

Sorbates

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
SORBATES (CALCIUM SORBATE)	SORBATE DE CALCIUM	agent de conservation	203	14.2.3.	Grape Wines	2000	42	6
SORBATES (POTASSIUM SORBATE)	SORBATE DE POTASSIUM	agent de conservation	202	14.2.3.	Grape Wines	2000	42	6
SORBATES (SODIUM SORBATE)	SORBATE DE SODIUM	agent de conservation	201	14.2.3.	Grape Wines	2000	42	6
SORBATES (SORBIC ACID)	ACIDE SORBIQUE	agent de conservation	200	14.2.3.	Grape Wines	2000	42	6

Adding sorbic acid or potassium sorbate to wine in order to stabilise it biologically, to prevent wines containing fermentescible ferments from refermenting, and to hinder the development of undesirable yeasts is an œnological practice accepted by the OIV (Resolution Oeno 5/1988). The dose to be used must not surpass 200 mg of sorbic acid per litre.

The OIV recommends inclusion of sorbates, limited to 200 mg/kg in the GSFA for 14.2.3 with a note in the « comments » column indicating "the only sorbates accepted are potassium sorbate (INS 202) and sorbic acid (INS 200)"

Tartrates

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
TARTRATES (DIPOTASSIUM) (DISODIUM) (MONOPOTASSIUM) (MONOSODIUM) (POTASSIUM-SODIUM) (TARTARIC ACID (L(+)-))	TARTRATES (DIPOTASSIQUE) (DISODIQUE) (MONOPOTASSIQUE) (MONOSODIQUE) (DE POTASSIUM-SODIUM) (ACIDE TARTRIQUE (L(+)-))	stabilisant séquestrant	334, 335i, 335ii, 336i, 336ii, 337	14.2. 3.1.	Still Grape Wines	9000	45	6
TARTRATES (DIPOTASSIUM) (DISODIUM) (MONOPOTASSIUM) (MONOSODIUM) (POTASSIUM-SODIUM) (TARTARIC ACID (L(+)-))	TARTRATES (DIPOTASSIQUE) (DISODIQUE) (MONOPOTASSIQUE) (MONOSODIQUE) (DE POTASSIUM-SODIUM) (ACIDE TARTRIQUE (L(+)-))	stabilisant séquestrant	334, 335i, 335ii, 336i, 336ii, 337	14.2. 3.2.	Sparkling and semi-sparkling Grape Wines	2560 - 2600	45	6
TARTRATES (DIPOTASSIUM) (DISODIUM) (MONOPOTASSIUM) (MONOSODIUM) (POTASSIUM-SODIUM) (TARTARIC ACID (L(+)-))	TARTRATES (DIPOTASSIQUE) (DISODIQUE) (MONOPOTASSIQUE) (MONOSODIQUE) (DE POTASSIUM-SODIUM) (ACIDE TARTRIQUE (L(+)-))	stabilisant séquestrant	334, 335i, 335ii, 336i, 336ii, 337	14.2. 3.3.	Fortified Grape Wines	2600	45	6

Adding neutral potassium tartrate to further biological deacidification and thus reduce titration and real acidity (increasing the pH) is an œnological practice approved by the OIV (Resolution oeno 6/1979).

Furthermore, increasing titration and real acidity (decreasing the pH) through the addition of tartaric acid L(+) so as to obtain wines with balanced taste and to promote a favourable biological development and a good level of preservation is an œnological practice approved by the OIV (Resolutions oeno 4/1999 and oeno 14/2001). Acids may be added to wine only insofar as the initial acidity is not increased by more than 54 meq/l (i.e. 4000 mg of tartaric acid per litre).

The OIV recommends including tartrates, limited to 4000 mg/kg, in the GSFA for category 14.2.3 (grouping together 14.2.3.1, 14.2.3.2 and 14.2.3.3), inserting a note in the « comments » column indicating: « only dipotassium tartrate (INS 336ii) and tartaric acid (INS 334) are acceptable »

Group VIICurcumin

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
CURCUMIN	CURCUMINES	colorant	100i	14.2.3.1.	Still Grape Wines	GMP 200	96	6 3
CURCUMIN	CURCUMINES	colorant	100i	14.2.3.2.	Sparkling and semi-sparkling Grape Wines	GMP 200	96	6 3
CURCUMIN	CURCUMINES	colorant	100i	14.2.3.3.	Fortified Grape Wines	200		3

The OIV recommends that the colouring agent curcumin should be dropped from categories 14.2.3.1., 14.2.3.2 and 14.2.3.3. and maintained in the new category 14.2.7 .

Polyoxyethylene Stearates

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
POLYOXYETHYLENE STEARATES (8 AND 40)	STEARATE DE POLYOXYETHYLENE (8 et 40)	émulsifiant	430/431	14.2.3.	Grape Wines	GMP		6

Polyoxyethylene stearates are technological aids (anti-foaming agents) inscribed in the Catalogue of technological aids sanctioned by the Codex Alimentarius. The OIV therefore recommends their withdrawal from the GSFA for category 14.2.3. (?)

Group VIIIAnnatto extracts

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
ANNATTO EXTRACTS	EXTRAITS DE ROCOU	colorant	160b	14.2.3.	Grape Wines	GMP 10		6 3
ANNATTO EXTRACTS	EXTRAITS DE ROCOU	colorant	160b	14.2.3.3	Fortified Grape Wines	GMP		6

The OIV recommends that the colouring agent annatto extract should be dropped for categories 14.2.3. and 14.2.3.3. and maintained in the new category 14.2.7 .

Canthaxanthin

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
CANTHAXANTHIN	CANTHAXANTHINE	colorant	161g	14.2.3.	Grape Wines	5		6

The OIV recommends dropping the colouring agent canthaxanthin for category 14.2.3. and maintaining it in the new category 14.2.7 .

Iron Oxides

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
IRON OXYDE BLACK	OXYDE DE FER NOIR	colorant	172i	14.2.3.2.	Sparkling and semi-sparkling Grape Wines	GMP		6
IRON OXYDE RED	OXYDE DE FER ROUGE	colorant	172ii	14.2.3.2.	Sparkling and semi-sparkling Grape Wines	GMP		6
IRON OXYDE YELLOW	OXYDE DE FER JAUNE	colorant	172iii	14.2.3.2.	Sparkling and semi-sparkling Grape Wines	GMP		6

The OIV recommends that iron oxides should be withdrawn as colouring agents for category 14.2.3.2 and maintained in the new category 14.2.7 .

2 – Specific comments on other additives listed in CL2002/442.1 – Colouring agents

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
BEET RED	ROUGE DE BETTERAVE	colorant	162	14.2.3.2. 14.2.3.2. & 14.2.3.3.	Grape Wines Sparkling & Fortified	GMP		6
CHLOROPHYLLS	CHLOROPHYLLES	colorant	140	14.2.3.2.	Sparkling Grape Wines	GMP		6
CHLOROPHYLLS	CHLOROPHYLLES	colorant	140	14.2.3.3.	Fortified Grape Wines	GMP		6
CHLOROPHYLLS, COPPER COMPLEXES	COMPLEXE CHLOROPHYLLE CUIVRE	colorant	141i	14.2.3.2.	Sparkling Grape Wines	GMP		6
CHLOROPHYLLS, COPPER COMPLEXES	COMPLEXE CHLOROPHYLLE CUIVRE	colorant	141i	14.2.3.3.	Fortified Grape Wines	GMP		6
TITANIUM DIOXYDE	BIOXYDE DE TITANE	colorant	171	14.2.3.2.	Sparkling and semi-sparkling Grape Wines	GMP		3 6

The OIV recommends removing these chemicals from categories 14.2.3.2 and 14.2.3.3 .

2.2. Technological aids

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
CALCIUM MALATE	MALATE DE CALCIUM	régulateur de l'acidité humectant	352ii	14.2.3.	Grape Wines	GMP		6
CALCIUM ALGINATE	ALGINATE DE CALCIUM	épaississant stabilisant gélifiant	404	14.2.3.	Grape Wines	4000 GMP		6
CALCIUM ALUMINIUM SILICATE	ALUMINOSILICATE DE CALCIUM	antiagglomérant	556	14.2.3.	Grape Wines	GMP		6
CAROB BEAN GUM	GOMME DE CAROUBE	épaississant stabilisant	410	14.2.3.	Grape Wines	500 GMP		6
GELLAN GUM	GOMME GELLANE	Epaississant, stabilisant	418	14.2.3.	Grape Wines	GMP		3 6
GUAR GUM	GOMME GUAR	épaississant stabilisant	412	14.2.3.	Grape Wines	500 GMP		6
KARAYA GUM	GOMME KARAYA	épaississant stabilisant	416	14.2.3.	Grape Wines	500 GMP		6
KONJAC FLOUR	FARINE DE KONJAC	Epaississant	425	14.2.3.	Grape Wines	GMP		3 6
MICROCRYSTALLINE CELLULOSE	CELLULOSE MICROCRISTALLINE	antiagglomérant	460i	14.2.3.	Grape Wines	GMP		3
MONO AND DIGLYCERIDES OF FATTY ACIDS	MONO- ET DIGLYCERIDES D'ACIDES GRAS	émulsifiant stabilisant	471	14.2.3.	Grape Wines	18		6
NITROGEN	AZOTE	gaz de conditionnement / cryogène	941	14.2.3.	Grape Wines	GMP	59	6
PAPAIN	PAPAINE	exalteur d'arôme stabilisant attendrisseur	1101ii	14.2.3.	Grape Wines	GMP		6
PECTINS	PECTINES	Epaississant, stabilisant, gélifiant	440	14.2.3	Grape Wines	GMP		
POTASSIUM ALGINATE	ALGINATE DE POTASSIUM	épaississant stabilisant	402	14.2.3-2.	Sparkling and semi-sparkling Grape Wines	GMP		6
POWDERED CELLULOSE	CELLULOSE EN POUDRE	antiagglomérant	460ii	14.2.3	Grape Wines	GMP		3 6
TARA GUM	GOMME TARA	Epaississant, stabilisant	417	14.2.3	Grape Wines	GMP		3
TRAGACANTH GUM	GOMME ADRAGANTE	épaississant stabilisant émulsifiant	413	14.2.3.	Grape Wines	500 GMP		3 6
XANTHAN GUM	GOMME XANTHANE	Epaississant, stabilisant	415	14.2.3	Grape Wines	GMP		3 6

The OIV recommends that all these products be removed from the GSFA for categorie 14.2.3.

2.3. Additives approved by the OIV or under study

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
CITRIC ACID	ACIDE CITRIQUE	régulateur de l'acidité antioxygène séquestrant	330	14.2. 3.	Grape Wines	700		6
FUMARIC ACID	ACIDE FUMARIQUE	régulateur de l'acidité	297	14.2. 3.	Grape Wines	3000	109	6
LACTIC ACID (L-, D- & DL-)	ACIDE LACTIQUE (L-, D- et DL-)	régulateur de l'acidité	270	14.2. 3.	Grape Wines	GMP 1		6
MALIC ACID (DL-)	ACIDE MALIQUE (DL-)	régulateur de l'acidité	296	14.2. 3.	Grape Wines	GMP 1		6

Increasing titration or real acidity (decreasing the pH) through the addition of lactic acid, L(-) DL malic acid or citric acid to balance the taste of wines and further a favourable biological development and a good level of preservation is an œnological practice approved by the OIV (Resolutions oeno 4/1999 and oeno 14/2001). The addition of acids to wine is permissible only insofar as the initial acidity is not raised by more than 54 meq/l (i.e. 4000 mg of tartaric acid per litre).

The OIV recommends that malic, citric and lactic acid, limited to 4000 mg/kg, should be included in the GSFA for category 14.2.3. The OIV wishes fumaric acid, currently under study by its competent experts, to be maintained in stage 6.

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
ASCORBIC ACID	ACIDE ASCORBIQUE (L-)	antioxygène	300	14.2. 3.	Grape Wines	200		6
ERYTHORBIC ACID	ACIDE ERYTHORBIQUE	antioxygène	315	14.2. 3.	Grape Wines	GMP		6

Addition of ascorbic acid to wine to gain the protection of its antioxidising properties against the effects of oxygen in the air, which alters its colour and taste is an œnological practice approved by the OIV protect it (Resolution oeno 12/2001). Isoascorbic acid or D-ascorbic acid or erythorbic acid have the same antioxidising power as ascorbic acid and may also be used in wine-making for this purpose. The dose used must not go beyond 250 mg/l.

The OIV recommends including ascorbic and erythorbic acid, limited to 250 mg/kg, in the GSFA for category 14.2.3.

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
CALCIUM CARBONATE	CARBONATE DE CALCIUM	anti-agglomérant / colorant surfacique	170i	14.2. 3.	Grape Wines	3500		6
CALCIUM SULPHATE	SULFATE DE CALCIUM	séquestrant raffermissant	516	14.2. 3.3.	<u>Fortified</u> Grape Wines	2000		6

The use of calcium carbonate, possibly containing small quantities of calcium double salts, L(+) tartaric acid and L(-) malic acid, as a wine additive to lower titration and real acidity (increasing the pH) is an œnological practice approved by the OIV (Resolution oeno 6/1979).

Calcium sulphate is not approved by the OIV as an additive to lower the pH of wine(14.2.3). (Resolution oeno 3/1985). It is, however, approved for use in certain botrytised sweet wines (14.2.3.3.)

The OIV recommends including calcium carbonate, limited to the GMP level, in the GSFA for category 14.2.3 and reserving calcium sulphate exclusively for category 14.2.3.3, specifying in note 36 that this is a residual limit.

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
CARAMEL COLOUR CLASS I	CARAMEL I	colorant	150a	14.2.3.	Grape Wines	GMP		6
CARAMEL COLOUR CLASS II	CARAMEL II	colorant	150b	14.2.3.	Grape Wines	GMP		3

The practice of adding caramel to wine (14.2.3) to colour it and modify the taste is not approved by the OIV (Resolution oeno 5/1987). It is nevertheless accepted for certain botrytised sweet wines (14.2.3.3.)

The OIV recommends that caramel should be kept in the GSFA only for category 14..2.3.3, within the limits of GMP usage for caramel I (with no ADI), and that caramel II, for which the OIV has undertaken a study to determine a numerically quantified usage dose, should be maintained in stage 6 at its ADI of 160 mg/kg.

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
CARBON DIOXIDE	ANHYDRIDE CARBONIQUE	agent de carbonatation gaz de conditionnement	290	14.2.3.	Grape Wines	GMP	60	6

The process of using carbon dioxide to create an inert atmosphere to protect the must from the air so as to avoid oxidation and the development of germs or aerobic organisms, and the use of carbon dioxide in racking operations do not involve an « addition » to the wine, but rather a technological measure to aid in processing. The OIV recommends that it should be dropped for category 14.2.3.

It can, however, be used as an additive for sparkling wines in category 14.2.3.2. The OIV recommends maintaining carbon dioxide as an additive only for category 14.2.3.2, within the GMP limits. Note 60 concerning still wines is to be eliminated.

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
POTASSIUM HYDROGENE CARBONATE	CARBONATE ACIDE DE POTASSIUM	régulateur de l'acidité stabilisant	501ii	14.2.3.	Grape Wines	5000		6

Adding potassium hydrogen carbonate to lower titration and real acidity (decreasing the pH) by promoting biological deacidification is an œnological practice approved by the OIV (Resolution oeno 6/1979).

The OIV recommends the inclusion of potassium hydrogen carbonate in the GSFA for category 14.2.3, within the GMP limits.

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
GUM ARABIC	GOMME ARABIQUE	épaississant stabilisant	414	14.2.3.	Grape Wines	500 - 300		6

The addition of arabic gum to wine in order to avoid copper casse, protect from light iron casse and prevent the precipitation of colloidal substances such as colouring agents present in the wine is an œnological practice approved by the OIV (Resolution oeno 12/1972) The acceptable dose must not surpass 300 mg/l.

The OIV recommends including arabic gum, limited to a dose of 300 mg/kg, in the GSFA for category 14.2.3.

2.4 Additives to be specified by sub-category or in a note apart

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
DIOCTYL SODIUM SULFOSUCCINATE	SULFOSUCCINATE DIOCTYLIQUE DE SODIUM	Emulsifiant, mouillant	480	14.2	Alcoholic beverages	10		6
PROPYLENE GLYCOL	ALGINATE DE PROPYLENE GLYCOL	Epaississant, émulsifiant	405	14.2	Alcoholic beverages	50000		6

As already indicated by the OIV for additives in the general category 14.2, the OIV recommends that these additives should be specified for the sub-categories in which they are of technological interest and excluded from category 14.2.3. (grape-derived wines).

Name	Nom	Fonction	INS	Food N°	Category	Max level	Note	Step
MALTOL	MALTOL	exalteur d'arôme	636	14.2.3	Grape Wines	250		6

The OIV approves the use of this additive except for the restriction in note 93 that excludes wines made from *Vitis vinifera*, in compliance with USA regulations.

2.5 - Additives not studied by the OIV and requiring technological

CALCIUM ASCORBATE	ASCORBATE DE CALCIUM	antioxygène	302	14.2.3.	Grape Wines	GMP		6
POTASSIUM ASCORBATE	ASCORBATE DE POTASSIUM	antioxygène	303	14.2.3.	Grape Wines	GMP		6
POTASSIUM CARBONATE	CARBONATE DE POTASSIUM	régulateur de l'acidité stabilisant	501i	14.2.3.	Grape Wines	5000		6
SODIUM ASCORBATE	ASCORBATE DE SODIUM	antioxygène	301	14.2.3.	Grape Wines	200		6
SODIUM ERYTHORBATE (ISOASCORBATE)	ISOASCORBATE DE SODIUM	antioxygène	316	14.2.3.	Grape Wines	GMP		6

The OIV needs to know the source of the proposal to use these additives in category 14.2.3 and fears it may a case of mistaken classification that is no longer valid in view of the new classification of food categories. The OIV recommends their removal from the GSFA but is willing to add them to its work agenda if member States of the Codex so desire.