codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 (b) **CX/FAC 06/38/9, Part 2**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

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FOOD ADDITIVES PROVISIONS OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES

Comments (in response to CL 2005/34-FAC, CL 2005/45-FAC and CL 2005/50-FAC)

The following comments have been received from the following Codex Observers: : CEFS, CIAA, ELC, FEDIOL, IADSA, ICBA, ICGA, IFAC, IFU, ISA, ISDI, NATCOL, OIV, WSRO

CEFS:

CEFS (Comité Européen des Fabricants de Sucre), on behalf of all sugar manufacturers in the EU and Switzerland, would like to present comments on the proposed draft food additives provisions for "priority additives" of the General Standard for Food Additives.

CEFS is concerned to reach a consistency between the Codex Standard for Sugars (CXSN 212-2001 rev 1) and the GSFA. A lack of correspondence between both standards could lead to abuse and unfair trade practices. It is the reason why CEFS insists on the following principles :

1) For **standardised sugars** (subcategory 11.1) : only the additives allowed in the Codex Standard for Sugars (CXSN 212-2001-rev 1) should be permitted in the GSFA. The Committee on Sugars includes experts that are able to justify the necessity or the non-necessity of the use of additives on a technological basis. According to the expertise of the vertical Committee on Sugars, there is no technological justification for more or other additives. There is a world wide consensus with respect to this, since the Codex Standard for Sugars has recently been revised (endorsement at the 24th Meeting of the Commission of the Codex Alimentarius in Geneva, July 2001)

2) For **non-standardised sugars** (subcategories 11.2-11.4) : CEFS is open to the addition of other additives if there is a technological justification and need, and in amounts which do not present a hazard for health. Moreover, the labelling should mention the presence of the additives.

According to these principles, CEFS would like to propose the following modifications to the provisions for "priority additives" in the Codex General Standard for Food Additives :

- **Standardised sugars :**

Subcategory	Additives	Maximum levels (mg/kg)
11.1.2. Powdered sugar, powdered dextrose	Caramel colour III (INS 150c) Caramel colour IV (INS 150d) Carotenoids (INS 160ai, 160aii, 160e, 160f (Colour)	*50000 (step 3); 50000 (step 3); 35 (step 6)* - ***Suppression***

Rationale : *The use of colours for powdered sugar and powdered dextrose is neither permitted by the Codex Standard on Sugars nor by European legislation, CEFS therefore asks for the suppression of the suggested maximum levels for the use of such colours in respect of Food Category No. 11.1.2.*

Subcategory	Additives	Maximum levels (mg/kg)
11.1.3. Soft white sugar, soft brown sugar, glucose syrup, dried glucose syrup, raw cane sugar	Sulphites (INS 220-225, 227, 228, 539)	***20 (step 6)*** *– Support*

Rationale : *The proposed level of sulphites is in accordance with the Codex Standard on Sugars, CEFS therefore supports the proposed level for category No. 11.1.3.*

- **Non-standardised sugars :**

Subcategory	Additives	Max Level (mg/kg)
11.2. Brown sugar excluding products of food category 11.1.3	Sulphites (INS 220-225, 227, 228, 539)	*40 (step 6)* **– *Support***

Rationale : *The proposed level of sulphites for the non-standardised category 11.2 is in accordance with European legislation, which ensures the technological justification and need of the additive in amounts which do not present a hazard for health. Therefore CEFS supports the proposed level for category No. 11.2.*

Subcategory	Additives	Max Level (mg/kg)
11.3. Sugar solutions and syrups, also (partially) inverted, including treacle and molasses, excluding products of food category 11.1.3.	Sulphites (INS 220-225, 227, 228, 539)	*500* **- *Suppression***

Rationale : *CEFS asks for the suppression of the suggested level because there is no technological justification why these non-standardised sugars should contain higher sulphite levels than standardised sugars. Furthermore, the proposed level goes significantly beyond EU legislation, which sets a maximum level of 70 mg/kg for this type of sugars.*

Subcategory	Additives	Max Level (mg/kg)
11.3. Sugar solutions and syrups, also (partially) inverted, including treacle and molasses, excluding products of food category 11.1.3.	Canthaxanthin (INS 161G) (Colour) Erythrosine (INS 127) (Colour) Allura Red AC (INS 129) (Colour) Indigotine (INS 132) (Colour) Sunset Yellow FCF (INS 110) (Colour) Sucralose (INS 955) (Sweetener)	*GMP (step 6)* *300 (step 6)* *300 (step 6)* *300 (step 6)* *300 (step 6)* *1500 (step 6)* - **Suppression**

Rationale : *Food Category No. 11.3 covers sugar solutions, invert sugar solutions and invert sugar syrups as defined in the EU "Sugars Directive" : there is* ***neither*** *a technological need for colouring these sugars or mixing them with intense sweeteners nor permission for the use of the above additives by EU legislation.*

CIAA:

In response to Codex Alimentarius' consultation regarding the provisions for priority additives in the General Standard for Food Additives (GSFA), the Confederation of the Food and Drink industries of the EU wishes to present the following preliminary comments:

- With regard to products from the "chocolate, biscuits and sugar confectionary" sector, our members note that the following additives are used and therefore should be kept in the priority list:

  - E903 - Carnauba Wax
  - E210, 211, 212, 213 - Benzoates in flavours, colours
  - E320 - Butylated Hydroxyanisole (BHA) in flavours
  - E321 - Butylated Hydroxytoluene (BHT) in flavours
  - E319 - Tertiary Butylhydroxyquinone (TBHQ)
  - E472e - Diacetyltartaric and Fatty Acid Esters of Glycerol
  - E220, 221, 222, 223, 224,225, 227, 228, 539 - Sulfites in coconuts, glucose syrups
  - E133- Brilliant Blue FCF
  - E120 - Carmines
  - E160aii - Carotenes, Vegetable
  - E1 er Complexes 41i & 141ii - Chlorophyll, Copp
  - E127 - Erythrosine
  - E172i, 172ii, 172iii - Iron Oxides
  - E101i, 101ii - Riboflavins

- E1503 - Castor Oil
- E432,433, 434, 435, 436 - Polysorbates in colours
- E129 - Allura Red AC
- E160ai,aii,e,f - Carotenoids
- E132 - Indigotine
- E124 - Ponceau 4R
- E110 - Sunset Yellow FCF
- E950 - Acesulfame Potassium
- E951 - Aspartame
- E955 - Sucralose

The "chocolate, biscuits and sugar confectionary" sector also asks that the following colours be kept in the list:

- E150c - Caramel Colour Class III
- 150d - Caramel Colour Class IV E
- E161- g Canthaxanthin
- E163ii - Grape Skin Extract

- CIAA would also like to support the comments tabled by the CEFS (Comité Européen des Fabricants de Sucre) with respect to the additives used in sugars.

Although CIAA is aware that other specific sectors may have similar comments with respect to the additives being used in their particular sector, we have not received at this stage any further comments from our sectorial associations. We would therefore like to be kept updated if there is still a possibility to submit further comments in the future in this respect.

ELC:

The ELC (Federation of European Food Additives, Food Enzymes and Food Cultures Industries) would like to make the following comments surrounding the above-mentioned document:

- We agree that as a matter of principle, all the definitions start with the wording "food additive, which…" because it helps clarifying the status of ingredients that are not additives but which however are able to show some of the functionalities referred to in the document.
- We support the addition of the sub-classes "bulk sweetener" to the list of sub-classes provided under Functional Class 27 "sweetener". Actually, bulk sweetener represents a well-defined class of additives, namely the polyols, that should be rightfully included in this sub-class. We also would draw your attention on the French translation "édulcorant de lest" : in our opinion, "édulcorant de charge" would be a more accurate wording.
- As regards the proposed definition for carrier, we would remind the reservation of the delegations of Switzerland and United States and of some observers at the 2005 CCFAC session, i.e. that the food additive class for "carrier" was not appropriate and needed further elaboration (Alinorm 05/28/12 – Para 93). We would suggest in particular to check the consequences of the introduction of this category on labelling.

FEDIOL

Additive	Food category	FEDIOL proposal	Justification	GSFA	Commodity standard
INS 320 BHA	02.0 Fats and oils and fat emulsions	200 mg/kg	The use of this antioxidant at the suggested level is needed in countries with a hot and humid climate. This level corresponds to the Indian law. There is no safety issue since the ADI is 0.5 mg/kg bw.	200 mg/kg	175 mg/kg
INS 321 BHT	02.0 Fats and oils and fat emulsions	200 mg/kg	The use of this antioxidant at the suggested level is needed in countries with a hot and humid climate. There is no safety issue since the ADI is 0.125 mg/kg bw.	200 mg/kg	75 mg/kg

Additive	Food category	FEDIOL proposal	Justification	GSFA	Commodity standard
INS 319 TBHQ	02.0 Fats and oils and fat emulsions	200 mg/kg	The use of this antioxidant at the suggested level is needed in countries with a hot and humid climate. This level corresponds to the Indian law. There is no safety issue since the ADI is 0.75 mg/kg bw.	200 mg/kg	120 mg/kg
INS 472e Diacyltartaric and fatty acid esters of glycerol	02.1 Fats and oils essentially free of water	20000 mg/kg	The use of this emulsifier at the suggested level is needed in countries with a hot and humid climate. The Indian law authorizes its use according GMP. There is no safety issue since the ADI is 50 mg/kg bw.	10000 mg/kg	Not authorized
INS 160aii Carotenes, vegetable	02.0 Fats and oils and fat emulsions	1000 mg/kg	Widely used as a colouring agent. No safety issue (authorized according GMP in the EU law)	1000 mg/kg for 02.2.1.2	25 mg/kg for 02.2.1.2
INS 160ai, 160aii, 160e, 160f Carotenoids	02.0 Fats and oils and fat emulsions	1000 mg/kg	Widely used as a colouring agent. No safety issue (authorized according GMP in the EU law)	1000 mg/kg for 02.1, 02.2.1.2 and 02.2.2.2	25 mg/kg each for 3 different carotenoids
INS 432-436 Polysorbates	02.0 Fats and oils and fat emulsions	24000 mg/kg		10000 mg/kg	Not authorized

IADSA:

At the 37th CCFAC Session in 2005 the Report of the Electronic Working Group on the General Standard for Food Additives (CX/FAC 05/37/9) queried the need for 8 additives in the category 13.6 Food Supplements. In addition, if there was a technological justification, levels of use were requested.

This information is provided below.

In assessing the impact of maximum levels of usage in terms of the ADI of the additive it must always be borne in mind that the daily intake of a food supplement product is unlikely to exceed 5g / day with an average figure being nearer 3g / day.

This is due to a number of reasons, an important one being the practicality of the consumer being able to swallow the tablet or capsule. To put this in perspective using Erythrosine (INS127) as an example, the Report (CX/FAC 05/37/9) gives a maximum level of 300mg / kg for dairy based drinks including drinking yoghurt etc. One serving of around 200g of such a drink would give an Erythrosine content of 60mg per serving, at the maximum level of 300mg / kg. By contrast 5g / day of a food supplement containing 500mg / kg of Erythrosine would only contribute 2.5mg / day.

A further request for information has been received in CL 34/2005 – FAC, Request for Comments and Information on Food Additive Provisions for Priority Additives in the General Standard for Food Additives (GSFA). The information is currently being acquired and IADSA will respond before the 1st December 2005 deadline.

1. Carnauba Wax

Carnauba Wax (INS: 903) is an important food additive for food supplements (category 13.6). Its principal use in food supplements is as a glazing agent for tablets.

In tablets containing vitamins and many other substances the vitamins particularly are susceptible to degradation if exposed to oxygen, moisture and/or light. As a consequence, such tablets have to be coated to prevent or reduce ingress of oxygen and moisture. The coated tablets are then additionally coated with a thin layer of carnauba wax, not only to provide an extra barrier but also to produce a smooth surface that makes the tablet easier to swallow.

From enquiries made across the food supplement industry it would appear that the majority of food supplement usage as described above could be accommodated within a maximum level of 500mg/kg.

2. Butylated Hydroxyanisole (BHA)

Butylated Hydroxyanisole (INS: 320) is used principally in food supplements (category 13.6) containing oil-soluble active ingredients such as vitamins A and D. The BHA is used as an antioxidant to protect the ingredients from oxidation, both during the manufacture of the food supplement and during the shelf life of the final product.

Whilst BHA is added to some susceptible supplement formulations as an antioxidant, in others it enters the product as a component of an oxygen-sensitive ingredient. The maximum level of usage is 400mg/kg oil (or proportionally when in combination with BHT). When considering this level it must be borne in mind that individual supplements are less than 2g in weight, with most being under 1.5g. In the majority of products the oil content is below 1g.

3. Butylated Hydroxytoluene (BHT)

Butylated Hydroxytoluene (INS: 321) is used primarily in food supplements (category 13.6) containing oil-soluble active ingredients such as vitamins A and D. The BHT is used as an antioxidant to protect the ingredients from oxidation, both during the manufacture of the food supplement and during the shelf life of the final product.

Whilst BHT is added to some susceptible supplement formulations as an antioxidant, in others it enters the product as a component of an oxygen-sensitive ingredient. The maximum level of usage is 400mg/kg oil (or proportionally when in combination with BHA). When considering this level it must be borne in mind that individual supplements are less than 2g in weight, with most being under 1.5g. In the majority of products the oil content is below 1g.

4. Chlorophylls, Copper Complexes of Chlorophylls

Chlorophylls and their copper complexes (INS: 141i and 141ii) are used in food supplements (category 13.6) to colour the coatings in the case of tablets and the shells in the case of capsules.

When manufactured, most food supplements are white or beige in colour even though they contain a range of active ingredients. Surface colouring of the products has been found to be the best way to differentiate between products, both in post-production handling and for the consumer's own control and recognition.

Usage level varies depending on the thickness of the coating or shell and the intensity of the colour required. However, all applications should be accommodated in a maximum level of 500mg/kg based on the content of the colour component. Chlorophyll is a preferred alternative to artificial colours.

5. Grape Skin Extract

Grape skin extract (INS: 163ii) is used in food supplements (category 13.6) to colour the coatings in the case of capsules. When manufactured, most food supplements are white or beige in colour even though they contain a range of active ingredients. Surface colouring of the products has been found to be the best way to differentiate between products, both in post-production handling and for the consumer's own control and recognition.

Usage level varies depending on the thickness of the coating or shell and the intensity of the colour required. However, all applications should be accommodated in a maximum level of 1500mg/kg based on the content of the colour component. Grape skin extract is a preferred alternative to the artificial colours.

6. Iron Oxides

Iron oxides (INS: 172i, 172ii and 172iii) are used in food supplements (category 13.6) to colour the coatings in the case of tablets and the shells in the case of capsules. When manufactured, most food supplements are white or beige in colour even though they contain a range of active ingredients. Surface colouring of the products has been found to be the best way to differentiate between products, both in post-production handling and for the consumer's own control and recognition.

Usage level varies depending on the thickness of the coating or shell and the intensity of the colour required. However, all applications should be accommodated in a maximum level of 7500mg/kg singly or in combination. Iron oxides are the preferred alternatives to artificial colours in many countries, including those in the European Union.

7. Erythrosine

Erythrosine (INS: 127) is used in food supplements (category 13.6) to colour the coatings in the case of tablets and the shells in the case of capsules. When manufactured, most food supplements are white or beige in colour even though they contain a range of active ingredients. Surface colouring of the products has been found to be the best way to differentiate between products, both in post-production handling and for the consumer's own control and recognition.

Usage level varies depending on the thickness of the coating or shell and the intensity of the colour required. However, all applications should be accommodated in a maximum level of 500mg/kg based on the content of the colour component.

8. Castor Oil

Castor oil (INS: 1503) is a food additive used in food supplements (category 13.6) primarily as a carrier solvent for components of the supplements.

The usage varies in quantity depending on the composition of the product formulation. From information supplied by supplement manufacturers, it would appear that all applications could be accommodated within a maximum level of 1000mg/kg of product. When considering this level it must be borne in mind that individual supplements are less than 2g in weight, with most being under 1.5g.

At the 37th CCFAC Session in 2005 the Report of the Electronic Working Group on the General Standard for Food Additives (CX/FAC 05/37/9) queried the need for 8 additives in the category 13.6 Food Supplements. In addition, if there was a technological justification, levels of use were requested. IADSA responded to this request on by 30 September 2005.

A further request for information was received in CL 34/2005 – FAC, Request for Comments and Information on Food Additive Provisions for Priority Additives in the General Standard for Food Additives (GSFA).

This information is provided below.

Introduction

In assessing the impact of maximum levels of usage in terms of the ADI of the additive it must always be borne in mind that the daily intake of a food supplement product is unlikely to exceed 5g / day with an average figure being nearer 3g / day.

This is due to a number of reasons, an important one being the practicality of the consumer being able to swallow the tablet or capsule. To put this in perspective using Indigotine (INS 132) as an example, the Report (CL 34/2005-FAC) gives a maximum level of 300mg / kg for dairy based drinks including drinking yoghurt etc. One serving of around 200g of such a drink would give an Indigotine content of 60mg per serving, at the maximum level of 300mg / kg. By contrast 5g / day of a food supplement containing 600mg / kg of Indigotine would only contribute 3.0mg / day.

1. Polysorbates

Polysorbates (INS Numbers 432, 433, 434, 435 and 436) are used in food supplements (category 13.6), particularly in soft gelatin capsules. In capsules it is used to disperse and emulsify the active components (e.g. vitamins and minerals) in the paste formulations. This also has the beneficial effect of dispersing the contents of the capsule more rapidly in the digestive system. A second and important function of the polysorbates is as an edible surfactant in the capsule fill. They help to improve the delivery of odiferous and unpleasant tasting active components such as fish oils. The polysorbates disperse and emulsify the oil in the stomach and therefore reduce the impact of post-ingestion odour/reflux.

All applications can be accommodated within a maximum level of 25000mg / kg. A daily intake of capsules would only deliver a maximum of 135mg polysorbates (JECFA ADI is 25mg / kg bw / d).

2. Colours

a) Allura Red AC

Allura Red AC (INS 129) is used in food supplements (category 13.6) to colour the coatings in the case of tablets and the shells in the case of capsules.

When manufactured, most food supplements are white or beige in colour, even though they contain a range of active ingredients. Surface colouring of the products has been found to be the best way to differentiate between products, both in post production handling and for the consumer's own recognition and control.

Usage levels vary depending on the thickness of the coating or capsule shell in relation to the total weight of the product. However, all applications should be accommodated within a maximum level of 600mg / kg based on the weight of the colour component. At this level the average intake from supplements would be less than 5mg per day.

b) Caramel Colour Class III

Caramel Colour Class III (INS Number 150c) is used as a colorant for food supplements (category 13.6) and is specifically used in capsule shells and tablet coatings to give an opaque dark-brown colour.

When manufactured, most food supplements are white or beige in colour, even though they contain a range of active ingredients. Surface colouring of the products has been found to be the best way to differentiate between products, both in post production handling and for the consumer's own recognition and control.

In certain soft-gel capsules the contents can settle with time producing an unsightly stain on the inner surface of the capsule shell. The opacity of caramel as a colour can hide the stain.

Usage level varies depending on the thickness of the capsule shell and its surface area, and in the case of tablets on the thickness of the coating, in relation to the total weight of the product. However, all applications should be accommodated within a maximum level of 20000mg / kg.

c) Caramel Colour Class IV

Caramel Colour Class IV (INS Number 150d) is used as a colorant for food supplements (category 13.6) and is specifically used in capsule shells and tablet coatings to give an opaque dark-brown colour.

When manufactured, most food supplements are white or beige in colour, even though they contain a range of active ingredients. Surface colouring of the products has been found to be the best way to differentiate between products, both in post production handling and for the consumer's own recognition and control.

In certain soft-gel capsules the contents can settle with time producing an unsightly stain on the inner surface of the capsule shell. The opacity of caramel as a colour can hide the stain.

Usage level varies depending on the thickness of the capsule shell and its surface area, and in the case of tablets on the thickness of the coating, in relation to the total weight of the product. However, all applications should be accommodated within a maximum level of 20000mg / kg.

d) Carotenoids

Carotenoids as beta carotene (INS 160ai and 160aii), β-Apo-8-carotenol (160e) and β-Apo-8-carotenoic acid, methyl or ethyl ester (160f) are used in food supplements (category 13.6) as a colorant. The main uses are to colour the shells of food supplement capsules and to colour the resulting solution from dissolving/effervescent food supplement tablets.

Usage level in capsules varies depending on the thickness of the capsule shells and in effervescent tablets the depth of colour required for the drink.

However, all applications of 160ai and 160aii should not exceed 600mg / kg and those for 160e and 160f should not exceed 300mg / kg. At these levels the average intake from supplements would be less than 5mg and 2.5mg respectively.

e) Fast Green FCF

Fast Green FCF (INS 143) is used in food supplements (category 13.6) to colour the coatings in the case of tablets and the shells in the case of capsules.

When manufactured, most food supplements are white or beige in colour, even though they contain a range of active ingredients. Surface colouring of the products has been found to be the best way to differentiate between products, both in post production handling and for the consumer's own recognition and control.

Usage levels vary depending on the thickness of the coating or capsule shell in relation to the total weight of the product. However, all applications should be accommodated within a maximum level of 600mg / kg based on the weight of the colour component. At this level the average intake from supplements would be less than 5mg per day.

f) Indigotine

Indigotine (INS 132) is used in food supplements (category 13.6) to colour the coatings in the case of tablets and the shells in the case of capsules.

When manufactured, most food supplements are white or beige in colour, even though they contain a range of active ingredients. Surface colouring of the products has been found to be the best way to differentiate between products, both in post production handling and for the consumer's own recognition and control.

Usage levels vary depending on the thickness of the coating or capsule shell in relation to the total weight of the product. However, all applications should be accommodated within a maximum level of 600mg / kg based on the weight of the colour component. At this level the average intake from supplements would be less than 5mg per day.

g) Ponceau 4R

Ponceau 4R (INS 124) is used in food supplements (category 13.6) to colour the coatings in the case of tablets and the shells in the case of capsules.

When manufactured, most food supplements are white or beige in colour, even though they contain a range of active ingredients. Surface colouring of the products has been found to be the best way to differentiate between products, both in post production handling and for the consumer's own recognition and control.

Usage levels vary depending on the thickness of the coating or capsule shell in relation to the total weight of the product. However, all applications should be accommodated within a maximum level of 600mg / kg based on the weight of the colour component. At this level the average intake from supplements would be less than 5mg per day.

h) Sunset Yellow FCF

Sunset Yellow FCF (INS 110) is used in food supplements (category 13.6) to colour the coatings in the case of tablets and the shells in the case of capsules.

When manufactured, most food supplements are white or beige in colour, even though they contain a range of active ingredients. Surface colouring of the products has been found to be the best way to differentiate between products, both in post production handling and for the consumer's own recognition and control.

Usage levels vary depending on the thickness of the coating or capsule shell in relation to the total weight of the product. However, all applications should be accommodated within a maximum level of 600mg / kg based on the weight of the colour component. At this level the average intake from supplements would be less than 5mg per day.

3. Sweeteners

a) Acesulfame Potassium

Acesulfame Potassium (INS number 950) is used in food supplements (category 13.6) as an intense sweetener. It is specifically used in liquid food supplements, in chewable tablets and capsules and in effervescent food supplement tablets that dissolve in water to make a drink.

Usage levels depend on the application and the level of sweetness required to mask unpleasant tastes of some vitamins, minerals and other substances. However, all applications could be accommodated within a maximum level of 2000mg / kg.

b) Aspartame

Aspartame (INS number 951) is used in food supplements (category 13.6) as an intense sweetener. It is specifically used in liquid food supplements, in chewable tablets and capsules and in effervescent food supplement tablets that dissolve in water to make a drink.

Usage levels depend on the application and the level of sweetness required to mask unpleasant tastes of some vitamins, minerals and other substances. However, all applications could be accommodated within a maximum level of 5500mg / kg.

c) Cyclamates

Cyclamates (INS number 952) are used in food supplements (category 13.6) as an intense sweetener. They are specifically used in liquid food supplements, in chewable tablets and capsules and in effervescent food supplement tablets that dissolve in water to make a drink.

Usage levels depend on the application and the level of sweetness required to mask unpleasant tastes of some vitamins, minerals and other substances. However, all applications could be accommodated within a maximum level of 1250mg / kg.

d) Neotame

Neotame (INS number 961) is used in food supplements (category 13.6) as an intense sweetener. It is specifically used in liquid food supplements, in chewable tablets and capsules and in effervescent food supplement tablets that dissolve in water to make a drink.

Usage levels depend on the application and the level of sweetness required to mask unpleasant tastes of some vitamins, minerals and other substances. However, all applications could be accommodated within a maximum level of 90mg / kg.

e) Saccharine

Saccharine and its sodium, calcium and potassium salts (INS number 954) are used in food supplements (category 13.6) as intense sweeteners. They are specifically used in liquid food supplements, in chewable tablets and capsules and in effervescent food supplement tablets that dissolve in water to make a drink.

Usage levels depend on the application and the level of sweetness required to mask unpleasant tastes of some vitamins, minerals and other substances. However, all applications could be accommodated within a maximum level of 1200mg / kg.

f) Sucralose

Sucralose (INS number 955) is used in food supplements (category 13.6) as an intense sweetener. It is specifically used in liquid food supplements, in chewable tablets and capsules and in effervescent food supplement tablets that dissolve in water to make a drink.

Usage levels depend on the application and the level of sweetness required to mask unpleasant tastes of some vitamins, minerals and other substances. However, all applications could be accommodated within a maximum level of 2400mg / kg.

4. Polyvinyl Alcohol

Polyvinyl Alcohol (INS Number 1203) is used in food supplements (category 13.6), mainly as a coating, sealing and surface finishing agent.

It has specific properties that enable it to help with film-forming in aqueous film-coatings for food supplement tablets. Polyvinyl alcohol possesses good moisture and oxygen barrier properties which are essential in a film-coating to protect sensitive active ingredients such as vitamins and to ensure that the expected shelf life of the product can be met.

All applications are likely to be met within a maximum level of 45000mg / kg.

ICBA:

INS	Additive	14.1.3 (Fruit and Vegetable Nectars)	14.1.4 (Water-based flavored drinks, including "sport", "energy", or "electrolyte" drinks and particulated drinks)
320	Butylated Hydroxyanisole (BHA)		ICBA would agree to **discontinue** the provision in **14.1.4** but notes that BHA is widely permitted as a flavor additive in essential oils used in drinks
321	Butylated Hydroxytoluene (BHT)		ICBA would agree to **discontinue** the provision in **14.1.4** but notes that BHT is widely permitted as a flavor additive in essential oils used in drinks
319	Tertiary Butylhydroxyquinone (TBHQ)		ICBA would agree to **discontinue** the provision in **14.1.4**
220, 221, 222, 223, 224, 225, 227, 228, 539	Sulphites (as SO_2)		ICBA suggest **adopting 70 mg/kg** in **14.1.4** based on the technological need in cordials and dry ginger ales. A large proportion of the cordial market has added juice. Sulphite is added to stop browning and used also as a preservative. For dry ginger ale, sulphite is added as a preservative. Sulphite also may be present at lower levels in juice drinks as a carry-over from juice ingredients.
161g	Canthaxanthin		ICBA supports **adopting 5 mg/kg** in **14.1.4.2.** We would agree to **discontinue** the proposed provision in Category **14.1.4.3** (**100 mg/kg**). Canthaxanthin is used in some drinks since it provides a different shade in the spectrum yellow-orange-red that is usually quite different from other carotenes.
120	Carmines		ICBA supports **adopting 100 mg/kg** in **14.1.4** as carmine. Since carmine and Cochineal extract have different levels of carminic acid (50% vs.2 %), **we suggest adding a footnote** to 100 mg/kg to avoid confusion between these two natural colours: **"1000 mg/kg as Cochineal extract."** .
141i, 141ii	Chlorophylls, Copper Complexes		ICBA notes the proposed maximum levels seem to be expressed as the colour extract and not as total copper as requested by the 37th CCFAC. While we believe that the levels should be expressed as the natural extract due to ease of use and control, we have calculated the maximum level in 14.1.4 as total copper based on the Codex specification. ICBA supports **adopting 300 mg/kg as the colour or 3 mg/kg expressed as total copper** in **14.1.4.**
127	Erythrosine		ICBA would agree to **discontinue** due to low ADI
163ii	Grape Skin Extract	ICBA supports adopting **1500 mg/kg** in **14.1.3.2** and **14.1.3.4.** Grape skin extract may be used in some vitamin C fortified nectars as the vitamin C degrades the natural	ICBA supports **adopting 500 mg/kg** in **14.1.4**

INS	Additive	14.1.3 (Fruit and Vegetable Nectars)	14.1.4 (Water-based flavored drinks, including "sport", "energy", or "electrolyte" drinks and particulated drinks)
		anthocyanins.	
1503	Castor Oil		ICBA would agree to **discontinue**
432, 433, 434, 435, 436	Polysorbates		ICBA supports **adopting 500 mg/kg** in **14.1.4**. Polysorbates are used in beverage applications in combination with other emulsifiers as flavor adjuvants and as an anti-foaming agent in nonalcoholic beverage mixes. Use of blends contributes to increased emulsion stability, particularly when one member of the mixture is more lipophilic (mono- and di-glycerides) and the other member is more hydrophilic (polysorbates). Further, members of this group of compounds have been used as emulsifiers of the cloud in some cloudy beverages. The capacity of polysorbates to blend with other surfactants increases the degree of versatility of their functional characteristics in the final product. It also results in an emulsion of enhanced stability. The versatility and increased stability of beverage emulsions provide technological justification for the use of this group of compounds in soft drink production.
129	Allura Red AC		ICBA supports **adopting 100 mg/kg** in **14.1.4**
150c	Caramel Colour Class III		ICBA believes that the ADI is sufficiently high to permit the use at **GMP** and suggests that it **should be transferred to Table 3.**
150d	Caramel Colour Class IV		ICBA believes that the ADI is sufficiently high to permit the use at **GMP** and suggests that it **should be transferred to Table 3.**
160ai,aii,e,f	Carotenoids		ICBA supports **adopting 100 mg/kg** in **14.1.4**
132	Indigotine		ICBA supports **adopting 100 mg/kg** in **14.1.4**
124	Ponceau 4R		ICBA supports **adopting 100 mg/kg** in **14.1.4**
110	Sunset Yellow FCF		ICBA supports **adopting 100 mg/kg** in **14.1.4**
950	Acesulfame Potassium		ICBA supports **adopting 600 mg/kg** in **14.1.4**
956	Alitame		ICBA supports **adopting 40 mg/kg** in **14.1.4**
951	Aspartame		ICBA supports **adopting the proposed 1000 mg/kg** but would agree to 600 mg/kg **in 14.1.4.** We note that 1000 mg/kg is permitted in many countries
952	Cyclamic Acid (Sodium, Potassium, and Calcium Salts)		ICBA supports **adopting 1000 mg/kg** in **14.1.4.** Cyclamate is a valuable and stable sweetener with a long history of safe use. The major use of cyclamates is for carbonated low-calorie soft drinks designed for and consumed by adults. Cyclamate has a low sweetening power relative to the other permitted sweeteners, which provide a sweetening power equivalent to between 3.2% and 13.2 % sugar. Therefore, cyclamate is generally not used as a single sweetener in drinks, since a total sweetness equivalent of 10% to 16% sugar is needed to sweeten a typical water-based flavoured beverage. Cyclamate contributes a balanced - sugar-like - sweetness profile, when blended with other nonnutritive sweeteners, in 2-component and 3-component mixtures. The technological need depends on the components of the mixture, those with saccharin requiring higher use levels (700 - 1000 mg/kg) while the optimum sweetness in 3-component mixtures is achieved at use levels of about 600 - 700 mg/kg, depending on the mixture. Such blends are technically effective due to the synergistic effects between sweeteners. In synergy, the sweetness of the mixture is greater than the sum of the individual components. But at very low addition levels of cyclamate (<< 400 mg/l), the synergistic effects are

INS	Additive	14.1.3 (Fruit and Vegetable Nectars)	14.1.4 (Water-based flavored drinks, including "sport", "energy", or "electrolyte" drinks and particulated drinks)
			substantially reduced, and the improvement in taste quality provided by cyclamate becomes negligible.
961	Neotame		ICBA supports **adopting 33 mg/kg** in **14.1.4**
954	Saccharin		ICBA supports **adopting 500 mg/kg** in **14.1.4**
955	Sucralose		ICBA supports **adopting 300 mg/kg** in **14.1.4**

ICGA:

INS 320 BUTYLATED HYDROXYANISOLE (BHA)

INS 321 BUTYLATED HYDROXYTOLUENE (BHT)

INS 319 TERTIARY BUTYLHYDROXYQUINONE (TBHQ)

Justification for use in chewing gum at 750 mg/kg[1]

Technological Justification

Antioxidants are needed in chewing gum due to the high degree of unsaturation of many of the materials used in gum base, particularly the elastomers, ester gums, and softeners. These materials are highly susceptible to oxidation, and will become brittle if not protected.

These antioxidants are necessary because of the great potential for oxidation in the absence of antioxidant protection. A smaller amount will not provide the needed degree of protection.

Concerning the levels of use, it should be noted that antioxidants present in chewing gum are not fully extracted from the gum during chewing. This is because they are relatively insoluble in water and saliva, and therefore remain in the gum base. Various extraction studies have shown that only very low levels, between 1% and 15%, of BHA and BHT are extracted from chewing gum during actual or simulated chewing. Similar level is expected for TBHQ.

Safety

BHA: JECFA assigned an ADI of 0.5 mg/kg body weight for BHA. The consumption of 3 g chewing gum[2] containing 750 mg/kg of BHA by a 60 kg adult would result in the ingestion of 2.3 g of BHA. Considering that the BHA will not be extracted at a level above 15%[3], the actual intake would be under 0.35 g or under 1.0% of the ADI.

BHT: JECFA assigned an ADI of 0.3 mg/kg body weight for BHT. The consumption of 3 g of chewing gum containing 750 mg/kg of BHT by a 60 kg adult would result in the ingestion of 2.3 g of BHT. Considering that the BHT will not be extracted at a level above 15%[3], the actual intake would be under 0.35 g or under 1.7% of the ADI.

TBHQ: JECFA assigned an ADI of 0.7 mg/kg body weight for TBHQ. The consumption of 3 g of chewing gum containing 750 mg/kg of TBHQ by a 60 kg adult would result in the ingestion of 2.3 g of TBHQ. Considering that the TBHQ will not be extracted at a level above 15%, the actual intake would be under 0.35 g or under 0.7% of the ADI.

Impact on Trade

There is **trade involving several Codex regions** on chewing gum products containing BHA, BHT and TBHQ at levels higher than 200 mg/kg. See in this respect, among others:

- the current clearance of BHA and BHT at 1000 mg/kg by the USA, Saudi Arabia, Oman, and United Arab Emirates, and their clearance with no specified level in China,
- the clearance of BHA and BHT at 750 mg/kg by South Korea, Taiwan, Vietnam, and South Africa,
- the clearance of BHA, BHT and TBHQ at 400 mg/kg by the EC, Iceland, Switzerland, Turkey, Russia, Argentina.

BASED ON THE ABOVE IT IS REQUESTED THAT BHA, BHT AND TBHQ BE LISTED FOR USE IN CHEWING GUM AT 750 mg/kg

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1 Singly or in combination : BHA, BHT, TBHQ and propyl gallate (INS 310)

2 Figures collected in all EEC countries show that the daily per capita consumption of chewing gum in the EEC is 1 g/day. The heavy users consumption is 3 times the consumption per capita as demonstrated in the FAO/WHO 18th session of the Codex Committee on Food Additives: "Guidelines for simple evaluation of food additive intake" and confirmed by a EEC survey conducted in some EEC countries.

3 "Estimates of the theoretical maximum daily intake of erythorbic acid, gallates, butylated hydroxyanisole (BHA) and butylated hydroxytuolene (BHT) in Italy : a stepwise approach" ; by C Leclerc, D Arcella, and A Turrini ; National Institute for Food and Nutrition Research, Via Ardeatina 546, 00178, Rome, Italy

INS 141 i & 141 ii CHLOROPHYLLS, COPPER COMPLEXES

Justification for use in chewing gum at 700 mg/kg

Technological Justification

Copper Complexes of Chlorophylls and Chlorophyllins (E141) are used as colours in pellet gum and slab gum. The copper complexes have two functions:

1) To colour the product

2) To act as a breath freshener

At least one product containing E141 is marketed as a breath freshening gum. To fulfill this function, it is necessary that a QS use level be allowed, or at least 1 mg per piece of chewing gum. These levels give an effective and acceptable level of colour to the product which is perceived by consumers as being the most appropriate to the product type. It also delivers the required quantity of E141 for breath freshening purposes. Copper Complexes of Chlorophylls and Chlorophyllins are well known absorbers of odours and work effectively in candy and gum products.

To illustrate the differences in usage in products, we have translated the following weight of tablets, each with 1 mg E141, to a mg/kg (i.e., mg of E141 per 1 kg finished product) value.

Product & Weight	**Content E141**	**ppm (mg/kg)**
Pellet gum Clorets 1,43 g per piece	1 mg	700
Slab gum Clorets 1,85 g per piece	1 mg	540
Hard boiled candy Clorets 3,8 g per piece	1 mg	263

Obviously, the smaller the weight of the gum piece, the greater the content of E141 on a mg/kg basis will be. It is important to use the product at QS or at least 1 mg E141 per gum piece to obtain the benefits required.

Safety

JECFA assigned an ADI of 15 mg/kg body weight per day for chlorophylls, copper complexes.

Consumption of a 3 g piece[4] of gum containing 700 mg/kg of the colour by a 60 kg adult would result in ingestion of 2.1 mg or about 0.2% of the ADI. This assumes 100% extraction of the colour during chewing.

BASED ON THE ABOVE IT IS REQUESTED THAT CHLOROPHYLLS, COPPER COMPLEXES BE LISTED FOR USE AT 700 mg/kg IN CHEWING GUM.

INS 120: CARMINES

Justification for use in chewing gum at 1020 mg/kg

Description

Carmines are also called Cochineal or Carminic Acid, and originate from the insect *Dactylopius coccus* Costa and are obtained by aqueous extraction of cochineal, which consists of the dried bodies of the female insect. The colouring principle is Carminic Acid. Colour Index number 75470 (Carmine). CAS number 1390-65-4 (Carmine). Specifications are described in FAO Food and Nutrition Paper 52 Add 8 (2000), EC specifications, in EU Commission Directive 95/45/EC and in the US Code of Federal Regulations, Title 21, Section 73.100.

Technical justification

This additive is needed to obtain desired colours of chewing gum when “natural” colours are required. Since the natural colour addition does not have a strong tinctorial effect, higher quantities are required to obtain a suitable colour effect when dispersed in chewing gum.

Used in sufficient amounts, Carmine gives chewing gum a typical bright pink shade (depending on the Carmine preparation) which is appropriate for red berry or cinnamon flavoured products. Carmine often has got a brighter bluish pink shade than other red colours which, upon blending with a blue colour, makes it suitable for obtaining chewing gum with purple colours. The purple shade may be varied by varying the ratio of Carmine and the blue colour component.

[4] Figures collected in all EEC countries show that the daily per capita consumption of chewing gum in the EEC is 1 g/day. The heavy users consumption is 3 times the consumption per capita as demonstrated in the FAO/WHO 18th session of the Codex Committee on Food Additives: "Guidelines for simple evaluation of food additive intake" and confirmed by a EEC survey conducted in some EEC countries.

Depending on the normal shade of other chewing gum ingredients (for example sugar, sorbitol, glucose syrup, gum base etc) the amount of Carmine required to produce the desired colour may vary. Based on previous and existing formulas 1020 mg of Carmine per kg of finished chewing gum is needed to produce the colour acceptable to the consumer.

Studies have shown that significant levels of colour are trapped in the chewing gum base during initial manufacturing and during chewing, and variable quantities are released relative to the colour used with significant quantities retained.

Additions of this colour at less than 1020 mg/kg may result in rather unattractive shades being produced, the colour being blended with the creamy white or grey colour of the gum base and/or with the bright white colour of the main sweetening components. Hence, higher levels are required to overcome and mask the colours of the base and sweeteners to provide some degree of brightness and an appealing appearance to the product.

Considering the fact that Carmine is a natural colour, it has very high stability properties, especially at neutral pH. It has excellent heat and light stability, hence its use in chewing gum.

Safety justification

The JECFA ADI value for Carmines is 0 – 5 mg/kg body weight/day. Consumption of 3 g chewing gum containing 1020 mg/kg Carmines by a 60 kg adult would result in an ingestion of 3.06 mg colour or about 1.02% of the ADI. This ingestion is based on an assumption of 100% extraction of the colour during chewing.

BASED ON THE ABOVE IT IS REQUESTED THAT CARMINES BE LISTED FOR USE IN CHEWING GUM AT 1020 mg/kg

INS 163 ii GRAPE SKIN EXTRACT (ANTHOCYANINS)

Justification for use in chewing gum at 10,000 mg/kg

Technological Justification

Anthocyanins are mainly a water soluble group of natural red and blue pigments responsible for the colours of most red fruits and berries and are mainly glycerides of anthocyanidins based on 2-phenol benzophriliums and extracted by either acidified water or alcohol and vacuum concentrated.

Anthocyanins are water soluble, difficult to disperse in chewing gum and are amphoteric in nature, having four principle pH dependent forms. Up to pH 3,8 commercial extracts are ruby red in shade but as Ph is increased, the colour shade becomes bluer, less intense and less stable. Considerable quantities have to be used to reach an acceptably coloured chewing gum that meets consumer expectations, when 'natural' colours are used. Because of the Ph constraints to stabilise colour, the anthocyanins are not used usually in products with a pH above 4,2. The colour effect is very low and high levels of colour are needed to achieve a good tinctorial effect and to achieve stability in the gum and mask the sweetener and base colours. The products are reasonably heat stable but extra colour is normally required to ensure a reasonable appearance when elevated processing temperatures are required since colour loss and browning may occur.

Being water soluble this colour can be combined with non-water soluble colours (Ponceau 4R) to achieve unique colour changes that take place during chewing and that can be associated with flavour changes. It is a key water soluble colour that is stable in acidic flavoured chewing gum.

Not all the colour is released from chewing gum during chewing since some is encapsulated in the chewing gum base. There is no other natural bluish colour available.

Safety

JECFA assigned an ADI of 2.5 mg/kg body weight per day for grape skin extract. Consumption of a 3 g of chewing gum[5] containing 10.000 mg/kg of grape skin extract by a 60 kg adult would result in the ingestion of 30 mg per day. This assumes 100% extraction of the colour during chewing.

BASED ON THE ABOVE IT IS REQUESTED THAT INS 163 ii GRAPE SKIN EXTRACT BE LISTED FOR USE AT 10,000 mg/kg IN CHEWING GUM.

INS 172i, 172ii, 172iii IRON OXIDES

Justification for use in chewing gum at 10,000 mg/kg

[5] Figures collected in all EEC countries show that the daily per capita consumption of chewing gum in the EEC is 1 g/day. The heavy users consumption is 3 times the consumption per capita as demonstrated in the FAO/WHO 18th session of the Codex Committee on Food Additives: "Guidelines for simple evaluation of food additive intake" and confirmed by a EEC survey conducted in some EEC countries.

Description:

Iron Oxides (including Iron Oxide Yellow, $FeO(OH) \cdot xH_20$, Iron Oxide Red, Fe_20_3, and Iron Oxide Black, $Fe0 \cdot Fe_20_3$) consist essentially of anhydrous and/or hydrated iron oxides produced from ferrous sulphate by heat soaking, removal of water, decomposition, washing, filtration, drying and finally grinding. The food quality Iron Oxides are primarily distinguished from technical grades by the comparatively low levels of contamination by other metals. This is ensured by proper selection of the source of iron and the extent of chemical purification during the manufacturing process. Iron Oxides are insoluble in water. CAS number 51274-00-1 (Iron Oxide Yellow), 1309-37-1 (Iron Oxide Red), 1317-61-9 (Iron Oxide Black). Colour Index number 77492 (Iron Oxide Yellow), 77491 (Iron Oxide Red), 77499 (Iron Oxide Black). Specifications may be found in FAO Food and Nutrition Paper 52 Add 12 (2004), EC specifications are described in Commission Directive 95/45/EC.

Technical justification:

This additive is needed to obtain desired black colours of chewing gum. Since the colour addition does not have a strong tinctorial effect, higher quantities are required to obtain a suitable colour effect when dispersed in chewing gum.

Used in sufficient amounts, Iron Oxides give chewing gum a typical bright black shade which is appropriate for products with certain flavours (eg. liquorice). Iron Oxides provide a brighter black shade than other black colours such as carbon black (E153) which produces a more greyish black shade than desired in certain products. Furthermore, Iron Oxides may be used in combination with other red, blue and brown colours in chewing gum to make these colours appear darker than if applied in their pure state.

Depending on the normal shade of other chewing gum ingredients (for example sugar, sorbitol, glucose syrup, gum base etc) the amount of Iron Oxides required to produce the desired colour may vary. Based on previous and existing formulas 10000 mg of Iron Oxides per kg of finished chewing gum is needed to produce the colour acceptable to the consumer.

Studies have shown that significant levels of colour are trapped in the chewing gum base during initial manufacturing and during chewing, and variable quantities are released relative to the colour used with significant quantities retained.

Additions of this colour at less than 10000 mg/kg may result in rather unattractive shades being produced, the colour being blended with the creamy white or grey colour of the gum base and/or with the bright white colour of the main sweetening components. Hence, higher levels are required to overcome and mask the colours of the base and sweeteners to provide some degree of brightness and an appealing appearance to the product.

Generally, the heat stability of Iron Oxides is good, hence their use, but they must be used in low moisture content products like chewing gum to retain their light stability.

BASED ON THE ABOVE IT IS REQUESTED THAT IRON OXYDES BE LISTED FOR USE IN CHEWING GUM AT 10.000 mg/kg

INS 432-436 POLYSORBATES

Justification for use in chewing gum at 20,000 mg/kg

Technological justification

Polyoxyethylene sorbitan esters are available in a hydrophilic/ lipophilic balance (HLB) range from 10 to 17 where ordinary mono- and diglycerides and acetylated monoglycerides are between HLB 1.8 to 5.

These additives are needed in order to establish the desired taste profiles for different types of chewing gums.

An emulsifier can change the release rate of a specific flavour. It affects the release rate of the flavour making the consumer distinguish the different flavour notes available in the gums.

Flavours differ very much, dependent on the type of flavour (i.e. a lemon flavour is chemically very different from a spearmint flavour). That is why it is necessary to be able to use different emulsifiers for different flavours.

It has been proven that emulsifiers with high HLB increase flavour release compared to emulsifiers with low HLB. Blends of various polysorbates permit selection of the exact HLB needed in the chewing gum, in accordance with the type of flavour used. Moreover, polyoxyethylene sorbitan esters have a positive effect on the texture properties of chewing gum, and they also assist in providing breath freshening characteristics to the flavours.

The level of 20.000 mg/kg reflects the quantities needed for achieving a safe effect on the release.

Safety

JECFA assigned a group ADI for the polysorbates considered of 25 mg/kg body weight.

The consumption of 3 g of chewing gum[6] containing 20.000 mg/kg of polysorbates by a 60 kg adult would result in the ingestion of 60 mg of polysorbates or about 4 % of the ADI. This assumes 100% extraction of the polysorbates during chewing.

BASED ON THE ABOVE IT IS REQUESTED THAT THE POLYSORBATES BE LISTED FOR USE AT 20,000 mg/kg IN CHEWING GUM.

INS 129 ALLURA RED AC

Justification for use in chewing gum at 467 mg/kg

Technological justification

Allura Red AC is also called FD&C Red N° 40 and is principally the disodium salt of 6-hydroxy-5 ((2-methyoxy-5-methyl-4-sulfophenyl)azo)-2-naphthalenesulfonic acid. Allura Red AC imparts a red-orange colour to chewing gum products. It is used primarily in cinnamon flavoured chewing gums. Consumers relate colour to flavour and vice versa. Consumers associate the brilliant red of Ponceau 4R with cherry flavour while they associate the fire red-orange colour of Allura Red AC to that or the red hot cinnamon flavoured chewing gum. The use of 467 mg/kg of Allura Red AC is justified because it takes this level of colour to produce the fire red-orange colour by masking the dark chocolate brown colour imparted by natural gum base or the whiteness of the gum sweeteners such as sucrose or sorbitol.

Safety

JECFA assigned an ADI of 7 mg/kg body weight per day for allura red AC.

The consumption of 3 g of chewing gum[7] containing 467 mg/kg of allura red by a 60 kg adult would result in the ingestion of 1.4 mg of colour or about 0.3% of the ADI. This assumes 100% extraction of the colour during chewing.

BASED ON THE ABOVE IT IS REQUESTED THAT ALLURA RED AC BE LISTED FOR USE AT 467 mg/kg IN CHEWING GUM.

INS 160 ai, 160 aii, 160e, 160f CAROTENOIDS

Justification for use in chewing gum at 500 mg/kg

Technological justification

Beta-carotene is a provitamin A. The natural or synthetic Beta-carotene is a brownish-red crystalline powder, sensitive to light and oxygen. The stabilized form is commercially available in edible oil suspensions, emulsions and water dispersible powders. It is insoluble in water. Beta-carotene is mainly used as a yellow colour in chewing gum, but since it is oil soluble, can be encapsulated in gum base and loses some of its appearance value as a colour. More colour is needed to mask white sweeteners and brown/cream gum base when the colour is added to the formulations during mixing. Not all the colour is extracted from the product when chewing. Significant quantities remain encapsulated in the base and do not release with soluble sweeteners. To achieve bright consumer acceptable shades of colour, the usage level is much higher in chewing gum, especially to make attractive appearance products such as lemon or orange flavoured gums. The range of carotenoids (E160a-160f) are utilised in varying levels and blends to achieve the range of colours desired. Since chewing gum base absorbs the colour, chewing gum requires significant quantities to mask and overcome dull shades when low quantities of colour are used.

Safety

JECFA assigned a group ADI of 5 mg/kg body weight per day for carotenoids INS 160 e, INS 160 f and INS 160 ai.

Consumption of a 3 mg of chewing gum[8] containing 500 mg of carotenoids by a 60 kg adult would result in ingestion of 1,5 mg of colour or about 0,5% of the ADI assuming all the colour is extracted from the gum.

BASED ON THE ABOVE IT IS REQUESTED THAT CAROTENOIDS BE LISTED FOR USE AT 500 mg/kg IN CHEWING GUM.

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6 Figures collected in all EEC countries show that the daily per capita consumption of chewing gum in the EEC is 1 g/day. The heavy users consumption is 3 times the consumption per capita as demonstrated in the FAO/WHO 18th session of the Codex Committee on Food Additives: "Guidelines for simple evaluation of food additive intake" and confirmed by a EEC survey conducted in some EEC countries.

7 Idem

8 Figures collected in all EEC countries show that the daily per capita consumption of chewing gum in the EEC is 1 g/day. The heavy users consumption is 3 times the consumption per capita as demonstrated in the FAO/WHO 18th session of the Codex Committee on Food Additives: "Guidelines for simple evaluation of food additive intake" and confirmed by a EEC survey conducted in some EEC countries.

INS 132 INDIGOTINE

Justification for use in chewing gum at 300 mg/kg

Description

Indigotine (often referred to as Indigo Carmine) is a synthetic colour essentially consisting of a mixture of disodium-3,3' –dioxo-[delta$^{2,2'}$-biindoline]-5,5'-disulfonate and disodium-3,3' –dioxo-[delta$^{2,2'}$-biindoline]-5,7'-disulfonate together with sodium chloride and/or sodium sulphate as the principal uncoloured components. Colour Index number 73015. CAS number 860-22-0 (5,5' isomer). Specifications may be found in FAO Food and Nutrition Paper 52 (1992), EC specifications are described in Commission Directive 95/45/EC, and in the US Code of Federal Regulations, Title 21, Section 74.102.

Technical justification

This additive is needed to obtain desired blue and/or purple colours of chewing gum, especially when considering that no blue colour of natural origin exists. Since the colour addition does not have a strong tinctorial effect, higher quantities are required to obtain a suitable colour effect when dispersed in chewing gum.

Used in sufficient amounts, Indigotine gives chewing gum a typical bright dark blue shade which is appropriate for dark berry flavoured products (eg. blueberry, black currant). Indigotine has got a brighter reddish blue shade than other blue colours which, upon blending with a red colour, makes it suitable for obtaining chewing gum with purple colours. The purple shade may be varied by changing the ratio of Indigotine and the red colour component. Furthermore, certain dark brown colour shades used in chewing gum may be obtained only by proper blending of Indigotine with red and yellow colour components. Here, alternative existing brown colours such as caramel (E150) produce a colour of the chewing gum which is lighter brown than desired.

Depending on the normal shade of other chewing gum ingredients (for example sugar, sorbitol, glucose syrup, gum base etc) the amount of Indigotine required to produce the desired colour may vary. Based on previous and existing formulas 300 mg of Indigotine per kg of finished chewing gum is needed to produce the colour acceptable to the consumer.

Studies have shown that significant levels of colour are trapped in the chewing gum base during initial manufacturing and during chewing, and variable quantities are released relative to the colour used with significant quantities retained.

Additions of this colour at less than 300 mg/kg may result in rather unattractive shades being produced, the colour being blended with the creamy white or grey colour of the gum base and/or with the bright white colour of the main sweetening components. Hence, higher levels are required to overcome and mask the colours of the base and sweeteners to provide some degree of brightness and an appealing appearance to the product.

Generally, the heat stability of Indigotine is good, hence its use, but it must be used in low moisture content products like chewing gum to retain its light stability.

Safety

The JECFA ADI value for Indigotine is 0 – 5 mg/kg body weight/day. Consumption of 3 g chewing gum containing 300 mg/kg Indigotine by a 60 kg adult would result in the ingestion of 0.9 mg colour or about 0.3% of the ADI. This ingestion is based on an assumption of 100 % extraction of the colour during chewing.

BASED ON THE ABOVE IT IS REQUESTED THAT INDIGOTINE BE LISTED FOR USE IN CHEWING GUM AT 300 mg/kg

INS 124 PONCEAU 4R

Justification for use in chewing gum at 300 mg/kg

Descripition

Ponceau 4R consists essentially of trisodium d-2-hydroxy-1-(4-sulfonato-1-naphthylazo)-6,8-naphthalenedisulfonate, and subsidiary colouring matters together with sodium chloride and/or sodium sulfate as the principal uncoloured components. Specifications prepared at the 28th JECFA (1984), published in FNP 31/1 (1984) and in FNP 52 (1992).

Technical Justification:

This additive is needed to obtain desired red, pink, and purple shades in certain chewing gum products. Ponceau 4R is one of only a few synthetic red colors that are available for coloring chewing gum. Ponceau 4R is associated with a unique shade of red and is desirable in bubble gums, fruit flavored gums, and cinnamon flavored gums. Particularly in the absence of any safety concerns, the General Standard on Food Additives should allow for its continued use in chewing gum, so as to give manufacturers needed flexibility as they design products for various markets.

Safety

There is no question about the safety of Ponceau 4R when used in chewing gum at the level of use under consideration, up to 300 mg/kg. The JECFA ADI for Ponceau 4R is currently 0-4 mg/kg b.w. A three-gram piece of chewing gum containing Ponceau 4R at 300 mg/kg contains only 0.9 mg of the color additive. This corresponds to a very small fraction of the JECFA ADI, which allows for up to 240 mg of Ponceau 4R daily in the diet of a 60-kg adult.

BASED ON THE ABOVE IT IS REQUESTED THAT PONCEAU 4R BE LISTED FOR USE IN CHEWING GUM AT 300 mg/kg

INS 110 SUNSET YELLOW

Justification for use in chewing gum at 300 mg/kg

Description:

Sunset Yellow FCF is a synthetic colour essentially consisting of disodium-6-hydroxy-5-(4-sulfonatophenylazo)-2-naphthalene-6-sulfonate together with sodium chloride and/or sodium sulphate as the principal uncoloured components. CAS number 2783-94-0. Colour Index number 15985. Specifications may be found in FAO Food and Nutrition Paper 52 (1992), EC specifications are described in Commission Directive 95/45/EC.

Technical justification:

This additive is needed to obtain desired orange yellow colours of chewing gum. Since the colour addition does not have a strong tinctorial effect, higher quantities are required to obtain a suitable colour effect when dispersed in chewing gum.

Used in sufficient amounts, Sunset Yellow FCF gives chewing gum a typical bright orange yellow shade which is appropriate for orange flavoured products (e.g. oranges, tangerine). Sunset Yellow FCF gives a very bright shade which is often brighter than the shades obtainable by employing other single colours or colour combinations.

Depending on the normal shade of other chewing gum ingredients (for example sugar, sorbitol, glucose syrup, gum base etc) the amount of Sunset Yellow FCF required to produce the desired colour may vary. Based on previous and existing formulas 300 mg of Sunset Yellow FCF per kg of finished chewing gum, and sometimes more, is needed to produce the colour acceptable to the consumer.

Studies have shown that significant levels of colour are trapped in the chewing gum base during initial manufacturing and during chewing, and variable quantities are released relative to the colour used with significant quantities retained.

Additions of this colour at less than 300 mg/kg may result in rather unattractive shades being produced, the colour being blended with the creamy white or grey colour of the gum base and/or with the bright white colour of the main sweetening components. Hence, higher levels are required to overcome and mask the colours of the base and sweeteners to provide some degree of brightness and an appealing appearance to the product.

Generally, the heat stability of Sunset Yellow FCF is good, hence its use, but it must be used in low moisture content products like chewing gum to retain its light stability.

Safety

The JECFA ADI for Sunset Yellow FCF is 2.5 mg/kg body weight. Consumption of 3 g of chewing gum containing Sunset Yellow FCF at the level of 300 mg/kg would result in ingestion of only 0.9 mg Sunset Yellow FCF, if all of the colour present is extracted during chewing. This corresponds to 0.015 mg/kg bw for a 60 kg adult or about 0.6% of the ADI.

BASED ON THE ABOVE IT IS REQUESTED THAT SUNSET YELLOW BE LISTED FOR USE IN CHEWING GUM AT 300 mg/kg

INS 950 ACESULFAME K (potassium)

INS 951 ASPARTAME

INS 952 CYCLAMIC ACID (sodium, potassium, calcium salts)

INS 954 SACCHARIN

INS 955 SUCRALOSE

INS 956 ALITAME

INS 961 NEOTAME

Justification for use in chewing gum at 5,000 mg/kg (Acesulfame K; Sucralose), 10,000 mg/kg (Aspartame) 3,000 mg/kg (Cyclamates; Saccharin) 1,000 mg/kg (Neotame) and 300 mg/kg (Alitame)

Technological justification

Intense sweeteners are used as sugar substitutes in sugarfree chewing gum, and, may also be used as flavour enhancers in products sweetened with sugar. The levels of use required to sweeten sugarfree chewing gum depend upon the sweetness and flavour perception expected by the consumer. Chewing gum requires relatively high percentage levels of intense sweeteners because the sweeteners must be released slowly over the course of a 20 or 30 minute chewing period.

In addition, in order to achieve optimum sweetening properties, two or more sweeteners may be used in combination.

It is well known that taste preferences for sweeteners vary. This variability includes both the degree and type of sweetness exhibited by a product.

Manufacturers should be afforded the flexibility of providing a variety of products to satisfy consumer tastes.

Some comments regarding use levels and properties of the specific sweeteners follow.

Acesulfame K

Acesulfame K is technologically needed at levels up to 5.000 mg per kilogram of chewing gum. Although the literature notes its solubility in water of 27 grams in 100 ml, acesulfame K does not dissolve rapidly in the mouth and, therefore, requires this level to compensate for this delayed sensory perception.

Aspartame

Aspartame is technologically needed at levels up to 10.000 mg per kilogram of chewing gum. Aspartame provides a very clean sweet taste with no after-taste. Aspartame is much less soluble than sucrose and requires a higher use level to achieve a sweetness impact compared to a sucrose-sweetened product. Its benefit over the Saccharin product is its clean after-taste.

Cyclamates and its salts

Cyclamate is approximately 30 times sweeter than sucrose. This sweetener is suitable for use in chewing gum as it has both a high sweetening power and a "pure" taste without the bitter aftertaste of saccharin.

Cyclamate is technologically needed at levels up to 3.000 mg per kilogram of chewing gum. At this level, cyclamate is released gradually and is available to sweeten the product during the whole chewing period. With the requested level of 3.000 mg of cyclamate per kilogram of chewing gum, due regard has also been paid to the sweetener's ADI value.

Saccharin and its salts

Saccharin is technologically needed up to levels of 3.000 mg per kilogram of chewing gum.

Saccharin's low solubility in water requires, as for aspartame, higher use levels to get the required sweetness. We believe that the small contribution of chewing gum products to the overall intake of saccharin justifies such level. Moreover, saccharin limits itself by its unpleasant aftertaste if used at levels too high.

The salts of saccharin have their own benefit in that they provide the fastest impact of flavour, due to their very high solubility in water.

Sucralose

Sucralose may be used as a sugar substitute in sugarfree chewing gum and is technologically needed up to levels of 5.000 mg/kg either singly or in combination with other permitted sweeteners.

Sucralose provides benefits over the other intense sweeteners such as Aspartame, by demonstrating enhanced stability at high processing temperatures, as well as enhanced stability in the presence of certain flavourings such as aldehydes and ketones. Sucralose also imparts a more sugary clean aftertaste than other intense sweeteners such as Acesulfame-K or Saccharin.

Sucralose’s high solubility in water requires higher use levels to get the required sweetness. Chewing gum also requires relatively high percentage levels of Sucralose because the sweetener must be released slowly over the course of a 20 or 30 minutes chewing period.

Neotame

Neotame is an intense sweetener derived from aspartame. It is 7.000 – 13.000 times as sweet as sugar and 30-60 times as sweet as aspartame. Neotame is technologically needed at levels up to 1.000 mg/kg of chewing gum. It provides zero calorie and has a clean, sweet, sugar-like taste with no undesirable taste characteristics like the ones of many other high intensity sweeteners. It can be used alone or blended with other high intensity or carbohydrate sweeteners. It is stable under dry conditions and more stable than aspartame in neutral pH conditions.

Alitame

Alitame is technologically needed at up to 300 mg/kg of chewing gum. It has 2000 times the sweetness of sucrose and provides a very clean sugary sweet taste with no aftertaste. Alitame also provides the following additional benefits: It is a significantly more potent sweetener than aspartame, acesulfame K, saccharin, cyclamates and sucralose, so less is required for a given level of sweetness. It has a much better taste quality than saccharin, thaumatin, NHDC and neotame. It is more thermally and hydrolytically stable than some of the other high intensity sweeteners, giving the chewing gum a longer shelf life.

Alitame is currently approved for use in chewing gum in Australia, New Zealand and PR China (at levels of up to 300 mg/kg) and Mexico, Chile and Colombia (unrestricted use level). The JECFA ADI is 1 mg/kg body weight.

Safety

It is obvious from the information summarized in the table below that chewing gum contributes only a very small fraction of the total exposure to intense sweeteners.

The table shows the ADI for each requested sweetener and the percentage of that ADI taken up by the use of the sweetener in chewing gum. The ADI analysis demonstrates the safety of these authorizations, particularly since the percentage of the ADI taken up by chewing gum as shown in the table is based on several exaggerated assumptions, i.e., 1) each sweetener is used to the exclusion of all others; 2) all chewing gum consumed is sugar-free; and 3) each sweetener is used at maximum levels.

Even with such exaggerations, the table demonstrates that only a very small percentage of the ADI is taken up by chewing gum. Most importantly, the exposure data support the view that where multiple sweeteners are legally permitted the exposure to individual sweeteners is less than where limits are imposed on their availability. It is self-evident that where many sweeteners are used individually or in combination, exposure to each will be less and that the safety margin, defined as the difference between the ADI and the actual intake of individual sweeteners, will be larger than if only one or two sweeteners were permitted.

INS NUMBER		JECFA'S ADI Mg/kg bw/day (Year)	Maximum use level in chewing gum	Daily intake of sweetener provided by chewing gum[9] for a heavy user	
				In mg per capita	% of the ADI
950	Acesulfame K	15 (1990)	5.000	15	1.7
951	Aspartame	40 (1981)	10.000	30	1.3
952	Cyclamic acids (salts)	11 (1982)	3.000	9	1.4
954	Saccharin	5 (1993)	3.000	9	3.0
955	Sucralose	15 (1990)	5.000	15	1.7
956	Alitame	1 (TBC)	300	0.9	1.5
961	Neotame	2 (1982)	1.000	3	2.5

N.B.: Is is assumed 100% extraction of the sweetener during chewing.

BASED ON THE ABOVE IT IS REQUESTED THAT THE FOLLOWING INTENSE SWEETENERS BE LISTED FOR USE IN CHEWING GUM AS FOLLOWS:

- **ACESULFAME K AT A LEVEL OF 5.000 mg/kg**
- **ASPARTAME AT A LEVEL OF 10.000 mg/kg**
- **CYCLAMIC ACIDS (SALTS) AT A LEVEL OF 3.000 mg/kg**
- **SACCHARIN AT A LEVEL OF 3.000 mg/kg**
- **SUCRALOSE AT A LEVEL OF 5.000 mg/kg**
- **ALITAME AT A LEVEL OF 300 mg/kg**
- **NEOTAME AT A LEVEL OF 1.000 mg/kg**

[9]Figures collected in all EEC countries show that the daily per capita consumption of chewing gum in the EEC is 1 g/day. The heavy users consumption is 3 times the consumption per capita as demonstrated in the FAO/WHO 18th session of the Codex Committee on Food Additives: "Guidelines for simple evaluation of food additive intake" and confirmed by a EEC survey conducted in some EEC countries.

IFAC:

Sucralose (INS 955)

1. Please indicate:

a. Which food additive provisions you support for adoption at Step 5/8 or 8;

IFAC supports the food additive provisions for sucralose for adoption at Step 5/8 or 8, including the revisions listed below.

b. Which food additive provisions you support requesting additional information and the type of information needed;

IFAC is not requesting any additional information.

c. Which food additive provisions you support revising (e.g., high/lower maximum use level, addition/subtraction of a note clarifying conditions of use, etc.); and

IFAC requests the following revisions for sucralose:

IFAC requests that the following Food Categories currently listed at GMP be assigned the maximum use levels shown below:

01.1.1	Milk and buttermilk (plain	400 mg/kg
01.2.1.1	Fermented milks (plain) not heat treated after fermentation	400 mg/kg
01.2.2	Renneted milk (plain)	400 mg/kg
01.3.1	Condensed milk (plain	1000 mg/kg
01.5	Milk powder and cream powder and powder analogs (plain)	400 mg/kg
01.6	Cheese and cheese analogs	500 mg/kg
02.3	Fat emulsions	500 mg/kg
12.2	Vinegars	1000 mg/kg

IFAC requests the maximum use levels for the following Food Categories be increased to the levels shown below:

01.1.2	Dairy based drinks	400 mg/kg
01.2.1.2	Fermented milks (plain) heat treated After fermentation	400 mg/kg
01.3.2	Beverage whiteners	3000 mg/kg

IFAC requests that for Food Category 11.6 Table-top sweeteners the use level be shown as GMP. Table-top sweeteners are used by consumers in quantities to provide desired sweetness. The consumer determines the amount used. It is therefore proposed to list aspartame for this category at GMP.

IFAC requests that the following Food Categories for sucralose be added to the GSFA at the maximum use levels shown below:

01.3	Condensed milk analogs	1000 mg/kg
01.5.2	Milk and cream powder analogs	1000 mg/kg
08.2	Processed meats	150 mg/kg
08.3	Processed comminuted meats	150 mg/kg
09.2	Processed fish and fish products	150 mg/kg
16.0	Composite foods	500 mg/kg

The following categories should have a note that the levels are on an as consumed basis:

04.2.2.2	Dry vegetables	150 mg/kg
07.2.3	Mixes for fine bakery wares	750 mg/kg
12.6.3	Mixes for sauces and gravies	450 mg/kg

d. Whether you support the previous recommendations of the Quality Control Working Group to discontinue work on specific provisions and to include the indicated amendments.

Please see IFAC requests for revisions.

2. Please indicate the basis of your views by addressing the following:

a. The technological need for a sweetener;

Sucralose, approximately 600 times sweeter than sucrose, is an intense sweetener used to replace carbohydrate sweeteners. Intense sweeteners make numerous low and reduced calorie foods and beverages possible. With the increase in obesity worldwide these products can be important tools to assist individuals in controlling and losing weight, when incorporated into an overall healthy diet. Having a variety of intense sweeteners available is important because no single sweetener is perfect for all uses. However, with several intense sweeteners available, each can be used in the applications for which it is best suited. Also, when necessary, manufacturers can overcome limitations of individual sweeteners by blending sweeteners together. Most sweetener blends are synergistic, i.e. the sweetness of the combination is greater than the sum of the individual parts and, therefore, less sweetener is needed. Also, having a variety of sweeteners available and the use of sweetener blends decreases exposure to any one sweetener.

b. Whether the proposed maximum use level is justified to achieve the intended technical need; or

The proposed/requested maximum use levels are justified to achieve the intended technical needs.

c. Whether this level is safe.

JECFA has reviewed sucralose, assigned an ADI of 15 mg/kg body weight, and deemed sucralose safe for its intended uses.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Alitame (INS 956)

1. Please indicate:

a. Which food additive provisions you support for adoption at Step 5/8 or 8;

IFAC supports the listed provisions for Alitame for adoption at Step 5/8 or 8, including the GMP level for Food Category 11.6, Table-top sweeteners. It is not realistic to establish a numerical maximum level of use for table-top sweeteners since the consumer determines the amount used.

b. Which food additive provisions you support requesting additional information and the type of information needed;

IFAC requests no additional information.

c. Which food additive provisions you support revising (e.g., high/lower maximum use level, addition/subtraction of a note clarifying conditions of use, etc.); and

IFAC requests no revisions.

2. Please indicate the basis of your views by addressing the following:

a. The technological need for a sweetener;

Intense sweeteners make numerous low and reduced calorie foods and beverages possible. With the increase in obesity worldwide these products can be important tools to assist individuals in controlling and losing weight, when incorporated into an overall healthy diet. Having a variety of intense sweeteners available is important because no single sweetener is perfect for all uses. However, with several intense sweeteners available, each can be used in the applications for which it is best suited. Also, when necessary, manufacturers can overcome limitations of individual sweeteners by blending sweeteners together. Most sweetener blends are synergistic, i.e. the sweetness of the combination is greater than the sum of the individual parts and, therefore, less sweetener is needed. Also, having a variety of sweeteners available and the use of sweetener blends decreases exposure to any one sweetener.

b. Whether the proposed maximum use level is justified to achieve the intended technical need; or

The maximum use levels provided are justified to achieve intended effects.

c. Whether this level is safe.

Alitame has been reviewed by JECFA and deemed safe for its intended uses. Consumption levels are below the JECFA ADI of 1 mg/kg body weight per day for alitame.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Aspartame (INS 951)

1. Please indicate:

a. Which food additive provisions you support for adoption at Step 5/8 or 8;

IFAC supports the food additive provisions for aspartame for adoption at Step 5/8 or 8, including the additions/revisions requested below.

b. Which food additive provisions you support requesting additional information and the type of information needed;

IFAC does not request additional information.

c. Which food additive provisions you support revising (e.g., high/lower maximum use level, addition/subtraction of a note clarifying conditions of use, etc.); and

IFAC requests an increase in the maximum use level for aspartame in Food Category 04.1.2.5 Jams, Jellies and Marmalades to 1000 mg/kg. Aspartame is used to enhance products with broad ranges of inherent sweetness. There is a technical need to allow a higher maximum use level for this category to address these inherent variations.

IFAC requests that Food Category 14.1.2 with a maximum use level of 2000 mg/kg replace 14.1.2.1 and 14.1.3.4 and that Food Category 14.1.3 Fruit and Vegetable Nectars at a maximum use level of 2000 mg/kg replace 14.1.3.2 and 14.1.3.4. It is requested that aspartame be listed in the GSFA in these higher level categories shown (i.e., 14.1.2 and 14.1.3) with the footnote that for concentrates the levels are the levels in the product as consumed.

Food Category 11.6 Table-top sweeteners, including those containing high-intensity sweeteners, should show GMP as the use level. Table-top sweeteners are used by consumers in quantities to provide desired sweetness. The consumer determines the amount used. It is therefore proposed to list aspartame for this category at GMP.

2. Please indicate the basis of your views by addressing the following:

a. The technological need for a flavour enhancer or sweetener;

Aspartame, approximately 200 times sweeter than sugar, is an intense sweetener used to replace the sweetness of carbohydrate sweeteners. Intense sweeteners make numerous low and reduced calorie foods and beverages possible. With the increase in obesity worldwide these products can be important tools to assist individuals in controlling and losing weight, when incorporated into an overall healthy diet. Having a variety of intense sweeteners available is important because no single sweetener is perfect for all uses. However, with several intense sweeteners available, each can be used in the applications for which it is best suited. Also, when necessary, manufacturers can overcome limitations of individual sweeteners by blending sweeteners together. Most sweetener blends are synergistic, i.e. the sweetness of the combination is greater than the sum of the individual parts and, therefore, less sweetener is needed. Also, having a variety of sweeteners available and the use of sweetener blends decreases exposure to any one sweetener.

b. Whether the proposed maximum use level is justified to achieve the intended technical need; or

The proposed maximum use levels are justified to achieve the intended technical needs.

c. Whether this level is safe.

JECFA has reviewed Aspartame, assigned an ADI of 40 mg/kg body weight and deemed it safe for its intended uses. Consumption levels are well below the ADI.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Cyclamates (INS 952)

1. Please indicate:

a. Which food additive provisions you support for adoption at Step 5/8 or 8;

IFAC supports the adoption of the food additive provisions for Cyclamates at Step 5/8 or 8, including Food Category 11.6 Table-top sweeteners at GMP.

b. Which food additive provisions you support requesting additional information and the type of information needed;

IFAC does not request additional information.

c. Which food additive provisions you support revising (e.g., high/lower maximum use level, addition/subtraction of a note clarifying conditions of use, etc.); and

IFAC is requesting no revisions.

d. Whether you support the previous recommendations of the Quality Control Working Group to discontinue work on specific provisions and to include the indicated amendments.

IFAC supports the Quality Control Working Group recommendation for Food Category 01.2 Fermented and Renneted Milk Products (plain), excluding food category 01.1.2 (dairy based drinks) at a maximum level of 250 mg/kg but requests that Food Category 04.2.2.4 Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds be maintained.

2. Please indicate the basis of your views by addressing the following:

a. The technological need for a flavour enhancer or sweetener;

Cyclamate, approximately 30 times sweeter than sucrose, is an intense sweetener used to replace carbohydrate sweeteners. Intense sweeteners make numerous low and reduced calorie foods and beverages possible. With the increase in obesity worldwide these products can be important tools to assist individuals in controlling and losing weight, when incorporated into an overall healthy diet. Having a variety of intense sweeteners available is important because no single sweetener is perfect for all uses. However, with several intense sweeteners available, each can be used in the applications for which it is best suited. Also, when necessary, manufacturers can overcome limitations of individual sweeteners by blending sweeteners together. Most sweetener blends are synergistic, i.e., the sweetness of the combination is greater than the sum of the individual parts and, therefore, less sweetener is needed. Also, having a variety of sweeteners available and the use of sweetener blends decreases exposure to any one sweetener.

b. Whether the proposed maximum use level is justified to achieve the intended technical need; or

The proposed maximum use levels are justified to achieve the intended technical needs.

c. Whether this level is safe.

JECFA has reviewed cyclamates, assigned an ADI of 11 mg/kg body weight, and deemed cyclamates safe for their intended uses. Although cyclamates have not yet been reapproved in the United States, the U.S. Food and Drug Administration's Cancer Assessment Committee has now determined that cyclamates are not carcinogenic, the basis on which cyclamates were banned in the U.S.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Neotame (INS 954)

1. Please indicate:

a. Which food additive provisions you support for adoption at Step 5/8 or 8;

IFAC supports the food additive provisions for Neotame for adoption at 5/8 or 8 with the revisions and notes shown below.

b. Which food additive provisions you support requesting additional information and the type of information needed;

IFAC does not request additional information.

c. Which food additive provisions you support revising (e.g., high/lower maximum use level, addition/subtraction of a note clarifying conditions of use, etc.); and

IFAC requests that Food Category 14.1.2 with a maximum use level of 65 mg/kg replace Food Categories 14.1.2.1 and 14.1.3.4 and that Food Category 14.1.3 Fruit and Vegetable Nectars at a maximum use level of 65 mg/kg replace Food Categories 14.1.3.2 and 14.1.3.4. It is requested that neotame be listed in the GSFA in these higher level categories shown (i.e., 14.1.2 and 14.1.3) with a footnote that for concentrates the levels are the levels in the product as consumed.

Food Category 11.6 Table-top sweeteners, including those containing high-intensity sweeteners, should show GMP as the use level. Table-top sweeteners are used by consumers in quantities to provide desired sweetness. The consumer determines the amount used. It is therefore proposed to list neotame for this category at GMP.

2. Please indicate the basis of your views by addressing the following:

a. The technological need for a flavour enhancer or sweetener;

Neotame, 7,000 to 12,000 times sweeter than sucrose, is an intense sweetener used to replace the sweetness of carbohydrate sweeteners. Intense sweeteners make numerous low and reduced calorie foods and beverages possible. With the increase in obesity worldwide these products can be important tools to assist individuals in controlling and losing weight, when incorporated into an overall healthy diet. Having a variety of intense sweeteners available is important because no single sweetener is perfect for all uses. However, with several intense sweeteners available, each can be used in the applications for which it is best suited. Also, when necessary, manufacturers can overcome limitations of individual sweeteners by blending sweeteners together. Most sweetener blends are synergistic, i.e. the sweetness of the combination is greater than the sum of the individual parts and, therefore, less sweetener is needed. Also, having a variety of sweeteners available and the use of sweetener blends decreases exposure to any one sweetener.

b. Whether the proposed maximum use level is justified to achieve the intended technical need; or

The proposed maximum use levels are justified to achieve the intended technical needs.

c. Whether this level is safe.

JECFA has reviewed neotame, assigned an ADI of 2 mg/kg body weight and deemed neotame safe for its intended uses.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

<u>Saccharin (INS 954)</u>

1. Please indicate:

a. Which food additive provisions you support for adoption at Step 5/8 or 8;

IFAC supports the listed provisions for Saccharin for adoption at Step 5/8 or 8, including the GMP level for Food Category 11.6, Table-top sweeteners. It is not realistic to establish a numerical maximum level of use for table-top sweeteners since the consumer determines the amount used.

b. Which food additive provisions you support requesting additional information and the type of information needed;

IFAC requests no additional information.

c. Which food additive provisions you support revising (e.g., high/lower maximum use level, addition/subtraction of a note clarifying conditions of use, etc.); and

IFAC requests no revisions.

d. Whether you support the previous recommendations of the Quality Control Working Group to discontinue work on specific provisions and to include the indicated amendments.

IFAC supports the previous recommendations of the Quality Control Working Group to discontinue work on the specific provisions noted and to include the indicated amendments.

2. Please indicate the basis of your views by addressing the following:

a. The technological need for a flavour enhancer or sweetener;

Intense sweeteners make numerous low and reduced calorie foods and beverages possible. With the increase in obesity worldwide these products can be important tools to assist individuals in controlling and losing weight, when incorporated into an overall healthy diet. Having a variety of intense sweeteners available is important because no single sweetener is perfect for all uses. However, with several intense sweeteners available, each can be used in the applications for which it is best suited. Also, when necessary, manufacturers can overcome limitations of individual sweeteners by blending sweeteners together. Most sweetener blends are synergistic, i.e. the sweetness of the combination is greater than the sum of the individual parts and, therefore, less sweetener is needed. Also, having a variety of sweeteners available and the use of sweetener blends decreases exposure to any one sweetener.

b. Whether the proposed maximum use level is justified to achieve the intended technical need; or

The maximum use levels provided are justified to achieve intended effects.

c. Whether this level is safe.

Saccharin has been reviewed by JECFA and determined safe for its intended uses. Typical use levels are below the JECFA ADI of 5 mg/kg body weight per day. Saccharin has been safely used for over 100 years.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Acesulfame Potassium (INS 950)

1. Please indicate:

a. Which food additive provisions you support for adoption at Step 5/8 or 8;

IFAC supports the adoption of the food additive provisions for adoption at Step 5/8 or 8, including those for which revisions and additions are requested – as shown under 1c below.

b. Which food additive provisions you support requesting additional information and the type of information needed;

IFAC is not requesting additional information.

c. Which food additive provisions you support revising (e.g., high/lower maximum use level, addition/subtraction of a note clarifying conditions of use, etc.); and

IFAC requests/supports the following revisions for acesulfame potassium:

01.5.1 Milk powder and cream powder (plain) – This category should be covered by 01.5 Milk powder and cream powder and powder analogues (plain), with a maximum level of 3000 mg/kg in place of the GMP level now shown.

01.6.5 Cheese analogues – The current 350 mg/kg use level should be increased to 500 mg/kg and thereby aligned with the 500 mg/kg level for 01.6.1 Unripened cheese.

04.1.2.3 Fruit in vinegar, oil, or brine – 200 mg/kg should be replaced by 1000 mg/kg. Sweetening agents can balance the acidity of vinegar used in these products and provide a balanced sweet-sour taste. Acesulfame K is neither degraded by lactic acid bacteria that may occur in brined products and can therefore improve shelf stability nor is it degraded during pasteurisation or storage of these products. The requested level is aligned with the level for category 04.1.2.10 with has similar technological requirements.

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) – 2500 mg/kg should be replaced by 1000 mg/kg. Some products of this category are sweet. Acesulfame K allows production of sweet products with no added sugar as it withstands heat processing. The listed level seems higher than technologically required. It is, therefore, proposed to replace it by 1000 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, candied vegetables) other than food category 04.2.2.5 – 350 mg/kg should be replaced by 1000 mg/kg. Intense sweeteners allow production of sweet sugar-free products. Acesulfame K can withstand the sterilisation conditions used for the common types of canned vegetables. The listed acesulfame K level is not sufficient to provide adequate sweetness. It is, therefore, proposed to align it with the level proposed for category 04.2.2.6 in order to provide adequate sweetness.

05.1.4 Cocoa and chocolate products – 2000 mg/kg should be replaced by 1000 mg/kg. Acesulfame K is used as sugar-free products of this category are based on polyols instead of sugar. Intense sweeteners are used to round the sweetness and bring it to the higher level of sugar-based products. Use of Acesulfame K in these products is common in many countries. As acesulfame K is normally used in combination with sugar alcohols, the proposed lower level, therefore, is sufficient.

05.1.5 Imitation chocolate, chocolate substitute products – 2500 mg/kg should be replaced by 1000 mg/kg. Acesulfame K is used as sugar-free products of this category based on polyols instead of sugar. These products very often contain intense sweeteners to round their sweetness and bring them to the higher level of sugar-based products. Use of Acesulfame K in these products is common in many countries. As acesulfame K is normally used in combination with sugar alcohols, the proposed lower level is sufficient.

05.2.1 Hard candy – 3500 mg/kg should be replaced by 2500 mg/kg. Sugar-free hard candy is based on sugar alcohols many of which have a lower sweetness than the sugar-glucose syrup basis of customary products. The sweetness is then rounded with intense sweeteners. Acesulfame K is well suited for these products as its taste rounds the sweetness of sugar alcohols. Acesulfame K is non-cariogenic. The proposed level represents the case of need for hard and soft candy.

05.2.3 Nougats and marzipans – 2500 mg/kg to be replaced by 1000 mg/kg. Acesulfame K is used as sugar-free products of this category based on polyols instead of sugar. These products often contain intense sweeteners to round their sweetness and bring it to the higher lever of sugar-based products. Use of Acesulfame K in these products is common in many countries. As acesulfame K is normally used in combination with sugar alcohols, the proposed lower level represents the case of need.

11.6 Table-top sweeteners, including those containing high intensity sweeteners – 15000 mg/kg should be replaced by GMP. Table-top sweeteners are used by consumers in quantities to provide desired sweetness. The consumer determines the amount used. It is therefore proposed to list acesulfame K for this category at GMP.

12.6.2 Non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy) – 350 mg/kg should be replaced by 500 mg/kg. Some products of this category contain vinegar and/or are sweet-sour. As with other vinegar-containing products, acesulfame K mellows the vinegar acidity. For sour-sweet products the proposed level is necessary to get an adequate balance between sweetness and acidity.

12.6.3 Mixes for sauces and gravies – 350 mg/kg should be replaced by 1000 mg/kg on a ready-to serve basis. Some of these products are intended for preparation of products of categories 12.6.1 and 12.6.2. The listed level should therefore be aligned with category 12.6.2 and be applied for the ready-to-serve product prepared from the mix.

12.6.4 Clear sauces (e.g., fish sauce) – 350 mg/kg to be replaced by 500 mg/kg. The level should be aligned with the level for 12.6.2 Non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy), as the technological requirements are often similar.

14.1.2.1 Fruit juice – 500 mg/kg is requested. Due to its good stability in liquids and during pasteurization, acesulfame K is widely used in beverages of all types, ready-to-drink as well as concentrates. Listing for non standardized juice is requested.

14.1.2.2 Vegetable juice – 600 mg/kg to be replaced by 500 mg/kg. Due to its good stability in liquids, acesulfame K is widely used in beverages of all types, ready-to-drink as well as concentrates. 500 mg/kg is sufficient.

14.1.2.3 Concentrates for fruit juice -- 500 mg/kg on a ready-to-drink basis is requested.

Due to its good stability in liquids and during pasteurisation acesulfame K is widely used in beverages of all types, ready-to-drink as well as concentrates. Listing for concentrates for non-standardised juice is proposed. Allocation of a numerical level for concentrates is, however, not in line with the carry-over provisions of the preamble of the standard. It is therefore proposed to list the same level as for the ready-to drink beverages, to add footnote 72 and to modify this footnote to ready-o-eat or ready-to-drink basis.

14.1.2.4 Concentrates for vegetable juice – 3000 mg/kg to be replaced by 500 mg/kg on a ready-to-drink basis. Due to its good stability in liquids and during pasteurisation, acesulfame K is widely used in beverages of all types, ready-to-drink as well as concentrates. Allocation of a numerical level for concentrates is, however, not in line with the carry-over provisions of the preamble of the standard. It is therefore proposed to list the same level as for the ready-to drink beverages, to add footnote 72 and to modify this footnote to ready-o-eat or ready-to-drink basis.

14.1.3.1 Fruit nectar – This category is missing and should be added at 500 mg/kg on a ready-to-drink basis. Due to its good stability in liquids and during pasteurisation acesulfame K is widely used in beverages of all types, ready-to-drink as well as concentrates.

14.1.3.2 Vegetable nectar –This category is missing and should be added at 500 mg/kg on a ready-to-drink basis. Due to its good stability in liquids and during pasteurisation acesulfame K is widely used in beverages of all types, ready-to-drink as well as concentrates.

14.1.3.3 Concentrates for fruit nectar – should be added at 500 mg/kg on a ready-to-drink basis. Due to its good stability in liquids and during pasteurisation, acesulfame K is widely used in beverages of all types, ready-to-drink as well as concentrates. Allocation of a numerical level for concentrates is, however, not in line with the carry-over provisions of the preamble of the standard. It is therefore proposed to list the same level as for the ready-to drink beverages, to add footnote 72 and to modify this footnote to ready-o-eat or ready-to-drink basis.

14.1.3.4 Concentrates for vegetable nectar – 2500 mg/kg to be replaced by 500 mg/kg on a ready-to-drink basis. Due to its good stability in liquids and during pasteurisation acesulfame K is widely used in beverages of all types, ready-to-drink as well as concentrates. Allocation of a numerical level for concentrates is, however, not in line with the carry-over provisions of the preamble of the standard. It is therefore proposed to list the same level as for the ready-to drink beverages, to add footnote 72 and to modify this footnote to ready-o-eat or ready-to-drink basis.

2. Please indicate the basis of your views by addressing the following:

a. The technological need for a sweetener;

Intense sweeteners make numerous low and reduced calorie foods and beverages possible. With the increase in obesity worldwide these products can be important tools to assist individuals in controlling and losing weight, when incorporated into an overall healthy diet. Having a variety of intense sweeteners available is important because no single sweetener is perfect for all uses. However, with several intense sweeteners available, each can be used in the applications for which it is best suited. Also, when necessary, manufacturers can overcome limitations of individual sweeteners by blending sweeteners together. Most sweetener blends are synergistic, i.e. the sweetness of the combination is greater than the sum of the individual parts and, therefore, less sweetener is needed. Also, having a variety of sweeteners available and the use of sweetener blends decreases exposure to any one sweetener.

b. Whether the proposed maximum use level is justified to achieve the intended technical need; or

The proposed maximum use levels provided are justified to achieve the intended technical needs.

c. Whether this level is safe.

Acesulfame potassium has been reviewed and determined safe for its intended uses by JECFA and numerous other scientific and regulatory bodies around the world.

Typical consumption levels are below the ADI of 15 mg/kg body weight assigned by JECFA.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Sulfites (INS 220,221,222,223,224,225,227,228,539)

1. Please indicate whether the WG should reaffirm the 37th CCFAC's decision to discontinue work on specific provisions for the use of sulfites in the GSFA if no additional information is provided to the 38th CCFAC.

IFAC requests that the WG continue work on the specific provisions for the use of sulfites in the GSFA, especially for Food Categories 04.2.2.2 Dried Fruit, 04.1.2.5 Jams, Jellies and Marmalades, 04.1.2.8 Fruit preparations, including pulp, purees, fruit toppings and coconut milk, and 12.4 Mustards.

2. If you support endorsement of these provisions for adoption at Step 8, for each of the food categories above, please comment on

a. The technological need for an acidity regulator, adjuvant, antioxidant, bleaching agent (not for flour), flour treatment agent, firming agent, preservative, sequestrant, or stabilizer;

b. Whether the proposed maximum use level is justified to achieve the intended technical need;

IFAC requests that the maximum use level of 3000 mg/kg for sulfites in Food Category 4.1.2.2 Dried Fruit be increased to 5000 mg/kg to improve the color of dried fruit, particularly apricots. This higher level significantly reduces the browning reactions at the critical water activity range needed for consumer acceptable flavor and texture.

c. Whether this level is safe; and

JECFA has reviewed sulfites, assigned sulfites a group ADI of 0.7 mg/kg body weight and determined they are safe for their intended uses.

d. Whether these provisions should be endorsed by the 38th CCFAC for adoption at Step 8.

IFAC supports the endorsement by the 38th CCFAC for adoption at Step 8 the provisions for sulfites, including an increase in the maximum use level for Food Category 4.1.2.2 Dried Fruit to 5000 mg/kg.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Butylated Hydroxytoluene (BHT) (INS 321)

1. Please indicate whether the WG should reaffirm the 37th CCFAC's decision to discontinue work on specific provisions for the use of BHT in the GSFA if no additional information is provided to the 38th CCFAC.

IFAC requests that the WG continue work on the specific provisions for the use of butylated hydroxytoluene in the GSFA, especially categories 05.1.4, 05.1.5, 05.2, 05.3, 05.4, 12.6, 13.6 and 15.0 .

2. If you support endorsement of these provisions, for each of the food categories above, please comment on

a. The technological need for an antioxidant;

Butylated hydroxytoluene is an antioxidant used in products such as cocoa and chocolate products, confectionary, chewing gum, food supplements, sauces and like products and ready-to-eat savouries. Butylated hydroxytoluene is used to prevent the oxidative rancidity of fats and oils. Butylated hydroxytoluene is necessary to suppress oxidative degradation and colour formation.

b. Whether the proposed maximum use level is justified to achieve the intended technical need,

The proposed maximum levels of use are justified to achieve the intended effect.

c. Whether this level is safe; and

Butylated hydroxytoluene has been reviewed by JECFA and deemed safe for its intended uses. Current consumption levels are below the JECFA ADI of 0-0.3 mg/kg body weight per day.

d. Provide a recommendation for whether the 38th CCFAC should endorse these provisions for adoption at Step 8 or should discontinue further consideration of these food additive provisions.

IFAC recommends that the 38th CCFAC endorse these provisions for butylated hydroxytoluene at Step 8.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Carnauba Wax (INS 903)

1. Please indicate whether the WG should reaffirm the 37th CCFAC's decision to discontinue work on specific provisions for the use of carnauba wax in the GSFA if no additional information is provided to the 38th CCFAC.

IFAC requests that the WG continue work on specific provisions for the use of carnauba wax in the GSFA for the following categories and use levels:

05.1.4	Cocoa and chocolate products	10,000 mg/kg
05.1.5	Imitation chocolate, chocolate substitutes	10,000 mg/kg
05.2	Confectionary including hard and soft candy, nougat, etc	10,000 mg/kg
13.6	Food supplements	500 mg/kg
15.0	Ready-to-eat savouries	2,000 mg/kg

2. If you support endorsement of these provisions, for each of the food categories above, please comment on

a. The technological need for an anticaking agent, adjuvant, bulking agent, carrier solvent, glazing agent, or release agent;

Carnauba wax is an approved substance used as a surface-finishing and polishing agent on products such as food supplements, chewing gum, confectionary, imitation chocolate, cocoa products, and ready-to-eat savouries. It enhances slip, gloss, release from a variety of surfaces and improves the solvent pick up to produce a better product. Carnauba wax is the hardest of the waxes commonly used and has the highest melting point of the waxes. Carnauba wax is used in an aqueous emulsion or as a powder and produces a very good luster on the finished product. Carnauba wax is the preferred ingredient for use as a glazing agent and polish for candies, gum and tablets.

b. Whether the proposed maximum use level is justified to achieve the intended technical need,

The proposed maximum levels of use are justified to achieve the desired appearance and protective coating for the foodstuffs.

c. Whether this level is safe; and

Carnauba wax has been reviewed by JECFA and deemed safe for its intended uses. Consumption levels are below the JECFA ADI of 7 mg/kg body weight per day.

d. Provide a recommendation for whether the 38th CCFAC should endorse these provisions for adoption at Step 8 or should discontinue further consideration of these food additive provisions.

IFAC recommends that the 38th CCFAC endorse these provisions for carnauba wax at Step 8.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Polydimethylsiloxane (INS 900a)

1. Please indicate whether the WG should reaffirm the 37th CCFAC's decision to discontinue work on specific provisions for the use of polydimethylsiloxane in the GSFA if no additional information is provided to the 38th CCFAC.

IFAC requests that the WG continue work on specific provisions for the use of polydimethylsiloxane in the GSFA.

2. If you support endorsement of these provisions for adoption at Step 8, for each of the food categories above, please comment on

a. The technological need for an anticaking agent or an antifoaming agent;

Polydimethylsiloxane safely and efficiently eliminates the problem of foam in food processing applications. It exhibits versatility, strength, effectiveness, safety and economy. Foam is comprised of bubbles. Polydimethylsiloxane disperses rapidly through the liquid film that makes up the bubble wall. Because polydimethylsiloxane has much lower surface tension (21 dynes/cm) than most fluids, it reduces the surface tension film. The bubbles collapse, and the foam disappears.

b. Whether the proposed maximum use level is justified to achieve the intended technical need,

The proposed maximum use levels are justified to achieve the intended technical needs.

c. Whether this level is safe; and

JECFA has reviewed polydimethylsiloxane, assigned an ADI of 1.5 mg/kg body weight and determine polydimethylsiloxane safe for its intended uses.

d. Whether these provisions should be endorsed by the 38th CCFAC for adoption at Step 8 or discontinue further work on the provisions; and

The provisions should be endorsed by the 38th CCFAC for adoption at Step 8.

e. Whether you support revoking the adopted provision polydimethylsiloxane in food category 04.2.2.1

IFAC does not support revoking the adopted provision of polydimethylsiloxane in Food Category 04.2.2.1. Polydimethysiloxane has been safely used as an anticaking agent for many years. For example, it is used in frozen vegetables (e.g., quick frozen French fries). A level of 10 mg/kg is sufficient to achieve the desired technical effect. IFAC urges the Working Group to continue work on polydimethylsiloxane for Food Category 04.2.2.1.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Benzoates (INS 210,211,212,213)

1. Please indicate whether the WG should reaffirm the 37th CCFAC's decision to discontinue work on specific provisions for the use of benzoates in the GSFA if no additional information is provided to the 38th CCFAC.

IFAC requests that the WG continue work on the specific provisions for the use of Benzoates in the GSFA, including the maximum level of 1500 mg/kg for 04.1.2.5 Jams, Jellies and Marmalades.

IFAC supports

If you support endorsement of these provisions, for each of the food categories above, please comment on

a. The technological need for a preservative;

b. Whether the proposed maximum use level is justified to achieve the intended technical need,

The proposed level is justified to achieve the intended technical need.

c. Whether this level is safe; and

JECFA has reviewed benzoates, assigned an ADI of 5 mg/kg and determined benzoates are safe for their intended uses.

d. Provide a recommendation for whether the 38th CCFAC should endorse these provisions for adoption at Step 8 or should discontinue further consideration of these food additive provisions.

IFAC recommends that the 38th CCFAC endorse these provisions, including the maximum level of 1500 mg/kg for 04.1.2.5 Jams, Jellies and Marmalades, for adoption at Step 8.

Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Tertiary Butylhydroxyquinone (TBHQ) (INS 319)

1. Please indicate whether the WG should reaffirm the 37th CCFAC's decision to discontinue work on specific provisions for the use of TBHQ in the GSFA if no additional information is provided to the 38th CCFAC.

IFAC requests that the WG continue work on specific provisions for the use of TBHQ in the GSFA, especially Food Category 12.4 Mustards.

2. If you support endorsement of these provisions at Step 8, for each of the food categories above, please comment on

a. The technological need for an antioxidant;

b. Whether the proposed maximum use level is justified to achieve the intended technical need,

The proposed maximum use levels are justified to achieve the intended technical needs.

c. Whether this level is safe; and

JECFA has reviewed TBHQ, assigned an ADI of 0.7 mg/kg body weight and determined it is safe for its intended uses.

d. Provide a recommendation for whether the 38th CCFAC should endorse these provisions for adoption at Step 8 or should discontinue further consideration of these food additive provisions.

IFAC recommends that the 38th CCFAC endorse these provision for adoption at Step 8.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is unaware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Polyvinyl Alcohol (INS 1203)

1. Please indicate:

a. Which food additive provisions you support for adoption at Step 5/8 or 8;

IFAC supports the food additives provisions for Polyvinyl Alcohol for adoption at Step 5/8 or 8.

b. Which food additive provisions you support requesting additional information and the type of information needed;

IFAC does not request any additional information.

c. Which food additive provisions you support revising (e.g., high/lower maximum use level, addition/subtraction of a note clarifying conditions of use, etc.); and

IFAC does not have any additional revisions to propose at this time.

2. Please indicate the basis of your views by addressing the following:

a. The technological need for a glazing agent or stabilizer;

Polyvinyl alcohol (PVA) can be used as a coating, sealing and surface finishing agent in food supplements and food products such as dairy-based desserts, confectionary and cereal products. For example, PVA possesses excellent properties that potentially enable it to become a universal film former in modern aqueous film-coating formulations for food supplement tablets. Specifically, PVA-based coatings are characterized by good film strength and adhesion qualities, can be sprayed at relatively high solids content, possess good moisture and oxygen barrier properties and do not compromise release of active ingredients from the coated food supplement product.

b. Whether the proposed maximum use level is justified to achieve the intended technical need; or

The proposed maximum levels of use are justified to achieve the intended effect.

c. Whether this level is safe.

Polyvinyl alcohol has been reviewed by JECFA and deemed safe for its intended uses. Consumption levels are below the JECFA ADI of 50 mg/kg body weight per day.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Indigotine (INS 132)

1. Please indicate:

a. Which food additive provisions you support for adoption at Step 5/8 or 8;

IFAC supports the food additive provision for Indigotine for adoption at Step 5/8 or 8 – with a request for increases in the maximum levels of use for Food Categories 05.2, 06.3, and13.6 (see 1c below).

b. Which food additive provisions you support requesting additional information and the type of information needed;

IFAC does not request any additional information.

c. Which food additive provisions you support revising (e.g., high/lower maximum use level, addition/subtraction of a note clarifying conditions of use, etc.); and

IFAC requests that the maximum level of use for Food Category 05.2 Confectionary be increased to 600 mg/kg; for Food Category 06.3 Breakfast Cereals be increased to 2000 mg/mg; and Food Category 13.6 (Food Supplements) be increased to 1452 mg/kg.

d. Whether you support the previous recommendations of the Quality Control Working Group to discontinue work on specific provisions and to include the indicated amendments.

2. Please indicate the basis of your views by addressing the following:

a. The technological need for a colour;

Indigotine is used as a colour additive in a variety of products, including confectionery, baked goods, cereals, snacks, ice cream and food supplements when a dark bluish-red hue is desired. Indigotine has wide acceptability and therefore is a commonly used color. Synthetic colours are widely used because they are brighter, more uniform and encompass a wider range of hues than natural colours. Colour is an important characteristic that enhances the appearance of food and food supplements, consumer appeal of the food and enjoyment of eating. Colour additives are used in foods to offset colour loss that can occur due to exposure to light, air, temperature extremes, moisture and storage conditions. Colour additives enhance colours that occur naturally and correct natural variations in colour. Colour additives also provide a colourful identity to foods that may otherwise be virtually colourless.

b. Whether the proposed maximum use level is justified to achieve the intended technical need; or

The proposed maximum levels of use are justified to achieve the intended effect with the exception of Food Category 13.6 (Food Supplements) for which IFAC requests that the maximum level be increased to 1452 mg/kg.

c. Whether this level is safe.

Indigotine has been reviewed by JECFA and deemed safe for its intended uses. Typical consumption levels are below the JECFA ADI of 5 mg/kg body weight per day.

The maximum level of Indigotine being proposed for food supplements is currently commercially used in nutritional supplements marketed in the United States and the following example shows daily intake using a typical coating system containing 3.63% Indigotine applied to a food supplement with a 4 % weight gain assuming a daily food supplement consumption of 3 g.

3 g (food supplement) x 4.0% (coating) = 0.12 g coating

0.12 g coating x 1000 mg=120 mg coating

120 mg coating x 0.0363* (Indigotine) = 4.4 mg Indigotine/Day

*the equivalent of 1452 mg/kg product

JECFA ADI multiplied by a 60 kg body weight results in a daily amount of 300 mg per day. The proposed use of 4.4 mg per day is significantly below the 300 mg/day.

In comparison to other food products, consumers self regulate daily intake levels of food supplements in their diet. Manufacturers of food supplements reinforce this by providing specific dosage recommendations on the product label. Therefore, the ultimate intake from dietary supplements is significantly less than the intake from traditional food use.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Ponceau 4R (INS 124)

1. Please indicate:

a. Which food additive provisions you support for adoption at Step 5/8 or 8;

IFAC supports adoption of the food additive provisions for Ponceau 4R at Step 5/8 or 8, especially for Food Categories 05.1.1, 05.1.2, 05.1.3, 05.1.4, 05.1.5, 05.3, 05.4, 07.0, 08.4, 13.6, 15.1, and 15.2, as well as the levels listed below.

b. Which food additive provisions you support requesting additional information and the type of information needed;

IFAC does not request any additional information.

c. Which food additive provisions you support revising (e.g., high/lower maximum use level, addition/subtraction of a note clarifying conditions of use, etc.); and

IFAC requests that the maximum use levels for the following categories be increased to the level noted.

01.1.2	Dairy based drinks	300 mg/kg
02.4	Fat based desserts	300 mg /kg
03.0	Edible ices	300 mg/kg
04.1.2.8	Fruit preparations	800 mg/kg
04.1.2.11	Fruit fillings	500 mg/kg
05.2	Confectionary	500 mg/kg
06.3	Breakfast cereals	500 mg/kg
14.1.4	Water based flavored drinks	300 mg/kg

The requested levels reflect current levels of use.

d. Whether you support the previous recommendations of the Quality Control Working Group to discontinue work on specific provisions and to include the indicated amendments.

2. Please indicate the basis of your views by addressing the following:

a. The technological need for a colour;

Ponceau 4R is a colour additive used in numerous products, including dessert toppings, jelly, salami, seafood dressings, tinned strawberries, fruit pie fillings, packaged cake mixes, cheesecakes, soups, trifles and food supplements where a bright red hue is desired. Ponceau 4R has good light and heat stability. Synthetic colours are widely used because they are brighter, more uniform and encompass a wider range of hues than natural colors. Colour is an important characteristic of food that enhances consumer appeal and enjoyment. Colour additives are used in foods to offset colour loss that can occur due to exposure to light, air, temperature extremes, moisture and storage conditions. Colour additives enhance colours that occur naturally and correct natural variations in colour. Colour additives also provide a colourful identity to foods that may otherwise be virtually colourless.

b. Whether the proposed maximum use level is justified to achieve the intended technical need; or

The proposed maximum levels of use are justified to achieve the intended effect.

c. Whether this level is safe.

Ponceau 4R has been reviewed by JECFA and deemed safe for its intended uses. Consumption levels are below the JECFA ADI of 4 mg/kg body weight per day.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Sunset Yellow FCF (INS 110)

1. Please indicate:

a. Which food additive provisions you support for adoption at Step 5/8 or 8;

IFAC supports the food additive provisions for Sunset Yellow FCF for adoption at Step 5/8 or 8 – and requests increases in the maximum levels for Food Categories 0.6.4, 04.1.2.8, 05.2, 06.3, 07.0 and 13.6 (see 1c below).

b. Which food additive provisions you support requesting additional information and the type of information needed;

IFAC does not request additional information.

c. Which food additive provisions you support revising (e.g., high/lower maximum use level, addition/subtraction of a note clarifying conditions of use, etc.); and

IFAC requests that the maximum level of use be increased to the noted levels for the Food Categories listed below:

01.6.4	Processed Cheese	500 mg/kg
04.1.2.8	Fruit Preparations	800 mg/kg
05.2	Confectionary	800 mg/kg
06.3	Breakfast Cereals	1500 mg/kg
07.0	Bakery	500 mg/kg
13.6	Food Supplements	1900 mg/kg

These requested levels reflect current levels of use.

d. Whether you support the previous recommendations of the Quality Control Working Group to discontinue work on specific provisions and to include the indicated amendments.

IFAC supports the previous recommendations of the Quality Control WG to include the indicated amendment.

2. Please indicate the basis of your views by addressing the following:

a. The technological need for a colour;

Sunset Yellow FCF is widely used as a coloring agent in numerous products, including in bakery goods, beverages, butter, candy, cereals, cheese, confections, desserts, ice cream and food supplements when an orange hue, characteristic of orange peel, is desired. Sunset Yellow has good stability to heat and light. Synthetic colours are widely used because they are brighter, more uniform and encompass a wider range of hues than natural colours. Colour is an important characteristic that enhances the appearance of food, consumer appeal of the food and enjoyment of eating. Colour additives are used in foods to offset colour loss that can occur due to exposure to light, air, temperature extremes, moisture and storage conditions. Colour additives enhance colours that occur naturally and correct natural variations in colour. Colour additives also provide a colourful identity to foods that would otherwise be virtually colourless.

b. Whether the proposed maximum use level is justified to achieve the intended technical need; or

The proposed maximum levels of use are justified to achieve the intended effect.

c. Whether this level is safe.

Sunset Yellow FCF has been reviewed by JECFA and deemed safe for its intended uses. Typical consumption levels are below the JECFA ADI of 2.5 mg/kg body weight per day.

The maximum level of Sunset Yellow FCF that IFAC is proposing for food supplements is currently commercially used in a nutritional supplement marketed in the United States and the following example shows daily intake using a typical coating system containing 4.75% Sunset Yellow FCF, applied to a food supplement with a 4% weight gain assuming a daily food supplement consumption of 3 g.

3 g (food supplement) x 4.0% (coating) = 0.12 g coating

0.12 g coating x 1000 mg=120 mg coating

120 mg coating x 0.0475* (Sunset Yellow FCF) = 5.7 mg Sunset Yellow/Day

*the equivalent of 1900 mg/kg product

JECFA ADI multiplied by a 60 kg body weight results in a daily amount of 150 mg per day. The proposed use of 5.7 mg per day is significantly below the 150 mg/day and only a fraction of the ADI.

In comparison to other food products, consumers self regulate daily intake levels of food supplements in their diet. Manufacturers of food supplements reinforce this by providing specific dosage recommendations on the product label. Therefore, the ultimate intake from dietary supplements is significantly less than the intake from traditional foods.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Fast Green FCF (INS 143)

1. Please indicate:

a. Which food additive provisions you support for adoption at Step 5/8 or 8;

IFAC supports the adoption of the food additive provisions for Fast Green FCF, especially for Food Categories 05.2, 05.4, 07.0, 07.1.1, 07.2, 08.4 and 13.6.

b. Which food additive provisions you support requesting additional information and the type of information needed;

IFAC not request any additional information.

c. Which food additive provisions you support revising (e.g., high/lower maximum use level, addition/subtraction of a note clarifying conditions of use, etc.); and

IFAC requests that the maximum use level for Food Category 04.1.2.8 Fruit Preparations be increased to 500 mg/kg and for Food Category 05.2 be increased to 300 mg/kg. These requested increases reflect current use levels.

2. Please indicate the basis of your views by addressing the following:

a. The technological need for a colour;

Fast Green FCF is a colour additive used in products, including beverages, cereals, desserts, soft drinks, confectionaries and food supplements when a sea green hue is required. Synthetic colours are widely used because they are brighter, more uniform and encompass a wider range of hues than natural colours. Colour is an important characteristic of food that enhances consumer appeal and enjoyment of eating. Colour additives are used in foods to offset colour loss that can occur due to exposure to light, air, temperature extremes, moisture and storage conditions. Colour additives enhance colours that occur naturally and correct natural variations in colour. Colour additives also provide a colourful identity to foods that may otherwise be virtually colourless.

b. Whether the proposed maximum use level is justified to achieve the intended technical need; or

The proposed and requested maximum levels of use are justified to achieve the intended effect.

c. Whether this level is safe.

Fast Green FCF has been reviewed by JECFA and deemed safe for its intended uses. Consumption levels are below the JECFA ADI of 25 mg/kg body weight per day.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Caramel Colour Class IV (INS 150d)

1. Please indicate:

a. Which food additive provisions you support for adoption at Step 5/8 or 8;

IFAC supports adoption of the food additive provisions for Caramel Colour Class IV at Step 5/8 or 8, including Food Categories 05.0, 05.1.1, 05.1.2, 05.1.4, 05.1.5, 05.2, 05.3, 05.4, 07.1.2, 07.1.3, 07.1.4, 07.1.5, 07.1.6, 07.2, 13.6 (food supplements at 20,000 mg/kg), 14.1.2.2, 14.1.2.4, 14.1.3.2 (vegetable nectar at 50,000 mg/kg), 14.1.3.4 (concentrates for vegetable nectar at 50,000 mg/kg), 14.1.4 (water-based flavoured drinks, including "sport," "energy" or "electrolyte" drinks and particulated drinks at 50,000 mg/kg) and 15.0 (ready-to-eat savouries at 10,000 mg/kg).

b. Which food additive provisions you support requesting additional information and the type of information needed;

IFAC does not request any additional information.

c. Which food additive provisions you support revising (e.g., high/lower maximum use level, addition/subtraction of a note clarifying conditions of use, etc.); and

IFAC does not have any additional revisions to propose at this time.

d. Whether you support the previous recommendations of the Quality Control Working Group to discontinue work on specific provisions and to include the indicated amendments.

2. Please indicate the basis of your views by addressing the following:

a. The technological need for a colour;

Caramel Colour is one of the most widely used colorants in foods. Colour is an important characteristic of food that enhances consumer appeal of the food and enjoyment of eating. Colour additives are used in foods to offset colour loss that can occur due to exposure to light, air, temperature extremes, moisture and storage conditions. Colour additives enhance colours that occur naturally and correct natural variations in colour. Colour additives also provide a colorful identity to foods that may otherwise be virtually colourless.

b. Whether the proposed maximum use level is justified to achieve the intended technical need; or

The proposed maximum levels of use are justified to achieve the intended effect.

c. Whether this level is safe.

Caramel Colour has been reviewed by JECFA and deemed safe for its intended uses. Consumption levels are below the JECFA ADI of 200 mg/kg body weight per day.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Carotenoids (INS 160ai,160aii,160e,160f)

1. Please indicate:

a. Which food additive provisions you support for adoption at Step 5/8 or 8;

IFAC supports adoption of provisions for carotenoids at Step 5/8 or 8, especially for Food Categories 05.1.1, 05.1.2, 05.1.3, 05.1.4, 05.1.5, 05.2, 05.3, 07.1.2, 07.1.3, 07.1.4, 07.1.5, 07.1.6, 07.2, 12.4 and 13.6.

b. Which food additive provisions you support requesting additional information and the type of information needed;

IFAC does not request any additional information.

c. Which food additive provisions you support revising (e.g., high/lower maximum use level, addition/subtraction of a note clarifying conditions of use, etc.); and

IFAC requests that maximum use levels for 06.3 Breakfast cereals be increased to 500 mg/kg and for 14.1.4 Water based flavored drinks be increased to 200 mg/kg. The increased levels reflect current use levels.

d. Whether you support the previous recommendations of the Quality Control Working Group to discontinue work on specific provisions and to include the indicated amendments.

2. Please indicate the basis of your views by addressing the following:

a. The technological need for a colour;

Carotenoids are naturally occurring red, yellow and orange pigments. Carotenoids are used to colour products such as beverages, frozen foods, fruit fillings, candies, baked goods, mustards, and food supplements. Colour is an important characteristic of food that enhances consumer appeal and enjoyment of eating. Colour additives are used in foods to offset colour loss that can occur due to exposure to light, air, temperature extremes, moisture and storage conditions. Colour additives enhance colours that occur naturally and correct natural variations in colour. Colour additives also provide a colourful identity to foods that may otherwise be virtually colourless.

b. Whether the proposed maximum use level is justified to achieve the intended technical need; or

The proposed maximum levels of use are justified to achieve the intended effect, including those for which increases are requested.

c. Whether this level is safe.

Carotenoids have been reviewed by JECFA and deemed safe for their intended uses. Consumption levels are below the JECFA ADI of 50 mg/kg body weight per day.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Caramel Colour Class III (INS 150c)

1. Please indicate:

a. Which food additive provisions you support for adoption at Step 5/8 or 8;

IFAC supports advancing all of the pending provisions for caramel colour class III for adoption at Step 5/8 or 8.

b. Which food additive provisions you support requesting additional information and the type of information needed;

IFAC does not request any additional information.

c. Which food additive provisions you support revising (e.g., high/lower maximum use level, addition/subtraction of a note clarifying conditions of use, etc.); and

IFAC does not have any additional revisions to propose at this time.

d. Whether you support the previous recommendations of the Quality Control Working Group to discontinue work on specific provisions and to include the indicated amendments.

2. Please indicate the basis of your views by addressing the following:

a. The technological need for a colour;

Caramel Colour is one of the most widely used colorants in foods. Colour is an important characteristic of food that enhances consumer appeal of the food and enjoyment of eating. Colour additives are used in foods to offset colour loss that can occur due to exposure to light, air, temperature extremes, moisture and storage conditions. Colour additives enhance colours that occur naturally and correct natural variations in colour. Colour additives also provide a colorful identity to foods that may otherwise be virtually colourless.

b. Whether the proposed maximum use level is justified to achieve the intended technical need; or

The proposed maximum levels of use are justified to achieve the intended effect.

c. Whether this level is safe.

Caramel Colour has been reviewed by JECFA and deemed safe for its intended uses. Consumption levels are below the JECFA ADI of 200 mg/kg body weight per day.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Allura Red AC (INS 129)

1. Please indicate:

a. Which food additive provisions you support for adoption at Step 5/8 or 8;

IFAC supports the food additive provisions for Allura Red AC for adoption at Step 5/8 or 8, with one exception (See 1c below).

b. Which food additive provisions you support requesting additional information and the type of information needed;

IFAC does not request any additional information.

c. Which food additive provisions you support revising (e.g., high/lower maximum use level, addition/subtraction of a note clarifying conditions of use, etc.); and

IFAC requests that the maximum level for Food Category 01.7 Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt) be increased to 500 mg/kg; 03.0 Edible ices, including sherbet and sorbet be increased to 500 mg/kg; 05.2 Confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4 be increased to 1000 mg/kg; 06.3 Breakfast cereals, including rolled oats be increased to 1500 mg/kg and Food Category 13.6 (Food Supplements) be increased to 3060 mg/kg.

d. Whether you support the previous recommendations of the Quality Control Working Group to discontinue work on specific provisions and to include the indicated amendments.

IFAC supports the previous recommendations of the Quality Control WG to discontinue work on specific provisions and to include the indicated amendments – with the exception of that for 06.3 Breakfast cereals for which IFAC's requests an increased maximum level.

2. Please indicate the basis of your views by addressing the following:

a. The technological need for a colour;

Allura Red AC is widely used as a colouring agent in products such as, beverages, candy, cereals, confections, deserts, ice cream and food supplements when an orange-red hue is required. Allura red is a general-purpose colour with reasonable stability in a variety of foods and tolerance to processing and storage. Synthetic colours are widely used because they are brighter, more uniform and encompass a wider range of hues than natural colours. Colour is an important characteristic that enhances the appearance of food, consumer appeal of the food and enjoyment of eating. Colour additives are used in foods to offset colour loss that can occur due to exposure to light, air, temperature extremes, moisture and storage conditions. Colour additives enhance colours that occur naturally and correct natural variations in colour. Colour additives also provide a colourful identity to foods that may otherwise be virtually colourless.

b. Whether the proposed maximum use level is justified to achieve the intended technical need; or

The proposed maximum levels of use are justified to achieve the intended effect. Again, IFAC requests that the maximum levels for the categories noted above be increased in order that the intended effect may be achieved. The requested levels reflect current use levels.

c. Whether this level is safe.

Allura Red AC has been reviewed by JECFA and deemed safe for its intended uses. Typical consumption levels are below the JECFA ADI of 0-7 mg/kg body weight per day.

The maximum level of Allura Red AC being proposed for food supplements is currently commercially used in a nutritional supplement marketed in the United States and the following example shows daily intake using a typical coating system containing 7.65% Allura Red AC, applied to a food supplement with a 4% weight gain and assuming a daily food supplement consumption of 3 g.

3 g (food supplement) x 4.0% (coating) = 0.12 g coating

0.12 g coating x 1000 mg=120 mg coating

120 mg coating x 0.0765* (Allura Red) = 9.18 mg Allura Red/Day

*the equivalent of 3060 mg/kg product

JECFA ADI multiplied by a 60 kg body weight results in a daily amount of 420 mg per day. The proposed use of 9.18 mg per day is significantly below, and only a small percentage the 420 mg/day.

In comparison to other food products, consumers self regulate daily intake levels of food supplements in their diet. Manufacturers of food supplements reinforce this by providing specific dosage recommendations on the product label. Therefore, the ultimate intake from food supplements is significantly less than the intake from traditional food use.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

<u>Castor Oil (INS 1503)</u>

1. Please indicate whether the WG should reaffirm the 37th CCFAC's decision to discontinue work on specific provisions for the use of castor oil in the GSFA if no additional information is provided to the 38th CCFAC.

IFAC requests that the WG continue work on the specific provisions for the use of castor oil in the GSFA.

2. If you support endorsement of these provisions, for each of the food categories above, please comment on:

a. The technological need for an anticaking agent, carrier solvent, glazing agent, or release agent;

Castor oil is a vehicle and carrier solvent used in products, such as food supplements, chewing gum, confectionery, imitation chocolate and cocoa products.

b. Whether the proposed maximum use level is justified to achieve the intended technical need;

The proposed maximum levels of use are justified to achieve the desired appearance and protective coating for the foodstuff.

c. Whether this level is safe; and

Castor oil has been reviewed by JECFA and deemed safe for its intended uses. Consumption levels are below the JECFA ADI of 0.7 mg/kg body weight per day.

d. Provide a recommendation for whether these provisions should be endorsed by the 37th CCFAC at Step 8.

IFAC recommends that the 38th CCFAC endorse these provisions for castor oil at Step 8.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Grape Skin Extract (INS 163ii)

1. Please indicate whether the WG should reaffirm the 37th CCFAC's decision to discontinue work on specific provisions for the use of grape skin extract in the GSFA if no additional information is provided to the 38th CCFAC.

IFAC requests that the WG continue work on the specific provisions for the use of Grape Skin Extract in the GSFA.

2. If you support endorsement of these provisions, for each of the food categories above, please comment on

IFAC supports the endorsement of these provisions, especially for Food Categories 05.1.5, 08.4, 13.6, 15.1 and 15.2.

a. The technological need for a colour;

Grape Skin Extract, a naturally occurring pigment, is used to color various food products, including beverages, sauces, snacks and dietary supplements providing red or purple hues. The colour hue progresses from red to blue as the pH increases. Colour is an important characteristic of food that enhances consumer appeal and enjoyment of eating. Colour additives are used in foods to offset colour loss that can occur due to exposure to light, air, temperature extremes, moisture and storage conditions. Colour additives enhance colors that occur naturally and correct natural variations in colour. Colour additives also provide a colorful identity to foods that may otherwise be virtually colourless.

b. Whether the proposed maximum use level is justified to achieve the intended technical need;

The proposed maximum levels of use are justified to achieve the intended effect.

c. Whether this level is safe; and

Grape Skin Extract has been reviewed by JECFA and deemed safe for its intended uses. Typical consumption levels are below the JECFA ADI of 2.5 mg/kg body weight per day.

d. Whether these provisions should be endorsed by the 37th CCFAC for adoption at Step 8.

IFAC recommends that the 38th CCFAC endorse these provisions for grape skin extract at Step 8.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Iron Oxides (INS 172i,172ii,172iii)

1. Please indicate whether the WG should reaffirm the 37th CCFAC's decision to discontinue work on specific provisions for the use of iron oxides in the GSFA if no additional information is provided to the 38th CCFAC.

IFAC requests that the WG continue work on the specific provisions for the use of Iron Oxides in the GSFA.

2. If you support endorsement of these provisions, for each of the food categories above, please comment on

a. The technological need for a colour;

Iron oxides provide basic yellow, red or black colours to foodstuffs. Iron oxides are used to colour a variety of products, including cocoa-based spreads, chewing gum, confectionery and food supplements. Iron oxides are highly stable, particularly to light and are suitable for products that are heat processed. Colour is an important characteristic that enhances the appearance of food and food supplements, consumer appeal and enjoyment of eating. Colour additives are used in foods to offset colour loss that can occur due to exposure to light, air, temperature extremes, moisture and storage conditions. Colour additives enhance colours that occur naturally and correct natural variations in colour. Colour additives also provide a colourful identity to foods that may otherwise be virtually colourless.

b. Whether the proposed maximum use level is justified to achieve the intended technical need;

The proposed maximum levels of use are justified to achieve the intended effect. IFAC requests Food Category 13.6 (Food Supplements) be assigned a maximum level of use of 7500 mg/kg singly or in combination (red, yellow, black) – in place of the current GMP level.

c. Whether this level is safe; and

Iron Oxides have been reviewed by JECFA and deemed safe for their intended uses. Typical consumption levels are below the JECFA ADI of 0-0.5 mg/kg body weight per day.

The maximum level of 7500 mg/kg iron oxides being proposed for food supplements is below levels that are already commercially used in nutritional supplements marketed in Australia. The following example shows daily intake using a typical coating system containing 18.7% iron oxide, applied to a food supplement with a 4 % weight gain assuming a daily food supplement consumption of 3g.

3g (food supplement) x 4.0% (coating) = 0.12 g coating

0.12 g coating x 1000 mg=120 mg coating

120 mg coating x 0.1817* (Iron Oxide) = 21.80 mg Iron Oxide/Day

*the equivalent of 7500 mg/kg product

JECFA ADI multiplied by a 60 kg body weight would result in a daily amount of 30 mg/day. The proposed use of 21.80 mg per day is below the 30 mg/day.

In comparison to other food products, consumers self regulate daily intake levels of food supplements in their diet. Manufacturers of food supplements reinforce this by providing specific dosage recommendations on the product label.

d. Whether these provisions should be endorsed by the 38th CCFAC for adoption at Step 8.

IFAC recommends that the 38th CCFAC endorse these provisions for iron oxides at Step 8.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Polysorbates (INS 432,433,434,435,436)

1. Please indicate whether the WG should reaffirm the previous eWG's decision to discontinue work on specific provisions for the use of polysorbates in the GSFA.

IFAC requests that the WG continue work on the specific provisions for the use of polysorbates in the GSFA, especially Food Categories 05.1.2, 05.1.3, 05.1.4, 05.1.5, 05.2, 05.2.1, 05.2.2, 05.2.3, 05.3, 05.4, 07.1.1, 07.1.2, 07.1.3, 07.1.4, 07.1.5, 07.1.6, 07.2, 08.4 and 13.6.

2. For each of the food categories above, please comment on:

a. The technological need for an antifoaming agent, adjuvant, emulsifier, foaming agent, flour treatment agent, or stabilizer;

Polysorbates are widely used as surfactants often in combination with other emulsifiers to form stable oil-in water emulsions. Polysorbates are soluble in hot and cold water but insoluble in edible oils.

b. Whether the proposed maximum use level is justified to achieve the intended technical need;

The proposed maximum levels of use are justified to achieve the intended effect.

c. Whether this level is safe; and

Polysorbates have been reviewed by JECFA and deemed safe for intended uses. Consumption levels are below the JECFA ADI of 25 mg/kg body weight per day.

d. Provide a recommendation for whether these provisions should be endorsed by the 37th CCFAC for adoption at Step 8.

IFAC recommends that the 38th CCFAC endorse these provisions for polysorbates at Step 8.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Riboflavins (INS 101i,101ii)

1. Please indicate whether the WG should reaffirm the 37th CCFAC's decision to discontinue work on specific provisions for the use of riboflavins in the GSFA if no additional information is provided to the 38th CCFAC.

IFAC requests that the WG continue work on the specific provisions for the use of riboflavins in the GSFA, especially Food Categories 05.1.2, 05.1.3 and 05.1.4.

2. If you support endorsement of these provisions, for each of the food categories above, please comment on

a. The technological need for a colour;

Riboflavin is used as a colour additive and as a nutrient supplement. In many cases, the nutrient content compliments its use as a colour in selected foods. Riboflavin is used to colour food products where a bright yellow lemon hue is desired.

b. Whether the proposed maximum use level is justified to achieve the intended technical need;

The proposed maximum levels of use are justified to achieve the intended effect.

c. Whether this level is safe; and

Riboflavins have been reviewed by JECFA and deemed safe for intended uses. Consumption levels are below the JECFA ADI of 0.5 mg/kg body weight per day.

d. Whether these provisions should be endorsed by the 38th CCFAC for adoption at Step 8.

IFAC recommends that the 38th CCFAC endorse these provisions for riboflavins at Step 8.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Erythrosine (INS 127)

1. Please indicate whether the WG should reaffirm the 37th CCFAC's decision to discontinue work on specific provisions for the use of erythrosine in the GSFA if no additional information is provided to the 38th CCFAC.

IFAC requests that the WG continue work on the specific provisions for the use of Erythrosine in the GSFA, especially Food Categories 05.1.3, 05.2, 05.1.3, 05.4, 07.0, 08.4, 12.6.2, 13.6 and 15.1.

2. If you support endorsement of these provisions, for each of the food categories above, please comment on

a. The technological need for a colour;

Erythrosine is used as a colouring agent in a number of products, including cherries, confections, baked goods, dairy, snack foods, beverages and food supplements providing a unique bright pink hue. Erythrosine has good stability to heat. Synthetic colours are widely used because they are brighter, more uniform and encompass a wider range of hues than natural colours. Colour is an important characteristic of food that enhances consumer appeal and enjoyment of eating. Colour additives are used in foods to offset colour loss that can occur due to exposure to light, air, temperature extremes, moisture and storage conditions. Colour additives enhance colors that occur naturally and correct natural variations in colour. Colour additives also provide a colorful identity to foods that may otherwise be virtually colorless.

b. Whether the proposed maximum use level is justified to achieve the intended technical need, and

The proposed maximum levels of use are justified to achieve the intended effect.

c. Whether this level is safe;

Erythrosine has been reviewed by JECFA and deemed safe for its intended uses. Consumption levels are below the JECFA ADI of 0.1 mg/kg body weight per day.

d. Whether these provisions should be endorsed by the 37th CCFAC for adoption at Step 8.

IFAC recommends that the 38th CCFAC endorse provisions for Erythrosine at Step 8.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Canthaxanthin (INS 161g)

1. Please indicate whether the WG should reaffirm the 37th CCFAC's decision to discontinue work on specific provisions for the use of canthaxanthin in the GSFA if no additional information is provided to the 38th CCFAC.

IFAC requests that the WG continue work on the specific provisions for the use of Canthaxanthin in the GSFA

2. If you support endorsement of the provisions, for each of the food categories above, please comment on

a. The technological need for a colour;

b. Whether the proposed maximum use level is justified to achieve the intended technical need

The proposed levels are justified to achieve the intended technical need.

c. Whether this level is safe; and

JECFA has reviewed canthaxanthin, assigned an ADI of 0.03 mg/kg and determined canthaxanthin is safe for its intended uses.

d. Provide a recommendation for whether these provisions should be endorsed by the 38th CCFAC for adoption at Step 8.

IFAC recommends that the 38th CCFAC adopt these provisions, including the maximum level of 100 mg/kg for 12.6 Sauces and Like Products at Step 8.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity

Carmines (INS 120)

1. Please indicate whether the WG should reaffirm the 37th CCFAC's decision to discontinue work on specific provisions for the use of carmines in the GSFA if no additional information is provided to the 38th CCFAC.

IFAC requests that the WG continue work on the specific provisions for the use of carmines in the GSFA.

2. If you support endorsement of these provisions, for each of the food categories above, please comment on

a. The technological need for a colour;

Carmines have a long history of use as colour additives in a wide range of products, including alcoholic drinks, bakery products and toppings, biscuits, desserts, drinks, icings, pie fillings, some varieties of cheddar cheese, sauces and sweets. Carmines provide a bright strawberry red shade. Colour is an important characteristic of food that enhances the consumer appeal of the food and enjoyment of eating. Colour additives are used in foods to offset colour loss that can occur due to exposure to light, air, temperature extremes, moisture and storage conditions. Colour additives enhance colours that occur naturally and correct natural variations in colour. Colour additives also provide a colorful identity to foods that may otherwise be virtually colourless.

b. Whether the proposed maximum use level is justified to achieve the intended technical need

The proposed maximum levels of use are justified to achieve the intended effect.

c. Whether this level is safe; and

Carmines have been reviewed by JECFA and deemed safe for intended uses. Consumption levels are below the JECFA ADI of 0-5 mg/kg body weight per day.

d. Provide a recommendation for whether these provisions should be endorsed by the 38th CCFAC for adoption at Step 8

IFAC recommends that the 38th CCFAC endorse these provisions for carmines at Step 8.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Carotenes, Vegetable (INS 160aii)

1. Please indicate whether the WG should reaffirm the 37th CCFAC's decision to discontinue work on specific provisions for the use of vegetable carotenes in the GSFA if no additional information is provided to the 38th CCFAC.

IFAC supports adoption of provisions for Vegetable Carotenes at Step 5/8 or 8.

2. If you support endorsement of these provisions, for each of the food categories above, please comment on

a. The technological need for a colour;

Carotenes can be used to colour a variety of food products. Colour is an important characteristic of food that enhances consumer appeal and enjoyment of eating. Colour additives are used in foods to offset colour loss that can occur due to exposure to light, air, temperature extremes, moisture and storage conditions. Colour additives enhance colours that occur naturally and correct natural variations in colour. Colour additives also provide a colourful identity to foods that would otherwise be virtually colourless.

b. Whether the proposed maximum use level is justified to achieve the intended technical need;

The proposed maximum levels of use are justified to achieve the intended effects.

c. Whether the level is safe; and

Vegetable carotenes have been reviewed by JECFA and determined acceptable for use as a colour.

d. Provide a recommendation for whether these provisions should be endorsed by the 38th CCFAC for adoption at Step 8.

IFAC recommends that these provisions be endorsed by the 38th CCFAC for adoption at Step 8.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Chlorophylls, Copper Complexes (INS 141i & 141ii)

1. Please indicate whether the WG should reaffirm the 37th CCFAC's decision to discontinue work on specific provisions for the use of chlorophyll copper complexes in the GSFA if no additional information is provided to the 38th CCFAC.

IFAC requests that the WG continue working on the specific provisions for the use of chlorophylls, copper complexes in the GSFA and is especially interested in categories 05.1.2, 05.1.3, 05.1.4, 05.1.5, 05.2.1, 05.2.2, 05.2.3, 05.3, 05.4, 12.4, 13.6, 15.1 and 15.2.

2. If you support endorsement of these provisions, for each of the food categories above, please comment on

a. The technological need for a colour;

Copper complexes of chlorophylls provide a blue green hue and are used as colour additives in products such as confectionary, chewing gum, processed food, vegetable oils and food supplements. Copper chlorophylls provide brighter and more stable colours than uncoppered colours. Colour is an important characteristic of food that enhances consumer appeal and enjoyment of eating. Colour additives are used in foods to offset colour loss that can occur due to exposure to light, air, temperature extremes, moisture and storage conditions. Colour additives enhance colours that occur naturally and correct natural variations in colour. Colour additives also provide a colorful identity to foods that may otherwise be virtually colorless.

b. Whether the proposed maximum use level is justified to achieve the intended technical need

The proposed maximum levels of use are justified to achieve the intended effect.

c. Whether this level is safe; and

Chlorophylls, copper complexes have been reviewed by JECFA and deemed safe for intended uses. Consumption levels are below the JECFA ADI of 15 mg/kg body weight per day.

d. Provide a recommendation for whether these provisions should be endorsed by the 38th CCFAC for adoption at Step 8.

IFAC recommends that the 38th CCFAC endorse these provisions for chlorophylls, copper complexes at Step 8.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

Brilliant Blue FCF (INS 133)

1. Please indicate whether the WG should reaffirm the 37th CCFAC's decision to discontinue work on specific provisions for the use of brilliant blue FCF in the GSFA if no additional information is provided to the 38th CCFAC.

IFAC requests that the WG continue work on the specific provisions for the use of Brilliant Blue FCF in the GSFA and is especially interested in the following categories and maximum use levels:

04.1.2.8	Fruit preparations, including pulp, purees, fruit toppingsand coconut milk	600 mg/kg

Brilliant Blue FCF has a proposed provision for use as a color additive in food category 04.1.2.8 (fruit preparations, including pulp, purees, fruit toppings and coconut milk) at a maximum use level of 500 mg/kg. IFAC, however, is recommending a maximum use level of 600 mg/kg, which is higher than the maximum use level being proposed. Brilliant Blue is used to enhance products with broad ranges of inherent color. There is a technical need to allow a higher maximum use level to address these inherent variations.

05.1.3	Cocoa-based spreads, including fillings	300 mg/kg
05.1.4	Cocoa and chocolate products	300 mg/kg
05.1.5	Imitation chocolate, chocolate substitute products	300 mg/kg
07.1	Bread and ordinary bakery wares	100 mg/kg
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	200 mg/kg
12.6	Sauces and like products	500 mg/kg

2. If you support endorsement of these provisions, for each of the food categories above, please comment on

a. The technological need for a colour;

Brilliant Blue FCF is a colour additive used in products such as fruit preparations, baked goods, candy and confections, and sauces and like products when a royal blue hue is required. Brilliant Blue FCF is a very stable colour. Synthetic colours are widely used because they are brighter, more uniform and encompass a wider range of hues than natural colors. Colour is an important characteristic of food that enhances the consumer appeal of the food and enjoyment of eating. Colour additives are used in foods to offset color loss that can occur due to exposure to light, air, temperature extremes, moisture and storage conditions. Colour additives enhance colours that occur naturally and correct natural variations in colour. Colour additives also provide a colorful identity to foods that might otherwise be virtually colourless.

b. Whether the proposed maximum use level is justified to achieve the intended technical need;

The proposed maximum levels of use are justified to achieve the intended effect.

c. Whether this level is safe; and

Brilliant Blue FCF has been reviewed by JECFA and deemed safe for its intended use. Consumption levels are below the JECFA ADI of 12.5 mg/kg body weight per day.

d. Provide a recommendation for whether these provisions should be endorsed by the 38th CCFAC for adoption at Step 8

IFAC recommends that the 38th CCFAC endorse the provisions for Brilliant Blue FCF at Step 8.

3. Please provide recommendations to resolve any inconsistencies between the proposed uses in the GSFA and Codex commodity standards.

IFAC is not aware of any inconsistencies between the proposed uses in the GSFA and Codex commodity standards

The International Food Additives Council (IFAC), an association representing companies who produce high quality substances used worldwide as food additives, holds official Non Governmental Organization (NGO) status before Codex Alimentarius and is an active participant in the Codex Committee on Food Additives and Contaminants (CCFAC).

Identity of the Food Additive

The 61st JECFA (2003) evaluated Polyvinyl Alcohol (PVA) and assigned PVA an Acceptable Daily Intake (ADI) of 50 mg/kg body weight per day.

The INS number for Polyvinyl Alcohol is 1203.

Functional Effect of the Food Additive

Polyvinyl Alcohol is used as a coating agent, surface finishing agent, polish finishing agent and film forming agent in food, food supplements and pharmaceutical products.

Proposed Use of the Food Additive

IFAC requests that the following adopted food additive provisions for Polyvinyl Alcohol remain in the GSFA.

Food Cat No.	Food Category	Max	Level	Step	Action
01.7	Dairy- based desserts (e.g. pudding, fruit or flavored yoghurt)	2,000	mg/kg	3	Maintain
05.1.4	Cocoa and chocolate products	15,000	mg/kg	3	Maintain
06.3	Breakfast cereals including rolled oats	5,000	mg/kg	3	Maintain
15.2	Processed nuts, including covered nuts and nut mixtures (with e.g., dried fruit)	15,000	mg/kg	3	Maintain

The eWorking Group on the General Standard for Food Additives has recommended in their report (CX/FAC 06/38/10) that the 38th CCFAC adopt a new maximum level of 20,000 mg/kg for PVA in food category 13.6 (food supplements). IFAC requests that the maximum level of PVA for food category (13.6) food supplements remain at 45,000 mg/kg as it appears in CL 34/2005-FAC.

Food Cat No.	Food Category	Max	Level	Step	Action
13.6	Food supplements	45,000	mg/kg	3	Maintain

IFAC requests that the following new food additive provisions for PVA be added to the GSFA.

Food Cat No.	Food Category	Max	Level	Action
05.2.1	Hard candy	21,000	mg/kg	**ADD**
05.2.2	Soft candy	21,000	mg/kg	**ADD**
05.3	Chewing gum	21,000	mg/kg	**ADD**

Justification for the use and technological need of the food additive

The migration of moisture is an ongoing problem in maintaining high quality standards for various foods. An important need exists to develop new and improved coatings to be used as barriers to prevent moisture migration.

Polyvinyl alcohol (PVA) is an ideal glazing agent, especially in applications where moisture barrier/protection properties are required. PVA is being evaluated in various foods where individual components of the food require protection from moisture, in order to retain the overall, satisfactory taste, texture and quality of the food. The foods include high moisture foods such as ice creams and frozen yoghurt desserts with moisture-sensitive inclusions such as nuts, cookie pieces, and toffee bits, or in foods incorporating low to intermediate moisture components including ready-to-eat savouries such as nut and fruit mixes, as well as cereals and cereal products such as ready-to-eat breakfast cereals containing dried fruits or nuts. An improved coating is needed to protect these moisture sensitive inclusions added to foods. In addition multi-component chocolate bars, confectionery products (hard and soft candy) and chewing gum are also being evaluated for PVA use in order to preserve the integrity of the moisture-sensitive constituents.

PVA is characterized by good film strength and adhesion qualities when used as a component of tablet coating formulations. PVA is currently commercially used on food supplement tablets. PVA protects the active ingredients from moisture, oxygen and other environmental components, while simultaneously masking their taste and odour. It allows for easy handling of finished product and facilitates ingestion and swallowing. The viscosity of PVA allows for the application of the PVA containing film coating agents to tablets, capsules and other forms to which film coatings are typically applied at relatively high solids contents.

Safe Use of the Food Additive

Use levels for the various food applications for PVA were developed assuming the appropriate application of the polymer in aqueous film coatings. Maximum estimates were derived for the use levels of PVA by selecting products within each food category with the greatest proportion of moisture sensitive components, estimating the surface area of those components, and assuming coating of the entire surface area with PVA.

JECFA assigned an ADI of 50 mg/kg bw per day for PVA.

The following example shows daily intake using a typical coating system containing 70% polyvinyl alcohol, applied to chewing gum with a 3% weight gain assuming a daily chewing gum consumption of 10 g.

10 g (chewing gum) x .03 (coating) = .3 g coating per day

.3 g coating x 1000 mg = 300 mg coating/day

300 mg coating x .70 (PVA) = 210 mg/PVA per day

JECFA ADI multiplied by a 60 kg body weight results in a daily amount of 3000 mg per day. The proposed use of 210 mg per day is significantly below the 3000 mg/day.

The following example shows daily intake using a typical coating system containing 70% polyvinyl alcohol, applied to hard or soft candy with a 3% weight gain assuming a daily combined consumption of 28.5 g of hard and soft candy.

28.5 g (hard & soft candy) x .03 (coating) = .855 g coating per day

.855 g coating x 1000 mg = 855 mg coating/day

855 mg coating x .70 (PVA) = 598.5 mg/PVA per day

JECFA ADI multiplied by a 60 kg body weight results in a daily amount of 3000 mg per day. The proposed use of 598.5 mg per day is significantly below the 3000 mg/day.

In regards to food supplement tablets, a maximum amount of 45,000 mg/kg is a 4.5% use level which equates to 45 mg per tablet (1000 mg tablet) and results in consumption of 450 mg per day when using an estimated daily intake of 10 tablets. The JECFA ADI results in 3000 mg per day using a typical human body weight of 60 kg. Therefore, the consumption of 450 mg per day for 10 tablets is well within the ADI assigned by JECFA.

Justification that the use does not mislead the consumer

Proper labeling, as required in national labeling regulations of the food, will ensure that the consumer is not misled.

IFU:

Food Additive	INS	Food Cat.No.	Food Category	Max. Level	Note	IFU Proposal	Comment
Diacetyltartaric and Fatty Acid Esters of Glycerol	472e	14.1.2.2	Vegetable juice	5000 mg/kg		Discontinue work	No technological need
		14.1.2.4	Concentrates for vegetable juices	5000 mg/kg		Discontinue work	No technological need
Sulphites	220-225 227-228 539	14.1.2.2	Vegetable juice	500 mg/kg	44	50 mg/kg Note 44, 122	Needed
		14.1.2.4	Concetrates for vegetable juices	70 mg/kg	44	50 mg/kg Note 44, 122, 127	Needed
		14.1.3.2	Vegetable nectar	50 mg/kg	44	50 mg/kg Note 44, 122	Needed
		14.1.3.4	Concentrates for vegetable nectars	70 mg/kg	44	50 mg/kg Note 44, 122, 127	Needed
Carotenes, vegetable	160aii	14.1.2.2	Vegetable juice	2000 mg/kg		Discontinue work	No technological need
		14.1.2.4	Concentrates for vegetable juices	2000 mg/kg		Discontinue work	No technological need
		14.1.3.2	Vegetable nectar	2000 mg/kg		Discontinue work	No technological need
		14.1.3.4	Concentrates for vegetable nectars	1000 mg/kg		Discontinue work	No technological need
Chlorophylls, Copper Complexes	141i, 141ii	14.1.3.2	Vegetable nectar	GMP		Discontinue work	No technological need
		14.1.3.4	Concentrates for vegetable nectars	GMP		Discontinue work	No technological need
Grape skin extract	163ii	14.1.3.2	Vegetable nectar	1500 mg/kg		Continue work	Needed
		14.1.3.4	Concentrates for vegetable nectars	1500 mg/kg		Continue work Note 127	Needed
Iron oxides	172i, ii, 172 iii	14.1.3.2	Vegetable nectar	GMP		Discontinue work	No technological need
		14.1.3.4	Concentrates for vegetable nectars	GMP		Discontinue work	No technological need
Riboflavins	101 I, ii	14.1.3.2	Vegetable nectar	300 mg/kg		Discontinue work	No technological need

Food Additive	INS	Food Cat.No.	Food Category	Max. Level	Note	IFU Proposal	Comment
		14.1.3.4	Concentrates for vegetable nectars	300 mg/kg		Discontinue work	No technological need
Caramel, Colour, class III	150 c	14.1.2.2	Vegetable juice	5000 mg/kg		Discontinue work	No technological need
		14.1.2.4	Concentrates for vegetable juices	5000 mg/kg		Discontinue work	No technological need
		14.1.3.2	Vegetable nectar	5000 mg/kg		Discontinue work	No technological need
		14.1.3.2	Vegetable nectar	GMP		Revoke	No technological need
		14.1.3.4	Concentrates for vegetable nectars	5000 mg/kg		Discontinue work	No technological need
		14.1.3.4	Concentrates for vegetable nectars	GMP		Revoke	No technological need
Caramel, Colour, class IV	150 d	14.1.2.2	Vegetable juice	5000 mg/kg		Discontinue work	No technological need
		14.1.2.4	Concentrates for vegetable juices	5000 mg/kg		Discontinue work	No technological need
		14.1.3.2	Vegetable nectar	5000 mg/kg		Discontinue work	No technological need
		14.1.3.2	Vegetable nectar	GMP		Revoke	No technological need
		14.1.3.4	Concentrates for vegetable nectars	5000 mg/kg		Discontinue work	No technological need
		14.1.3.4	Concentrates for vegetable nectars	GMP		Revoke	No technological need
Carotenoids	160ai,ii 160c, f	14.1.3.2	Vegetable nectar	100 mg/kg		Discontinue work	No technological need
		14.1.3.4	Concentrates for vegetable nectars	100 mg/kg		Discontinue work	No technological need
Ponceau 4R	124	14.1.2.2	Vegetable juice	300 mg/kg		Discontinue work	No technological need
Sunset Yellow FCF	110	14.1.2.2	Vegetable juice	GMP		Discontinue work	No technological need
Acesulfame potassium	950	14.1.2.2	Vegetable juice	600 mg/kg		Discontinue work	No technological need
		14.1.2.4	Concentrates for vegetable juices	3000 mg/kg	14	Discontinue work	No technological need
		14.1.3.2	Vegetable nectar			New entry at 350 mg/kg,	Needed
		14.1.3.4	Concentrates for vegetable nectars	2500 mg/kg	14	Continue work 350 mg/kg, replace Note 14 by 127	Needed
Aspartame	951	14.1.2.2	Vegetable juice	2000 mg/kg		Discontinue work	No technological need
		14.1.2.4	Concentrates for vegetable juices	2000 mg/kg		Discontinue work	No technological need
		14.1.3.2	Vegetable nectar	2000 mg/kg		600 mg/kg	Needed
		14.1.3.4	Concentrates for vegetable nectars	2000 mg/kg		600 mg/kg, Note 127	Needed
Ciyclamates	952	14.1.3.2	Vegetable nectar	400 mg/kg	17	Continue work	Needed
		14.1.3.4	Concentrates for vegetable nectars	400 mg/kg	17, 127	Continue work	Needed
Neotame	961	14.1.2.2	Vegetable juice	65 mg/kg		Discontinue work	No technological need
		14.1.2.2	Concentrates for vegetable juices	65 mg/kg		Discontinue work	No technological need
		14.1.3.2	Vegetable nectar	65 mg/kg		Continue work	Needed
		14.1.3.4	Concentrates for vegetable nectars	65 mg/kg		Continue work, Note 127	Needed

Food Additive	INS	Food Cat.No.	Food Category	Max. Level	Note	IFU Proposal	Comment
Saccharin	954	14.1.2.4	Concentrates for vegetable juices	300 mg/kg		Discontinue work	No technological need
		14.1.3.2	Vegetable nectar			New entry at 80 mg/kg,	Needed
		14.1.3.4	Concentrates for vegetable nectars	300 mg/kg		Continue work at 80 mg/kg Note 127	Needed
Sucralose	955	14.1.2.2	Vegetable juice	300 mg/kg		Discontinue work	No technological need
		14.1.2.2	Concentrates for vegetable juices	1500 mg/kg		Discontinue work	No technological need
		14.1.3.2	Vegetable nectar	300 mg/kg		Continue work	Needed
		14.1.3.4	Concentrates for vegetable nectars	1500 mg/kg		Continue work, at 300 mg/kg Note 127	Needed

ISA

I am writing to you on behalf of the International Sweeteners Association (ISA), representing manufacturers and industrial users of intense sweeteners, in relation to the above mentioned document. ISA has Non-Governmental Observer Status with Codex Alimentarius and would like to submit the following comments to document CL 2005/45-FAC in relation to Neotame (INS 961) and Aspartame-acesulfame salt (INS 962).

Neotame (INS 961)

We would like to submit the attached comments on Neotame (**Annex I**), in line with our response to the call for comments on the requested provisions for Neotame on the priority list of additives in the GSFA (CL 2005/45-FAC and CL34/2005-FAC).

Aspartame-acesulfame salt (INS 962)

Aspartame-acesulfame salt is an intense sweetener containing ionically bound aspartame and acesulfame. On a weight basis aspartame-acesulfame salt consists of 64% aspartame and 36% acesulfame. Aspartame-acesulfame salt is approximately 350 times sweeter than sugar.

JECFA concluded that the aspartame and acesulfame moieties in aspartame-acesulfame salt are covered by the acceptable daily intake (ADI) values previously established for aspartame and acesulfame-K (respectively 0-40 mg/kg body weight per day for aspartame and 0-15g/kg bodyweight per day for acesulfame-K).

The opinion of the Scientific Committee for Food (now European Food Safety Authority or EFSA) from 2000 offers a similar conclusion, namely that the aspartame and acesulfame moieties in aspartame-acesulfame salt are covered by the acceptable daily intake (ADI) values previously established for aspartame and acesulfame-K (respectively 0- 40 mg/kg body weight per day for aspartame and 0-9 mg/kg bodyweight per day for acesulfame-K).

ISA would like to propose a positive list approach for the inclusion of this substance in the table of the GSFA, under the heading ***"Aspartame-Acesulfame Salt (INS 962) Sweetener"***, based on the combined existing maximum use levels for Aspartame (INS 951) and Acesulfame-K (INS 950), as shown in the table attached **(Annex II, column B in bold font,)**. These proposed maximum use levels for Aspartame-Acesulfame Salt are the lower of the two equivalent maximum use levels for Aspartame and Acesulfame K, rounded down to an even figure. The relevant calculations explaining how this maximum level is justified are also shown in subsequent columns in the table, for information.

If the maximum use levels for Aspartame (INS 951) and Acesulfame-K (INS 950) were to be modified, then the proposed maximum use levels for Aspartame-Acesulfame Salt (INS 962) would have to be modified accordingly, to remain in line with the 'parent' sweeteners.

We would also suggest that the following footnote be included underneath the positive list for Aspartame-Acesulfame Salt (INS 962), Sweetener:

"Maximum dosage levels for aspartame-acesulfame salt are derived from the maximum dosage levels for its constituent parts aspartame (INS 951) and acesulfame-K (INS 950). The maximum dosage levels for aspartame (INS 951) and acesulfame-K (INS 950) shall not be exceeded by their use in combination with aspartame-acesulfame salt."

All of the requested provisions for Neotame in CL 2005/45-FAC and CL34/2005-FAC are supported for inclusion in the GSFA at step 5/8 with the qualifications and notes shown in the table below.

Unless otherwise specified, Neotame is used as an intense sweetener to replace the sweetness of sucrose and other carbohydrate sweeteners. Neotame has a sweetness potential of between 7.000 to 12,000 times that of sucrose, depending upon factors such as the level of sweetness to be achieved and the physical and chemical nature and components of the individual food matrix.

Neotame was evaluated at the 61st JECFA and allocated an ADI of 2 mg/kg bw/day. The meeting also concluded that if total dietary sugar was replaced by Neotame, the ADI would not be exceeded. This indicates that the uses of Neotame as proposed are very safe.

Food Cat No.	**Food Category**	**Max Level**	**Step**	**Comments**
01.2	fermented and renneted milk products (plain), excluding food category 01.1.2 (dairy based drinks)	65 mg/kg	3	Function: Sweetener Replacement of sugars, for making reduced and low joule/calorie sweetened yogurts and renneted milk products. This appears to be the only category in the GSFA system relevant to these foods.
01.4.1	pasteurized cream (plain)	GMP	3	Function: Sweetener Replacement of sugars, for making r low and reduced joule/calorie and no added sugar sweetened creams and related products. These appear to be the only categories in the GSFA system relevant to these foods. A level of GMP as indicated is appropriate and preferred for 1.4.1, 1.4.2, & 1.4.3 due to variation in ingoing ingredients. If a numerical value is required a level of 33 mg/kg is recommended.
01.4.2	sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)	GMP	3	
01.4.3	clotted cream (plain)	GMP	3	
01.4.4	cream analogues	33 mg/kg	3	
01.5.1	milk powder and cream powder (plain)	GMP	3	Function: Sweetener Replacement of sugars, for making low and reduced joule/calorie and no added sugar sweetened milk and cream powders and analogues. A level of GMP as indicated is appropriate and preferred for 1.5.1 due to variation in ingoing ingredients. If a numerical value is required a level of 65 mg/kg is recommended.
01.5.2	milk and cream powder analogues	65 mg/kg	3	
02.4	fat-based desserts excluding dairy-based dessert products of food category 01.7	100 mg/kg	3	Function: Sweetener - includes the uses of Neotame in reduced and low joule desserts which are non-dairy analogues of category 1.7
05.2	confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	1000 mg/kg	3	Function Sweetener The proposed level corresponds to that necessary for microsweets and breath freshening mints.
05.3	chewing gum	1000 mg/kg	3	Function: Sweetener/Flavour enhancer The sweetener is released progressively as the gum is chewed. The highest level proposed corresponds to that necessary for the extended chew-out of gum compared to other confectionery.

Food Cat No.	Food Category	Max Level	Step	Comments
11.6	table-top sweeteners, including those containing high-intensity sweeteners	GMP		Tabletop sweeteners are usually formulated for sweetness intensity per dose unit (i.e. 1 tablet, 1 sachet, 1 spoonful, xx drops) to be equivalent in sweetness to a dose unit of sucrose (i.e. 1 spoonful or 1 cube, respectively 4 to 6 grams of sucrose). Tabletop sweeteners are sold to the ultimate consumer, for use in conjunction with other foods (such as tea, coffee and desserts), to sweeten according to taste. The use of sweeteners in this application is therefore self-limiting. Setting a maximum numerical use level for Neotame, or for any other approved intense sweetener, in tabletop sweeteners is therefore not appropriate.
14.1.2	Fruit and Vegetable Juices	65 mg/kg	3	The requested categories in original Australian proposal ref CX/FAC 04/36/9 were for Fruit and Vegetable Juices and nectars (including concentrates). It appears that this has been transcribed in error only to the categories 14.1.2.2, 14.1.2.4, 14.1.3.2, 14.1.3.4. It is requested that permission for use of Neotame be listed in the GSFA at the higher level categories shown (i.e. 14.1.2 and 14.1.3) with the footnote that for concentrates the level is the level in the product as consumed. If CCFAC wishes to list Neotame in the lower level categories it should appear in all sub-categories of 14.1.2 and 14.1.3 at 65 mg/kg in the product as consumed.
14.1.3	Fruit and Vegetable Nectars	65 mg/kg	3	
~~14.1.2.2~~	~~vegetable juice~~	~~65 mg/kg~~	3	
~~14.1.2.4~~	~~concentrates for vegetable juice~~	~~65 mg/kg~~	3	
~~14.1.3.2~~	~~vegetable nectar~~	~~65 mg/kg~~	3	
~~14.1.3.4~~	~~concentrates for vegetable nectar~~	~~65 mg/kg~~	3	

Proposed Use levels for Aspartame-Acesulfame Salt(Twinsweet)

Food cat. no.	**Max level (mg/kg)**	*Limiting sweetener*	*Max level(mg/kg)*		*Max Twinsweet level based:*	
			APM	*ACK*	*on APM*	*on ACK*
1.1.2	**790**	*ACK*	*600*	*350*	*933*	*796*
1.2	**1130**	*ACK*	*2000*	*500*	*3109*	*1137*
1.3.2	**4540**	*ACK*	*6000*	*2000*	*9326*	*4546*
1.4.1	**2270**	*ACK*	*6000*	*1000*	*9326*	*2273*
1.4.2	**2270**	*ACK*	*6000*	*1000*	*9326*	*2273*
1.4.3	**2270**	*ACK*	*6000*	*1000*	*9326*	*2273*
1.4.4	**1550**	*APM*	*1000*	*1000*	*1554*	*2273*
1.5.1	**6820**	*ACK*	*5000*	*3000*	*7772*	*6820*
1.5.2	**3100**	*APM*	*2000*	*3000*	*3109*	*6820*
1.6.1	**1130**	*ACK*	*1000*	*500*	*1554*	*1137*
1.6.5	**790**	*ACK*	*1000*	*350*	*1554*	*796*
1.7	**1130**	*ACK*	*1000*	*500*	*1554*	*1137*
2.3	**1550**	*APM*	*1000*	*1000*	*1554*	*2273*
2.4	**1130**	*ACK*	*1000*	*500*	*1554*	*1137*
3.0	**1550**	*APM*	*1000*	*800*	*1554*	*1819*
4.1.2.1	**1130**	*ACK*	*2000*	*500*	*3109*	*1137*
4.1.2.2	**1130**	*ACK*	*3000*	*500*	*4663*	*1137*
4.1.2.3	**450**	*ACK*	*300*	*200*	*466*	*455*
4.1.2.4	**790**	*ACK*	*1000*	*350*	*1554*	*796*
4.1.2.5	**540**	*APM*	*350*	*1000*	*544*	*2273*

Food cat. no.	**Max level (mg/kg)**	*Limiting*	*Max level(mg/kg)*		*Max Twinsweet level based:*	
4.1.2.6	**2270**	*ACK*	*2000*	*1000*	*3109*	*2273*
4.1.2.7	**1130**	*ACK*	*2000*	*500*	*3109*	*1137*
4.1.2.8	**790**	*ACK*	*1000*	*350*	*1554*	*796*
4.1.2.9	**790**	*ACK*	*1000*	*350*	*1554*	*796*
4.1.2.10	**790**	*ACK*	*1000*	*350*	*1554*	*796*
4.1.2.11	**790**	*ACK*	*1000*	*350*	*1554*	*796*
4.1.2.12	**1130**	*ACK*	*2000*	*500*	*3109*	*1137*
4.2.2.3	**460**	*APM*	*300*	*1000*	*466*	*2273*
4.2.2.4	**790**	*ACK*	*1000*	*350*	*1554*	*796*
4.2.2.5	**4660**	*APM*	*3000*	*2500*	*4663*	*5683*
4.2.2.6	**790**	*ACK*	*1000*	*350*	*1554*	*796*
4.2.2.7	**2270**	*ACK*	*2500*	*1000*	*3886*	*2273*
5.1.1	**4660**	*APM*	*3000*	*2500*	*4663*	*5683*
5.1.2	**1130**	*ACK*	*1000*	*500*	*1554*	*1137*
5.1.3	**4540**	*ACK*	*3000*	*2000*	*4663*	*4546*
5.1.4	**2270**	*ACK*	*2500*	*1000*	*3886*	*2273*
5.1.5	**2270**	*ACK*	*3000*	*1000*	*4663*	*2273*
5.2.1	**5680**	*ACK*	*10000*	*2500*	*15543*	*5683*
5.2.2	**4540**	*ACK*	*3000*	*2000*	*4663*	*4546*
5.2.3	**2270**	*ACK*	*3000*	*1000*	*4663*	*2273*
5.3	**4540**	*ACK*	*10000*	*2000*	*15543*	*4546*
5.4	**1130**	*ACK*	*1000*	*500*	*1554*	*1137*
6.3	**1550**	*APM*	*1000*	*1200*	*1554*	*2728*
6.5	**790**	*ACK*	*1000*	*350*	*1554*	*796*
7.1	**2270**	*ACK*	*4000*	*1000*	*6217*	*2273*
7.2	**2270**	*ACK*	*1700*	*1000*	*2642*	*2273*
9.3	**450**	*ACK*	*300*	*200*	*466*	*455*
9.4	**450**	*ACK*	*300*	*200*	*466*	*455*
10.4	**790**	*ACK*	*1000*	*350*	*1554*	*796*
11.4	**2270**	*ACK*	*3000*	*1000*	*4663*	*2273*
11.6	**GMP**	*ACK*	*GMP*	*GMP*	*GMP*	*GMP*
12.2.2	**3100**	*ACK*	*2000*	*2000*	*3109*	*4546*
12.3	**4540**	*ACK*	*GMP*	*2000*	*GMP*	*4546*
12.4	**540**	*APM*	*350*	*350*	*544*	*796*
12.5	**250**	*ACK*	*600*	*110*	*933*	*250*
12.6.1	**770**	*APM*	*500*	*1000*	*777*	*2273*
12.6.2	**540**	*APM*	*350*	*500*	*544*	*1137*
12.6.3	**540**	*APM*	*350*	*1000*	*544*	*2273*
12.6.4	**540**	*APM*	*350*	*500*	*544*	*1137*
12.7	**1550**	*ACK*	*1000*	*1000*	*1554*	*2273*
13.1.3	**1020**	*ACK*	*800*	*450*	*1243*	*1023*
13.3	**1020**	*ACK*	*1000*	*450*	*1554*	*1023*
13.4	**1020**	*ACK*	*800*	*450*	*1243*	*1023*
13.5	**1130**	*ACK*	*1000*	*500*	*1554*	*1137*
13.6	**790**	*ACK*	*600*	*350*	*933*	*796*
14.1.2.2	**1360**	*ACK*	*2000*	*600*	*3109*	*1364*
14.1.2.4	**3100**	*ACK*	*2000*	*3000*	*3109*	*6820*

Food cat. no.	**Max level (mg/kg)**	*Limiting*	*Max level(mg/kg)*		*Max Twinsweet level based:*	
14.1.3.4	**3100**	*ACK*	*2000*	*2500*	*3109*	*5683*
14.1.4	**930**	*APM*	*600*	*600*	*933*	*1364*
14.1.5	**1360**	*ACK*	*5000*	*600*	*7772*	*1364*
14.2.1	**790**	*ACK*	*600*	*350*	*933*	*796*
14.2.2	**790**	*ACK*	*600*	*350*	*933*	*796*
14.2.4	**1080**	*ACK*	*700*	*500*	*1088*	*1137*
14.2.5	**1080**	*ACK*	*700*	*500*	*1088*	*1137*
14.2.6	**790**	*ACK*	*700*	*350*	*1088*	*796*
14.2.7	**930**	*APM*	*600*	*500*	*933*	*1137*
15.0	**770**	*ACK*	*500*	*1000*	*777*	*2273*

	Molecular weight
APK	294.31
ACK	201.24
Twinsweet	457.46

ISDI:

1. SUCRALOSE INS 955

Additive	***Product***	***Age Group***	***Maximum Level Permitted***
Sucralose INS 955	Formula for Special Medical Purposes Dietetic Foods Intended for Special Medical Purposes	Young Children and Adults > 1 year	400 mg/kg

Summary

Intense sweeteners are a vital ingredient in the formulation of Formulae for Special Medical Purposes and Dietetic Foods Intended for Special Medical Purposes (FSMP).

Technological limitations of individual sweeteners and the variety of presentations required for FSMP mean it is vitally important to have a range of permitted sweeteners, including sucralose, which may be used singly or in combination.

Safety of sucralose has been assessed by international regulatory authorities. Sucralose is approved for use at a maximum level of 400 mg/kg in Foods for Special Medical Purposes in the EU (2003/115/EC) and as a general food sweetener at GMP levels in the US (21CFR 172.831).

FSMP are formulated so that intakes of Sucralose remain within the ADI and below the proposed maximum level (400 mg/kg) which is also consistent with the maximum permitted level in the EU. Usage of FSMP is controlled by the recommended intake for a specific age and is administered under medical supervision unlike normal foods containing sweeteners.

Patient Acceptability

FSMP are flavoured and sweetened to improve palatability as these products are often taken orally in the dietary management of patients over long periods of time. The availability of a range of flavoured products will aid patient compliance with their dietary regime and therefore lead to better management of their medical condition. Sweet flavours are usually the flavours of choice both from a patient preference point of view and from the point of view of product type. This requires the addition of sweetness by using sucrose or other sweetening agents.

The limitations of sucrose or other bulk sweeteners/sugars as a source of sweetness in FSMP are listed below:

Providing the correct balance of calories to active nutrients is important in FSMP and this can often not be achieved if very high levels of sucrose are required for sweetening purposes.

Where the FSMP is a supplement to the diet, high levels of sucrose in that supplement may provide too many calories on daily basis in addition to normal food intake.

High levels of sucrose increase bulk, resulting in a high volume of feed required to obtain the active nutrients. This can be off-putting to patients and therefore can effect compliance.

The osmolality of FSMP is often high due to high levels of osmotically active components e.g. amino acids, peptides. The addition of sucrose or other sugars as sweetening agents would exacerbate this and may be problematic for patients who cannot tolerate high osmolality formulas, but still require a sweet flavoured palatable product.

For some diseases, carbohydrate free, flavoured formulas may be required, and carbohydrate based ingredients such as sucrose cannot be used at all.

Although there is a need to limit use of sweeteners in foods for young children in good health, restriction of their use in FSMP (used by a very small number of the population) may adversely effect compliance with dietary regimes. The artificial nature of these often very restrictive diets benefits greatly from the addition of flavours and sweeteners. In the interest of ensuring compliance to specialist diets there is a need for the use of a small number of sweeteners in FSMP for young children.

Natural sweetening agents are used whenever possible with sweeteners used only when absolutely necessary.

The inclusion of high levels of sugar in FSMP for young children is discouraged to avoid dental caries and particularly for patients on calorie restricted diets

Technological Issues

There are a number of technological issues which are paramount to product design which must be optimised in order to achieve palatable, stable and safe products. FSMP utilise many ingredients which are very different to normal foods. Unpalatable ingredients such as amino acids, peptides and minerals/trace elements are often used at high levels to achieve nutritionally complete formulations. The unpleasant taste of these nutrients is often enhanced in FSMP by the absence of natural taste masking ingredients, such as whole milk proteins and fat. The unpleasant tasting components of many FSMP mean that the maximum permitted level of an appropriate single sweetener may be insufficient to produce a palatable product.

FSMP can be presented in different forms e.g. sterile liquids, powders for reconstitution. Each of these presentations has specific technological requirements for intense sweeteners.

A further limitation is the individual properties or composition of certain sweeteners which can render them unsuitable for particular product applications or disease states.

A combination of permitted sweeteners is therefore often necessary in FSMP. The availability of a range of permitted intense sweeteners allows combination of the different properties of sweeteners and helps to overcome their individual limitations.

Sucralose has an intensity of between 450 and 600 times the sweetness of sucrose, which is comparable if not higher than other permitted sweeteners. Sucralose has a clean sweet taste, similar to sugar, with little or no after-taste. Sucralose is stable to high temperature processing (such as that required for sterile liquid FSMP) and a wide pH range. Sucralose has a nutritional composition which renders it suitable for all disease applications.

Safety of Sucralose

JECFA reviewed available scientific evidence on sucralose at its 37th Meeting in 1991 and allocated a full ADI of 0 to 15 mg/kg body wt (JECFA, 1991)[1]. Following the allocation of an ADI by JECFA, sucralose has been approved as a sweetener in a number of countries.

The European Scientific Committee on Food (SCF) has also reviewed the safety of sucralose and issued an opinion in 2000 (SCF 2000)2. The SCF was satisfied that the range of scientific studies available were sufficient for a full safety evaluation of sucralose. The SCF concluded that sucralose is acceptable as a sweetener for general food use and that an ADI of 0 to 15 mg/kg bw can be established based on application of a 100 fold safety factor to the overall NOEL of 1500 mg/kg bw/day. Based on the SCF opinion, Directive 2003/115/EC amended Directive 94/35/EC on sweeteners for use in foodstuffs to include provisions for use of sucralose (E955) in dietary foods for special medical purposes at a maximum permitted level of 400 mg/kg and as a general food sweetener at GMP levels in the US (21 CFR 172.831).

Use of Sucralose in FSMP is kept to a minimum and only used for technological reasons. FSMP are formulated so that daily intake of Sucralose remains within the ADI and below the maximum permitted level (400 mg/kg as consumed). In addition usage of FSMP is controlled by the recommended intake for a specific age and is administered under medical supervision.

Conclusions

Sucralose is used in foods for special dietary purposes in the EU and medical foods in the US. These products are used by a limited population under the care of a health professional. Availability of these sweetened palatable products aids patient compliance with an otherwise very restricted diet.

Safety of Sucralose has been reviewed by international regulatory authorities. Products are formulated so that maximum daily intakes of Sucralose are within the ADI. The availability of Sucralose to be used singly or in combination with other permitted sweeteners is important in overcoming technological issues present in the formulation of FSMP and for the development of a range of products to aid patient compliance.

References

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2. SCF (2000) Opinion of the Scientific Committee on Food on Sucralose http://europa.eu.int/comm/food/fs/sc/scf/out68_en.pdf

I. CAROTENES VEGETABLES INS 160A(I), 160A(II), 160E, 160F

Additive	*Product*	*Age Group*	*Maximum Level Permitted*
Carotenes Vegetable INS 160a (ii)	Formula for Special Medical Purposes	Young Children >1 year	30 mg/kg
Carotenes Vegetable INS 160a (i),	Dietetic Foods intended for Special Medical Purposes		QS
Carotenes Vegetable INS 160e	Dietetic Foods intended for Special Medical Purposes		50 mg/kg
Carotenoids (INS 160ai, 160aii, 160e, 160f	Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks.		Level proposed

FSMPs

Carotenes Vegetable INS 160a (ii)

Summary

Colours are a vital ingredient in the formulation of formulas for special medical purposes for infants over I year of age.

There is a technological need for permitted colours for used in these formulas for special medical purposes. These products utilise many ingredients which are very different to standard infant formulas or normal foods. Unpalatable ingredients such as amino acids, peptides and minerals/trace elements are often used at high levels to achieve nutritionally complete formulations. The uncoloured products when reconstituted have a grey cloudy appearance. As a result, formulas for special medical purposes are of very limited acceptability unless flavoured and coloured.

The safety of Carotenes Vegetable INS 160a (ii) has been evaluated by International Regulatory Authorities and is approved for use in a wide variety of food products. Carotenes, Vegetable (E160a) are classified for use at quantum satis levels in most foodstuffs in the EU (94/36/EC).

In the US, β-Carotene is permitted for colouring foods generally in amounts consistent with good manufacturing practice (21 CFR 73.95). The Joint FAO/WHO Expert Committee on Food additives (JECFA) assigned an ADI of acceptable to Carotenes, Vegetable provided the level of use does not exceed the level normally found in vegetables (41St JECFA ,1993)[1]. JECFA have assigned an ADI of 0-5 mg/kg bw/day to β-carotene (synthetic)[2].

FSMP are formulated so that intakes of Carotenes, Vegetable INS160 a (ii) remain within the ADI and below the proposed maximum level (30 mg/kg). Usage of FSMP is controlled by the recommended intake for a specific age and is administered under medical supervision unlike normal foods containing colours.

Patient Acceptability

Formulas for special medical purposes play a key role in the dietary management of a number of medical conditions in young children such as inborn errors of metabolism. Products are formulated and presented in such as way as to fulfil the daily nutritional requirements, or supplement restricted diets. In many cases, dietary management is commenced at an early age, and products are taken for a prolonged period of time.

Formulas for special medical purposes may contain a variety of nutrients including single amino acids, selected carbohydrate and fat sources vitamins and minerals. The unpleasant taste of these nutrients is often enhanced in these products by the absence of natural taste masking ingredients, such as whole milk proteins. The resulting products are generally of low acceptability unless coloured and flavoured. Unflavoured and uncoloured products are available on the market; these products have generally low acceptability, palatability and poor compliance especially with younger children.

The acceptability of the formulas is considered by physicians and paediatricians to be of a vital component of the treatment, particularly for younger age groups. Non-compliance by the children prescribed these diets will have a serious and detrimental effect on their clinical state which can manifest in problems with their growth and mental development.

While the addition of flavours to these foods can improve the taste it has been found in practice that colours are also required enhancing their acceptability particularly for children over 1 year of age. The uncoloured products when reconstituted have a grey cloudy appearance. In addition, parents, who have a crucial role in ensuring dietary compliance of young children, find it very difficult to encourage their child to take such unappealing products.

The joint FAO/WHO Expert Committee on Food Additives recognised that colour has an effect on food choices and acceptability (3). This is supported by a report by the Institute of Food Technologists(4) which quotes studies that show that food is not perceived as tasting as it should when it is not coloured appropriately. Studies by Rolls et al (5) have also shown that flavour alone without colour and texture does not influence consumption of foods. Colour plays a key role in food choice by influencing taste thresholds, sweetness perception, food preference, pleasantness and acceptability (6).

Various researchers have shown that colour serves as a cue for flavour expectations as well as for flavour identification (7, 8, 9). It has also been shown that colour in food is related to the strong appetite appeal associated with specific foods and that pre-school children prefer yellow and orange coloured foods (7).

A study of 120 children aged between 5 and 9 years investigated the effects of colour on children's food choices. It was found that children preferred foods that were coloured red, green, orange and yellow, in that order. Colour was verified in the study to have potential separate and interactive effects with flavour association (10).

As a result, in addition to being nutritionally sound, it is vital that formulas for special medical purposes for young children have acceptable appearance and taste to aid dietary compliance.

Acceptability trials on a number of formulas for special medical purposes with and without flavours and colours were carried out by clinicians and dieticians at a number of hospitals in the United Kingdom which specialise in the treatment of metabolic disorders.

Patients were first given products which had no added flavouring or colouring. Acceptance and tolerance over a short period of time was recorded by the consultant clinician or dietician. The patients were transferred to identical products to which flavouring and colouring had been added. A summary of the trial is given in the table below.

Acceptance Trials on Coloured, Flavoured and Uncoloured, Unflavoured Products

		% TOLERANCE	
Product function/indication	Number of patients	Unflavoured Uncoloured	Flavoured Coloured
Crohn's disease Product A	19	11	79
Crohn's disease Product B	3	0	100
Liver failure	6	0	100
Inborn Errors (PKU)	5	0	100

A questionnaire accompanied the products tested and this highlighted the demand not only for flavoured products but also for a selection of colours and flavours. This was considered particularly important for conditions where compliance to a liquid elemental diet is often necessary for prolonged periods.

A year long clinical evaluation of a coloured, flavoured PKU product in 14 children aged between 2 and 9 years showed that the acceptance of the product was excellent. The children accepted the product extremely well and any emotional difficulties arising from their refusal and unwillingness to take their previous uncoloured and unflavoured products were quickly overcome.

Psychological reports were made on children with PKU in France who began taking a coloured, flavoured PKU product. The children ranged in age from 2 years 11 months to 6 years 4 months and had experienced difficulties in taking uncoloured, unflavoured products and complying with their diet. All the children found the coloured, flavoured product to be more acceptable and perceived the product to be like orange juice. The fact that the diet was taken more easily by the children was a great relief to the parents.

Taste tests in the laboratory have shown a very much lower acceptance of products containing only added flavouring and no added colouring. It is a well accepted principle of sensory science that most of the perception of a flavour is derived from the associated colour (4, 5).

Safety and Intake of Carotenes Vegetable INS 160a (ii) at the Proposed Maximum Level

Carotenes, Vegetable have no ADI other than not to exceed the level present naturally in vegetables1. JECFA have assigned an ADI of 0-5 mg/kg bw/day to β-carotene (synthetic) 2. The European SCF have reviewed safety of intakes of β-carotene from all dietary sources including food additive sources and concluded that there are no indications that the level of intake from food additives (1-2 mg/day) is harmful in the context of the overall dietary intake of ß-carotene from carotenoids-rich foods.11.

Use of carotenes vegetable E160a (ii) is kept to a minimum in formulas for special medical purposes for use in young children and only used for technological reasons. Products are formulated so that intakes of carotenes vegetable E160 a(ii) remains within the ADI and maximum product levels are below the proposed maximum of 30 mg/kg (as consumed).

Formulas for special medical purposes are taken in prescribed amounts appropriate for the particular age group and under medical supervision, unlike normal foods containing mixed carotenes E160 a (ii) which are targeted at young children and may be consumed in an unrestricted manner. There is no scientific evidence to suggest that children consuming formulas for special medical purposes are more sensitive to E160a (ii) compared with healthy children. The ability to add E160 a (ii) to formulas for special medical purposes means children suffering from medical conditions are not unnecessarily disadvantaged with regard to having an acceptable palatable product which aids compliance with an already restricted diet.

Conclusions

ISDI accepts that there is a need to restrict colours in foods for young children. However, formulas for special medical purposes are a vital part of the dietary management of a number of medical conditions.

The nature of ingredients used to formulate these products results in poor patient acceptability without the addition of colours and flavours. The ability to use a limited number of colours is a key factor in dietary compliance of patients.

Safety of Carotenes, Vegetable E160a (ii) has been reviewed by international regulatory authorities. Products are formulated so that intakes of E160a (ii) remains within the assigned ADI.

References

1. Carotenes, Vegetable; JECFA Food Additive Specifications Database. Prepared By the 51st JECFA (1998), published in FNP52 ADD6 (1998)
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9. Hyman, A. 1983. The influence of colour on the taste perception carbonated water preparations.Bulletin of the Psychonomic Society 21 (2), 145-148.
10. Walsh, L.M., Toma, R.B., Tuveson, R.V. and Sondhi, L. 1990.Colour Preference and food choice among children. J. Psychol. 124 (6), 645-653.
11. Opinion of the Scientific Committee on Food on the Safety of Use of Beta Carotene from all Dietary Sources. (Opinion adopted by the SCF on 7 September 2000). European Commission SCF/CS/ADD/COL/159 Final

Carotenoids E160a (i)

Technological Justification of the use of carotenoids in clinical nutrition

A lot of patients, both in hospitals and at home, suffer from disease related malnutrition. To help these people gain weight the clinical nutrition industry has developed a wide portfolio of tube feeds and sip feeds. Some of these products need to be used as a supplement, others as a sole source of nutrition.

All products have to meet very strict requirements with respect to safety, as the target group for these products are vulnerable people (often sick and/or elderly). To be sure about the microbiological safety of the products a sterilisation treatment is necessary.

This sterilisation however, leads to a possibly somewhat unappealing appearance of the products due to Maillard reactions that occur during the heat treatment.

To reach an optimal result in patients with clinical nutrition it is important that the patients take the required amount of product. This means that product compliance is very important, which can be seen as compliance in both appearance and taste.

An attractive appearance of a product is therefore of crucial importance. With a specific combination of carotenoids the colour of the products is improved, giving them an attractive, slightly yellow appearance, which is essential for compliance.

Besides the very good colour there are several other advantages to the use of carotenoids:

- They are natural colourings. Carotenoids are present in all kinds of fruits and vegetables e.g. tomato, carrot and paprika (see also reference 1). Also carotenoids naturally occur in human tissues.
- They do not contain allergens.
- They are stable in a broad pH range.

Because of the above-mentioned properties carotenoids are ideal to be used in a wide variety of products that are used by a wide variety of people. Therefore they are extremely suitable for clinical nutrition products.

The specific mixture of carotenoids consists of carotenoids that are originating from marigold flowers, fruits of the oil palm and tomatoes and is partly described by E160ai (mixed carotenes).

The addition of E160ai is fully in line with the European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs (1).

An ideal colour is reached with a dosage of E160ai between 1.3 and 6.6 mg/kg. The EC-directive states that E160ai can be used at ‘quantum satis’ levels in complete formulae and nutritional supplements for use under medical supervision.

Patient Acceptability

No ADI has been set for E160ai. Patients that receive clinical nutrition as a sole source of nutrition will have the maximum intake of E160ai.

As these patients rarely require or receive more than 2000-2500 kcal of enteral formula, maximum intakes of E160ai will not exceed 3.3 mg in total per day. A typical dietary intake of carotenes in a normal diet is 4 mg in total per day.

References

1. The European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs.
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Carotenoids E160e

Technological Justification of the use of beta-apo-8-carotenal (E160e)

Industry uses the colouring beta-apo-8-carotenal (E160e) in clinical nutrition products (sipfeeds) with several flavour varieties to facilitate compliance with the diet. These sipfeeds can be used as a sole source of nutrition by people with disease related malnutrition.

Most sip feeds for these patients contain sweet/fruity flavours. To offer a better variety of flavours industry also introduced savoury flavours, tomato being one of them.

To reach an optimal result in patients with clinical nutrition it is important that the patients take the required amount of product. Therefore it is extremely important that we offer consumers choice.

Therefore industry offers a wide variety of flavours and with an attractive appearance. To reach this attractive appearance for the tomato variety an orange-red colour was needed. Requirements to this colouring were:

- Good stability in the specific recipe
- Attractive orange-red colour
- Should meet legislation on colourings
- Should meet our requirements with respect to contaminants and residues

Several colourings were tested but only beta-apo-8-carotenal met all requirements mentioned above. It is a natural colouring that is present in a lot of plants.

For an optimal colour a concentration of 45.6 mg beta-apo-8-carotenal/kg end product is used. This is in line with the European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs that mentions a maximum addition of 50 mg/kg.

Patient Acceptability

The Acceptable Daily Intake of this colouring is 2.5 mg/kg body weight resulting in a maximum daily dose of 175 mg for an average person (70 kg body weight).

Sipfeeds can be used as a sole source of nutrition. The intake will then usually be 1.10 kg of end product and maximally 1.83 kg of end product (at an intake of 2500 kcal per day), resulting in an intake of 50 to 83 mg of beta-apo-8-carotenal per day.

This means that the Acceptable Daily Intake of 175 mg per day will not be exceeded.

Sports Foods

Justification for use

ISDI would also like to support the ongoing work for Carotenoids (INS 160ai, 160aii, 160e, 160f or use in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks.

ISDI particularly wishes to demonstrate the need for the use of these colours in sport and electrolyte drinks.

These drinks are designed for use by individuals who are in a specific physiological condition, due to the expenditure of intense muscular effort.

A key feature of sport and electrolyte drinks is that they must appeal to the intended consumer.

The visual appeal of any beverage is an important aspect of its appeal and organoleptic properties, and the ability to add a range of colours is an important determinant of consumer preference and consumption.

Safety Issues

ISDI supports the levels proposed for the use of Carotenoids (INS 160ai, 160aii, 160e, 160f for Food Catgeory14.1.4.

As noted in the request for comments, this colour has been reviewed by JECFA and ADI set for their safe use.

Additionally, this colour has been approved for use throughout Europe for a range of products, and those listed in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks, are not excluded from using colours in Directive 94.36.EC.

II. SACCHARIN INS 954

Additive	*Product*	*Age Group*	*Maximum Level Permitted*
Saccharin E954 (including sodium and potassium salts)	Formula for Special Medical Purposes Dietetic Foods Intended for Special Medical Purposes	Young Children and Adults >1 year	200 mg/kg

Summary

Intense sweeteners are a vital ingredient in the formulation of Formula for Special Medical Purposes and Dietetic Foods Intended for Special Medical Purposes (FSMP).

Technological limitations of individual sweeteners and the variety of presentations required for FSMP mean it is vitally important to have a range of permitted sweeteners, including saccharin and its salts, which may be used individually or in combination

Safety of Saccharin and its salts has been assessed by International regulatory authorities. Saccharin is approved for use in complete formula and nutritional supplements for use under medical supervision in the EU (94/35/EC) and in medical foods in the US (21 CFR 180.37).

FSMP are formulated so that intakes of Saccharin and its salts remain within the ADI and below the proposed maximum levels. Usage of FSMP is controlled by the recommended intake for a specific age and is administered under medical supervision unlike normal foods containing sweeteners.

Patient Acceptability

FSMP are flavoured and sweetened to improve palatability as these products are often taken orally in the dietary management of patients over long periods of time. The availability of a range of flavoured products will aid patient compliance with their dietary regime and therefore lead to better management of their medical condition. Sweet flavours are usually the flavours of choice both from a patient preference point of view and from the point of view of product type. This requires the addition of **sweetness** by using sucrose or other sweetening agents.

The limitations of sucrose or other bulk sweeteners/sugars as a source of sweetness in FSMP are listed below:

Providing the correct balance of calories to active nutrients is important in FSMP and this can often not be achieved if very high levels of sucrose are required for sweetening purposes.

Where the FSMP is a supplement to the diet, high levels of sucrose in that supplement may provide too many calories on daily basis in addition to normal food intake.

High levels of sucrose increase bulk, resulting in a high volume of feed required to obtain the active nutrients. This can be off-putting to patients and therefore can effect compliance.

The osmolality of FSMP is often high due to high levels of osmotically active components e.g. amino acids, peptides. The addition of sucrose or other sugars as sweetening agents would exacerbate this and may be problematic for patients who cannot tolerate high osmolality formulas, but still require a sweet flavoured palatable product.

For some diseases, carbohydrate free, flavoured formulas may be required, and carbohydrate based ingredients such as sucrose cannot be used at all.

Although there is a need to limit use of sweeteners in foods for young children with good health, restriction of their use in FSMP (used by a very small number of the population) may adversely effect compliance with dietary regimes. The artificial nature of these often very restrictive diets benefits greatly from the addition of flavours and sweeteners. In the interest of ensuring compliance to specialist diets there is a need for the use of a small number of sweeteners in FSMP for young children.

Natural sweetening agents are used whenever possible with sweeteners used only whenever absolutely necessary.

The inclusion of high levels of sugar in FSMP for young children is discouraged to avoid dental caries and particularly for patients on calorie restricted diets

Technological Issues

There are a number of technological issues which are paramount to product design which must be optimised in order to achieve palatable, stable and safe products. FSMP utilise many ingredients which are very different to normal foods. Unpalatable ingredients such as amino acids, peptides and minerals/trace elements are often used at high levels to achieve nutritionally complete formulations. The unpleasant taste of these nutrients is often enhanced in FSMP by the absence of natural taste masking ingredients, such as whole milk proteins and fat. The unpleasant tasting components of many FSMP mean that the maximum permitted level of an appropriate single sweetener may be insufficient to produce a palatable product.

FSMP can be presented in different forms e.g. sterile liquids, powders for reconstitution. Each of these presentations has specific technological requirements for intense sweeteners.

A further limitation is the individual properties or composition of certain sweeteners which can render them unsuitable for particular product applications or disease states.

A combination of permitted sweeteners is therefore often necessary in FSMP. The availability of a range of permitted intense sweeteners allows combination of the different properties of sweeteners and helps to overcome their individual limitations. Saccharin is approximately 450 times sweeter than sugar. It is stable at a wide range of pH and temperatures and acts synergistically with other intense sweeteners.

Safety of Saccharin

Saccharin and its sodium, potassium and calcium salts have been evaluated by the EU Scientific Committee on Foods (SCF). The SCF have assigned a full ADI of 5mg/kg BW to sodium saccharin and an ADI of 3.8 mg/kg for the free acid[1]. EU Directive 94/35/EC permits use of saccharin and its sodium, potassium and calcium salts in complete formula and nutritional supplements for use under medical supervision to a maximum level of 200 mg/kg product as consumed. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) have also evaluated safety of saccharin at its 41st meeting and assigned a group ADI of 5 mg/kg bw/d to saccharin and its sodium, potassium and calcium salts[2, 3].

Sodium saccharin has been used in foods for special medical purposes for many years with no specific safety concerns.

Use of Sodium saccharin in FSMP is kept to a minimum and only used for technological reasons. FSMP are formulated so that daily intake of sodium saccharin remains within the ADI and below the maximum permitted levels. In addition usage of FSMP is controlled by the recommended intake for a specific age and these products are administered under medical supervision.

Conclusions

Sodium saccharin is currently used in a number of foods for special medical purposes in the US and medical foods in the US. These products are used by a limited population under the care of a health professional. Availability of these sweetened palatable products aids patient compliance with an otherwise restricted diet.

Products are formulated so that maximum acceptable daily intakes of saccharin and its salts are within the ADI assigned by JECFA. The availability of saccharin and its salts for use singly or in combination with other permitted sweeteners is important in overcoming technological issues present in the formulation of foods for special medical purposes and for developing a range of products which aid patient compliance.

References

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III. ASPARTAME INS 951

Additive	*Product*	*Age Group*	*Maximum Level Permitted*
Aspartame E951	Formula for Special Medical Purposes	Young Children > 1 year	800 mg/Kg
	Dietetic Foods Intended for Special Medical Purposes (excluding 13.1)	Adults	1000 mg/kg
	Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks.		Level proposed

FSMPs

Summary

Intense sweeteners are a vital ingredient in the formulation of Formulae for Special Medical Purposes and Dietetic Foods Intended for Special Medical Purposes (FSMP).

Technological limitations of individual sweeteners and the variety of presentations required for FSMP mean it is vitally important to have a range of permitted sweeteners, including Aspartame, which may be used individually or in combination.

Safety of Aspartame has been assessed by International regulatory authorities, Aspartame is approved for use in a range of foods in the EU (94/35/EC) and in the US (21 CFR172.804).

FSMP are formulated so that intakes of Aspartame remain within the ADI and below the proposed maximum levels. Usage of FSMP is controlled by the recommended intake for a specific age and these products are administered under medical supervision unlike normal foods containing sweeteners.

Patient Acceptability

FSMP are flavoured and sweetened to improve palatability as these products are often taken orally in the dietary management of patients over long periods of time. The availability of a range of flavoured products will aid patient compliance with their dietary regime and therefore lead to better management of their medical condition. Sweet flavours are usually the flavours of choice both from a patient preference point of view and from the point of view of product type. This requires the addition of sweetness by using sucrose or other sweetening agents.

The limitations of sucrose or other bulk sweeteners/sugars as a source of sweetness in FSMP are listed below:

Providing the correct balance of calories to active nutrients is important in FSMP and this can often not be achieved if very high levels of sucrose are required for sweetening purposes.

Where the FSMP is a supplement to the diet, high levels of sucrose in that supplement may provide too many calories on daily basis in addition to normal food intake.

High levels of sucrose increase bulk, resulting in a high volume of feed required to obtain the active nutrients. This can be off-putting to patients and therefore can effect compliance.

The osmolality of FSMP is often high due to high levels of osmotically active components e.g. amino acids, peptides. The addition of sucrose or other sugars as sweetening agents would exacerbate this and may be problematic for patients who cannot tolerate high osmolality formulas, but still require a sweet flavoured palatable product.

For some diseases, carbohydrate free, flavoured formulas may be required, and carbohydrate based ingredients such as sucrose cannot be used at all.

Although there is a need to limit use of sweeteners in foods for young children with good health, restriction of their use in FSMP (used by a very small number of the population) may adversely effect compliance with dietary regimes. The artificial nature of these often very restrictive diets benefits greatly from the addition of flavours and sweeteners. In the interest of ensuring compliance to specialist diets there is a need for the use of a small number of sweeteners in FSMP for young children.

Natural sweetening agents are used whenever possible with sweeteners used only whenever absolutely necessary.

The inclusion of high levels of sugar in FSMP for young children is discouraged to avoid dental caries and particularly for patients on calorie restricted diets

Technological Issues

There are a number of technological issues which are paramount to product design which must be optimised in order to achieve palatable, stable and safe products. FSMP utilise many ingredients which are very different to normal foods. Unpalatable ingredients such as amino acids, peptides and minerals/trace elements are often used at high levels to achieve nutritionally complete formulations. The unpleasant taste of these nutrients is often enhanced in FSMP by the absence of natural taste masking ingredients, such as whole milk proteins and fat. The unpleasant tasting components of many FSMP mean that the maximum permitted level of an appropriate single sweetener may be insufficient to produce a palatable product.

FSMP can be presented in different forms e.g. sterile liquids, powders for reconstitution. Each of these presentations has specific technological requirements for intense sweeteners.

A further limitation is the individual properties or composition of certain sweeteners which can render them unsuitable for particular product applications or disease states.

A combination of permitted sweeteners is therefore often necessary in FSMP. The availability of a range of permitted intense sweeteners allows combination of the different properties of sweeteners and helps to overcome their individual limitations.

The use of sweeteners in FSMP is kept to a minimum and only used for technological reasons. Also unlike other foods containing sweeteners which are consumed by young children, FSMP are consumed under medical supervision and intake is limited to the recommend intake for a specific age group.

Aspartame is the methyl ester of a dipeptide composed of the amino acids L-aspartic acid and L-phenylalanine. Aspartame has sweetness potency approximately 200 times that of sugar. Aspartame also has a clear sweet taste similar to sugar with little after-taste. Aspartame is however unstable in liquid formulation and cannot be used in FSMP which must be phenylalanine free such as low protein or protein supplements used in the dietary management of phenylketonuria.

Safety of Aspartame

Aspartame is used in a wide range of food products in many countries around the world. The EU Scientific Committee on Food (SCF) have evaluated safety of aspartame on a number of occasions (1985, 1989, 1997, 2002)[1]. Aspartame has also been evaluated by the Joint FAO/WHO Expert Committee on Food Additives[2] and the US FDA.[3]

JECFA and the SCF have assigned an ADI of 40mg/kg bw/day to aspartame. Based on published intakes levels in European countries, the SCF concluded that intakes of Aspartame in high level consumers, including adults, children and diabetics range up to 10mg/kg bw/day and are thus unlikely to exceed the ADI (40mg/kg bw/day). The SCF also concluded that data presented in a report suggesting a link between aspartame and an increase in the incidence of brain tumours in the US did not support an increase in the incidence of brain tumours[4]. This data was also evaluated by the FDA[5] and the UK Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment[6,7], both concluded that the data and not support on association between aspartame and an increase in the incidence of brain tumours.

Aspartame has been approved for use in the EU in Complete Formulae and Nutritional Supplements for use under medical supervision (94/35/EC) at a maximum level of 1000 mg/kg and in the US in medical foods (21 CFR 172.804) at GMP level.

Use of Aspartame in FSMP is kept to a minimum and only used for technological reasons. FSMP are formulated so that daily intake of Aspartame remains within the ADI and below the maximum permitted levels. In addition intake of FSMP is controlled by the recommended intake for a specific age group and these products are administered under medical supervision.

Conclusions

Aspartame is currently used in a number of foods for special dietary purposes in the EU and medical foods in the US. These products are used by a limited population under the care of a health professional. Availability of these sweetened palatable products aids patient compliance with an otherwise very restricted diet.

Safety of Aspartame has been reviewed by international regulatory authorities. Products are formulated so that maximum daily intakes of Aspartame are within the ADI assigned by JECFA. The availability of Aspartame to be used singly or in combination with other permitted sweeteners is important in overcoming technological issues present in the formulation of FSMP and for the development of a range of range of products to aid patient compliance.

References

1. Opinion of the Scientific Committee on Food: Update on the Safety of Aspartame SCF/CS/ADD/EDUL/222 Final 10 December 2002
2. Aspartame: Evaluation of Certain Food Additives Joint FAO/WHO Expert Committee on Food Additives. 1980 Technical Report Series 653 WHO Health Organisation Geneva
3. FDA (1984) Food Additives Permitted for Direct Addition to Food for Human Consumption: Aspartame. Food and Drug Administration. Federal Register, 46FR38285
4. Olney JW, Farber NB, Spitznagel E & Robins LN (1996) Increasing Brain Tumor Rates: Is there a Link to Aspartame? J Neuropathol Exp Neurol 55 115-1123
5. FDA (1996). Food and Drug Administration Statement on Aspartame. Talk Paper T96-74 November 18, 1996
6. COT 1996 Aspartame. Committee on Carcinogenicity of Chemical in Food, Consumer Products and the Environment. Annual Report of the Committees on Toxicity, Mutagenicity and Carcinogenicity. The Stationery Office London pp 56-57

Sports Foods

Justification for Use

ISDI would like to support the ongoing work to include Aspartame (INS 951) for use in Food Category 14.1.4 water-based flavoured drinks, including “sport”, “energy” or “electrolyte” drinks and particulate drinks. Discussions on this sweetener are at step 6 in the procedure.

ISDI particularly wishes to demonstrate the need for the use of intense sweeteners in sport and electrolyte drinks. These drinks are designed for use by individuals who are in a specific physiological condition, due to the expenditure of intense muscular effort.

As a result, such individuals require the provision of drinks which supply fluid, sodium (and other electrolytes) and carbohydrate, in carefully controlled levels to maximise fluid delivery and rehydration and, for beverages supplying appropriate levels of carbohydrate, a source of energy for the working muscles.

Drinking sport and electrolyte drinks has been demonstrated to improve sporting performance.

A key feature of sport and electrolyte drinks is that they must be palatable for the intended consumer.

Most soft drinks have a carbohydrate content of 8 to 12%, whereas for physiological functionality sports and electrolyte drinks have a lower carbohydrate level, generally between 1.5% and 8%.

Sports and electrolyte drinks are also often formulated with less sweet carbohydrate sources, such as glucose polymers and maltodextrins to help control the osmolality of the drinks.

The inclusion of intense sweeteners as part of the formulation of sport and electrolyte drinks is important to give the flexibility required to produce a palatable drink using these carefully controlled amounts of carbohydrate (amount and type), electrolytes and product osmolality.

ISDI therefore requests that provisions for the use of Aspartame (INS 951) for Food Category 14.1.4 water-based flavoured drinks, including “sport”, “energy” or “electrolyte” drinks and particulate drinks is retained.

Safety Issues

ISDI supports the levels proposed for the use of Aspartame (INS 951) for Food Category 14.1.4.

As noted in the request for comments, Aspartame (INS 951) has been reviewed by JECFA and ADI set for it safe use.

Additionally, Aspartame (INS 951) has been approved for use throughout Europe for many categories of non-alcoholic drinks.

Although specific levels for use of these sweeteners in sport and electrolyte drinks have not been set in Europe, the European Commission has agreed to address this in the forthcoming directive on foods intended to meet the expenditure of intense muscular effort, especially for sports people (Council of the European Union, Interinstitutional file: 2004/0237(COD)).

IV. CARAMEL COLOUR CLASS III INS 150C

Additive	*Product*	*Age Group*	*Maximum Level Permitted*
Caramel Colour Class III E150c	Dietetic Foods Intended for Special Medical Purposes (excluding category 13.1) Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks.	Young Children and Adults >1 year	GMP, but proposed level of 20 mg/kg would be acceptable GMP

FSMPs

Summary

Colours are a vital ingredient in the formulation of Dietetic Foods for Special Medical Purposes.

There is a technological need for permitted colours for used in Dietetic Foods for Special Medical Purposes. These products utilise many ingredients which are very different to standard foods. Unpalatable ingredients such as amino acids, peptides and minerals/trace elements are often used at high levels to achieve nutritionally complete formulations. As a result, these foods are of very limited acceptability unless flavoured and coloured.

Safety of E150(c) has been reviewed by international regulatory authorities. JECFA have assigned an ADI of 200 mg/kg bw/d to Caramel Colour Class III[1]. Caramel Colour Class III is permitted for use in a wide variety of foods in the (EU 94/36/EC) [2] at quantum satis level and is GRAS for use in food products in the US (21 CFR 73.85)

E150 (c) is currently used in foods for special medical purposes, with no particular safety concerns.

References

1. Caramel Colours; Joint FAO/WHO Food Additives Database http://apps3.fao.org/jecfa/additive_specs/docs/8/additive-0800.htm
2. European Parliament and Council Directive 94/36/EC on Colours for Sue in Foodstuffs; Official Journal of the European Communities No L237 10.9.94 p13-29

Sports Foods

Justification for use

ISDI would also like to support the ongoing work for its use in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks.

With respect to Caramel Colour, Class III (INS 150c), ISDI supports the current position and the use of these colours as adopted at GMP.

ISDI particularly wishes to demonstrate the need for the use of these colours in sport and electrolyte drinks.

These drinks are designed for use by individuals who are in a specific physiological condition, due to the expenditure of intense muscular effort.

A key feature of sport and electrolyte drinks is that they must appeal to the intended consumer.

The visual appeal of any beverage is an important aspect of its appeal and organoleptic properties, and the ability to add a range of colours is an important determinant of consumer preference and consumption.

Safety Issues

ISDI supports the current position and the use of these colours as adopted at GMP for the use of Caramel Colour, Class III (INS 150c).

As noted in the request for comments, this colour has been reviewed by JECFA and ADI set for their safe use.

Additionally, this colour has been approved for use throughout Europe for a range of products, and those listed in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks, are not excluded from using colours in Directive 94.36.EC.

V. CARAMEL COLOUR CLASS IV INS 150D

Additive	*Product*	*Age Group*	*Maximum Level Permitted*
Caramel Colour Class IV E150d	Dietetic Foods Intended for Special Medical Purposes (excluding category 13.1) Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks.	Young Children and Adults >1 year	GMP, but proposed level of 20 mg/kg would be acceptable GMP

FSMPs

Justification for Use

Colours are a vital ingredient in the formulation of Dietetic Foods for Special Medical Purposes including products for young children.

There is a technological need for permitted colours for use in these products as these products utilise many ingredients which are very different to normal foods. Unpalatable ingredients such as amino acids, peptides and minerals/trace elements are often used at high levels to achieve nutritionally complete formulations. The uncoloured products are of very limited acceptability unless flavoured and coloured. Patients frequently consume these products for long periods as a supplement to a very restricted diet, the availability of a restricted range of permitted colours; including Carmel Colour Class IV E150 (d) is important for developing a range of products to aid compliance.

Safety of Caramel Colour Class IV E150 (d) has been evaluated by international regulatory authorities. An ADI of 0-200 mg/kg BW (0-150 mg/kg BW on solids basis) was established at the 29th JECFA (1985) for Caramel Colour Class IV[1]. E150 (d) is permitted at a quantum satis level in a wide variety of foods in the EU (94/36/EC)[2] and is GRAS for use in food products in the US (21 CFR 73.85).

Caramel Colour Class IV E150 (d) is currently used in Foods for Special Medical Purposes in the EU and in medical foods in the US. Products are formulated so that daily intakes of Caramel Colour Class IV from these products are within the ADI.

References

1. Caramel Colours; Joint FAO/WHO Food Additives Database http://apps3.fao.org/jecfa/additive_specs/docs/8/additive-0800.htm
2. European Parliament and Council Directive 94/36/EC on Colours for Use in Foodstuffs;Official Journal of the European Communities No L237 10.9.94 p13-29

Sports Foods

Justification for use

ISDI would also like to support the ongoing work for the use of Caramel Colour, Class IV (INS 150D) in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks.

With respect to Caramel Colour, Class IV (INS 150D), ISDI supports the current position and the use of these colours as adopted at GMP.

ISDI particularly wishes to demonstrate the need for the use of these colours in sport and electrolyte drinks.

These drinks are designed for use by individuals who are in a specific physiological condition, due to the expenditure of intense muscular effort.

A key feature of sport and electrolyte drinks is that they must appeal to the intended consumer.

The visual appeal of any beverage is an important aspect of its appeal and organoleptic properties, and the ability to add a range of colours is an important determinant of consumer preference and consumption.

Safety Issues

In the case of Caramel Colour, Class IV (INS 150D), ISDI supports the current position and the use of these colours as adopted at GMP.

As noted in the request for comments, this colour has been reviewed by JECFA and ADI set for their safe use.

Additionally, this colour has been approved for use throughout Europe for a range of products, and those listed in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks, are not excluded from using colours in Directive 94.36.EC.

VI. ACESULFAME POTASSIUM INS 950

Additive	*Product*	*Age Group*	*Maximum Level Permitted*
Acesulfame Potassium E950	Formula for Special Medical Purposes Dietetic Foods Intended for Special Medical Purposes (excluding category 13.1) Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks.	Young Children and Adults >1 year	450 mg/kg Level proposed

FSMPs

Summary

Intense sweeteners are a vital ingredient in the formulation of Formulae for Special Medical Purposes and Dietetic Foods Intended for Special Medical Purposes (FSMP).

Technological limitations of individual sweeteners and the variety of presentations required for FSMP mean it is vitally important to have a range of permitted sweeteners including Acesulfame Potassium which may be used individually or in combination.

Safety of Acesulfame Potassium has been assessed by International regulatory authorities, Acesulfame Potassium is approved for use in complete formulae and nutritional supplements for use under medical supervision in the EU (94/35/EC) and in medical foods in the US (21 CFR 172.800).

FSMP are formulated so that intakes of Acesulfame Potassium remain within the ADI and below the proposed maximum level (450 mg/kg) which is also consistent with the maximum permitted level in the EU. Usage of FSMP is controlled by the recommended intake for a specific age and is administered under medical supervision unlike normal foods containing sweeteners.

Patient Acceptability

FSMP are flavoured and sweetened to improve palatability as these products are often taken orally in the dietary management of patients over long periods of time. The availability of a range of flavoured products will aid patient compliance with their dietary regime and therefore lead to better management of their medical condition. Sweet flavours are usually the flavours of choice both from a patient preference point of view and from the point of view of product type. This requires the addition of **sweetness** by using sucrose or other sweetening agents.

The limitations of sucrose or other bulk sweeteners/sugars as a source of sweetness in FSMP are listed below:

Providing the correct balance of calories to active nutrients is important in FSMP and this can often not be achieved if very high levels of sucrose are required for sweetening purposes.

Where the FSMP is a supplement to the diet, high levels of sucrose in that supplement may provide too many calories on daily basis in addition to normal food intake.

High levels of sucrose increase bulk, resulting in a high volume of feed required to obtain the active nutrients. This can be off-putting to patients and therefore can effect compliance.

The osmolality of FSMP is often high due to high levels of osmotically active components e.g. amino acids, peptides. The addition of sucrose or other sugars as sweetening agents would exacerbate this and may be problematic for patients who cannot tolerate high osmolality formulas, but still require a sweet flavoured palatable product.

For some diseases, carbohydrate free, flavoured formulas may be required, and carbohydrate based ingredients such as sucrose cannot be used at all.

Although there is a need to limit use of sweeteners in foods for young children with good health, restriction of their use in FSMP (used by a very small number of the population) may adversely effect compliance with dietary regimes. The artificial nature of these often very restrictive diets benefits greatly from the addition of flavours and sweeteners. In the interest of ensuring compliance to specialist diets there is a need for the use of a small number of sweeteners in FSMP for young children.

Natural sweetening agents are used whenever possible with sweeteners used only whenever absolutely necessary.

The inclusion of high levels of sugar in FSMP for young children is discouraged to avoid dental caries and particularly for patients on calorie restricted diets

Technological Issues

There are a number of technological issues which are paramount to product design which must be optimised in order to achieve palatable, stable and safe products. FSMP utilise many ingredients which are very different to normal foods. Unpalatable ingredients such as amino acids, peptides and minerals/trace elements are often used at high levels to achieve nutritionally complete formulations. The unpleasant taste of these nutrients is often enhanced in FSMP by the absence of natural taste masking ingredients, such as whole milk proteins and fat. The unpleasant tasting components of many FSMP mean that the maximum permitted level of an appropriate single sweetener may be insufficient to produce a palatable product.

FSMP can be presented in different forms e.g. sterile liquids, powders for reconstitution. Each of these presentations has specific technological requirements for intense sweeteners.

A further limitation is the individual properties or composition of certain sweeteners which can render them unsuitable for particular product applications or disease states.

A combination of permitted sweeteners is therefore often necessary in FSMP. The availability of a range of permitted intense sweeteners allows combination of the different properties of sweeteners and helps to overcome their individual limitations.

Acesulfame Potassium is an intense sweetener with approximately 200 times the sweetness potency of sucrose. Unlike some other sweeteners, Acesulfame Potassium is stable under a wide range of processing conditions tolerating pH levels from 3 to 9 and temperatures up to 200^0C. In addition, Acesulfame Potassium has no compositional limitations.

Safety of Acesulfame Potassium

Safety of Acesulfame Potassium has been assessed by both the European Scientific Committee on Foods (SCF)[1] and the Joint FAO/WHO Expert Committee on Food Additives (JECFA)[2,3], JECFA have assigned an ADI of 15 mg/kg bw/day to Acesulfame Potassium, the SCF have assigned an ADI of 0 to 9 mg/kg bw/day. Safety of Acesulfame potassium has also been assessed by the FDA, and an ADI of 15 mg/kg/day assigned.[4]

Based on the evaluation of safety of Acesulfame Potassium, Directive 94/35/EC[5] of the European Parliament permits use of Acesulfame Potassium in complete formulae and nutritional supplements for use under medical supervision at a maximum level of 450 mg/kg. Acesulfame Potassium has now been used in FSMP in the EU for a number of years with no safety concerns.

The US FDA have approved Acesulfame Potassium for use as a general purpose sweetener and flavour enhancer in foods generally apart from meat and poultry at a level consistent with good manufacturing practice (21 CFR 172.800).

Worldwide Acesulfame Potassium is approved in more than 90 countries.

Use of Acesulfame K in FSMP is kept to a minimum and only used for technological reasons. FSMP are formulated so that daily intake of Acesulfame Potassium remains within the ADI and below the maximum permitted level (450 mg/kg as consumed). In addition usage of FSMP is controlled by the recommended intake for a specific age and these products are administered under medical supervision.

Conclusions

Acesulfame Potassium is currently used in a number of foods for special dietary purposes in the EU and medical foods in the US. These products are used by a limited population under the care of a health professional. Availability of these sweetened palatable products aids patient compliance with an otherwise very restricted diet.

Safety of Acesulfame Potassium has been reviewed by international regulatory authorities. Products are formulated so that maximum daily intakes of Acesulfame Potassium are within the ADI assigned by JECFA. The availability of Acesulfame Potassium to be used singly or in combination with other permitted sweeteners is important in overcoming technological issues present in the formulation of FSMP and for the development of a range of products to aid patient compliance.

References

1. SCF Opinion: Re-evaluation of Acesulfame K with reference to the previous SCF opinion of 1991. SCF/CS/ADD/EDUL/194 final 13 March 2000
2. Joint FAO/WHO Expert Committee on Food Additives. Toxicological Evaluation of Certain Food Additives. WHO Food Additives Series 18:12-14, 1983. WHO, Geneva.

3. Joint FAO/WHO Expert Committee on Food Additives. Toxicological Evaluation of Certain Food Additives. WHO Food Additives Series 28:183-218. 1991 WHO, Geneva.
4. Food Additives Permitted for Direct Addition to Food for Human Consumption; Acesulfame Potassium; Department of Health and Human Services. Food and Drug Administration 21 CFR Part 172 [Docket No. 2002F-0220] Final rule http://www.cfsan.fda.gov/~lrd/fr031231.html
5. European Parliament and Council Directive 94/35/EC on Sweeteners for use in Foodstuffs.Official Journal of the European Community 10.9.94 No L237 pp 3-12

Sports Foods

Justification for Use

ISDI would like to support the ongoing work to include Aspartame (INS 951) for use in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks. Discussions on this sweetener are at step 6 in the procedure.

ISDI particularly wishes to demonstrate the need for the use of intense sweeteners in sport and electrolyte drinks. These drinks are designed for use by individuals who are in a specific physiological condition, due to the expenditure of intense muscular effort.

As a result, such individuals require the provision of drinks which supply fluid, sodium (and other electrolytes) and carbohydrate, in carefully controlled levels to maximise fluid delivery and rehydration and, for beverages supplying appropriate levels of carbohydrate, a source of energy for the working muscles.

Drinking sport and electrolyte drinks has been demonstrated to improve sporting performance.

A key feature of sport and electrolyte drinks is that they must be palatable for the intended consumer.

Most soft drinks have a carbohydrate content of 8 to 12%, whereas for physiological functionality sports and electrolyte drinks have a lower carbohydrate level, generally between 1.5% and 8%.

Sports and electrolyte drinks are also often formulated with less sweet carbohydrate sources, such as glucose polymers and maltodextrins to help control the osmolality of the drinks.

The inclusion of intense sweeteners as part of the formulation of sport and electrolyte drinks is important to give the flexibility required to produce a palatable drink using these carefully controlled amounts of carbohydrate (amount and type), electrolytes and product osmolality.

ISDI therefore requests that provisions for the use of Acesulfame Potassium (INS 950), for Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks is retained.

Safety Issues

ISDI supports the levels proposed for the use of Acesulfame Potassium for Food Category 14.1.4.

As noted in the request for comments, Acesulfame Potassium (INS 950) has been reviewed by JECFA and ADI set for it safe use.

Additionally, Acesulfame Potassium has been approved for use throughout Europe for many categories of non-alcoholic drinks.

Although specific levels for use of these sweeteners in sport and electrolyte drinks have not been set in Europe, the European Commission has agreed to address this in the forthcoming directive on foods intended to meet the expenditure of intense muscular effort, especially for sports people (Council of the European Union, Interinstitutional file: 2004/0237(COD)).

VII. DIACETYLTARTARIC ACID ESTERS OF GLYCEROL E472E

Additive	*Product*	*Age Group*	*Maximum Level Permitted*
Diacetyltartaric Acid Esters of Glycerol E472e	*Formulas for Special Medical Purposes* Dietetic Foods Intended for Special Medical Purposes (excluding category 13.1)	Infants 0-12 months	0.4 g/L 400 mg/kg
		Young Children 1- 3 years Adults	0.4 g/L 400 mg/kg

Technological Issues

There are a number of technological difficulties encountered in the development of stable formulas for special medical purposes for infants. These products frequently contain hydrolysed proteins, amino acids and certain combinations of lipids or fatty acids which have inherently poor emulsifying properties resulting in unstable formulations.

Formulas for special medical purposes are frequently given via narrow nasogastric tubes. As a result prolonged emulsion stability is required to avoid tube blockage and maintain adequate feeding regimes.

For products taken orally, palatability is particularly important, especially for infants over 6 months of age. Poor palatability can affect dietary compliance in young children and therefore compromise their dietary management.

Safety Issues

DATEM (E472e) was assigned an ADI (0 – 50 mg/kg BW) by JECFA in 20031. DATEM is a permitted additive in the US, Canada, Australia/New Zealand. DATEM has been used in protein free products since the 1980s, including those for highly allergic sick infants. Products containing E472(e) have been clinically evaluated and infants taking these products have had normal growth and development. DATEM is included in the proposed list of additives for use in Formulas for Special Medical Purposes in the Codex Draft Revised Standard for Infant Formulas and Formulas for Special Medical Purposes (CX/NFSDU 05/27/6-Add.1).

Technological Justification for Use of DATEM in Formulas for Special Medical Purposes

Products for infants are required to provide a large percentage (40-50%) of energy from fat. This means that it is difficult to achieve a stable product. In addition, formulas for special medical purposes for infants may require other attributes which make them difficult to emulsify such as use of hydrolysed proteins or free amino acids and the presence of high levels of medium chain triglycerides (MCT). Unlike whole protein, protein hydrolysates and amino acids have little or no emulsifying properties.

It is particularly important for formulas for special medical purposes for infants (FSMP) to remain stable over prolonged periods. FSMP for infants are frequently fed through very narrow-bore nasogastric tubes. Poor emulsion stability can lead to separation of fat and sedimentation of insoluble particles which may block feeding tubes. This can adversely affect the ability to maintain adequate feeding regimes. Poor palatability can affect dietary compliance in young children and therefore compromise their dietary management.

The majority of FSMPs for infants are formulated as oil in water emulsions, and as such require a surface-active agent, which is able to promote this type of system. The use of the HLB (Hydrophilic Lipophilic Balance) principle is a useful and effective tool at achieving this. Emulsifiers with HLB values of between 8 and 18, at the high end of the scale, are considered to be most suitable for solubilising oil into water [(2)].

E472(e) (HLB value 8) is an effective emulsifier of oil in water emulsions. Its ability to produce a stable emulsion gives the final product an acceptable taste and makes it an extremely useful additive particularly where there is an absence of protein in the formulation. E472(e) has been used effectively in formulas for special medical purposes that have a wide range of fatty acids within the oil phase, particularly those containing high levels of saturated fat which would otherwise be difficult to emulsify. E472(e) is a robust, non-ionic substance that can withstand harsh processing such as spray drying and ultra heat treatment. Its resistance to ionic interactions makes it suitable for use in products containing mineral and trace element ions.

Alternative permitted emulsifiers, lecithin (E322) or mono and diglycerides of fatty acids (E471) have low HLB values and are insufficient to support stable oil in water emulsions[(2)]. However when both are used in combination with E472e a rigorous emulsification system is obtained. Together, the emulsifiers coat the fat globules and lower fat agglomeration due to the hydrophilic/lipophilic balance (HLB) values of the emulsifiers, emulsion breakdown is prevented and a stable, palatable product is possible.

Safety Issues

E472e has been used in protein free products since the 1980's, including those for highly allergic, sick infants. Products containing E472e have been clinically evaluated and infants taking these products have had normal growth and development. No reported adverse reactions have been reported.

DATEM (E472e) was assigned an ADI (0 – 50 mg/kg BW) by JECFA in 2003[1]. DATEM is included in the proposed list of additives for use in Formulas for Special Medical Purposes in the Codex Draft Revised Standard for Infant Formulas and Formulas for Special Medical Purposes (CX/NFSDU 05/27/6-Add.1). Typical daily intakes of DATEM from a nutritionally complete amino acid based formula by during the first 12 months of life are within the ADI assigned by JECFA.

E472 (e) is currently permitted in a number of countries worldwide:

In the USA mono and diacetyl tartaric acid esters of mono and diglycerides of fatty acids (DATEM) is affirmed as GRAS (21 CFR 184.1101).

In Canada, mono and diacetyl tartaric acid esters of mono and diglycerides of fatty acids (DATEM) are currently permitted by section B16.100 Table IV of the Canadian Food and Drugs Act and Regulations.

In Australia/New Zealand: E472(e) Diacetyltartaric and fatty acid esters of glycerol are permitted in infant formula products for specific dietary use based on protein substitutes up to a level of 400mg/l (0.4g/l) according to FSANZ Standard 1.3.1.

In the EU, E472(e) is included in Directive 95/2/EC for a wide variety of general foods at quantum satis levels [3], but not in foods for special medical purposes.

Summary

There are a number of technological difficulties encountered in the development of stable and acceptable formulas for special medical purposes for infants, particularly when they contain hydrolysed proteins, amino acids and certain combinations of lipids. It is essential that a robust emulsifier such as E472e can be used in formulas for special medical purposes where product delivery is critical to the successful dietary management of patients.

References

1. Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA 1956-2004) (First through Sixty-Third Meetings) Report: TRS 922-JECFA 61/22 Specifications: COMPENDIUM ADDENDUM 9/FNP 52 Add.9/33 (2001)Tox monograph*:* FAS 52-JECFA 61/61
2. Jim Smith (Ed.) 1991 Food Additive User's Handbook. Chapter 8 Emulsifiers p 177-179. European Parliament and Council directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners. Official Journal of the European Communities, L 61/1, 18.3.95

VIII. SUNSET YELLOW E110

Additive	*Product*	*Maximum Level Permitted*
Sunset Yellow FCF E110	Dietetic Foods intended for Special Medical Purposes	3.75 mg/L

Justification for Use

Sunset Yellow (also known as Orange Yellow S, and FD&C Yellow 6; disodium salt of 6-hydroxy-5 -[(4-sulfophenyl)azo]-2-naphthalenesulfonic acid) is a colourant that may be added to foods to induce a colour change. It is denoted by E Number E110, and conforms with the Dutch Food Law "Warenwet", kleurstoffen levensmiddelen A0-10.2 and EC legislation 94/36/EC and 95/45/EC. It is a synthetic coal tar and azo yellow dye useful in fermented foods which must be heat treated. It may be found in a wide variety of foodstuffs.

Sunset Yellow is currently used in a dietetic food for special medical purposes which contains no proteins or fat and is used for patients who suffer from disease related malnutrition or have increased energy needs. This product requires colour to increase customer compliance.

The technological demands required by a colorant used in such a product are as follows:

1. Must be water soluble (fat soluble colorants, such as carotenoids, will not be effective because these products do not contain fat)
2. Must be soluble at low pH and must function as an effective colorant at low pH (pH of product is 2.35)
3. Must have acceptable light stability if the product will be stored in transparent glass bottle
4. Must be heat stable as the product undergoes sterilisation for 15 minutes at 90°C

Safety Issues

The desired colour intensity may be obtained at a concentration of 3.75 mg E110 per litre. As the suggested intake of the product is 200 mL per day, the daily intake of E110 from such a product would be 0.75mg, which is well below the maximum recommended daily intake of 2.5 mg/kg body weight.

Moreover, Sunset Yellow E110 is one of the few yellow colorants that fulfills the four technological requirements mentioned above.

IX. ALITAME INS 956

Additive	*Product*	*Maximum Level Permitted*
Alitame INS 956	Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks.	Level proposed

Justification for Use

ISDI would like to support the ongoing work to include Alitame (INS 956) for use in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks. Discussions on this sweetener are at step 6 in the procedure.

ISDI particularly wishes to demonstrate the need for the use of intense sweeteners in sport and electrolyte drinks. These drinks are designed for use by individuals who are in a specific physiological condition, due to the expenditure of intense muscular effort.

As a result, such individuals require the provision of drinks which supply fluid, sodium (and other electrolytes) and carbohydrate, in carefully controlled levels to maximise fluid delivery and rehydration and, for beverages supplying appropriate levels of carbohydrate, a source of energy for the working muscles.

Drinking sport and electrolyte drinks has been demonstrated to improve sporting performance.

A key feature of sport and electrolyte drinks is that they must be palatable for the intended consumer.

Most soft drinks have a carbohydrate content of 8 to 12%, whereas for physiological functionality sports and electrolyte drinks have a lower carbohydrate level, generally between 1.5% and 8%.

Sports and electrolyte drinks are also often formulated with less sweet carbohydrate sources, such as glucose polymers and maltodextrins to help control the osmolality of the drinks.

The inclusion of intense sweeteners as part of the formulation of sport and electrolyte drinks is important to give the flexibility required to produce a palatable drink using these carefully controlled amounts of carbohydrate (amount and type), electrolytes and product osmolality.

ISDI therefore requests that provisions for the use of Alitame (INS 956) for Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks is retained.

Safety Issues

ISDI supports the levels proposed for the use of Alitame (INS 956) for Food Category 14.1.4.

As noted in the request for comments, Alitame (INS 956) has been reviewed by JECFA and ADI set for it safe use.

X. CARMINES INS 120

Additive	*Product*	*Maximum Level Permitted*
Carmines INS 120	Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks.	Level proposed

Justification for use

ISDI would also like to support the ongoing work for Carmines (INS 120) for use in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks.

ISDI particularly wishes to demonstrate the need for the use of these colours in sport and electrolyte drinks.

These drinks are designed for use by individuals who are in a specific physiological condition, due to the expenditure of intense muscular effort.

A key feature of sport and electrolyte drinks is that they must appeal to the intended consumer.

The visual appeal of any beverage is an important aspect of its appeal and organoleptic properties, and the ability to add a range of colours is an important determinant of consumer preference and consumption.

Safety Issues

ISDI supports the levels proposed for the use of Carmines (INS 120) for Food Catgeory14.1.4.

As noted in the request for comments, this colour has been reviewed by JECFA and ADI set for their safe use.

Additionally, this colour has been approved for use throughout Europe for a range of products, and those listed in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks, are not excluded from using colours in Directive 94.36.EC.

XI. CHLOROPHYLLS

Additive	*Product*	*Maximum Level Permitted*
Chlorophylls	Food Category 14.1.4 water-based flavoured drinks,	Level proposed

Additive	*Product*	*Maximum Level Permitted*
	including "sport", "energy" or "electrolyte" drinks and particulate drinks.	

Justification for use

ISDI would also like to support the ongoing work for Chlorophylls for use in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks.

ISDI particularly wishes to demonstrate the need for the use of these colours in sport and electrolyte drinks.

These drinks are designed for use by individuals who are in a specific physiological condition, due to the expenditure of intense muscular effort.

A key feature of sport and electrolyte drinks is that they must appeal to the intended consumer.

The visual appeal of any beverage is an important aspect of its appeal and organoleptic properties, and the ability to add a range of colours is an important determinant of consumer preference and consumption.

Safety Issues

ISDI supports the levels proposed for the use of Chlorophylls for Food Catgeory14.1.4.

As noted in the request for comments, this colour has been reviewed by JECFA and ADI set for their safe use.

Additionally, this colour has been approved for use throughout Europe for a range of products, and those listed in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks, are not excluded from using colours in Directive 94.36.EC.

XII. COPPER COMPLEXES INS 141 (I) & 141 (II)

Additive	*Product*	*Maximum Level Permitted*
Copper Complexes INS 141i & 141ii	Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks.	Level proposed

Justification for use

ISDI would also like to support the ongoing work for Copper Complexes (INS 141i and 141ii) for use in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks.

ISDI particularly wishes to demonstrate the need for the use of these colours in sport and electrolyte drinks.

These drinks are designed for use by individuals who are in a specific physiological condition, due to the expenditure of intense muscular effort.

A key feature of sport and electrolyte drinks is that they must appeal to the intended consumer.

The visual appeal of any beverage is an important aspect of its appeal and organoleptic properties, and the ability to add a range of colours is an important determinant of consumer preference and consumption.

Safety Issues

ISDI supports the levels proposed for the use of Copper Complexes (INS 141i and 141ii) for Food Catgeory14.1.4.

As noted in the request for comments, this colour has been reviewed by JECFA and ADI set for their safe use.

Additionally, this colour has been approved for use throughout Europe for a range of products, and those listed in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks, are not excluded from using colours in Directive 94.36.EC.

XIII. ERYTHROSINE INS 127

Additive	*Product*	*Maximum Level Permitted*
Erythrosine INS 127	Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks.	Level proposed

Justification for use

ISDI would also like to support the ongoing work for Erythrosine (INS 127) for use in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks.

ISDI particularly wishes to demonstrate the need for the use of these colours in sport and electrolyte drinks.

These drinks are designed for use by individuals who are in a specific physiological condition, due to the expenditure of intense muscular effort.

A key feature of sport and electrolyte drinks is that they must appeal to the intended consumer.

The visual appeal of any beverage is an important aspect of its appeal and organoleptic properties, and the ability to add a range of colours is an important determinant of consumer preference and consumption.

Safety Issues

ISDI supports the levels proposed for the use of Erythrosine (INS 127) for Food Catgeory14.1.4.

As noted in the request for comments, this colour has been reviewed by JECFA and ADI set for their safe use.

Additionally, this colour has been approved for use throughout Europe for a range of products, and those listed in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks, are not excluded from using colours in Directive 94.36.EC.

XIV. GRAPE SKIN EXTRACT INS 163 (II)

Additive	*Product*	*Maximum Level Permitted*
Grape Skin Extract INS 163ii	Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks.	Level proposed

Justification for use

ISDI would also like to support the ongoing work for Grape Skin Extract (INS 163ii) for use in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks.

ISDI particularly wishes to demonstrate the need for the use of these colours in sport and electrolyte drinks.

These drinks are designed for use by individuals who are in a specific physiological condition, due to the expenditure of intense muscular effort.

A key feature of sport and electrolyte drinks is that they must appeal to the intended consumer.

The visual appeal of any beverage is an important aspect of its appeal and organoleptic properties, and the ability to add a range of colours is an important determinant of consumer preference and consumption.

Safety Issues

ISDI supports the levels proposed for the use of Grape Skin Extract (INS 163ii) for Food Catgeory14.1.4.

As noted in the request for comments, this colour has been reviewed by JECFA and ADI set for their safe use.

Additionally, this colour has been approved for use throughout Europe for a range of products, and those listed in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks, are not excluded from using colours in Directive 94.36.EC.

XV. PONCEAU 4R INS 124

Additive	*Product*	*Maximum Level Permitted*
Ponceau 4R INS 124	Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks.	Level proposed

Justification for use

ISDI would also like to support the ongoing work for Ponceau 4R (INS 124) for use in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks.

ISDI particularly wishes to demonstrate the need for the use of these colours in sport and electrolyte drinks.

These drinks are designed for use by individuals who are in a specific physiological condition, due to the expenditure of intense muscular effort.

A key feature of sport and electrolyte drinks is that they must appeal to the intended consumer.

The visual appeal of any beverage is an important aspect of its appeal and organoleptic properties, and the ability to add a range of colours is an important determinant of consumer preference and consumption.

Safety Issues

ISDI supports the levels proposed for the use of Ponceau 4R (INS 124) for Food Catgeory14.1.4.

As noted in the request for comments, this colour has been reviewed by JECFA and ADI set for their safe use.

Additionally, this colour has been approved for use throughout Europe for a range of products, and those listed in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks, are not excluded from using colours in Directive 94.36.EC.

NATCOL:

Thank you for giving NATCOL the opportunity to comment on the Food Additive Provisions for Priority Additives in the General Standard for Food Additives (GSFA). NATCOL - Natural Food Colour Association - is an international body acting on behalf of the natural food colour industry. NATCOL offers expertise on natural colours regarding their properties, use, and regulatory status. NATCOL is a non-profit organisation.

General Comments:

We fully endorse NATCOL's previous comments on the Draft Revised Codex General Standard for Food Additives (GSFA) from 15 January 2001 and refer you to these.

We find it very difficult to get an overview. We find that CODEX CL 34/2005-FAC by itself provides an incomplete status of the colour additive provisions for which comments were requested. It is necessary to also include the provisions already adopted (or forwarded to CC 28 for adoption) from CCFAC 37 (ALINORM 05/28/12, Appendix X) and the several provisions for discontinuation from CCFAC 37 (ALINORM 05/28/12, Appendix XII). The working document CX/FAC 05/37/6 from November 2004 cannot stand alone and needs to be combined with the above mentioned documents from CCFAC 37.

The technological justification for the use of a colour additive in a food category (i.e. adding colour to a foodstuff or restoring the colour of a foodstuff, without misleading the consumer) is related to the appeal of the foodstuffs within this category. If, addition of colour to a food category is found acceptable, the choice of colour additive and its dosage is dependant on several factors such as: colour shade needed, the colour of the foodstuff in itself, physical state of the foodstuff, carriers and solvents of the colour additive. To be able to align and balance the use of all colour additives in a food category **Table 2** of the GSFA is also needed.

Due to the large number of colour additives provisions contained in **Appendix 1** of CL 34/2005-FAC and the consequences (deletion from GSFA), NATCOL suggests that these provisions are kept at their current position (step6 and 3) until an updated version of all the colour additive provisionsboth in form of **Table 1** (additive entry) and **Table 2** (food category entry) is available.

There are 9 colours in **Appendix 1** of CL 34/2005-FAC of interest to NATCOL members:

161g Canthaxanthin
120 Carmines
160aii Carotenes vegetable
141i & 141ii Chlorophyll, Copper Complexes
163ii Grape Skin Extract
101i, 101ii Riboflavins
150c Caramel Colour Class III
150d Caramel Colour Class IV
160ai, aii, e, f Carotenoids

All of these colours have been reviewed by JECFA and deemed safe for intended uses. Typical consumption values are well below the assigned ADI values. NATCOL is of the opinion that food colours posing no significant risk to the consumer should continue to be permitted at levels consistent with GMP without further restrictions.

If we compare the provisions for colour additives in CX/FAC 05/37/6, Appendix I, GSFA-TABLE-I and outcome from CCFAC 36: ALINORM 05/28/12 (Appendix X: Adoption at Step 8 and Appendix XII: Discontinuation) with those provisions to be deleted if use not justified in CL 2005/34-FAC, we see some major inconsistencies.

In the case of Grape Skin Extract 163ii and 141i & 141ii Chlorophyll, Copper Complexes, we note that the majority of the provisions are common to the two Appendices. It would appear that if justification is not accepted by CCFAC for these provisions, then there will be very few provisions remaining for Grape Skin Extract or Chlorophyll, Copper Complexes in the GSFA! The situation for Vegetable Carotenes and Carmines is slightly better but still not acceptable.

It is not very clear from **Appendix II** of CL 34/2005-FAC what the dosage for the priority colours in these food categories is based on? It should be on the basis of colouring principle only. However some of the extremely high levels stated suggest this not to be always the case. Dosages must be expressed in terms of colouring principle or active pigment.

NATCOL wishes to provide specific comments and information for the provisions for several food colours: **Attachment 1** Vegetable Carotenes (160aii); **Attachment 2** Carotenoids (160ai, aii, e, f); **Attachment 3** Grape Skin Extracts (163ii); **Attachment 4** Carmine (120); and **Attachment 5** Chlorophylls, Copper Complexes (141i/ii). The attachments are self-explanatory.

Food additives in general shall be permitted in foodstuffs reasonably. Regulations should accurately reflect the technological need without being overly restrictive, the permitted levels should avoid unnecessarily high as well as too low levels. Foodstuffs must be safe when consumed in reasonable amounts what also applies for food additive intake. In main staple foods and foods for special dietetic nutrition the use of food additives may be regulated more strictly. However, regulation of food additives and their uses should respect present practices and allow for future opportunities and developments. NATCOL would like to offer our expertise on natural colours regarding their technological justification of current use as well as future opportunities and developments.

Attachment 1

INS 160 aii Carotenes Vegetable

Dosage is based on colouring principle

Food Cat. No.	Food Category	NATCOL supports mg/kg	Comments
01.4	cream (plain) and the like	20	as colouring substance
01.6.3	whey cheese	100	1000 mg/kg is excessive
02.2.1.2	margarine and similar products	25	supported, can be used *quantum satis* in EU regulations
04.1.2.8	fruit preparations, including pulp, purees, fruit toppings and coconut milk	GMP	4 mg/kg too low, GMP supported, can be used *quantum satis* in EU regulations
04.1.2.11	fruit fillings for pastries	GMP	4 mg/kg too low, GMP supported, can be used *quantum satis* in EU regulations
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	Supported
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	supported, can be used *quantum satis* in EU regulations
04.2.2.4	canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweeds	GMP	Supported
05.1.3	Cocoa-based spreads, including fillings	GMP	Supported
05.1.4	Cocoa and chocolate products	GMP	Supported
05.1.5	imitation chocolate, chocolate substitute products	GMP	supported, can be used at *quantum satis* in confectionary in EU regulations
07.1.6	mixes for breads and ordinary bakery wares	GMP	Supported
08.1.2	fresh meat, poultry, and game, comminuted	GMP	Supported
09.1.1	fresh fish	GMP	supported in Salmon substitute, Surimi, fish roe and smoked fish, can be used *quantum satis* in EU regulations
09.1.2	Fresh mollusks, crustaceans, and echinoderms	GMP	supported in Salmon substitute, Surimi, fish roe and smoked fish, can be used *quantum satis* in EU regulations
09.2.1	Frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	GMP	supported in Salmon substitute, Surimi, fish roe and smoked fish, can be used *quantum satis* in EU regulations
09.2.4.1	cooked fish and fish products	GMP	supported in Salmon substitute, Surimi, fish roe and smoked fish, can be used *quantum satis* in EU regulations
12.2	herbs, spices, seasonings, and condiments (e.g., seasoning for instant noodles)	GMP	supported, can be used *quantum satis* in EU regulations

Food Cat. No.	Food Category	NATCOL supports mg/kg	Comments
12.10.3	fermented soybean paste (e.g., miso)	GMP	Supported
14.1.2.2	vegetable juice	GMP	supported, can be used *quantum satis* in EU regulations
14.1.2.4	concentrates for vegetable juice	GMP	supported, can be used *quantum satis* in EU regulations
14.1.3.2	vegetable nectar	GMP	supported, can be used *quantum satis* in EU regulations
14.1.3.4	concentrates for vegetable nectar	GMP	supported, can be used *quantum satis* in EU regulations
15.1	snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	GMP	supported, can be used *quantum satis* in EU regulations
15.2	processed nuts, including covered nuts and nut mixtures (with e.g., dried fruit)	GMP	supported, can be used *quantum satis* in EU regulations
16.0	composite foods - foods that could not be placed in categories 01 - 15	GMP	supported, can be used *quantum satis* in EU regulations
12.10.3	fermented soybean paste (e.g., miso)	GMP	Supported
14.1.2.2	vegetable juice	GMP	supported, can be used *quantum satis* in EU regulations
14.1.2.4	concentrates for vegetable juice	GMP	supported, can be used *quantum satis* in EU regulations
14.1.3.2	vegetable nectar	GMP	supported, can be used *quantum satis* in EU regulations
14.1.3.4	concentrates for vegetable nectar	GMP	supported, can be used *quantum satis* in EU regulations
15.1	snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	GMP	supported, can be used *quantum satis* in EU regulations
15.2	processed nuts, including covered nuts and nut mixtures (with e.g., dried fruit)	GMP	supported, can be used *quantum satis* in EU regulations
16.0	composite foods - foods that could not be placed in categories 01 - 15	GMP	supported, can be used *quantum satis* in EU regulations

Attachment 2

INS 160 ai, aii, e, f Carotenoids

Dosage is based on colouring principle

Food Cat. No	Food Category	NATCOL supports mg/kg	Comments
01.1.2	dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	GMP	Supported, can be used *quantum satis* in EU regulations
01.3.2	beverage whiteners		
01.4	cream (plain) and the like	GMP	Supported
01.6.1	unripened cheese	GMP	Supported
01.6.2.1	ripened cheese, includes rind	GMP	Supported
01.6.2.2	rind of ripened cheese	GMP	Supported
01.6.2.3	Cheese powder (for reconstitution; e.g., for cheese sauces)	GMP	Supported
01.6.3	whey cheese	GMP	Supported
01.6.4	processed cheese	GMP	Supported
01.6.5	cheese analogues	GMP	Supported
01.6.6	Whey protein cheese	GMP	Supported
01.7	dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	GMP	Supported, can be used *quantum satis* in EU regulations
02.1	Fats and oils essentially free from water	GMP	Supported, can be used *quantum satis* in EU regulations

Food Cat. No	Food Category	NATCOL supports mg/kg	Comments
02.2.1.1	butter and concentrated butter	GMP	Supported, can be used *quantum satis* in EU regulations
02.2.1.2	margarine and similar products	GMP	Supported, can be used *quantum satis* in EU regulations
02.2.1.3	Blends of butter and margarine	GMP	Supported, can be used *quantum satis* in EU regulations
02.2.2	Emulsions containing less than 80% water	GMP	Supported, can be used *quantum satis* in EU regulations
02.3	Fat emulsions maily on type oil-in-water, including mixed and/or flavoured products based on fat emulsions	GMP	Supported, can be used *quantum satis* in EU regulations
02.4	fat-based desserts excluding dairy-based dessert products of food category 01.7	GMP	Supported, can be used *quantum satis* in EU regulations
3.0	edible ices, including sherbet and sorbet	GMP	Supported, can be used *quantum satis* in EU regulations
04.1.2.3	fruit in vinegar, oil, or brine	GMP	Supported, can be used *quantum satis* in EU regulations
04.1.2.4	canned or bottled (pasteurized) fruit	GMP	Preserves of red fruit, can be used *quantum satis* in EU regulations
04.1.2.5	jams, jellies and marmelades	GMP	Supported, can be used *quantum satis* in EU regulations
04.1.2.6	fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	GMP	Supported, can be used *quantum satis* in EU regulations
04.1.2.7	candied fruit	GMP	Supported, can be used *quantum satis* in EU regulations
04.1.2.8	fruit preparations, including pulp, purees, fruit toppings and coconut milk	GMP	Supported, can be used *quantum satis* in EU regulations
04.1.2.9	fruit-based desserts, including fruit-flavoured water-based desserts	GMP	Supported, can be used *quantum satis* in EU regulations
04.1.2.11	fruit fillings for pastries	GMP	Supported, can be used *quantum satis* in EU regulations
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	Supported
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	Supported, can be used *quantum satis* in EU regulations
04.2.2.4	canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweeds	GMP	Supported
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)	GMP	Supported
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, candied vegetables) other than food category 04.2.2.5	GMP	Supported
04.2.2.7	fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweed products, excluding fermented soybean products of food category 12.10	GMP	Supported
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	GMP	Supported
05.1.2	Cocoa mixes (syrups)	GMP	Supported
05.1.3	Cocoa-based spreads, including fillings	GMP	Supported
05.1.4	Cocoa and chocolate products	GMP	Supported
05.1.5	imitation chocolate, chocolate substitute products	GMP	Supported, can be used *quantum satis* in EU regulations

Food Cat. No	Food Category	NATCOL supports mg/kg	Comments
05.2	confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	GMP	Supported, can be used *quantum satis* in EU regulations
05.3	chewing gum	GMP	Supported, can be used *quantum satis* in EU regulations
05.4	decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	GMP	Supported, can be used *quantum satis* in EU regulations
06.3	breakfast cereals, including rolled oats	GMP	Supported, can be used *quantum satis* in EU regulations
06.5	cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	GMP	Supported, can be used *quantum satis* in EU regulations
06.6	Batters (e.g., for breading or batters for fish or poultry)	GMP	Supported, can be used *quantum satis* in EU regulations
07.1.1	Breads and rolls	GMP	Supported
07.1.2	crackers, excluding sweet crackers	GMP	Supported
07.1.3	other ordinary bakery products (e.g., bagels, pita, English muffins)	GMP	Supported
07.1.4	bread-type products, including bread stuffing and bread crumbs	GMP	Supported
07.1.5	steamed breads and buns	GMP	Supported
07.1.6	mixes for breads and ordinary bakery wares	GMP	Supported
07.2	fine bakery wares (sweet, salty, savoury) and mixes	GMP	Supported, can be used *quantum satis* in EU regulations
08.3.1.1	cured (including salted) non-heat treated processed comminuted meat, poultry, and game products	GMP	Supported, can be used *quantum satis* in EU regulations
08.3.1.2	cured (including salted) and dried non-heat treated processed comminuted meat, poultry, and game products	GMP	Supported, can be used *quantum satis* in EU regulations
08.3.1.3	fermented non-heat treated processed comminuted meat, poultry, and game products	GMP	Supported, can be used *quantum satis* in EU regulations
08.3.2	heat-treated processed comminuted meat, poultry, and game products	GMP	Supported, can be used *quantum satis* in EU regulations
08.4	edible casings (e.g., sausage casings)	GMP	Supported, can be used *quantum satis* in EU regulations
09.1.1	fresh fish	GMP	supported in Salmon substitute, Surimi, fish roe and smoked fish, can be used *quantum satis* in EU regulations
09.1.2	Fresh mollusks, crustaceans, and echinoderms	GMP	supported in Salmon substitute, Surimi, fish roe and smoked fish, can be used *quantum satis* in EU regulations
09.2	processed fish and fish products, including mollusks, crustaceans, and echinoderms	GMP	supported in Salmon substitute, Surimi, fish roe and smoked fish, can be used *quantum satis* in EU regulations
09.2.1	Frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	GMP	supported in Salmon substitute, Surimi, fish roe and smoked fish, can be used *quantum satis* in EU regulations
09.2.2	frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	GMP	supported in Salmon substitute, Surimi, fish roe and smoked fish, can be used *quantum satis* in EU regulations
09.2.3	frozen minced and creamed fish products, including mollusks, crustaceans, and echinoderms	GMP	supported in Salmon substitute, Surimi, fish roe and smoked fish, can be used *quantum satis* in EU regulations
09.2.4.1	cooked fish and fish products	GMP	supported in Salmon substitute, Surimi, fish roe and smoked fish, can be used *quantum satis* in EU regulations
09.2.4.2	cooked mollusks, crustaceans, and echinoderms	GMP	supported in Salmon substitute, Surimi, fish roe and smoked fish, can be used *quantum satis* in EU regulations

Food Cat. No	Food Category	NATCOL supports mg/kg	Comments
09.2.4.3	fried fish and fish products, including mollusks, crustaceans, and echinoderms	GMP	supported in Salmon substitute, Surimi, fish roe and smoked fish, can be used *quantum satis* in EU regulations
09.2.5	smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	GMP	supported in Salmon substitute, Surimi, fish roe and smoked fish, can be used *quantum satis* in EU regulations
09.3	semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	GMP	supported in Salmon substitute, Surimi, fish roe and smoked fish, can be used *quantum satis* in EU regulations
09.3.1	fish and fish products, including mollusks, crustaceans, and echinoderms, marinated and/or in jelly	GMP	supported in Salmon substitute, Surimi, fish roe and smoked fish, can be used *quantum satis* in EU regulations
09.3.2	fish and fish products, including mollusks, crustaceans, and echinoderms, pickled and/or in brine	GMP	supported in Salmon substitute, Surimi, fish roe and smoked fish, can be used *quantum satis* in EU regulations
09.3.3	salmon substitutes, caviar, and other fish roe products	GMP	supported in Salmon substitute, Surimi, fish roe and smoked fish, can be used *quantum satis* in EU regulations
09.3.4	semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms (e.g., fish paste), excluding products of food categories 09.3.1 - 09.3.3	GMP	supported in Salmon substitute, Surimi, fish roe and smoked fish, can be used *quantum satis* in EU regulations
09.4	fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	200	supported in Salmon substitute, Surimi, fish roe and smoked fish, can be used *quantum satis* in EU regulations
10.2	egg products	GMP	Supported
10.4	egg-based desserts (e.g., custard)	GMP	Supported, can be used *quantum satis* in EU regulations
12.2.2	Seasonings and condiments	GMP	Supported, can be used *quantum satis* in EU regulations
12.4	mustards	GMP	Supported, can be used *quantum satis* in EU regulations
12.5	soups and broths	GMP	Supported, can be used *quantum satis* in EU regulations
12.6	Sauces and like products	GMP	Supported, can be used *quantum satis* in EU regulations
12.7	salads (e.g., macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based spreads of food categories 04.2.2.5 and 05.1.3	GMP	Supported, can be used *quantum satis* in EU regulations
13.3	dietetic foods intended for special medical purposes (excluding products of food category 13.1)	GMP	Supported, can be used *quantum satis* in EU regulations
13.4	dietetic formulae for slimming purposes and weight reduction	GMP	Supported, can be used *quantum satis* in EU regulations
13.5	dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6	GMP	Supported, can be used *quantum satis* in EU regulations
13.6	food supplements	GMP	Supported, can be used *quantum satis* in EU regulations
14.1.3.2	vegetable nectar	GMP	Supported, can be used *quantum satis* in EU regulations
14.1.3.4	concentrates for vegetable nectar	GMP	Supported, can be used *quantum satis* in EU regulations
14.1.4	water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	GMP	Supported, can be used *quantum satis* in EU regulations
14.2.2	cider and perry	GMP	Supported, can be used *quantum satis* in EU regulations
14.2.4	wines (other than grape)	GMP	Supported, can be used *quantum satis* in EU regulations

Food Cat. No	Food Category	NATCOL supports mg/kg	Comments
14.2.6	distilled spirituous beverages containing more than 15% alcohol	GMP	Supported, can be used *quantum satis* in EU regulations
14.2.7	aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	GMP	Supported, can be used *quantum satis* in EU regulations
15.1	snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	GMP	Supported, can be used *quantum satis* in EU regulations
15.2	processed nuts, including covered nuts and nut mixtures (with e.g., dried fruit)	GMP	Supported, can be used *quantum satis* in EU regulations
16.0	composite foods - foods that could not be placed in categories 01 - 15	GMP	Supported, can be used *quantum satis* in EU regulations

Attachment 3

INS 163 ii Grape skin extract

Dosage is based on colouring principle

Food Cat. No	Food Category	NATCOL supports mg/kg	Comments
01.1.2	dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	150	Reduce level from 1500mg/kg to the needed 150mg/kg pigment
01.3.2	beverage whiteners	150	Reduce level from 1500mg/kg to the needed 150mg/kg pigment
01.4	cream (plain) and the like	150	Reduce level from 1500mg/kg to the needed 150mg/kg pigment
01.5.2	milk and cream powder analogues	150	Reduce level from 1500mg/kg to the needed 150mg/kg pigment
01.6.1	unripened cheese	100	Reduce level from 1000mg/kg to the needed 100mg/kg pigment
01.6.2.1	ripened cheese, includes rind	100	Reduce level from 125mg/kg to the needed 100mg/kg
01.6.2.2	rind of ripened cheese	100	Reduce level from 1000mg/kg to the needed 100mg/kg pigment
01.6.3	whey cheese	100	Reduce level from 1000mg/kg to the needed 100mg/kg pigment
01.6.4.2	flavoured processed cheese, including containing fruit, vegetables, meat, etc.	100	Reduce level from 1000mg/kg to the needed 100mg/kg pigment
01.6.5	cheese analogues	100	Reduce level from 1000mg/kg to the needed 100mg/kg pigment
01.7	dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	200	Increase level from 100mg/kg to the needed 200mg/kg pigment as can be used *quantum satis* in EU regulations
02.4	fat-based desserts excluding dairy-based dessert products of food category 01.7	200	Reduce level from 1500mg/kg to the needed 200mg/kg pigment
3.0	edible ices, including sherbet and sorbet	200	Reduce level from 1000mg/kg to the needed 200mg/kg pigment
04.1.1.2	surface-treated fresh fruit	150	Reduce level from GMP to the needed 150mgkg pigment
04.1.2.3	fruit in vinegar, oil, or brine	300	Reduce level from 1500mg/kg to the needed 300mg/kg pigment
04.1.2.4	canned or bottled (pasteurized) fruit	300	Reduce level from 1500mg/kg to the needed 300mg/kg pigment
04.1.2.5	jams, jellies and marmelades	300	Reduce level from 1500mg/kg to the needed 300mg/kg pigment
04.1.2.6	fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	300	Reduce level from 500mg/kg to the needed 300mg/kg pigment

Food Cat. No	Food Category	NATCOL supports mg/kg	Comments
04.1.2.7	candied fruit	500	Reduce level from 1500mg/kg to the needed 500mg/kg pigment
04.1.2.8	fruit preparations, including pulp, purees, fruit toppings and coconut milk	500	Reduce level from 1500mg/kg to the needed 500mg/kg pigment
04.1.2.9	fruit-based desserts, including fruit-flavoured water-based desserts	300	Reduce level from 1500mg/kg to the needed 300mg/kg pigment
04.1.2.10	fermented fruit products	300	Reduce level from 1500mg/kg to the needed 300mg/kg pigment
04.1.2.11	fruit fillings for pastries	500	Reduce level from 1500mg/kg to the needed 500mg/kg pigment
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	100	Reduce level from GMP to the needed 100mg/kg pigment
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	100	Reduce level from 500mg/kg to the needed 100mg/kg pigment
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)	100	Reduce level from 1500mg/kg to the needed 100mg/kg pigment
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, candied vegetables) other than food category 04.2.2.5	100	Reduce level from 1500mg/kg to the needed 100mg/kg pigment
04.2.2.7	fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweed products, excluding fermented soybean products of food category 12.10	100	Reduce level from 1500mg/kg to the needed 100mg/kg pigment
05.1.5	imitation chocolate, chocolate substitute products	200	Reduce level from 500mg/kg to the needed 200mg/kg pigment
05.2	confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	500	Reduce level from 10000mg/kg to the needed 500mg/kg pigment
05.3	chewing gum	500	Reduce level from 10000mg/kg to the needed 500mg/kg pigment
05.4	decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	500	Reduce level from 10000mg/kg to the needed 500mg/kg pigment
06.3	breakfast cereals, including rolled oats	200	Supported
06.5	cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	200	Reduce level from 1500mg/kg to the needed 200mg/kg pigment
7	bakery wares	200	Reduce level from 1500mg/kg to the needed 200mg/kg pigment
08.1.1	fresh meat, poultry, and game, whole pieces or cuts	200	Reduce level from 5000mg/kg to the needed 200mg/kg pigment
08.1.2	fresh meat, poultry, and game, comminuted	200	Reduce level from 1000mg/kg to the needed 200mg/kg pigment
08.2	processed meat, poultry, and game products in whole pieces or cuts	200	Reduce level from 5000mg/kg to the needed 200mg/kg pigment
08.3.1.1	cured (including salted) non-heat treated processed comminuted meat, poultry, and game products	200	Reduce level from 5000mg/kg to the needed 200mg/kg pigment
08.3.1.2	cured (including salted) and dried non-heat treated processed comminuted meat, poultry, and game products	200	Reduce level from 5000mg/kg to the needed 200mg/kg pigment
08.3.1.3	fermented non-heat treated processed comminuted meat, poultry, and game products	200	Reduce level from 5000mg/kg to the needed 200mg/kg pigment
08.3.2	heat-treated processed comminuted meat, poultry, and game products	200	Reduce level from 5000mg/kg to the needed 200mg/kg pigment
08.3.3	frozen processed comminuted meat, poultry, and game products	200	Reduce level from 5000mg/kg to the needed 200mg/kg pigment
08.4	edible casings (e.g., sausage casings)	500	Reduce level from 5000mg/kg to the needed 500mg/kg pigment

Food Cat. No	Food Category	NATCOL supports mg/kg	Comments
09.2.2	frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	200	Reduce level from 500mg/kg to the needed 200mg/kg pigment
09.2.3	frozen minced and creamed fish products, including mollusks, crustaceans, and echinoderms	200	Reduce level from GMP to the needed 200mg/kg pigment
09.2.4.1	cooked fish and fish products	200	Reduce level from 500mg/kg to the needed 200mg/kg pigment
09.2.4.2	cooked mollusks, crustaceans, and echinoderms	200	Reduce level from 1000mg/kg to the needed 200mg/kg pigment
09.2.4.3	fried fish and fish products, including mollusks, crustaceans, and echinoderms	200	Reduce level from 1000mg/kg to the needed 200mg/kg pigment
09.2.5	smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	200	Reduce level from 1000mg/kg to the needed 200mg/kg pigment
09.3.1	fish and fish products, including mollusks, crustaceans, and echinoderms, marinated and/or in jelly	200	Reduce level from 500mg/kg to the needed 200mg/kg pigment
09.3.2	fish and fish products, including mollusks, crustaceans, and echinoderms, pickled and/or in brine	200	Reduce level from 1500mg/kg to the needed 200mg/kg pigment
09.3.3	salmon substitutes, caviar, and other fish roe products	200	Reduce level from 1500mg/kg to the needed 200mg/kg pigment
09.3.4	semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms (e.g., fish paste), excluding products of food categories 09.3.1 - 09.3.3	200	Reduce level from 1500mg/kg to the needed 200mg/kg pigment
09.4	fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	200	Reduce level from 1500mg/kg to the needed 200mg/kg pigment
10.1	fresh eggs	200	Reduce level from 1500mg/kg to the needed 200mg/kg pigment
10.4	egg-based desserts (e.g., custard)	200	Reduce level from 500mg/kg to the needed 200mg/kg pigment
12.2	herbs, spices, seasonings, and condiments (e.g., seasoning for instant noodles)	500	Reduce level from 1500mg/kg to the needed 500mg/kg pigment
12.4	mustards	200	Reduce level from 500mg/kg to the needed 200mg/kg pigment
12.5	soups and broths	500	Reduce level from 1500mg/kg to the needed 500mg/kg pigment
12.6.1	emulsified sauces (e.g., mayonnaise, salad dressing)	300	Reduce level from 1500mg/kg to the needed 300mg/kg pigment
12.6.2	non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)	300	Reduce level from 500mg/kg to the needed 300mg/kg pigment
12.6.3	mixes for sauces and gravies	300	Reduce level from 500mg/kg to the needed 300mg/kg pigment
12.7	salads (e.g., macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based spreads of food categories 04.2.2.5 and 05.1.3	200	Reduce level from 1500mg/kg to the needed 200mg/kg pigment
12.9.5	other protein products	150	Reduce level from 500mg/kg to the needed 150mg/kg pigment
13.1.3	formulae for special medical purposes for infants	50	Increase level from 20mg/kg to the needed 50mg/kg pigment
13.3	dietetic foods intended for special medical purposes (excluding products of food category 13.1)	250	Reduce level from 1500mg/kg to the needed 250mg/kg pigment
13.4	dietetic formulae for slimming purposes and weight reduction	250	Reduce level from 1500mg/kg to the needed 250mg/kg pigment
13.5	dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6	250	Reduce level from 1500mg/kg to the needed 250mg/kg pigment
13.6	food supplements	150	Reduce level from 1500mg/kg to the needed 150mg/kg pigment
14.1.3.2	vegetable nectar	150	Reduce level from 1500mg/kg to the needed 150mg/kg pigment

Food Cat. No	Food Category	NATCOL supports mg/kg	Comments
14.1.3.4	concentrates for vegetable nectar	150	Reduce level from 1500mg/kg to the needed 150mg/kg pigment
14.1.4	water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	300	Reduce level from 500mg/kg to the needed 300mg/kg pigment
14.2.1	beer and malt beverages	300	Reduce level from 1500mg/kg to the needed 300mg/kg pigment
14.2.2	cider and perry	300	Reduce level from 1500mg/kg to the needed 300mg/kg pigment
14.2.3.2	sparkling and semi-sparkling grape wines	300	Reduce level from 1500mg/kg to the needed 300mg/kg pigment
14.2.3.3	fortified grape wine, grape liquor wine, and sweet grape wine	300	Reduce level from 1500mg/kg to the needed 300mg/kg pigment
14.2.4	wines (other than grape)	300	Reduce level from 1500mg/kg to the needed 300mg/kg pigment
14.2.6	distilled spirituous beverages containing more than 15% alcohol	300	Reduce level from 1500mg/kg to the needed 300mg/kg pigment
14.2.7	aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	300	Reduce level from 1500mg/kg to the needed 300mg/kg pigment
15.1	snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	500	Reduce level from 10000mg/kg to the needed 500mg/kg pigment
15.2	processed nuts, including covered nuts and nut mixtures (with e.g., dried fruit)	500	Reduce level from 10000mg/kg to the needed 500mg/kg pigment
16.0	composite foods - foods that could not be placed in categories 01 - 15	200	Reduce level from 1500mg/kg to the needed 200mg/kg pigment

Attachment 4

INS 120 Carmines

Dosage is based on colouring principle

Food Cat. No	Food Category	NATCOL supports mg/kg	Comments
01.6.1	unripened cheese	200	not only surface
01.6.2.2	rind of ripened cheese		
01.6.3	whey cheese	200	not only surface
01.6.5	cheese analogues	200	not only surface
02.2.1.3	Blends of butter and margarine	500	supported
02.2.2	Emulsions containing less than 80% water	500	supported
02.3	Fat emulsions maily on type oil-in-water, including mixed and/or flavoured products based on fat emulsions	50	supported
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	500	supported
05.3	chewing gum	500	technical relevant
06.4.2	Dried pastas and noodles and like products	200	technical relevant
06.4.3	Pre-cooked pastas and noodles and like products	200	technical relevant
07.1	Bread and ordinary bakery wares	200	technical relevant
07.1.4	bread-type products, including bread stuffing and bread crumbs	500	suppported
09.2.1	Frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	250	technical relevant
09.2.2	frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	250	technical relevant
09.2.4.3	fried fish and fish products, including mollusks, crustaceans, and echinoderms	250	technical relevant
14.1.4	water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	200	technical relevant

14.2.7	aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	500	supported

Attachment 5

INS 141 i, ii Chlorophylls, Copper Complexes

Dosage is based on colouring principle

Food Cat. No.	Food Category	NATCOL supports mg/kg	Comments
01.1.2	dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	100	Increase level from 50mg/kg to the needed 100mg/kg pigment as can be used *quantum satis* in EU regulations
01.6.1	unripened cheese	50	Supported
01.6.2.1	ripened cheese, includes rind	50	Supported at 50mg/kg pigment
01.6.2.2	rind of ripened cheese	75	Supported
01.6.2.3	Cheese powder (for reconstitution; e.g., for cheese sauces)	50	Supported
01.6.3	whey cheese	50	Supported
01.6.4	processed cheese	100	Increase level from 50mg/kg to the needed 100mg/kg pigment as can be used *quantum satis* in EU regulations
01.6.5	cheese analogues	50	Supported
01.6.6	Whey protein cheese	50	Supported
01.7	dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	200	Supported at 200mg/kg pigment
02.0	Fats and oils, and fat emulsions	GMP	Supported
02.4	fat-based desserts excluding dairy-based dessert products of food category 01.7	200	Reduce level from 500mg/kg to the needed 200mg/kg pigment
3.0	edible ices, including sherbet and sorbet	200	Supported at 200mg/kg pigment
04.1.1.2	surface-treated fresh fruit	GMP	Supported
04.1.2.1	frozen fruit	100	Reduce level from 2000mg/kg to the needed 100mg/kg pigment
04.1.2.2	dried fruit	100	Reduce level from 2000mg/kg to the needed 100mg/kg pigment
04.1.2.5	jams, jellies and marmelades	200	Supported
04.1.2.6	fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	200	Increase level from 150mg/kg to the needed 200mg/kg pigment as can be used *quantum satis* in EU regulations
04.1.2.7	candied fruit	250	Supported at 250mg/kg pigment
04.1.2.9	fruit-based desserts, including fruit-flavoured water-based desserts	150	Reduce level from 3000mg/kg to the needed 150mg/kg pigment
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	GMP	Supported
04.2.2.1	frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	100	Reduce level from 2000mg/kg to the needed 100mg/kg pigment
04.2.2.2	Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) seaweeds, and nuts and seeds	100	Reduce level from 2000mg/kg to the needed 100mg/kg pigment
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	200	Reduce level from 500mg/kg to the needed 200mg/kg pigment
04.2.2.4	canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweeds	200	Reduce level from 2000mg/kg to the needed 200mg/kg pigment
05.1.2	Cocoa mixes (syrups)	100	Reduce level from 128mg/kg to the needed 100mg/kg pigment
05.1.3	Cocoa-based spreads, including fillings	100	Reduce level from 128mg/kg to the needed 100mg/kg pigment

Food Cat. No.	Food Category	NATCOL supports mg/kg	Comments
05.1.4	Cocoa and chocolate products	500	Reduce level from 700mg/kg to the needed 500mg/kg pigment
05.1.5	imitation chocolate, chocolate substitute products	500	Reduce level from 700mg/kg to the needed 500mg/kg pigment
05.2.1	hard candy	500	Reduce level from 700mg/kg to the needed 500mg/kg pigment
05.2.2	soft candy	500	Increase level from 100mg/kg to the needed 500mg/kg pigment as can be used *quantum satis* in EU regulations
05.2.3	nougats and marzipans	200	Increase level from 100mg/kg to the needed 200mg/kg pigment as can be used *quantum satis* in EU regulations
05.3	chewing gum	500	Reduce level from 700mg/kg to the needed 500mg/kg pigment
05.4	decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	500	Increase level from 100mg/kg to the needed 500mg/kg pigment as can be used *quantum satis* in EU regulations
06.3	breakfast cereals, including rolled oats	100	Supported
06.4.2	Dried pastas and noodles and like products	GMP	Supported
06.4.3	Pre-cooked pastas and noodles and like products	GMP	Supported
06.5	cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	75	Supported at 75mg/kg pigment
07.1.4	bread-type products, including bread stuffing and bread crumbs	75	Reduce level from 128mg/kg to the needed 75mg/kg pigment
07.2	fine bakery wares (sweet, salty, savoury) and mixes	100	Increase level from 75mg/kg to the needed 100mg/kg pigment as can be used *quantum satis* in EU regulations
07.2.2	Other fine bakery products (e.g., doughnuts, sweet rolls, scones, and muffins)	GMP	Supported
07.2.3	Mixes for fine bakery wares (e.g., cakes, pancakes)	GMP	Supported
09.2.1	Frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	GMP	Supported
09.2.3	frozen minced and creamed fish products, including mollusks, crustaceans, and echinoderms	40	Supported
09.2.4.1	cooked fish and fish products	40	Reduce level from 600mg/kg to the needed 40mg/kg pigment
09.2.4.3	fried fish and fish products, including mollusks, crustaceans, and echinoderms	40	Reduce level from 800mg/kg to the needed 40mg/kg pigment
09.2.5	smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	200	Supported at 200mg/kg pigment
09.3.1	fish and fish products, including mollusks, crustaceans, and echinoderms, marinated and/or in jelly	100	Increase level from 40mg/kg to the needed 100mg/kg pigment as pre-cooked crustaceans are *quantum satis* in EU regulations
09.3.2	fish and fish products, including mollusks, crustaceans, and echinoderms, pickled and/or in brine	100	Increase level from 40mg/kg to the needed 100mg/kg pigment as pre-cooked crustaceans are *quantum satis* in EU regulations
09.3.3	salmon substitutes, caviar, and other fish roe products	200	Supported
09.3.4	semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms (e.g., fish paste), excluding products of food categories 09.3.1 - 09.3.3	75	Supported
09.4	fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	200	Reduce level from 500mg/kg to the needed 200mg/kg pigment
10.4	egg-based desserts (e.g., custard)	300	Supported
12.2.2	Seasonings and condiments	200	Increase level from 100mg/kg to the needed 200mg/kg pigment as can be used *quantum satis* in EU regulations

Food Cat. No.	Food Category	NATCOL supports mg/kg	Comments
12.4	mustards	GMP	Supported
12.5.1	ready-to-use soups and broths, including canned, bottled, and frozen	400	Supported
12.5.2	Mixes for soups and broths	400	Increase level from 100mg/kg to the needed 400mg/kg pigment as can be used *quantum satis* in EU regulations
12.6	Sauces and like products	400	Increase level from 100mg/kg to the needed 400mg/kg pigment as can be used *quantum satis* in EU regulations
12.9.5	other protein products	GMP	Supported
13.1.3	formulae for special medical purposes for infants	20	Supported
13.3	dietetic foods intended for special medical purposes (excluding products of food category 13.1)	GMP	Supported
13.4	dietetic formulae for slimming purposes and weight reduction	GMP	Supported
13.5	dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6	GMP	Supported
13.6	food supplements	GMP	Supported
14.1.3.2	vegetable nectar	GMP	Supported
14.1.3.4	concentrates for vegetable nectar	GMP	Supported
14.1.4	water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	GMP	Increase level from 300mg/kg to GMP as can be used *quantum satis* in EU regulations
14.2.2	cider and perry	GMP	Supported
14.2.4	wines (other than grape)	GMP	Supported
14.2.6	distilled spirituous beverages containing more than 15% alcohol	GMP	Supported
15.1	snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	350	Supported
15.2	processed nuts, including covered nuts and nut mixtures (with e.g., dried fruit)	350	Increase level from 100mg/kg to the needed 350mg/kg pigment as can be used *quantum satis* in EU regulations

INTENDED FOOD USES AND MAXIMUM LEVEL FOR ZEAXANTHIN INS No 161h

Food Cat. No.[1]	Food Category[1]	Max Level
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yogurt, whey-based drinks)	100 mg/kg
01.2	Fermented and renneted milk products (plain), excluding food category 01.1.2 (dairy-based drinks)	100 mg/kg
01.6	Cheese and analogues	100 mg/kg
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yogurt)	150 mg/kg
02.2.1.2	Margarine and similar products	100 mg/kg
02.2.2	Emulsions containing less than 80% fat	100 mg/kg
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	50 mg/kg
02.4	Fat based desserts	150 mg/kg
03.0	Edible ices, including sherbet and sorbet	150 mg/kg
04.1.2.7	Candied fruits	200 mg/kg
04.1.2.9	Fruit based desserts	150 mg/kg
05.2	Confectionary including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3, and 05.4	300 mg/kg
05.3	Chewing gum	100 mg/kg
06.3	Breakfast cereals, including rolled oats	100 mg/kg
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	100 mg/kg
07.1.2	Crackers, excluding sweet crackers	50 mg/kg
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	100 mg/kg

Food Cat. No.[1]	Food Category[1]	Max Level
08.4	Edible casings	GMP
10.2	Egg products	100 mg/kg
10.4	Egg-based desserts (e.g., custard)	100 mg/kg
12.2.2	Seasonings and condiments	500 mg/kg
12.5.	Soups and broths	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)	50 mg/kg
12.9.	Protein products	100 mg/kg
13.3	Dietetic foods intended for special medical purposes (excluding products of food category 13.1)	50 mg/kg
13.4	Dietetic formulae for slimming purposes and weight reduction	50 mg/kg
13.5	Dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1-13.4 and 13.6	100 mg/kg
13.6	Food supplements	300 mg/kg
14.1.3	Fruit and vegetable nectars	100 mg/kg
14.1.4	Water-based flavoured drinks, including “sport”, “energy” or “electrolyte” drinks and particulated drinks	100 mg/kg
15.0	Ready-to-eat savouries	100 mg/kg
16.	Composite foods – foods that could not be placed in categories 01 – 15	100 mg/kg

[1] Food Category System for the General Standard for Food Additives (GSFA) (Annex B)

OIV:

General comments

The OIV makes the following comments at the request of CL 34/2005-FAC on the proposed food additives provisions.

The OIV has commented on some of these additives provisions at a prior step.

The OIV seeks to better define the prescriptions and conditions of oenological practices uniquely necessary for the production and conservation of grape wines (category 14.2.3), by limiting inputs which are not technologically justified.

In carefully examining the document CL 34/2005-FAC, the OIV proposes the withdrawal of certain additives, particularly colourings and sweeteners of the GSFA as not necessary to the development of healthy products in accordance with usual practice and which risk creating confusion in consumers.

Finally, the OIV recalls that “CCFAC noted concerns expressed by the OIV as to the excessive use of additives in the category 14.2.3 and decided to put them to the working group for consideration at the thirty-fifth session of CCFAC” (alinorm 03/12 § 63).

Specific comments

SULPHITES (INS 220-225, 227-228, 539)

The addition of sulphur dioxide to wine is a common œnological practice permitted by the OIV.

The OIV supports endorsement of these provisions for category grape wines 14.2.3. considering that this practice is technologically justified in order to:

- -obtain the microbiological stabilisation of wine by limiting and/or preventing the growth of yeast and technologically unwanted bacteria,
- use its reducing and antioxidant properties,
- combine certain molecules that give undesirable odours,
- inhibit possible oxidasic activities.

Considering the proposed maximum use level, and in order to achieve the intended technical need, the OIV considers that total sulphur dioxide content (residual limit) at the time the wine is offered for sale should comply with the following OIV limits:

- 150 mg/l for red wines containing at most 4 g/l of reducing agents
- 200 mg/l for white and rosé wines containing at most 4 g/l of reducing agents
- 300 mg/l for red, white, and rosé wines containing more than 4 g/l of reducing agents

- 400 mg/l for certain special sweet white wines

However the OIV is aware that the level of residual limits of SO_2 in wines are different among various of its member countries.

CANTHAXANTHIN (INS 161g)

The OIV considers that the WG should reaffirm the 37th CCFAC's decision to recommend that the 38th CCFAC discontinue work on specific provisions for the use of canthaxanthin in category 14.2.3 in the GSFA.

In the OIV standard on Oenological Practices, no colorants may be used in grape wines (category 14.2.3). Their inclusion in category 14.2.3 does not seem technologically justified and could mislead consumers.

The OIV recommends that this draft provision be deleted from category 14.2.3.

GRAPE SKIN EXTRACT (INS 163ii)

The OIV considers that the WG should reaffirm the 37th CCFAC's decision to recommend that the 38th CCFAC discontinue work on specific provisions for the use of grape skin extract, as colour, in category 14.2.3 in the GSFA.

In the OIV standard on Oenological Practices, no colours may be used in grape wines (category 14.2.3). Their inclusion in these categories does not seem technologically justified and could mislead consumers. The OIV recommends that this draft provision be deleted from categories 14.2.3.2 and 14.2.3.3.

IRON OXIDES (INS 172i, 172ii, 172iii)

The OIV considers that the WG should reaffirm the 37thCCFAC's decision to recommend that the 38th CCFAC discontinue work on specific provisions for the use of iron oxides in category 14.2.3.2 in the GSFA.

In fact, in the wine making process and sparkling wine making process, there are a number of practices employed to reduce or eliminate the level of heavy metals. It appears technologically nonsensical to allow the addition of iron oxides in wine making processes.

The OIV recommends that this draft provision be deleted from category 14.2.3.2

CARAMEL (150c, 150d)

No comments on the use of this additive in categories 14.2.3.3 since these provisions were adopted in 1999.

CAROTENOIDS (INS 160ai, 160 aii, 160e, 160f)

The OIV does not support the recommendation to endorse the proposed provisions in the GSFA for the use of carotenoids in categories 14.2.3.2 for adoption. This was mentioned in previous OIV comments (CX/FAX 05/37/10), in reply to the circular letter CL 2004/44 FAC.

In the OIV standard on Oenological Practices, no colorants may be used in grape wines (category 14.2.3). Their inclusion in category 14.2.3 does not seem technologically justified and could mislead consumers.

The OIV recommends this draft provision be deleted from categories 14.2.3.2

In any event, the compounds included in this group of additives should be clarified. In fact, taking into account the different INS Number, Carotenes, vegetables (INS 160aii) appear to be included. However specific provisions related to Carotenes, vegetable (INS 160aii) already exist in another part of the document (Appendix II pages 22). So, it is important to verify if these provisions concerning carotenoids include Carotenes, vegetables or not.

ACESULFAM POTASSIUM (INS 950)

The OIV does not support the recommendation to endorse the proposed provisions in the GSFA for the use of acesulfam potassium in categories 14.2.3 for adoption. This was mentioned in previous OIV comments (CX/FAX 05/37/10), in reply to the circular letter CL 2004/44 FAC.

The OIV considers that no sweeteners should be used for grape wines (category 14.2.3). Their inclusion in category 14.2.3. does not seem technologically justified and could mislead consumers.

SUCRALOSE (INS 955)

The OIV does not support the recommendation to endorse the proposed provisions in the GSFA for the use of sucralose in categories 14.2. for adoption. This was mentioned in previous OIV comments (CX/FAX 05/37/10) in reply to the circular letter CL 2004/44 FAC.

The OIV considers that no sweeteners should be used for grape wines (category 14.2.3 and sub categories).

Their inclusion in category 14.2.3. does not seem technologically justified and could mislead consumers.

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

WSRO:

There are discrepancies between additives proposed to be included in the GSFA and the Codex Standard for Sugars (Codex Stan 212 – 1999, Amd.1-2001). These are:

- The proposed addition of sulphites at a max level of 20mg/kg to Food Category 11.1.4 – lactose
- The proposed addition of Caramel Colour Class III 150c, Caramel Colour Class IV 150d and Carotenoids to Food Category 11.1.2 – powdered sugar, powdered dextrose

WSRO is concerned with these inconsistencies, and recommend that conflicting standards are not adopted.