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FOOD AND AGRICULTURE
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Agenda Item 7 (d)

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

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CONSIDERATION OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES (GSFA) PROPOSED DRAFT AND DRAFT REVISIONS TO TABLE 1 OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES

Report of the CCFAC's Electronic Quality Control Working Group for the GSFA

Governments and international organizations wishing to submit comments 3 on the following subject matter are invited to do so **no later than 16 February 2004** as follows: Netherlands Codex Contact Point, Ministry of Agriculture, Nature and Food Quality, P.O. Box 20401, 2500 E.K., The Hague, The Netherlands (Telefax: +31.70.378.6141; E-mail: info@codexalimentarius.nl, with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00100 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: Codex@fao.org).

BACKGROUND

1. The 35th Session of the Codex Committee on Food Additives and Contaminants (CCFAC) reinstated its informal *ad hoc* Quality Control Working (Australia, Brazil, Japan, South Africa, and European Commission) with the addition of Morocco, Tanzania, and Thailand under the direction of the USA. The CCFAC charged them with working through electronic means to examine food additive provisions in the Codex General Standard for Food Additives (GSFA) based on technological need and provide recommendations to the CCFAC on maximum levels of use in the GSFA. The CCFAC also requested that the Quality Control Group attempt to resolve differences between the GSFA and commodity standards.¹
2. The CCFAC's *ad hoc* electronic Quality Control Working Group (eQC WG) on the GSFA offers the following recommendations for consideration by the CCFAC. The eQC WG only discussed pending provisions (proposed draft or draft provisions) for the additives listed in the table below. Proposals for other uses of these additives were not considered.

INS No.	Additive	INS No.	Additive
901	Beeswax, White and Yellow	900a	Polydimethylsiloxane
902	Candelilla Wax	1201	Polyvinylpyrrolidone
903	Carnauba Wax	905ci	Microcrystalline Wax
210, 211, 212, 213	Benzoates	512	Stannous Chloride
483	Stearyl Tartrate	477	Propylene Glycol Esters of Fatty Acids
181	Tannic Acid	384	Isopropyl Citrates

¹ ALINORM 03/12A, paras. 38-39

INS No.	Additive	INS No.	Additive
387	Oxystearin	385, 386	EDTAs
999	Quillaia Extract	459	Cyclodextrin, Beta
905d	Mineral Oil (High Viscosity)	310	Gallate, Propyl
905e	Mineral Oil (Medium and Low Viscosity, Class I)	304, 305	Ascorbyl Esters
905f	Mineral Oil (Medium and Low Viscosity, Classes II)	320	Butylated Hydroxyanisole (BHA)
905g	Mineral Oil (Medium and Low Viscosity, Classes III)	321	Butylated Hydroxytoluene (BHT)
242	Dimethyl Dicarbonate	319	Tertiary Butylhydroxyquinone (TBHQ)
445	Glycerol Ester of Wood Rosin	472e	Diacetyltartaric and Fatty Acid Esters of Glycerol (DATEM)
314	Guaiac Resin	472f	Tartaric, Acetic & Fatty Acid Esters of Glycerol (Mixed)
1105	Lysozyme HCl		

BEESWAX (INS 901) AND CANDELILLA WAX (INS 902)

3. The 34th CCFAC noted that JECFA determined Beeswax (901) and Candelilla wax (902) to be “Acceptable” for use as carriers for flavors. Their use in water-based flavored drinks, including “sport,” “energy” or “electrolyte” drinks and particulated drinks (14.1.4) should be examined since the intake of these additives through carry-over has not been assessed by JECFA.² These substances have been placed on the CCFAC’s JECFA Priority List but there is no commitment or timetable from any delegation to provide the information necessary for JECFA’s review.³

4. Japan reports that beeswax is allowed at levels up to 1000 ppm in category 14.1.4 in Japan. They estimate beeswax consumption is 0.9 mg/person/day based upon an annual consumption study.

Recommendation for Beeswax (INS 901) & Candelilla Wax (INS 902)

The eQC WG recommends that the CCFAC identify a delegation(s) to commit to providing the information and data on beeswax and candelilla wax necessary to JECFA so that it can perform an exposure assessment based on their proposed uses in water-based flavored drinks, including “sport,” “energy” or “electrolyte” drinks and particulated drinks (14.1.4) and other uses based on adopted provisions in the GSFA. If no delegation is willing to take responsibility for providing this information, then the 36th CCFAC should agree to delete these provisions from the draft GSFA.

CARNAUBA WAX (INS 903)

5. The 39th JECFA (1992) assigned an ADI of 7 mg/kg bw for carnauba wax. Several provisions for carnauba wax have been adopted at Step 8 by the CAC.

Recommendation 1 for Carnauba Wax, INS 903

The eQC WG recommends that the CCFAC endorse the following provisions for adoption at Step 8 by the CAC.

² ALINORM 03/12, para 58

³ ALINORM 03/12A, App. XV

Carnauba Wax (INS 903) (Anticaking Agent, Adjuvant, Bulking Agent, Carrier Solvent, Glazing Agent, Release Agent)			
Food Cat. No.	Food Category	ML	Comments
04.1.1.2	Surface-treated fresh fruit	50,000 mg/kg	
04.1.2	Processed fruit	50,000 mg/kg	
04.2.1.2	Surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes [(including soybeans)], seaweeds, and nuts and seeds	50,000 mg/kg	Note 79 ⁴

Recommendation 2 for Carnauba Wax, INS 903

The eQC WG could not reach consensus on the following draft provisions for carnauba wax.

The eQC WG recommends that the 36th CCFAC request information on the use of carnauba wax in the noted categories, with the understanding that if no information is received by the 37th CCFAC to justify these uses, the listings of carnauba wax in these food categories will be deleted

Food Cat. No.	Food Category	ML	Comments	Step
05.4 ⁵	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	10000 mg/kg		6
12.6	Sauces and like products	GMP		6
14.1.2.1	Canned or bottled (pasteurized) fruit juice	GMP		6

BENZOATES (INS 210, 211, 212, 213)

6. The 29th CCFAC requested that JECFA perform intake assessments for benzoates (JECFA (1973) group ADI 5 mg/kg bw (benzoic acid)) based on the levels of maximum use in the draft GSFA. Benzoates were identified for JECFA exposure assessment because several delegations expressed concern that the draft provisions for these additives might contribute significantly to their intake resulting in exceeding their ADI.

Recommendation 1 for Benzoates, INS 210, 211, 212, 213

The eQC WG could not reach consensus on the following draft provisions for the use of benzoates as a preservative. The eQC WG recommends that the 36th CCFAC request information on the use of benzoates in the noted categories, with the understanding that if no information is received by the 37th CCFAC to justify these uses, the listings of benzoates in these food categories will be deleted.

In particular, the eQC WG recommends that the 36th CCFAC request information in support of the use of preservatives in food categories 04.1.2.4 and 04.2.2.4 and whether or not the 37th CCFAC should either add a note restricting these provisions only to unpasteurized foods in these categories or delete them.

The eQC WG also recommends that the 36th CCFAC request information to support a maximum use level of greater than 1000 mg/kg for benzoates in categories 04.1.2.5, 05.3, 14.1.2.2, 14.1.2.4 and 14.1.3.2.

The eQC WG also recommends that the 36th CCFAC request information to support the use of preservatives in categories 8.2.1.2, 8.3.1.2, 8.3.2, and 9.2.5.

Benzoates INS 210-213 (Preservative)					
Food Cat. No.	Food Category	Max Level		Comment	Step
04.1.2.4	Canned or bottled (pasteurized) fruit	800	mg/kg	Note 13 ⁶	6
04.1.2.5	Jams, jellies and marmelades	1500	mg/kg	Note 13	3
04.2.2.4	Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and tubers, pulses and legumes, and aloe vera), and seaweeds	1000	mg/kg	Note 13	6
05.3	Chewing gum	1500	mg/kg	Note 13	6

⁴ Note 79 For use on nuts only.

⁵ The CAC (2001) adopted a maximum use level of 4000 mg/kg for carnauba wax in category 05.4

⁶ Note 13: As benzoic acid.

Benzoates INS 210-213 (Preservative)					
Food Cat. No.	Food Category	Max Level		Comment	Step
08.2.1.2	Cured (including salted) and dried non-heat treated processed meat, poultry, and game products in whole pieces or cuts		GMP	Notes 3 ⁷ & 13	6
08.3.1.2	Cured (including salted) and dried non-heat treated processed comminuted meat, poultry, and game products	1000	mg/kg	Note 13	6
08.3.2	Heat-treated processed comminuted meat, poultry, and game products	1000	mg/kg	Note 13	3
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg	Note 13	6
14.1.2.1	Canned or bottled (pasteurized) fruit juice	2000	mg/kg	Note 13	6
14.1.2.2	Canned or bottled (pasteurized) vegetable juice	2000	mg/kg	Note 13	6
14.1.2.3	Concentrate (liquid or solid) for fruit juice	2000	mg/kg	Note 13	6
14.1.2.4	Concentrate (liquid or solid) for vegetable juice	1400	mg/kg	Note 13	6
14.1.3.1	Canned or bottled (pasteurized) fruit nectar	2000	mg/kg	Note 13	6
14.1.3.2	Canned or bottled (pasteurized) vegetable nectar	2000	mg/kg	Note 13	6

Category 5.1.1

7. Neither the Codex Cocoa Powders (Cocoa) and Dry Mixtures of Cocoa and Sugar standard (CX STAN 105) nor the Cocoa (Cacao) Mass (Cocoa/Chocolate Liquor) and Cocoa Cake standard (CX STAN 141) contain provisions for the use of benzoates or other preservatives. The scopes of these standards are limited to cocoa powders (cocoas) and dry mixtures of cocoa and sugars intended for direct consumption; and cocoa (cacao) mass or cocoa/chocolate liquor, and cocoa cake, for the use in the manufacture of cocoa and chocolate products or to be sold directly to the consumer, respectively.

8. Comparison of the description of the scopes of the two commodity standards with the scope of the category 5.1.1 indicates that the breadth of the two commodity standards encompasses all of the foods covered by category 5.1.1. The absence of provisions for preservatives in these two commodity standards suggests that preservatives are not needed in the foods covered by category 5.1.1.

Recommendation 2 for Benzoates, INS 210, 211, 212, 213

The eQC WG recommends that the CCFAC delete the draft provision for food category 05.1.1 from the GSFA.

Categories 14.1.2.1, 14.1.2.3, 14.1.3.1, 14.1.3.3

9. The Codex *ad hoc* Intergovernmental Task Force on Fruit and Vegetable Juice is developing a General Standard for Fruit Juices and Nectars that contains an ML for benzoate at 1000 mg/kg, "Subject to national legislation of the importing country".⁸ The scope of this standard corresponds to the foods contained in food categories 14.1.2.1, 14.1.2.3, 14.1.3.1, 14.1.3.3. Therefore, the eQC WG agrees that the maximum use level in these food categories should be 1000 mg/kg for consistency with the Standard.

Category 14.1.4 et seq

10. The 34th CCFAC had extensive discussions on the ML for benzoates in category 14.1.4, but could not reach consensus on endorsement for adoption at Step 8. The Committee returned this entry to Step 6 for further consideration as to the technological need in different geographical regions. Specifically, the CCFAC is interested in information on the relationship between climatic differences and the specific types of soft drinks requiring MLs of 1000 mg/kg.

11. Based on available information to the eQC WG, provided below, a maximum use level of 1000 mg/kg is safe and many Codex countries accept 1000 mg/kg as the acceptable ML for products in category 14.1.4.

⁷ Note 3: Surface treatment.

⁸ ALINORM 03/39A, App. II

Technological Need and Justification

12. Benzoates have many of the properties of an ideal preservative from a food technology perspective. Their addition at a level inhibitory for many microorganisms does not (or only slightly) affect(s) 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 (e.g., 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 good manufacturing practices regardless of the acceptable ML, and only the amount necessary should be used to achieve its intended technical effect as a preservative. Therefore, the acceptable ML varies among countries.

13. The use of benzoates in beverages lengthens the shelf-life and minimizes unnecessary food losses caused by microbial contamination and growth. Also, their use is necessary so that beverages can be transported safely over long distances and be made available to a larger number of consumers. In many instances, processed beverages are the safest sources of liquids for people living in areas that lack access to potable water.

14. The 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. Public health hazards and food losses also are minimized.

15. The use of benzoates protects beverage quality and minimizes risks to consumers due to yeast, molds and bacteria. Thus, the use of benzoates in soft drink manufacture is technologically justified.

16. A food manufacturer considers several factors when selecting the appropriate use level of benzoate for a beverage included in food category 14.1.4 that will be marketed worldwide. Different production environments and climatic conditions will determine the extent of the technological need for benzoates to achieve their intended technical effect as a preservative.

17. The growth of spoilage microorganisms in water-based drinks, including “sport” or “electrolyte” drinks, may result in a variety of undesirable effects, including off-taste, off-odor, scum, and sedimentation. Gas formation because of microbial activity as well as changes in beverage color and clarity can result if the microbial load is not controlled. The growth of the majority of these organisms may be controlled by the addition of benzoates.

18. Several types of microorganisms may contaminate beverages. Most cases of microbial spoilage of carbonated soft drinks have been caused by yeast. Included among beverage spoilage organisms are the acid-tolerant bacteria such as *Lactobacillus* and *Acetobacter*. In non-carbonated drinks, molds are often a problem as well.

19. The major factors influencing yeast growth are beverage composition, pH, degree of carbonation, and preservative level in the beverage. 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, and fruit drinks provide an environment in which yeast, molds and bacteria can grow readily. The addition of benzoates can provide the necessary stabilization for carbonated as well as non-carbonated soft drinks.

20. While no substitute exists 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.

21. It is important to note that the ingredients and the processing environment used in the production of beverages 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 at levels necessary 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).

22. The potential for contamination makes it technologically necessary to add preservatives like benzoates to susceptible beverages to control microbial growth to ensure product safety. These beverages are often products that are not treated by heat or other processing means to destroy microorganisms. The use of benzoates also provides a cost-effective and a safe way to preserve beverages enabling lower prices for consumers.

23. Benzoates have a long history of safe use as preservatives in foods. They are particularly well suited for use in soft drinks, such as carbonated and still beverages, or fruit juices. 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. As a result, benzoates are least active in neutral medium, and their 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. This is due to the fact that more undissociated benzoic acid exists at the lower pH. At pH 4.5, only 33% of total benzoate (dissociated and undissociated forms of benzoic acid) exists as the undissociated acid but at pH 3.0, as much as 94% of total benzoate exists as the undissociated acid.

24. Benzoates inhibit the growth of microorganisms by interrupting many enzymatic processes in microorganisms at concentrations that retard their growth rate. In addition, benzoates may destroy microorganisms by altering the cell's membrane permeability so that a microorganism cannot maintain cellular activity for growth and reproduction.

25. Benzoates are effective against yeasts and molds. Benzoates also inhibit the growth of bacterial pathogens, such as *Vibrio parahaemolyticus*, *Staphylococcus aureus*, *Bacillus cereus*, and *Listeria monocytogenes*. Common soft drink spoilage bacteria, namely *Acetobacter* and lactobacilli, are also inhibited by benzoates.

26. In beverages with a relatively high pH (3.5-4.0), benzoate concentrations in the range of, 600-1,000 mg/kg (ppm) are often required to prevent growth of fermentative organisms. For example, in the case of some spoilage fungi (yeast and mold) that possess a natural tolerance to benzoic acid, amounts of benzoates are needed that provide for 500 ppm of the active undissociated form (i.e., benzoic acid) of the preservative in order to avoid spoilage. Addition of more than 500 ppm of benzoate to the beverage is usually required in order to compensate for the amount of the non-active (dissociated) form of the preservative that develops upon reaching its equilibrium concentration.

27. The minimum inhibitory concentration (MIC) of benzoates at pH less than 5.0 against most yeasts ranges from 20 to 700 ppm, and from 20 to 2,000 ppm for molds. A few fungal species possess mechanisms of resistance to weak acid preservatives, such as benzoic acid; the most notable is the yeast *Zygosaccharomyces bailii*; MIC 4500 ppm).

28. Benzoates are usually added to beverages as the sodium, potassium, or calcium salt of benzoic acid. 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).

29. Some types of soft drinks do not require the use of benzoates and others require levels dependent 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 (vitamins, etc.), the nature of acidulants, essential oils, sweeteners, and stabilizers must also be considered. Furthermore, some soft drinks may undergo additional processing (for example syrup pasteurization) minimizing or eliminating 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.

30. A recent trend to bring more beverages to the market with pHs approaching 5 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 (benzoic acid) present is only 275 ppm when 1,000 ppm of sodium benzoate is added.

Safety Evaluations of Benzoic Acid and its Salts

31. JECFA has evaluated benzoic acid and its salts several times and has established an ADI of 0-5 mg/kg bw/p/d 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. 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.

Intake of Benzoic acid and its Salts

32. 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 U.S., where the intake was calculated using the maximum use level of 1,000 ppm. Since the JECFA evaluation, additional intake studies have been conducted in Brazil, Japan, Norway, and the U.S.

33. Results from a 14-day food frequency intake study conducted in the U.S. in 1999 shows that the JECFA ADI is not exceeded at a maximum level of 1,000 ppm. According to JECFA, 14-day intake studies are indicative of long-term exposure. The maximum level used in the calculations was 1,000 ppm in soft drinks. Results of the intake surveys in Brazil⁹ and Japan¹⁰ also show that the ADI is not exceeded. 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.¹¹

Regulatory Limits in Codex Member Countries that Permit the use of Benzoic Acid and its Salts in Soft Drinks

34. Based on information available to eQC WG, approximately 50 countries worldwide permit benzoic acid and its salts in soft drinks at levels of 1,000 ppm. This clearly establishes that a maximum level of 1000 ppm is the norm internationally.

Categories 14.2.2 and 14.2.5

35. The following information on the use of benzoates in cider and perry (14.2.2.) and mead (14.2.5) was provided to the eQC WG. Benzoates are added to these beverages to inhibit the growth of bacteria, especially *E. coli*, and acetic and lactic acid producing bacteria. Benzoates and sorbates are used in combination because benzoates inhibit bacterial growth, whereas sorbates are more effective at inhibiting fungal growth (i.e., yeast and mold). Based on available information, maximum use level of 1000 mg/kg benzoates is safe and effective for these food categories.

Recommendation 3 for Benzoates, INS 210, 211, 212, 213

The eQC WG recommends that the CCFAC endorse for adoption at Step 8 by the CAC the following provisions for benzoates in the GSFA.

Benzoates INS 210-213 (Preservative)				
Food Cat. No.	Food Category	Max Level		Comment
06.4.3	Pre-cooked pastas and noodles and like products	1000	mg/kg	Note 13 ¹²
07.0	Bakery wares	1000	mg/kg	Note 13
12.5	Soups and broths	1000	mg/kg	Note 13

⁹ Tfouni, S.A.V. and Toledo, M.C.F. Estimates of the mean per capita daily intake of benzoic and sorbic acids in Brazil. Food Additives and Contaminants 19 (7): 647-654, 2002.

¹⁰ Ishiwata, H., Nishijima, M., and Fukasawa, Y. Estimation of preservative concentrations in foods and their daily intake based on official inspection results in Japan in fiscal year 1998, J. Food Hyg. Soc. Japan 42(6): 404-412, 2001

¹¹ Bergsten, C. Intakes of Preservatives in Norway. Benzoic acid and sorbic acid. SNT-Rapport 2, 2000 (<http://www.snt.no.dokumentasjon/rapporter/2000/200002.htm>)

¹² Note 13: As benzoic acid

Benzoates INS 210-213 (Preservative)				
Food Cat. No.	Food Category	Max Level		Comment
14.1.1.2	Table waters and soda waters	350	mg/kg	Note 13
14.1.2.1	Canned or bottled (pasteurized) fruit juice	1000	mg/kg	Note 13
14.1.2.3	Concentrate (liquid or solid) for fruit juice	1000	mg/kg	Note 13
14.1.3.1	Canned or bottled (pasteurized) fruit nectar	1000	mg/kg	Note 13
14.1.3.3	Concentrate (liquid or solid) for fruit nectar	1000	mg/kg	Note 13
14.1.3.4	Concentrate (liquid or solid) for vegetable nectar	500	mg/kg	Note 13
14.1.4	Water-based flavoured drinks, including "sport" "energy" or "electrolyte" drinks and particulated drinks	1000	mg/kg	Note 13
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	1000	mg/kg	Note 13
14.2.2	Cider and perry	1000	mg/kg	Note 13
14.2.5	Mead	1000	mg/kg	Note 13
15.1	Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	1000	mg/kg	Note 13
16.0	Composite foods - foods that could not be placed in categories 01 – 15	1000	mg/kg	Note 13

STEARYL TARTRATE (INS 483)

36. The 9th JECFA (1965) determined stearyl tartrate to be “Acceptable” for use as a flour treatment agent at treatment levels not to exceed 500 mg/kg of flour. At its 55th meeting (2000), the JECFA could draw no conclusions about the acceptability of other uses proposed in the draft GSFA by the CCFAC because information on toxicity and intake was not available.

Recommendation-Stearyl Tartrate, INS 483

The eQC WG recommends that the 36th CCFAC identify a delegation(s) to commit to providing the data and information necessary for JECFA to assign an ADI for stearyl tartrate for uses other than as a flour treatment agent. If no delegation is willing to take responsibility for providing this information, then all of the provisions in the draft GSFA for stearyl tartrate that are inconsistent with its use as a flour treatment agent should be deleted by the 36th CCFAC.

TANNIC ACID (INS 181)

37. There are several pending provisions in the draft GSFA for the use of tannic acid based on its use as a color. The 35th JECFA (1989) assigned an ADI of “Not Specified” for tannic acid when used as a filtering aid where the application of good manufacturing practice ensures that it is removed from food after use. JECFA has noted that tannic acid is used as a clarifying agent, flavouring agent or flavour adjunct. The JECFA has not evaluated the safety of the use of tannic acid as a color. The Codex Standard for Class Names and the International Numbering System for Food Additives (INS) associates the functional classes color, emulsifier, stabilizer and thickener with tannins, food grade (INS 181)

Recommendation 1 for Tannic Acid, INS 181

The eQC WG recommends that the CCFAC revise the functional effects associated with tannic acid in the GSFA by removing colors, and adding clarifying agent, flavor enhancer. The CCFAC should also propose to amend the INS to associate the functional class flavor enhancer with INS 181 and disassociate the functional classes of color, emulsifier, stabilizer and thickener with INS 181.

Recommendation 2 for Tannic Acid, INS 181

The eQC WG recommends that CCFAC endorse for adoption at Step 8 by the CAC the following provisions for tannic acid in the GSFA.

Tannic Acid (Tannins, Food Grade), INS 181 (Flavor Enhancer)			
Food Cat. No.	Food Category	ML	Comments
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	400 mg/kg	
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	50 mg/kg	Note 7 ¹³
04.1.2.9	Fruit-based desserts, including fruit-flavoured water- based desserts	50 mg/kg	
04.1.2.11	Fruit fillings for pastries	50 mg/kg	
05.1.3	Cocoa-based spreads, including fillings	50 mg/kg	
05.2	Confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	400 mg/kg	
05.3	Chewing gum	GMP	
07.0	Bakery wares	100 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	
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	50 mg/kg	
14.2.1	Beer and malt beverages	150 mg/kg	
14.2.2	Cider and perry	200 mg/kg	
14.2.3	Grape wines	3000 mg/kg	
14.2.4	Wines (other than grape)	150 mg/kg	
14.2.5	Mead	150 mg/kg	
14.2.6	Distilled spirituous beverages containing more than 15% alcohol	150 mg/kg	
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	150 mg/kg	

OXYSTEARIN (INS 387)

38. There are four pending provisions in the draft GSFA for the use of oxystearin. The 57th JECFA (2001) withdrew the ADI of 25 mg/kg bw for oxystearin that was assigned by the 17th JECFA (1973) following the JECFA's decision to withdraw the specifications due to lack of commercial use of the additive.

Recommendation-Oxystearin, INS 387

The eQC WG recommends that the CCFAC identify a delegation(s) to commit to providing evidence that oxystearin is currently in use and the data necessary for JECFA to develop specifications and to assign an ADI for oxystearin. If no delegation is willing to provide this information, then all of the provisions in the GSFA for oxystearin, including those adopted by the CAC in 1999, should be deleted from the GSFA and oxystearin will not be considered further by the CCFAC.

QUILLAIA EXTRACTS (INS 999)

39. The only provision under consideration for inclusion in the GSFA is in food category 14.1.4 (Water-based flavoured drinks, including "sport" "energy" or "electrolyte" drinks and particulated drinks) with a maximum use level of 500 mg/kg at Step 6.

40. Quillaia extracts were reviewed toxicologically by the 26th JECFA (1982). The available toxicological data included adequate lifetime studies in mice and rats, from which a NOEL was identified. However, in the absence of data, no specifications were prepared, and, hence, no ADI could be allocated. The 29th JECFA (1985) prepared new tentative specifications and established an ADI of 0–5mg/kg bw.

41. The 57th JECFA's (2001) evaluation of quillaia extracts was conducted in response to a request by the 32nd CCFAC that the JECFA re-evaluate all relevant information on the toxicity and, in particular, the intake of quillaia extracts. No new data were submitted to the 57th JECFA and therefore, the JECFA evaluated published reports on quillaia extracts or specific saponins that provided information relevant to a toxicological assessment of quillaia extracts. The 57th JECFA revised the tentative specifications for quillaia extract and maintained them as temporary.

¹³ Note 7: Use level not in finished food.

42. The report of the 57th JECFA concluded that the use at a maximum level of 95–100 mg/kg (that reported by the manufacturers), as in the UK and the USA, appeared to be adequate for achieving the technological function as a foaming agent in soft drinks and did not appear to result in intakes that exceed the ADI. Young children are a possible exception, but, as the results of a short-term nutritional survey were used, the frequency or duration of their potential excursion above the ADI could not be determined.

43. The 57th JECFA recommended that the CCFAC review the use of quillaia extracts at 500 mg/kg as proposed in the draft GSFA.

44. The 61st JECFA (2003) assigned an ADI of 5 mg/kg bw for quillaia extracts with a saponin content of 20 - 26% (Quillaia Extract Type 1). The JECFA was unable to assign an ADI for quillaia extracts with a saponin content of 75 - 90% (Quillaia Extract Type 2) due to limited information on the qualitative and quantitative composition of quillaia extract type 2.

Recommendation-Quillaia Extract, INS 999

The eQC WG recognizes the technological need for the use of foaming agents in foods covered by food category 14.1.4. In light of the recommendation of the 57th JECFA to the CCFAC regarding the maximum use level of 500 mg/kg and the decision of the 61st JECFA regarding the specifications for quillaia extract Type 2, the eQC WG recommends that the 36th CCFAC identify a delegation(s) to provide the necessary information to JECFA on the qualitative and quantitative composition of quillaia extract type 2.

In addition, the 36th CCFAC should identify a delegation(s) to provide adequate information so that JECFA can estimate the dietary exposure at a maximum use level at 500 mg/kg in category 14.1.4.

In the meantime, the eQC WG recommends that the CCFAC endorse for adoption at Step 8 by the CAC a maximum level of 100 mg/kg quillaia extract in food category 14.1.4, with the understanding that once JECFA completes its review of the additional information, the CCFAC will reconsider this use of quillaia extract.

MINERAL OILS (INS 905D-G)

45. The JECFA has developed specifications of identity and purity and assigned ADIs for the following four classes of mineral oil:

- i. Mineral Oils (High Viscosity) (ADI = 20 mg/kg bw) (INS No. 905d),
- ii. Mineral Oil (Medium and Low Viscosity Class I) (ADI = 10 mg/kg bw) (INS No. 905e),
- iii. Mineral Oil (Medium and Low Viscosity Class II) (0.01 mg/kg bw (temporary) (INS No. 905f), and
- iv. Mineral Oil (Medium and Low Viscosity Class III) (0-0.01 mg/kg bw (temporary) (INS No. 905g).

46. Prior to the 35th CCFAC, INS 905a was assigned to all mineral oils regardless of their viscosity. The 26th CAC (2003) adopted revisions to the INS numbers for mineral oils so that there are separate INS numbers for each class of mineral oils.

47. The draft GSFA contains provisions for mineral oils, mineral oil high viscosity, mineral oil (medium and low viscosity class I) and mineral oil (medium and low viscosity class II and III).

Recommendation 1 for Mineral Oils, INS 905a, 905f, and 905g

The eQC WG recommends that the 36th CCFAC delete all provisions in the draft GSFA for the following additives: mineral oil (905a), mineral oil - medium and low viscosity class II (905f) and mineral oil -medium and low viscosity class III (905g), with the understanding that these uses will be considered if JECFA assigns a full ADI to these substances.

Recommendation 2 for Mineral Oils, INS 905d & 905e

The eQC WG recommends that the 36th CCFAC endorse for adoption at Step 8 by the CAC the following provisions in the GSFA for mineral oils, 905d and 905e. The eQC WG recommends that the CCFAC delete all other pending provisions for INS 905e and 905d.

Mineral Oil (High Viscosity), INS: 905d (Glazing Agent, Release Agent)			
Food Cat. No.	Food Category	Max Level	Comments
05.1	Cocoa products and chocolate products including imitations and chocolate substitutes	2000 mg/kg	Note 3 ¹⁴
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3, and 05.4	2000 mg/kg	Note 3
05.3	Chewing gum	20000 mg/kg	
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit), and sweet sauces	2000 mg/kg	Note 3
06.1	Whole, broken, or flaked grain, including rice	800 mg/kg	Note 98 ¹⁵
07.0	Bakery wares	1500 mg/kg	Note 123 ¹⁶
08.2.3	Frozen processed meat, poultry, and game products in whole pieces or cuts	950 mg/kg	Note 3
08.3.3	Frozen processed comminuted meat, poultry, and game products	950 mg/kg	Note 3

Mineral Oil (Medium & Low Viscosity, Class I), INS: 905e (Glazing Agent, Release Agent)			
Food Cat. No.	Food Category	Max Level	Comments
05.0	Confectionery	2000 mg/kg	Note 3
07.1.1	Breads & rolls	1000 mg/kg	Notes 36 ¹⁷ & 124 ¹⁸

DIMETHYL DICARBONATE (INS 242)

48. The 37th JECFA (1990) assigned an “Acceptable” ADI for the use of dimethyl dicarbonate (DMDC) as a cold sterilization agent in beverages in accordance with good manufacturing practice up to a maximum concentration of 250 mg/l.

49. The proposed provision for food category 14.1.5 is a revision of the already-adopted provision that would delete Note 2, which limits the use of DMDC on a dry ingredient, dry weight, dry mix, or concentrate basis.

50. DMDC is a cold sterilizing agent or preservative used in the production of soft drinks and wine, generally post-fermentation/pre bottling. It has broad antimicrobial activity against yeasts, mould fungi and bacteria. In winemaking its effectiveness is enhanced when used in combination with sulfur dioxide. This combination also acts to reduce the amount of sulfur dioxide necessarily added to wine: however, DMDC has no antioxidant activity. When used under good manufacturing practices, DMDC breaks down almost immediately to primarily methanol and carbon dioxide after addition to beverages. There should be no residue of DMDC in the final product as sold to consumers.

Recommendation for Dimethyl Dicarbonate, INS 242

The eQC WG recommends that the 36th CCFAC endorse deletion of Note 2 (On dry ingredient, dry weight, dry mix or concentrate basis) which is associated with the adopted provision for the use of dimethyl dicarbonate in food category 14.1.5 and endorse for adoption at Step 8 by the CAC the following provisions for the use of dimethyl dicarbonate.

¹⁴ Note 3: Surface treatment.

¹⁵ Note 98: For dust control.

¹⁶ Note 123: For use as a release agent for baking pans in a mixture with vegetable oil.

¹⁷ Note 36: Residual level.

¹⁸ Note 124: For releasing dough in dividing or in baking only. For releasing dough in dividing or in baking only.

DIMETHYL DICARBONATE, INS 242 (Preservative)				
Food Cat. No.	Food Category	Max Level		Comment
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	250	mg/kg	Note 18 ¹⁹
14.2.2	Cider and perry	250	mg/kg	Note 18
14.2.3	Grape wines	200	mg/kg	Note 18
14.2.4	Wines (other than grape)	250	mg/kg	Note 18
14.2.5	Mead	200	mg/kg	Note 18

GLYCEROL ESTER OF WOOD ROSIN (INS 445)

51. The 46th JECFA assigned an ADI of 25 mg/kg bw for glycerol ester of wood rosin. The table below lists the provisions in the draft GSFA for glycerol ester of wood rosin.

GLYCEROL ESTER OF WOOD ROSIN, INS 445 (Adjuvant, Bulking Agent, Emulsifier, Stabilizer, Thickener)				
Food Cat. No.	Food Category	Max Level		Step
04.1.1.2	Surface-treated fresh fruit	5	mg/kg	3
04.2.1.2	Surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	5	mg/kg	3

Recommendation for Glycerol Ester of Wood Rosin, INS 445

The eQC WG recommends that the 36th CCFAC identify a delegation(s) to commit to providing evidence that glycerol ester of wood rosin is used as a surface treatment agent on fruit and vegetables and to commit to providing the data necessary for JECFA to evaluate the safety of this use of glycerol ester of wood rosin. If no delegation is willing to provide this information, then these provisions for glycerol ester of wood rosin should be deleted from the draft GSFA by the 36th CCFAC.

GUAIAIC RESIN (INS 314)

52. There is one pending provision in the draft GSFA for the use of guaiac resin in food category 12.6 (Sauces and like products) with a maximum use level of 600 mg/kg. The 18th JECFA (1973) assigned an ADI of 2.5 mg/kg bw for guaiac resin.

53. Guaiac resin is added to food to prevent the oxidation of lipids. Therefore, a note should be added to this provision to indicate that the maximum use level is based on the fat or oil content of the food.

Recommendation for Guaiac Resin INS 314

The eQC WG recommends that the CCFAC endorse for adoption at Step 8 by the CAC the use of guaiac resin in food category 12.6 with a maximum level of 600 mg/kg and a note specifying that this level is based on the fat or oil content of the food (Note 15).

LYSOZYME HYDROCHLORIDE (INS 1105)

54. The 39th JECFA (1992) determined lysozyme hydrochloride to be “Acceptable” for use as a preservative.

55. Lysozyme (including lysozyme hydrochloride) when used at a level of 500 mg/kg is effective at lysing the cell walls of gram-positive bacteria in cider and perry (14.2.2) and grape wines (14.2.3). Its use is effective against Gram (+) bacteria such as lactic acid bacteria, especially in high pH wines where SO₂ impact is reduced. Lysozyme is also used to block or delay malo-lactic fermentation in wine and to reduce production of biogenic amines during aging.

¹⁹ Note 18: Added level; residue not detected in ready-to-eat food.

Recommendation for Lysozyme Hydrochloride, INS 1105

The eQC WG recommends that the CCFAC endorse for adoption at Step 8 by the CAC the following provisions for the use of lysozyme hydrochloride.

LYSOZYME HYDROCHLORIDE, INS 1105 (Preservative)				
Food Cat. No.	Food Category	Max Level		Comment
14.2.2	Cider and perry	500	mg/kg	
14.2.3	Grape wines	500	mg/kg	

POLYDIMETHYLSILOXANE (INS 900A)

56. The 3rd Codex *ad hoc* Task Force on Fruit and Vegetable Juices (2003) requested that the CCFAC withdraw the provisions for polydimethylsiloxane (JECFA (1979) ADI 1.5 mg/kg bw) in food categories 14.1.2 (Fruit and vegetable juices; 10 mg/kg; adopted (1999)) and 14.1.3 (Fruit and vegetable nectars; 50 mg/kg; step 6) from the draft GSFA and to consider it as a processing aid for the products covered by the Codex General Standard for Fruit Juices and Nectars.²⁰

Recommendation 1 for Polydimethylsiloxane, INS 900a

The eQC WG recommends that the CCFAC delete the following provisions from the GSFA.

POLYDIMETHYLSILOXANE, INS 900a (Anticaking Agent, Antifoaming Agent)					
Food Cat. No.	Food Category	Max Level		Comment	Step
08.1.1	Fresh meat, poultry, and game, whole pieces or cuts		GMP		6
14.1.2	Fruit and vegetable juices	10	mg/kg		8
14.1.3	Fruit and vegetable nectars	50	mg/kg		6

Recommendation 2 for Polydimethylsiloxane, INS 900a

The eQC WG recommends that the CCFAC endorse the following provisions for adoption at Step 8 by the CAC.

POLYDIMETHYLSILOXANE, INS 900a (Anticaking Agent, Antifoaming Agent)					
Food Cat. No.	Food Category	Max Level		Comment	
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	50	mg/kg		
03.0	Edible ices, including sherbet and sorbet	50	mg/kg		
04.1.2.11	Fruit fillings for pastries	50	mg/kg		
04.2.2.6	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces and candied vegetables) other than food category 04.2.2.5	50	mg/kg		
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	50	mg/kg		
07.0	Bakery wares	10	mg/kg	Notes 3 ²¹ & 36 ²²	
08.2	Processed meat, poultry, and game products in whole pieces or cuts	50	mg/kg		
08.3	Processed comminuted meat, poultry, and game products	50	mg/kg		
09.2	Processed fish and fish products, including mollusks, crustaceans, and echinoderms	50	mg/kg		
10.2	Egg products	50	mg/kg		
10.3	Preserved eggs, including alkaline, salted, and canned eggs	50	mg/kg		

²⁰ ALINORM 03/39A, para. 35.

²¹ Note 3: Surface treatment.

²² Note 36: Residual level.

POLYDIMETHYLSILOXANE, INS 900a (Anticaking Agent, Antifoaming Agent)				
Food Cat. No.	Food Category	Max Level		Comment
10.4	Egg-based desserts (e.g., custard)	50	mg/kg	
11.1	Refined and raw sugars	50	mg/kg	
11.3	Sugar solutions and syrups, also (partially) inverted, including treacle and molasses, excluding products of food category 11.1.3	10	mg/kg	
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	50	mg/kg	
11.6	Table-top sweeteners, including those containing high-intensity sweeteners	50	mg/kg	
12.2	Herbs, spices, seasonings (including salt substitutes), and condiments (e.g., seasoning for instant noodles)	50	mg/kg	
12.6.1	Emulsified sauces (e.g., mayonnaise, salad dressing)	50	mg/kg	
12.6.2	Non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)	10	mg/kg	
12.6.3	Mixes for sauces and gravies	10	mg/kg	
12.6.4	Clear sauces (e.g., fish sauce)	50	mg/kg	
12.8	Yeast and like products	50	mg/kg	
13.0	Foodstuffs intended for particular nutritional uses	50	mg/kg	
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	50	mg/kg	

Recommendation 3 for Polydimethylsiloxane, INS 900a

The eQC WG could not reach consensus on the following draft provisions for polydimethylsiloxane. The eQC WG recommends that the 36th CCFAC request information on the use of polydimethylsiloxane in the noted categories, with the understanding that if no information is received by the 37th CCFAC to justify these uses, the listings of polydimethylsiloxane in these food categories will be deleted.

POLYDIMETHYLSILOXANE, INS 900a (Anticaking Agent, Antifoaming Agent)				
Food Cat. No.	Food Category	Max Level		Comment
14.2.2	Cider and perry	50	mg/kg	
14.2.6	Distilled spirituous beverages containing more than 15% alcohol	50	mg/kg	

POLYVINYLPIRROLIDONE (PVP) (INS 1201)

57. The draft GSFA contains one pending provision for polyvinylpyrrolidone (PVP) (JECFA (1986) ADI of 50 mg/kg bw): use in food category 14.2.3 (Grape Wines) at a maximum level of 60 mg/kg. Based on information available to the eQC WG, the use of PVP has been largely replaced by PVPP (polyvinylpolypyrrolidone, INS 1202), a cross-linked PVP. Because PVP is no longer used as a clarifier and stabilizer in wine manufacturing, this draft provision should be deleted from the GSFA.

Recommendation for Polyvinylpyrrolidone, INS 1201

The eQC WG recommends that the CCFAC delete the draft provision for the use of PVP (INS 1201) in food category 14.2.3.

MICROCRYSTALLINE WAX (INS 905C)

58. The JECFA specifications for microcrystalline wax (JECFA (1995) ADI 20 mg/kg bw) note that it is used as a chewing gum base, protective coating, defoaming agent or surface finishing agent. The INS associates microcrystalline wax with use as a glazing agent. However, the GSFA also lists functionality as an antifoaming agent and bulking agent. Use as a bulking agent applies to 05.3 (chewing gum), which was adopted by the CAC in 2001. This use is consistent with the use of other waxes (e.g., beeswax, candelilla wax, carnauba wax, and shellac).

59. The food categories under consideration or adopted for microcrystalline wax appear to be for use as a surface treatment (e.g., coating, glazing).

Recommendation 1 for Microcrystalline Wax, INS 905c

The eQC WG recommends that the 36th CCFAC request comment on whether microcrystalline wax the levels proposed (10,000 mg/kg) are adequate to achieve its intended technical effect by food category 5.1.4, 5.1.5, 05.2 and 05.4, with the understanding that if no information is received by the 37th CCFAC the listings of microcrystalline wax in the GSFA as an antifoaming agent will be deleted.

Recommendation 2 for Microcrystalline Wax, INS 905c

The eQC WG could not reach consensus on the maximum level of use of microcrystalline wax as a glazing agent in food categories 5.1.4, 5.1.5, 5.2, and 5.4. The eQC WG recommends that the 36th CCFAC request information on the technological effect and maximum level for the use of microcrystalline wax in the noted categories, with the understanding that if no information is received by the 37th CCFAC to justify these uses, the listings of microcrystalline wax in these food categories will be deleted.

Recommendation – Microcrystalline Wax, INS 905c

The eQC WG recommends that the CCFAC endorse the following provisions for adoption at Step 8 by the CAC.

MICROCRYSTALLINE WAX, INS 905c (Bulking Agent, Glazing Agent)		
Food Cat. No.	Food Category	Max Level
01.6.2.2	Rind of ripened cheese	30,000 mg/kg
04.1.1.2	Surface-treated fresh fruit	50 mg/kg
04.2.1.2	Surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	50 mg/kg

STANNOUS CHLORIDE (INS 512)

60. The GSFA contains one provision for stannous chloride (JECFA (1988) PTWI 14 mg/kg bw (as tin); JEFA (2000) ADI maintained): use in category 14.1.2 (Fruit and Vegetables Juices) at 8 mg/kg (as tin).

61. The source of the provision in the GSFA for the use of stannous chloride in food category 14.1.2.1 is the Codex Standard for Concentrated Pineapple Juice Preserved Exclusively by Physical Means (CX STAN 138). The Codex *ad hoc* Intergovernmental Task Force on Fruit and Vegetable Juice is developing a General Standard for Fruit Juices and Nectars²³ with the understanding that the standard for concentrated pineapple juice and other Codex fruit juice standards will be revoked once the Commission adopts the general standard for fruit juice. The current draft general standard for fruit juice contains provisions for the use of antioxidants, preservatives, and sequestrants. The current draft general standard for fruit juice is good evidence supporting the technological need for these functional effects in fruit juices. The existing Codex standard for concentrated pineapple juice provides further evidence justifying the use of stannous chloride at levels up to 8 mg/kg (as tin) in pineapple juice from frozen concentrate; however the technical effect that the addition of stannous chloride is intended to achieve is not specified. The draft general standard for fruit juices does not list stannous chloride as a suitable antioxidant, preservative, or sequestrant.

Recommendation for Stannous Chloride, INS 512

The eQC WG recommends that the 36th CCFAC request confirmation from the Codex Secretariat that Codex Standard 138-1983 (Concentrated Pineapple Juice Preserved Exclusively by Physical Means) will be revoked when work on the General Standard for Fruit Juices and Nectars is completed.

Information supporting the need for the use of stannous chloride as a color retention agent, preservative, or sequestrant in fruit and vegetable juices should be requested, with the understanding that if no information is forthcoming, the 37th CCFAC should delete this provision from the draft GSFA.

²³ ALINORM 03/39A, App. II.

PROPYLENE GLYCOL ESTERS OF FATTY ACIDS (INS 477)

62. The draft GSFA contains one pending provision for propylene glycol esters of fatty acids (JECFA ADI 25 mg/kg bw): use in food category 02.4 (Fat-based desserts excluding dairy-based dessert products of food category 01.7) with a maximum use level of 40,000 mg/kg. The CAC has adopted at Step 8 a maximum level of 10,000 mg/kg for propylene glycol esters of fatty acids in food category 2.4. The eQC WG recognizes the technological need for the use of emulsifiers and stabilizers in foods included under food category 02.4. However, the QC WG was unable to reach consensus on the need for a higher maximum level for the use of propylene glycol esters of fatty acids.

Recommendation for Propylene Glycol Esters of Fatty Acids, INS 477

The eQC WG recommends that the 36th CCFAC request information explaining the need for the proposed higher maximum level (40,000 mg/kg), with the understanding that if this information is not provided to the 37th CCFAC, the committee will delete this draft provision from the GSFA.

ISOPROPYL CITRATES (INS 384)

63. The GSFA contains one pending provision for isopropyl citrates (JECFA (1973) ADI 14 mg/kg bw): use in food category 02.1.2 (Vegetable oils and fats) at levels not to exceed 200 mg/kg. The CAC has adopted at Step 8 a maximum level of 100 mg/kg isopropyl citrate in food category 02.1.2.

Recommendation for Isopropyl Citrates, INS 384

The eQC WG could not reach consensus on the inclusion of the higher proposed use level (200 mg/kg) in the GSFA. The eQC WG recommends that the 36th CCFAC request information explaining the need for the proposed higher maximum level, with the understanding that if this information is not provided to the 37th CCFAC, the committee will delete this provision from the draft GSFA.

CALCIUM DISODIUM ETHYLENE DIAMINE TETRA-ACETATE & DISODIUM ETHYLENE DIAMINE TETRA-ACETATE (EDTAS), (INS 385 AND 386)

64. The CAC has adopted several provisions for the use of the two EDTAs (JECFA (1973) group ADI 2.5 mg/kg bw).

65. The proposed maximum use level for EDTAs in category 4.2.2.1 is limited to french fried potatoes. The Codex standard for Quick Frozen French Fried Potatoes (CODEX STAN 114-1981) contains a provision for the use of EDTA (INS 385) as a sequestrant at levels not to exceed 100 mg/kg. The draft level in the GSFA is 250 mg/kg. Based on the commodity standard for Quick Frozen French Fried Potatoes, the technological need for a sequestrant in french fried potatoes is justified; however, the justification for a higher level than that in the commodity standard is unclear.

66. The technological need for the use of a sequestrant for metal ions to reduce oxidation in foods conforming to category 9.2.4.1 (Cooked fish and fish products) is unclear.

67. The proposed provision for EDTAs in category 14.2 (Alcoholic beverages, including alcohol-free and low-alcoholic counterparts) includes subcategories for 14.2.1 (Beer and Malt Beverages), 14.2.2 (Cider and Perry), 14.2.3 (Grape Wines), 14.2.4 (Wines (Other than Grape)), 14.2.5 Mead, and 14.2.6 (Distilled Spirituous Beverages Containing more than 15% Alcohol). The technological need for a sequestrant in categories 14.2.2, 14.2.3, 14.2.4, and 14.2.5 is not clear.

Recommendation 1 for Calcium Disodium Ethylene Diamine Tetra-acetate & Disodium Ethylene Diamine Tetra-acetates (EDTAs) (INS 385 & 386)

The eQC WG recommends that the 36th CCFAC request information explaining the need for the use of EDTAs in the following food categories, with the understanding that if this information is not provided to the 37th CCFAC will delete these provisions from the draft GSFA:

04.2.2.1 (Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes and aloe vera), and nuts and seeds),

09.2.4.1 (Cooked fish and fish products),

14.2.2 (Cider and Perry),
 14.2.3 (Grape Wines),
 14.2.4 (Wines (Other than Grape)), and
 14.2.5 Mead

Recommendation 2 for Calcium Disodium Ethylene Diamine Tetra-acetate & Disodium Ethylene Diamine Tetra-acetates (EDTAs) (INS 385 & 386)

The eQC WG recommends that the CCFAC endorse for adoption at Step 8 by the CAC, the following provisions for the use of EDTAs.

Calcium Disodium Ethylene Diamine Tetra-acetate & Disodium Ethylene Diamine Tetra-acetates (EDTAs), INS 385 & 386 (Antioxidant, Preservative, Sequestrant)				
Food Cat. No.	Food Category	Max Level		Comment
04.1.2.8	Fruit preparations, including pulp, purees, fruit toppings and coconut milk	650	mg/kg	Note 21 ²⁴
11.6	Table-top sweeteners, including those containing high-intensity sweeteners	100 0	mg/kg	Note 21
12.6.3	Mixes for sauces and gravies	75	mg/kg	Note 21 & 72 ²⁵
12.6.4	Clear sauces (e.g., fish sauce)	75	mg/kg	Note 21
14.2.1	Beer and Malt Beverages	25	mg/kg	Note 21
14.2.6	Distilled Spirituous Beverages Containing more than 15% Alcohol	25	mg/kg	Note 21

BETA-CYCLODEXTRIN (INS 459)

68. The GSFA contains one pending provision for use in food category 15.1 (Snacks – potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)) at levels not to exceed 500 mg/kg (JECFA (1995) ADI 5 mg/kg bw).

Recommendation for Beta-Cyclodextrin, INS 459

The eQC WG recommends that the CCFAC endorse for adoption at Step 8 the use of beta-cyclodextrin in category 15.1 at a level not to exceed 500 mg/kg.

PROPYL GALLATE (INS 310)

69. The 41st JECFA (1993) assigned an ADI of 1.4 mg/kg bw for propyl gallate. The 46th JECFA maintained this ADI. Propyl gallate is added to food to prevent the oxidation of lipids. Propyl gallate is a valuable food technology alternative to other antioxidants because of organoleptic needs.

70. The eQC WG reached consensus on the maximum levels (MLs) proposed for use of propyl gallate in food categories 04.2.2.5 (Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)) and 12.5 (Soups and broths) at 200 mg/kg on the fat or oil basis.

71. The eQC WG also reached consensus that the qualifier “on the fat or oil basis” (Note 15) should be added to the provisions for use at 200 mg/kg in food categories 06.4.2 (Dried pastas and noodles and like products) and 06.4.2 (Pre-cooked pastas and noodles and like products).

²⁴ Note 21: As anhydrous calcium disodium EDTA.

²⁵ Note 72: Ready-to-eat basis

72. The eQC WG questions the maximum use levels proposed for food category 7.0 (Bakery wares; 1000 mg/kg on the fat or oil basis, carried over from use in fats) and 9.2.1 (Frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms; 1000 mg/kg, for use in dipping solution only). Given that category 2.0 (fats and oils) includes foods that are completely or mostly composed of fats and oils, and contains foods in which propyl gallate is used at a maximum level of 200 mg/kg on the fat or oil basis, the eQC WG questions why with less fat or oil (e.g., bakery wares) it should require a higher level of antioxidant (1000 mg/kg) than a food composed entirely of fat or oil (200 mg/kg).

73. When considering whether there are inconsistencies between the food additive provisions in the GSFA and a Codex commodity standard, it is important to recognize that the purpose of commodity standards is to promote fair trade practices and prevent consumer deception by providing qualitative and quantitative information describing or defining the composition and labeling of a specific food. In contrast, the GSFA food category system is intended to organize the wide variety of foods in international trade based on their composition, processing, and consumption patterns. Importantly, the titles of the GSFA's food categories are not intended for labeling purposes, whereas commodity standards often contain conforming criteria for labeling of foods.

74. In determining whether inconsistencies exist between the additive provisions in commodity standards and the provisions in the GSFA, the relationship between the scope of a commodity standard and the scope of the GSFA food category must be understood. If the scope of a commodity standard is a subset of the GSFA food category, the food additive provisions (e.g., maximum use level, individual additives, and functional effect classes) in the GSFA might differ from the provisions in the commodity standard. This is a necessary outcome from the principles of the food category system and the scope of the GSFA which covers standardized foods (i.e., conforming to a Codex commodity standard) and non-standardized foods in the Codex system. If the scope of the commodity standard is identical to the scope of the GSFA food category, the additive provisions in the commodity standard and the GSFA food category should be the same.

75. The scope of the Codex Standard for Bouillon and Consommés (CODEX STAN 117-1981, Rev. 2-2001) is a subset of the scope of food category 12.5 (Soups and broths). Therefore, additive provisions in the GSFA for category 12.5 might be more extensive (more functional classes, higher maximum use levels, etc.) than those in the bouillon and consommés standard in order to allow for the use of additives in foods not conforming to the commodity standard. A similar situation exists between the Codex Processed Tomato Concentrates Standard (CODEX STAN 57-1981) and category 4.2.2.5 (Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)) and the Codex Quick Frozen Fish Products Standard (CODEX STAN 190-1995) and category 9.2.1 (Frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms). In instances such as these, a food must meet all criteria in the commodity standard, in order to be in conformance with the standard. With respect to food additives, if the commodity standard lists the use of an additive with an ML of 100 mg/kg and the GSFA ML is 200 mg/kg in the relevant GSFA food category, then in order for the food to conform to the commodity standard, the food must contain no more than 100 mg/kg of the additive. Alternatively, if the commodity standard lists only the acceptable functional effect classes (e.g., emulsifiers and antioxidants) and refers to the relevant GSFA food category (e.g., 1.6.2), which contains provisions for additives with functional effects that are not listed in the commodity standard, then foods that will conform to the commodity standard may only contain those additives with the functional effects listed in the commodity standard at levels no greater than the MLs specified in the GSFA category.

76. In contrast to the above examples, the scope of the Codex Standard for Butter (CODEX STAN A-1-1971, Rev. 1-1999) is identical to the scope of food category 2.2.1.1 (Butter and concentrated butter). Therefore, the food additive provisions in the GSFA for 2.2.1.1 and the Codex Standard for Butter should be the same because there is no food covered by the scope of the GSFA food category that would not be included in the scope of the butter standard. The Codex Standard for Butter contains provisions for the use of colours and acidity regulators. It does not contain provisions for antioxidants (e.g., propyl gallate). Therefore, the eQC WG is recommending revisions to the propyl gallate provisions in the GSFA to be consistent with the Codex Standard for Butter i.e., the deletion of the provision for food category 02.0 and addition of provisions for all sub-categories of 02.0, excluding 02.2.1.1 (Butter)

Recommendation for Propyl Gallate, INS 310

The eQC WG recommends that the CCFAC endorse for adoption at Step 8 by the CAC, the following provisions for the use of propyl gallate.

PROPYL GALLATE, INS 310 (Antioxidant)				
Food Cat. No.	Food Category	Max Level		Comment
2.1	Fats and oils essentially free from water	200	mg/kg	Note 15
2.2.1.2	Butter oil, anhydrous milkfat, ghee	200	mg/kg	Note 15
2.2.1.3	Blends of butter and margarine	200	mg/kg	Note 15
2.2.2	Emulsions containing less than 80% fat	200	mg/kg	Note 15
2.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	200	mg/kg	Note 15
2.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	200	mg/kg	Note 15
04.2.2.5	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)	200	mg/kg	Note 15
06.4.2	Dried pastas and noodles and like products	200	mg/kg	Note 15
06.4.3	Pre-cooked pastas and noodles and like products	200	mg/kg	Note 15
07.0	Bakery wares	200	mg/kg	Notes 15 & 96 ²⁶
09.2.1	Frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg	Notes 15 & 111 ²⁷
12.5	Soups and broths	200	mg/kg	Note 15

ASCORBYL ESTERS (INS 304, 305)

77. JECFA has assigned a group ADI of 1.25 mg/kg bw for ascorbyl palmitate (INS 304) and ascorbyl stearate (INS 305). There are three pending provisions in the GSFA, one of which (for food category 12.6.2) would amend a previously adopted a maximum use level (200 mg/kg, as ascorbyl stearate).

Recommendation for Ascorbyl Esters, INS 304 & 305

The eQC WG recommends that the CCFAC endorse for adoption at Step 8 by the CAC, the following provisions for the use of ascorbyl esters.

ASCORBYL ESTERS, INS 304, 305 (Antioxidant)				
Food Cat. No.	Food Category	Max Level		Comment
12.6.2	Non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)	500	mg/kg	Note 10 ²⁸
13.4	Dietetic formulae for slimming purposes and weight reduction	500	mg/kg	Note 10
13.5	Dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6	500	mg/kg	Note 10

BUTYLATED HYDROXYANISOLE (BHA) (INS 320)

78. The 29th CCFAC requested that JECFA perform intake assessments for BHA based on the levels of maximum use in the draft GSFA. BHA was identified for JECFA exposure assessment because several delegations expressed concern that the draft provisions for these additives may contribute significantly to its intake exceeding its ADI. The 51st JECFA (1998) reviewed national intake data on benzoates.

79. JECFA has assigned an ADI of 0.5 mg/kg bw for BHA.

²⁶ Note 96: Carryover from use in fats.

²⁷ Note 111: For use in dipping solution only.

²⁸ Note 10: As ascorbyl stearate.

Recommendation 1 for BHA, INS 320

BHA is added to food to inhibit lipid oxidation; therefore, the eQC WG recommends that all provisions for BHA in the GSFA be expressed on a fat or oil basis (Note 15).

Recommendation 2 for BHA, INS 320

The eQC WG reaffirms its recommendation that the CCFAC agree to delete the following provisions for BHA from the GSFA

Butylated Hydroxyanisole (BHA), INS 320 (Antioxidant)					
Food Cat. No.	Food Category	Max Level		Comment	Step
01.3.2	Beverage whiteners (plain)	100	mg/kg		6
01.5.2	Milk and cream powder analogues (plain)	100	mg/kg		6
02.0	Fats and oils, and fat emulsions	200	mg/kg	Note 15 ²⁹	6
02.2.1.1	Butter & concentrated butter	200	mg/kg	Note 15	6
04.1.2.6	Fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	100	mg/kg		6
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	100	mg/kg		6
05.1.1	Cocoa mixes (powders) & cocoa mass/cake	90	mg/kg		6
05.1.3	Cocoa-based spreads, including fillings	100	mg/kg		6
06.1	Whole, broken, or flaked grain, including rice	100	mg/kg		6
08.1	Fresh meat, poultry, and game	100	mg/kg	Note 15	6
09.3	Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg		6
09.4	Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg		6
12.4	Mustards	200	mg/kg		6
12.5.1	Ready-to-eat soups and broths, including canned, bottled, and frozen	200	mg/kg	Note 15	6
12.5.2	Mixes for soups and broths	300	mg/kg	Note 15	6
12.7	Salads (e.g., macaroni salad, potato salad) & sandwich spreads excluding cocoa- & nut-based spreads of 04.2.2.5 and 05.1.3	200	mg/kg		6

Recommendation 3 for BHA, INS 320

The eQC WG could not reach consensus on the following provisions in the draft GSFA for BHA and recommends that the 36th CCFAC request information on the need for antioxidants in foods subject to the food categories listed below, with the understanding that if this information is not provided to the 37th CCFAC, these draft provisions will be deleted from the GSFA.

Butylated Hydroxyanisole (BHA), INS 320 (Antioxidant)					
Food Cat. No.	Food Category	Max Level		Comment	Step
09.2.1	Frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	1000	mg/kg		6
09.2.2	Frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg	Note 15	
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg		6

29

Note 15 Fat or oil basis

Recommendation 4 for BHA, INS 320

The eQC WG recommends that the CCFAC endorse the following provisions for adoption at Step 8 by the CAC.

Butylated Hydroxyanisole (BHA), INS 320 (Antioxidant)				
Food Cat. No.	Food Category	Max Level		Comment
01.1.2 ³⁰	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	200	mg/kg	Notes 15 ³¹ & 88 ³²
01.5.1	Milk powder and cream powder (plain)	200	mg/kg	Note 15
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	2	mg/kg	Note 15
02.1	Fats & oils essentially free from water	200	mg/kg	Note 15
02.2.1.2	Margarine & similar products	200	mg/kg	Note 15
02.2.2	Emulsions containing less than 80% fat	200	mg/kg	Note 15
02.3	Fat emulsions other than 02.2, including mixed and/or flavoured products based on fat emulsions	200	mg/kg	Note 15
02.4	Fat-based desserts excl. dairy-based dessert prods. of 01.7	200	mg/kg	Note 15
03.0	Edible ices, including sherbet and sorbet	200	mg/kg	Note 15
04.1.2.2	Dried fruit	200	mg/kg	Note 15
04.1.2.7	Candied fruit	32	mg/kg	Note 15
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	2	mg/kg	Note 15
04.1.2.12	Cooked fruit	100	mg/kg	Note 15
04.2.2.2	Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	200	mg/kg	Notes 15 & 76 ³³
04.2.2.5	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)	200	mg/kg	Note 15
05.1.4	Cocoa and chocolate products	200	mg/kg	Note 15
05.1.5	Imitation chocolate, chocolate substitute products	200	mg/kg	Note 15
05.2	Confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	200	mg/kg	Note 15
05.3	Chewing gum	750	mg/kg	Note 15
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	200	mg/kg	Note 15
06.3	Breakfast cereals, including rolled oats	200	mg/kg	Note 15
06.4.3	Pre-cooked pastas and noodles and like products	200	mg/kg	Note 15
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	2	mg/kg	Note 15
07.0	Bakery wares	200	mg/kg	Note 15
08.2	Processed meat, poultry, and game products in whole pieces or cuts	200	mg/kg	Note 15
08.3	Processed comminuted meat, poultry, and game products	200	mg/kg	Note 15
10.4	Egg-based desserts (e.g., custard)	2.5	mg/kg	Note 15
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	20	mg/kg	Note 15
12.2	Herbs, spices, seasonings (including salt substitutes), and condiments (e.g., seasoning for instant noodles)	200	mg/kg	Note 15
12.5	Soups & broths	200	mg/kg	Note 15
12.6	Sauces and like products	200	mg/kg	Note 15

³⁰ This provision has been reassigned from 01.3.3 (see CL 2002/44-FAC, App. I) due to the changes in the food category system by the 35th CCFAC (ALINORM 03/12A, App. II).

³¹ Note 15: Fat or oil basis

³² Note 88: Carryover from the ingredient.

³³ Note 76: Use in potatoes only.

Butylated Hydroxyanisole (BHA), INS 320 (Antioxidant)				
Food Cat. No.	Food Category	Max Level		Comment
12.8	Yeast and like products	1000	mg/kg	Note 15
13.6	Food supplements	400	mg/kg	Note 15
14.1.4	Water-based flavoured drinks, including "sport" "energy" or "electrolyte" drinks and particulated drinks	1000	mg/kg	Note 15
15.1	Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	200	mg/kg	Note 15
15.2	Processed nuts, including covered nuts and nut mixtures (with e.g., dried fruit)	200	mg/kg	Note 15

BUTYLATED HYDROXYTOLUENE (BHT) (INS 321)

80. The 29th CCFAC requested that JECFA perform intake assessments for BHT based on the levels of maximum use in the draft GSFA. BHT was identified for JECFA exposure assessment because several delegations expressed concern that the draft provisions for these additives may contribute significantly to its intake exceeding its ADI. The 51st JECFA (1998) reviewed national intake data on benzoates.

81. JECFA has assigned an ADI of 0.3 mg/kg bw for BHT.

Recommendation 1 for BHT, INS 321

BHT is added to food to inhibit lipid oxidation; therefore, the eQC WG recommends that all provisions for BHT in the GSFA be expressed on a fat or oil basis (Note 15).

Recommendation 2 for BHT, INS 321

The eQC WG reaffirms its recommendation that the CCFAC agree to delete the following provisions for BHT from the GSFA

Butylated Hydroxytoluene (BHT), INS 321 (Adjuvant, Antioxidant)					
Food Cat. No.	Food Category	Max Level		Comment	Step
01.3.2	Beverage whiteners (plain)	100	mg/kg		6
01.5.1	Milk powder and cream powder (plain)	200	mg/kg	Note 15 ³⁴	6
01.5.2	Milk and cream powder analogues (plain)	100	mg/kg		6
02.2.1.1	Butter and concentrated butter	200	mg/kg	Note 15	6
04.1.2.2	Dried fruit	100	mg/kg		6
04.1.2.6	Fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	100	mg/kg		6
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	90	mg/kg		6
06.1	Whole, broken, or flaked grain, including rice	200	mg/kg		6
08.1	Fresh meat, poultry, and game	100	mg/kg	Note 15	6
09.3	Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	100	mg/kg		6
09.4	Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	100	mg/kg		6
12.4	Mustards	100	mg/kg		6
12.7	Salads (e.g., macaroni salad, potato salad) & sandwich spreads excluding cocoa- & nut-based spreads of 04.2.2.5 and 05.1.3	100	mg/kg		6
12.8	Yeast and like products	100	mg/kg		6

³⁴

Note 15: Fat or oil basis.

Recommendation 3 for BHT, INS 321

The eQC WG could not reach consensus on the following provisions in the draft GSFA and recommends that 36th CCFAC request information on the need for antioxidants in foods subject to the food categories listed below, with the understanding that if this information is not provided to the 37th CCFAC, these draft provisions will be deleted from the GSFA.

Butylated Hydroxytoluene (BHT), INS 321 (Adjuvant, Antioxidant)					
Food Cat. No.	Food Category	Max Level		Comment	Step
09.2.1	Frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	1000	mg/kg		6
09.2.2	Frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg	Note 15	6
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg		6

Recommendation 4 for BHT, INS 321

The eQC WG recommends that the CCFAC endorse the following provisions for adoption at Step 8 by the CAC.

Butylated Hydroxytoluene (BHT), INS 321 (Adjuvant, Antioxidant)					
Food Cat. No.	Food Category	Max Level		Comment	
01.1.2 ³⁵	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	200	mg/kg	Notes 15 & 88 ³⁶	
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	90	mg/kg	Notes 2 ³⁷ & 15	
02.1	Fats and oils essentially free from water	200	mg/kg	Note 15	
02.2.1.2	Margarine and similar products	500	mg/kg	Note 15	
02.2.2	Emulsions containing less than 80% fat	200	mg/kg	Note 15	
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	200	mg/kg	Note 15	
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	200	mg/kg	Note 15	
03.0	Edible ices, including sherbet and sorbet	100	mg/kg	Note 15	
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	90	mg/kg	Notes 2 & 15	
04.1.2.12	Cooked fruit	100	mg/kg	Note 15	
04.2.2.2	Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	200	mg/kg	Notes 15 & 76 ³⁸	
04.2.2.5	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)	200	mg/kg	Note 15	
05.1.4	Cocoa and chocolate products	200	mg/kg	Note 15	
05.1.5	Imitation chocolate, chocolate substitute products	200	mg/kg	Note 15	
05.2	Confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	200	mg/kg	Note 15	
05.3	Chewing gum	750	mg/kg	Note 15	
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	200	mg/kg	Note 15	

³⁵ This provision has been reassigned from 01.3.3 (see CL 2002/44-FAC, App. I) due to the changes in the food category system by the 35th CCFAC (ALINORM 03/12A, App. II).

³⁶ Note 88: Carryover from the ingredient.

³⁷ Note 2: On dry ingredient, dry weight, dry mix or concentrate basis.

³⁸ Note 76: Use in potatoes only.

Butylated Hydroxytoluene (BHT), INS 321 (Adjuvant, Antioxidant)				
Food Cat. No.	Food Category	Max Level		Comment
06.3	Breakfast cereals, including rolled oats	50	mg/kg	Note 15
06.4.3	Pre-cooked pastas and noodles and like products	200	mg/kg	Note 15
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	90	mg/kg	Notes 2 & 15
07.0	Bakery wares	200	mg/kg	Note 15
08.2	Processed meat, poultry, and game products in whole pieces or cuts	100	mg/kg	Note 15
08.3	Processed comminuted meat, poultry, and game products	100	mg/kg	Note 15
10.4	Egg-based desserts (e.g., custard)	90	mg/kg	Notes 2 & 15
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	20	mg/kg	Note 15
12.2	Herbs, spices, seasonings (including salt substitutes), and condiments (e.g., seasoning for instant noodles)	200	mg/kg	Note 15
12.5	Soups and broths	200	mg/kg	Note 15
12.6	Sauces and like products	200	mg/kg	Note 15
13.6	Food supplements	400	mg/kg	Note 15
14.1.4	Water-based flavoured drinks, including "sport" "energy" or "electrolyte" drinks and particulated drinks	1000	mg/kg	Note 15
15.0	Ready-to-eat savouries	200	mg/kg	Note 15

TERTIARY BUTYLHYDROXYQUINONE (TBHQ) (INS 319)

82. The 29th CCFAC requested that JECFA perform intake assessments for TBHQ based on the levels of maximum use in the draft GSFA. TBHQ was identified for JECFA exposure assessment because several delegations expressed concern that the draft provisions for these additives may contribute significantly to its intake exceeding its ADI. The 51st JECFA (1998) reviewed national intake data on benzoates.

83. JECFA has assigned an ADI of 0.7 mg/kg bw for TBHQ.

84. The use of phenolic antioxidants in foods had its beginning in the late 1940s when butylated hydroxyanisole (BHA) was found to have antioxidant effectiveness in fatty foods. Somewhat earlier, several alkyl (including *n*-propyl) esters of gallic acid had been investigated and approved for food use in a number of countries. Later on, around 1954, butylated hydroxytoluene (BHT) was put to widespread use in the United States along with the previously available food antioxidants. The next major development on phenolic antioxidants occurred in 1972, when *ter*-butyl hydroquinone (TBHQ) was commercialized as a food grade antioxidant.³⁹

85. BHA and BHT serve a vast range of fat-containing products. They give good carry-through for baking but are too volatile for frying. BHA and BHT are most frequently used as antioxidants for granola bars, breakfast cereals, animal fats, potato granules and flakes, chewing gum base, candies and baked goods (Coulter 1988).⁴⁰ TBHQ is particularly effective in stabilizing highly unsaturated oils such as soy bean, sunflower, safflower and fish oils.⁴¹ It is carried through during deodorization, thereby protecting the deodorized oil from oxidative deterioration thereafter.⁴² TBHQ offers good carry-through activity to protect fried food products against oxidative deterioration, but is not effective for baked food applications (Coulter 1988).

Recommendation 1 for TBHQ, INS 319

TBHQ is added to food to inhibit lipid oxidation; therefore, the eQC WG recommends that all provisions for TBHQ in the GSFA be expressed on a fat or oil basis (Note 15).

³⁹ Sherwin, E.R., 1990, Antioxidants. *Food Additives*, edited by A.L. Branen, P.M. Davidson and S. Salminen (New York: Marcel Dekker, Inc.), pp.139-193.

⁴⁰ Coulter, R.B., 1988, Extending shelf life by using traditional phenolic antioxidants. *Cereal Foods World*, 33, 207-210.

⁴¹ Lavers, B., 1991, Rancidity restrained. *Food Processing*, 60, 11-12

⁴² Charteris, W.P., 1995, Minor ingredients of edible table spreads. *Journal of the Society of Dairy Technology*, 48, 101-106.

Recommendation 2 for TBHQ, INS 319

The eQC WG recommends that the CCFAC agree to delete the following provisions for TBHQ from the GSFA

Tertiary Butyl Hydroxyquinone (TBHQ), INS 319 (Antioxidant)					
Food Cat. No.	Food Category	Max Level		Comment	Step
01.1.2 ⁴³	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	200	mg/kg	Note 88 ⁴⁴	6
02.0	Fats and oils, and fat emulsions (type water-in-oil)	200	mg/kg	Note 15 ⁴⁵	6
05.1	Cocoa products and chocolate products including imitations and chocolate substitutes	200	mg/kg	Note 15	6
08.1	Fresh meat, poultry, and game	100	mg/kg	Note 15	6
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg	Note 15	6

Recommendation 3 for TBHQ, INS 319

The eQC WG recommends that the CCFAC endorse the following provisions for adoption at Step 8 by the CAC.

Tertiary Butyl Hydroxyquinone (TBHQ), INS 319 (Antioxidant)					
Food Cat. No.	Food Category	Max Level		Comment	
01.1.2 ⁴⁶	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	100	mg/kg	Note 88 ⁴⁷	
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	200	mg/kg	Note 15	
02.1	Fats and oils essentially free from water	200	mg/kg	Note 15	
02.2.1.2	Margarine and similar products	200	mg/kg	Note 15	
02.2.1.3	Blends of butter and margarine	200	mg/kg	Note 15	
02.2.2	Emulsions containing less than 80% fat	200	mg/kg	Note 15	
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	200	mg/kg	Note 15	
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	200	mg/kg	Note 15	
03.0	Edible ices, including sherbet and sorbet	200	mg/kg	Note 15	
04.1.2.2	Dried fruit	200	mg/kg	Note 15	
04.2.2.5	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)	200	mg/kg	Note 15	
05.1.2	Cocoa mixes (syrups)	200	mg/kg	Note 15	
05.1.3	Cocoa-based spreads, incl. fillings	200	mg/kg	Note 15	
05.1.4	Cocoa and chocolate products	200	mg/kg	Note 15	
05.1.5	Imitation chocolate, chocolate substitute products	200	mg/kg	Note 15	
05.2	Confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	200	mg/kg	Note 15	

⁴³ This provision has been reassigned from 01.3.3 (see CL 2002/44-FAC, App. I) due to the changes in the food category system by the 35th CCFAC (ALINORM 03/12A, App. II).

⁴⁴ Note 88: Carryover from the ingredient.

⁴⁵ Note 15: Fat or oil basis.

⁴⁶ This provision has been reassigned from 01.3.3 (see CL 2002/44-FAC, App. I) due to the changes in the food category system by the 35th CCFAC (ALINORM 03/12A, App. II).

⁴⁷ Note 88: Carryover from the ingredient

Tertiary Butyl Hydroxyquinone (TBHQ), INS 319 (Antioxidant)				
Food Cat. No.	Food Category	Max Level		Comment
05.3	Chewing gum	750	mg/kg	
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	200	mg/kg	Note 15
06.4.3	Pre-cooked pastas and noodles and like products	200	mg/kg	Note 15
07.1.1	Breads and rolls	200	mg/kg	Note 15
07.1.2	Crackers, excluding sweet crackers	200	mg/kg	Note 15
07.1.3	Other ordinary bakery products (e.g., bagels, pita, English muffins)	200	mg/kg	Note 15
07.1.4	Bread-type products, including bread stuffing and bread crumbs	200	mg/kg	Note 15
08.2	Processed meat, poultry, and game products in whole pieces or cuts	100	mg/kg	Note 15
08.3	Processed comminuted meat, poultry, and game products	100	mg/kg	Note 15
09.2.1	Frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	1000	mg/kg	Note 111 ⁴⁸
12.2	Herbs, spices, seasonings (including salt substitutes), and condiments (e.g., seasoning for instant noodles)	200	mg/kg	Note 15
12.4	Mustards	200	mg/kg	Note 15
12.5	Soups and broths	200	mg/kg	Note 15
12.6	Sauces and like products	200	mg/kg	Note 15
14.1.4	Water-based flavoured drinks, including "sport" "energy" or "electrolyte" drinks and particulated drinks	200	mg/kg	Note 15
15.0	Ready-to-eat savouries	200	mg/kg	Note 15

DIACETYLTARTARIC AND FATTY ACID ESTERS OF GLYCEROL (DATEM) (INS 472E) AND TARTARIC, ACETIC AND FATTY ACID ESTERS OF GLYCEROL, MIXED (INS 472F)

86. The 23rd CAC (1999) adopted the inclusion of tartaric, acetic and fatty acid esters of glycerol, mixed (INS 472f) in Table 3 of the GSFA.

87. The 57th JECFA withdrew the ADI for tartaric, acetic and fatty acid esters of glycerol, mixed (INS 472f) due to its specifications being combined with diacetyltartaric and fatty acid esters of glycerol (INS 472e). As a result, the 34th CCFAC agreed that the listing for this additive (INS 472f) in Table 3 should be deleted.

88. The 57th JECFA assigned a temporary grouped ADI of 0-50 mg/kg bw for both DATEM (INS 472e), and tartaric, acetic and fatty acid esters of glycerol, mixed (INS 472f) because of unresolved toxicological questions. The 61st JECFA (2003), upon receiving the needed information assigned an ADI of 50 mg/kg for INS 472e.

89. The 34th CCFAC agreed to combine the food additive provisions for INS 472e and INS 472f under "DATEM."

Recommendation 1 for Diacetyltartaric and Fatty Acid Esters of Glycerol, INS 472e, 472f

The eQC WG recommends that the CCFAC agree to delete the following provisions for Diacetyltartaric and Fatty Acid Esters of Glycerol from the GSFA

Diacetyltartaric and Fatty Acid Esters of Glycerol (INS 472e, 472f) (Emulsifier, Sequestrant, Stabilizer)				
Food Cat. No.	Food Category	Max Level	Comment	Step
01.6.2.1	Ripened cheese, includes rind	GMP		6
02.2	Fat emulsions mainly of type water-in-oil	10000 mg/kg		6
13.1	Infant formulae and follow-up formulae	GMP		6
14.2.2	Cider and perry	GMP		6
14.2.4	Wines (other than grape)	GMP		6

⁴⁸ Note 111: Use in dipping solution only

Recommendation 2 for Diacetyltartaric and Fatty Acid Esters of Glycerol, INS 472e, 472f

The eQC WG could not reach consensus on the following provisions in the draft GSFA and recommends that 36th CCFAC request information on the need for emulsifiers, sequestrants and stabilizers in foods subject to food categories listed below, with the understanding that if this information is not provided to the 37th CCFAC, these draft provisions will be deleted from the GSFA.

Diacetyltartaric and Fatty Acid Esters of Glycerol (INS 472e, 472f) (Emulsifier, Sequestrant, Stabilizer)				
Food Cat. No.	Food Category	Max Level	Comment	Step
02.1	Fats and oils essentially free from water	10,000 mg/kg		6
04.1.2.2	Dried fruit	GMP		6
04.1.2.6	Fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	GMP		6
04.2.2.2	Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	GMP		6
04.2.2.3	Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds in vinegar, oil, brine, or soy sauce	GMP		6
04.2.2.6	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts etc.) other than food category 04.2.2.5	GMP		6
04.2.2.7	Fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweed products	GMP		6
04.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweeds	GMP		6
05.1	Cocoa products and chocolate products including imitations and chocolate substitutes	10,000 mg/kg		6
06.2	Flours and starches	5,000 mg/kg		6
08.2.2	Heat-treated processed meat, poultry, and game products in whole pieces or cuts	GMP		6
08.3.2	Heat-treated processed comminuted meat, poultry, and game products.	GMP		6
9.1.2	Fresh Mollusks, Crustaceans and Echinoderms	GMP	Note 16 ⁴⁹	6
9.2.1	Frozen Fish, Fish Fillets, and Fish Products, Including Mollusks, Crustaceans, and Echinoderms.	GMP		6
09.2.5	Smoked, dried, fermented and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	GMP		6
09.4	Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	GMP		6
12.2	Herbs, spices, seasonings (including salt substitutes) and condiments (e.g. seasoning for instant noodles)	1 mg/kg		6
12.5	Soups and broths	GMP		6
12.9	Protein products.	GMP		6
13.4	Dietetic formulae for slimming purposes and weight reduction	GMP		6
14.1.2.2	Canned or bottled (pasteurized) vegetable juice	GMP		6

Recommendation 3 for Diacetyltartaric and Fatty Acid Esters of Glycerol, INS 472e, 472f

The eQC WG recommends that the CCFAC endorse the following provisions for adoption at Step 8 by the CAC.

⁴⁹ For use in glaze, coatings or decorations for fruit, vegetables, meat or fish.

Diacetyltartaric and Fatty Acid Esters of Glycerol (INS 472e, 472f) (Emulsifier, Sequestrant, Stabilizer)			
Food Cat. No.	Food Category	Max Level	Comment
01.1.1.2	Buttermilk (plain)	5000 mg/kg	
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	5000 mg/kg	
01.2.1.2	Fermented milks (plain), heat-treated after fermentation	5000 mg/kg	
01.2.2	Renneted milk (plain)	5000 mg/kg	
01.3.2	Beverage whiteners (plain)	5000 mg/kg	
01.4	Cream (plain) and the like	5000 mg/kg	
01.5.1	Milk powder and cream powder (plain)	10,000 mg/kg	
01.5.2	Milk and cream powder analogues (plain)	10,000 mg/kg	
01.6.1	Unripened cheese	10,000 mg/kg	
01.6.4	Processed cheese	10,000 mg/kg	
01.6.5	Cheese analogues	10,000 mg/kg	
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	10,000 mg/kg	
02.2.1.2	Margarine and similar products	10,000 mg/kg	
02.2.1.3	Blends of butter and margarine	10,000 mg/kg	
02.2.2	Emulsions containing less than 80% fat	10,000 mg/kg	
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	10,000 mg/kg	
02.4	Fat-based desserts excluding dairy-based products of food category 01.7	5000 mg/kg	
03.0	Edible ices, including sherbet and sorbet	10,000 mg/kg	
04.1.1.2	Surface-treated fresh fruit	10,000 mg/kg	Note 16 ⁵⁰
04.1.2.3	Fruit in vinegar, oil, or brine	10,00 mg/kg	
04.1.2.7	Candied fruit	10,00 mg/kg	
04.1.2.8	Fruit preparations, including pulp, purees, fruit toppings and coconut milk	2500 mg/kg	
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	2500 mg/kg	
04.1.2.10	Fermented fruit products	2500 mg/kg	
04.1.2.12	Cooked fruit	2500 mg/kg	
04.2.1.2	Surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	10,000 mg/kg	Note 16
05.2	Confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 & 05.4	10000 mg/kg	
05.3	Chewing gum	50,000 mg/kg	
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	10,000 mg/kg	
06.4.2	Dried pastas and noodles and like prods.	10,000 mg/kg	
06.4.3	Pre-cooked pastas and noodles and like prods.	10,000 mg/kg	
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	5000 mg/kg	
06.6	Batters (e.g., for breading or batters for fish or poultry)	5000 mg/kg	
07.0	Bakery wares	20,000 mg/kg	
08.1.1	Fresh meat, poultry, and game, whole pieces or cuts	10,000 mg/kg	Note 16
08.1.2	Fresh meat, poultry, and game, comminuted	10,000 mg/kg	
08.2.1	Non-heat treated processed meat, poultry, and game products. in whole pieces or cuts	10,000 mg/kg	
08.2.3	Frozen processed meat, poultry, and game products in whole pieces or cuts	10,000 mg/kg	Note 16
08.3.1	Non-heat treated processed comminuted meat, poultry, and game products	10,000 mg/kg	
08.3.3	Frozen processed comminuted meat, poultry, and game products	10,000 mg/kg	Note 16
08.4	Edible casings (e.g., sausage casings)	10,000 mg/kg	
09.1.1	Fresh fish and fish	10,000 mg/kg	Note 16

⁵⁰ Note 16: For use in glaze, coatings or decorations for fruit, vegetables, meat, or fish.

Diacyltartaric and Fatty Acid Esters of Glycerol (INS 472e, 472f) (Emulsifier, Sequestrant, Stabilizer)			
Food Cat. No.	Food Category	Max Level	Comment
09.2.2	Frozen battered fish, fish fillets, and creamed fish products, including mollusks, crustaceans, and echinoderms	50,000 mg/kg	Note 41 ⁵¹⁵²
09.2.3	Frozen minced and/or fried fish and fish products, including mollusks, crustaceans, and echinoderms	50,000 mg/kg	Note 16
09.2.4	Cooked and/or fried fish and fish products, including mollusks, crustaceans, and echinoderms	10000 mg/kg	
09.3	Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	10,000 mg/kg	
10.2.3	Dried and/or heat coagulated egg prods.	5000 mg/kg	
10.4	Egg-based desserts (e.g., custard)	5000 mg/kg	
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	10,00 mg/kg	
12.3	Vinegars	10,00 mg/kg	
12.4	Mustards	10,000 mg/kg	
12.6	Sauces and like products	10,000 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 & 05.1.3	5000 mg/kg	
13.3.1	Dietetic foods for special medical purposes intended for adults	5000 mg/kg	
13.5	Dietetic foods (e.g. supplementary foods for dietary use) excluding products of food categories 13.1–13.4	5000 mg/kg	
13.6	Food supplements	5000 mg/kg	
14.1.2.4	Concentrate (liquid or solid) for vegetable juice	5000 mg/kg	
14.1.4	Water-based flavoured drinks, including “sport,” “energy,” or “electrolyte” drinks and particulated drinks	5000 mg/kg	
14.1.5	Coffee, coffee substitutes, tea, herbal infusions and other hot cereal and grain beverages excluding cocoa	5000 mg/kg	
14.2.6	Distilled spirituous beverages containing more than 15% alcohol	5000 mg/kg	
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	10,000 mg/kg	
15.1	Snacks – potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	20,000 mg/kg	
15.2	Processed nuts, including covered nuts and nut mixtures (with e.g., dried fruit)	10,000 mg/kg	

⁵¹ Note 41: For use in breadings and batters only.