CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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**Agenda Item 5b** **CX/FA 21/52/8[1]**

**March 2021**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON FOOD ADDITIVES**

**Fifty-second Session**

**GENERAL STANDARD FOR FOOD ADDITIVES (GSFA)**

**PROPOSALS FOR NEW AND/OR REVISION OF FOOD ADDITIVE PROVISIONS**

**Replies to CL 2019/40-FA of Australia, Uganda and Food Drink Europe**

**and**

**Replies to CL 2020/36-FA of Colombia and ISC**

## Part A: Replies to CL 2019/40-FA

### Australia

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| **THE PROPOSAL IS SUBMITTED BY:** | | Australia | |
| **IDENTITY OF THE FOOD ADDITIVE:** | | | |
| **Name of the Additive**<br>*As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989* | | Lauric arginate ethyl ester | |
| **INS Number** | | 243 | |
| **Functional Class**<br>*As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989* | | Preservative | |
| **PROPOSED USE(S) OF THE FOOD ADDITIVE ([1]):**<br>*The rows below may be copied as many times as needed.* | | The proposal for:<br>☐ a new provision; or<br>**X** revising an existing provision in Tables 1 and 2 of the GSFA; or<br>☐ revising an existing provision in Table 3 of the GSFA (skip to "Is the proposal intended to revise products covered by the commodity standard"). | |
| **Food Category No. ([2])** | **Food Category Name ([2])** | **Maximum Use Level ([3])** | **Comments ([4])** |
| 01.6.2.1 | Ripened Cheese, includes rind | 200 mg/kg | ~~Note XS263~~<br>~~Note XS264~~<br>~~Note XS265~~<br>~~Note XS266~~<br>~~Note XS267~~<br>~~Note XS268~~<br>~~Note XS269~~<br>~~Note XS270~~<br>~~Note XS271~~ |

[1] This document is an updated version of CX/FA 20/52/8 and proposals in reply to CL 2020/36-FA have been included.

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| | | | ~~Note XS272~~<br>Remove these exclusions from the lauric arginate ethyl ester provisions |

**Is the proposal related to a FC with corresponding commodity standards?**

(if yes indicate the relevant FC)

Yes. FC 01.6.2.1

Standard for Cheddar (CXS 263-1966)

Standard for Danbo (CXS 264-1966)

Standard for Edam (CXS 265-1966)

Standard for Gouda (CXS 266-1966)

Standard for Havarti (CXS 267-1966)

Standard for Samsø (CXS 268-1966)

Standard for Emmental (CXS 269-1967)

Standard for Tilsiter (CXS 270-1968)

Standard for Saint-Paulin (CXS 271-1968)

Standard for Provolone (CXS 272-1968)

**Is the proposal also intended to revise the products covered by the commodity standards?**

(if yes indicate the relevant commodity standards)

Yes, to revise the products covered by the commodity listed above to permit the use of lauric arginate ethyl ester (INS 243) (LAEE).

**EVALUATION BY JECFA:**

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| **Evaluation by JECFA**<br>*Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).* | Evaluation date: 2008<br>Report: TRS 952-JECFA 69/27<br>Tox Monograph: FAS 60-JECFA 69<br>Specifications: FAO JECFA Monographs 7 (2009)<br>ADI 0-4 mg/kg bw for Ethyl-Nα-Lauroyl-L-Arginate |

**JUSTIFICATION:**

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| **Justification for use and technological need**<br>*Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).* | Based on Section 3.2 of the Preamble of the General Standard for Food Additives, the main technological need for the use of LAEE in food category 01.6.2.1 is 3.2(c) 'To enhance to keeping quality or stability of a food'.<br>Provisions were adopted at Step 8 in 2011 for LAEE (INS 243) in food category 01.6.2.1 at a level of 200 mg/kg. The provisions were adopted with footnotes that restrict the use of the additive in products conforming to corresponding commodity standards associated with this category.<br>The thirteen footnotes adopted were as follows:<br>**XS263:** Excluding products conforming to the Standard for Cheddar (CXS 263-1966)<br>**XS264:** Excluding products conforming to the Standard for Danbo (CXS 264-1966)<br>**XS265:** Excluding products conforming to the Standard for Edam (CXS 265-1966)<br>**XS266:** Excluding products conforming to the Standard for Gouda (CXS 266-1966)<br>**XS267:** Excluding products conforming to the Standard for Havarti (CXS 267-1966)<br>**XS268:** Excluding products conforming to the Standard for Samsø (CXS 268-1966)<br>**XS269:** Excluding products conforming to the Standard for Emmental (CXS 269-1967)<br>**XS270:** Excluding products conforming to the Standard for Tilsiter (CXS 270-1968) |

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| | **XS271:** Excluding products conforming to the Standard for Saint-Paulin (CXS 271-1968)<br>**XS272:** Excluding products conforming to the Standard for Provolone (CXS 272-1968)<br>**XS274:** Excluding products conforming to the Standard for Coulommiers (CXS 274-1969)<br>**XS276:** Excluding products conforming to the Standard for Camembert (CXS 276-1973)<br>**XS277:** Excluding products conforming to the Standard for Brie (CXS 277-1973)<br>The current request is to authorize the use LAEE in the same cheese standards as many other preservatives, including lysozyme, sorbates, nisin, natamycin, nitrates and propionate. Therefore, it is sought to remove the following **ten** footnotes:<br>**XS263:** Excluding products conforming to the Standard for Cheddar (CXS 263-1966)<br>**XS264:** Excluding products conforming to the Standard for Danbo (CXS 264-1966)<br>**XS265:** Excluding products conforming to the Standard for Edam (CXS 265-1966)<br>**XS266:** Excluding products conforming to the Standard for Gouda (CXS 266-1966)<br>**XS267:** Excluding products conforming to the Standard for Havarti (CXS 267-1966)<br>**XS268:** Excluding products conforming to the Standard for Samsø (CXS 268-1966)<br>**XS269:** Excluding products conforming to the Standard for Emmental (CXS 269-1967)<br>**XS270:** Excluding products conforming to the Standard for Tilsiter (CXS 270-1968)<br>**XS271:** Excluding products conforming to the Standard for Saint-Paulin (CXS 271-1968)<br>**XS272:** Excluding products conforming to the Standard for Provolone (CXS 272-1968)<br>The acceptability of the use of preservatives in these ten food standards is recognised in the GSFA by way of the inclusion of provisions permitting the use of various preservatives, including lysozyme, sorbates, nisin, natamycin, nitrates and propionates[2] in these standards. The use of LAEE provides an effective alternative to the use of such preservatives in products falling under these standards.<br>Technological effect of Lauric arginate ethyl ester in cheese<br>LAEE is a preservative that is also used in products that conform to these corresponding ten commodity standards associated with FC 01.6.2.1. The technical effect of LAEE in food is to inhibit microbial growth in the food to which it has been added, and it is effective in controlling the growth of potentially pathogenic organisms in products falling under 01.6.2.1. The active ingredient of LAEE, as a cationic surfactant, has a wide spectrum of activity against bacteria, yeasts and moulds. Specifically, LAEE affects negatively charged compounds such as microbial proteins present in cellular membranes or in enzyme systems.<br>Both hard or ripened and soft or unripened cheese benefit from the addition of preservatives. Age-ripened cheese retain their quality for long periods due to comparatively low pH, low water activity and low redox potential. However, spoilage may occur through the action of fungi, lactic acid bacteria and spore-forming bacteria. Unripened cheeses spoil more rapidly than aged cheeses, |

[2] Proprionates are not permitted for use in Emmental and have the following Note - XS269: Excluding products conforming to the *Standard for Emmental* (CXS 269-1967). But they are permitted in the other nine standards as described here.

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| | and typical spoilage microorganisms include psychrotrophs, coliforms, fungi and lactic acid bacteria (Ledenbach and Marshall, 2009). Pasteurisation may eliminate many spoilage microorganisms originating from milk production and processing, but post-process contamination of milk and cheese can still occur.<br><br>Use of the currently authorised preservatives in cheese has some disadvantages. When used to prevent mould growth on the surface of cheese, sorbates tend to diffuse into the cheese decreasing the surface concentration and thereby decreasing their preservative effect, and also modifying the favour, appearance and ripening process of the cheese (de Ruig and van den Berg, 1985). In addition, some moulds that grow on cheese are capable of metabolising sorbic acid and sorbate to trans-1,3-pentadiene, which causes an off-odour and flavour (Ledenbach and Marshall, 2009; Sensidoni et al., 1994). In addition, the near neutral pH of fresh cheese is not optimal for the antimicrobial activity of sorbates. The use of other preservatives on cheese also have disadvantages, such as natamycin which is a polyene fungicide and is not active against pathogenic bacteria such as *L. monocytogenes* (EFSA, 2009). Nisin has a narrow spectrum of activity against only gram-positive bacteria and does not inhibit gram-negative bacteria, yeasts or moulds (EFSA, 2006). In addition, some strains of bacteria, including some strains of *L. monocytogenes* have been shown to develop gradual resistance against nisin (Soni et al., 2010).<br><br>The technological advantages of LAEE over other preservatives for use in cheeses (i.e. FC 01.6.2.1) include the following:<br><br>• LAEE is effective at low and near-neutral pH. In contrast, some currently approved preservatives are only effective at low pH.<br><br>• LAEE is similarly effective against bacteria (Gram +ve and Gram –ve), yeasts and moulds. Other preservatives must be combined to enhance their antimicrobial efficacy because they cannot inhibit the growth of such a wide range of micro-organisms by themselves<br><br>• The minimum inhibitory concentrations (MICs) of LAEE are considerably lower than the MICs of the other preservatives against the same micro-organisms. This means that the effective application dose is lower for LAEE than for other food preservatives<br><br>• On ingestion, LAEE can be easily and rapidly metabolised to common, natural constituent metabolic compounds. This implies a lack of adverse effects because it is a unique food preservative that is metabolically decomposed into constituent products.<br><br><u>Efficacy</u><br><br>The efficacy of LAEE as an antimicrobial preservative for use on cheese has been demonstrated in a number of studies. Some of these studies are now described:<br><br>An internal study examined effect of LAEE on fresh cheese (50 ppm and 100 ppm) (Internal study VED-EC-21). Treating fresh cheese with LAE did not change their taste and general appearance. Found that LAEE reduces the concentration of the standard microbiological contamination present in the samples (*E. coli*, Coliform bacteria and yeasts). The antimicrobial activity increases with higher concentrations of LAEE. At 50 ppm there is a clear reduction effect, while at 100 ppm the reduction increases significantly.<br><br>A separate internal study examined the effect of LAEE on blue cheese to prevent the presence of *Listeria monocytogenes* without affecting the technological characteristics of this type of product (Internal study VED-EC-22). During ripening, soaking of blue cheeses was done using a 1% LAEE solution. Soaking was carried out 4 times during ripening. Treating blue cheeses with solutions of LAE during ripening period did not change their general appearance. LAEE surface treatment reduces the population of *Listeria spp.* in blue cheese and prevents the presence of *Listeria monocytogenes* on the surface of blue cheese.<br><br><u>International authorisation of LAEE</u> |

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| | The use of lauric arginate ethyl ester (LAEE) is permitted for use in products falling under FC 01.6.2.1 in a number of countries worldwide (e.g. Australia, New Zealand, Canada, and the USA), without further restriction on its use in products conforming to the relevant Codex commodity standards. These products are also available in international trade. As such, consideration should be given to revising the provisions of the GSFA to reflect the acceptable use of LAEE as a preservative in these products in numerous countries. |
| **Safe use of additive: Dietary intake assessment**<br>(*as appropriate*) | Table 3 additive:<br>☐ Yes<br>**X** No (Please provide information on dietary intake assessment below)<br>The use of lauric acid ethyl ester (INS 243) in cheese products that fall under Codex food category 01.6.2.1, as well as its use in a broad range of other foods, was taken into consideration as part of the JECFA assessment of the safety of the additive in 2009. |
| **Justification that the use does not mislead consumer** | When used as a preservative, the use of LAEE would be in the list of ingredients on the label of the products. |

**REFERENCES**

De Ruig, WG and van den Berg G. (1985). Influence of the fungicides sorbate and natamycin in cheese coatings on the quality of the cheese*. Neth. Milk Dairy J. ,*39, 165-172.

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the use of natamycin (E 235) as a food additive. EFSA Journal 2009;7(12):1412 [25 pp.].

EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food. Scientific Opinion on the use of nisin (E 234) as a food additive. Question number EFSA-Q-2005-031. Adopted on 26 January 2006. The EFSA Journal (2006) 314, 1-16.

Internal study - VED-EC-21. Technical report of Efficacy test. Lauric Arginate as Preservative for treatment of Blue Cheese. Laboratorios Miret S.A. Lamirsa. 15 September 2008.

Internal study - VED-EC-22. Technical report of Efficacy test. Lauric Arginate as Preservative for Fresh Cheese. Laboratorios Miret S.A. Lamirsa. 22 Febuary 2008.

Ledenbach, LH and Marshall, RT. (2009). Microbiological Spoilage of Dairy Products. In: Compendium of the Microbiological Spoilage of Foods and Beverages. Ed. Sperber, W.H. and Doyle, M.P. Food microbiology and Food Safety. Springer p.41-67

Sensidoni A, Rondinini G, Peressini D, Maifreni M, Bortolomeazzi R. (1994). Presence of an off-flavour associated with the use of sorbates in cheese and margarine. Ital. J. Food Sci. 2: 237-242.

Soni KA, Nannapaneni R, Schilling MW, Jackson V. (2010). Bactericidal activity of lauric arginate in milk and Queso Fresco cheese against Listeria monocytogenes cold growth. J Dairy Sci., Oct;93(10):4518-25.

## Uganda

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| **THE PROPOSAL IS SUBMITTED BY:** | Uganda |
| **IDENTITY OF THE FOOD ADDITIVE:** | |
| **Name of the Additive**<br>*As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989* | Azorubine (Carmoisine) |
| **INS Number** | 122 |
| **Functional Class**<br>*As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989* | Colour |

| **PROPOSED USE(S) OF THE FOOD ADDITIVE ([1]):**<br>*The rows below may be copied as many times as needed.* | | The proposal for:<br>**X** a new provision; or<br>☐ revising an existing provision in Tables 1 and 2 of the GSFA; or<br>☐ revising an existing provision in Table 3 of the GSFA (skip to "Is the proposal intended to revise products covered by the commodity standard"). | |
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| **Food Category No. ([2])** | **Food Category Name ([2])** | **Maximum Use Level ([3])** | **Comments ([4])** |
| 14.1.4 | Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks | 50 mg/l | Labelling requirement: "may have an adverse effect on activity and attention in children" |
| **Is the proposal related to a FC with corresponding commodity standards?**<br>(*if yes indicate the relevant FC*)<br>No | | | |
| **Is the proposal also intended to revise the products covered by the commodity standards?**<br>(*if yes indicate the relevant commodity standards*)<br>No | | | |
| **EVALUATION BY JECFA:** | | | |
| **Evaluation by JECFA**<br>*Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).* | • 27th JECFA (1983)<br>• ADI: 0 – 4 mg/kg bw<br>• FAS 18-JECFA 27/15 (monograph) | | |
| **JUSTIFICATION:** | | | |
| **Justification for use and technological need**<br>*Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).* | To enhance products' organoleptic properties.<br>The colourant is not mutagenic, carcinogenic, or teratogenic and it produces no serious histopathological effects (JECFA, 1983) | | |
| **Safe use of additive: Dietary intake assessment** (*as appropriate*) | Table 3 additive:<br>☐ Yes<br>**X** No (Please provide information on dietary intake assessment below) | | |
| **Justification that the use does not mislead consumer** | Products containing the food additive to conform to food labelling requirements for food additives in the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) | | |

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| **THE PROPOSAL IS SUBMITTED BY:** | Uganda |
| **IDENTITY OF THE FOOD ADDITIVE:** | |
| **Name of the Additive**<br>*As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989* | Quinoline yellow |
| **INS Number** | 104 |

<table>
<tr><td colspan="2">Functional Class<br>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</td><td colspan="2">Colour</td></tr>
<tr><td colspan="2">PROPOSED USE(S) OF THE FOOD ADDITIVE (<sup>1</sup>):<br>The rows below may be copied as many times as needed.</td><td colspan="2">The proposal for:<br>General Standard for the Labelling of Prepackaged Foods a new provision; or<br>☐ revising an existing provision in Tables 1 and 2 of the GSFA; or<br>☐ revising an existing provision in Table 3 of the GSFA (skip to “Is the proposal intended to revise products covered by the commodity standard”).</td></tr>
<tr><td>Food Category No. (<sup>2</sup>)</td><td>Food Category Name (<sup>2</sup>)</td><td>Maximum Use Level (<sup>3</sup>)</td><td>Comments (<sup>4</sup>)</td></tr>
<tr><td>14.1.4</td><td>Water-based flavoured drinks, including “sport,” “energy,” or “electrolyte” drinks and particulated drinks</td><td>10 mg/l</td><td>Labelling requirement:<br>“may have an adverse effect on activity and attention in children”</td></tr>
<tr><td colspan="4">Is the proposal related to a FC with corresponding commodity standards?<br>(if yes indicate the relevant FC)<br>No</td></tr>
<tr><td colspan="4">Is the proposal also intended to revise the products covered by the commodity standards?<br>(if yes indicate the relevant commodity standards)<br>No</td></tr>
<tr><td colspan="4">EVALUATION BY JECFA:</td></tr>
<tr><td colspan="2">Evaluation by JECFA<br>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or “not specified”); specifications monograph).</td><td colspan="2">• 82nd JECFA (2016)<br>• ADI: 0 – 3 mg/kg bw<br>• FAO JECFA monographs 19</td></tr>
<tr><td colspan="4">JUSTIFICATION:</td></tr>
<tr><td colspan="2">Justification for use and technological need<br>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</td><td colspan="2">To enhance products’ organoleptic properties.<br>Dietary exposure to quinoline yellow for children and all other age groups does not present a health concern. (WHO food additives series: 73, 2017)</td></tr>
<tr><td colspan="2">Safe use of additive: Dietary intake assessment (as appropriate)</td><td colspan="2">Table 3 additive:<br>☐ Yes<br>X No (Please provide information on dietary intake assessment below)<br>• EFSA (European Food Safety Authority), 2015. Refined exposure assessment for Quinoline Yellow (E 104). EFSA Journal 2015;13(3):4070, 33 pp., doi:10.2903/j.efsa.2015.4070<br>• Safety evaluation of certain food additives (JECFA, 2017)</td></tr>
<tr><td colspan="2">Justification that the use does not mislead consumer</td><td colspan="2">Products containing the food additive to conform to food labelling requirements for food additives in the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985)</td></tr>
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| **THE PROPOSAL IS SUBMITTED BY:** | Uganda |
| **IDENTITY OF THE FOOD ADDITIVE:** | |
| **Name of the Additive**<br>*As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989* | Tartrazine |
| **INS Number** | 102 |
| **Functional Class**<br>*As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989* | Colour |

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| **PROPOSED USE(S) OF THE FOOD ADDITIVE ([1]):**<br>*The rows below may be copied as many times as needed.* | The proposal for:<br>X a new provision; or<br>☐ revising an existing provision in Tables 1 and 2 of the GSFA; or<br>☐ revising an existing provision in Table 3 of the GSFA (skip to "Is the proposal intended to revise products covered by the commodity standard"). |

| **Food Category No. ([2])** | **Food Category Name ([2])** | **Maximum Use Level ([3])** | **Comments ([4])** |
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| 14.1.4 | Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks | 100 mg/l | Labelling requirement:<br>"may have an adverse effect on activity and attention in children" |

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| **Is the proposal related to a FC with corresponding commodity standards?**<br>(*if yes indicate the relevant FC*)<br>No |
| **Is the proposal also intended to revise the products covered by the commodity standards?**<br>(*if yes indicate the relevant commodity standards*)<br>No |
| **EVALUATION BY JECFA:** |

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| **Evaluation by JECFA**<br>*Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).* | • 82nd JECFA Report (2016)<br>• ADI: 0 – 10 mg/kg bw<br>• FAO JECFA Monographs 19 |
| **JUSTIFICATION:** | |
| **Justification for use and technological need**<br>*Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).* | To enhance products' organoleptic properties.<br>Dietary exposure to tartrazine for the general population, including children, does not present a health concern (WHO Food Additive Series: 73, 2017) |
| **Safe use of additive: Dietary intake assessment** (*as appropriate*) | Table 3 additive:<br>☐ Yes<br>**X** No (Please provide information on dietary intake assessment below)<br>(WHO/JECFA, 2017) Safety evaluation of certain food additives |

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| **Justification that the use does not mislead consumer** | Products containing the food additive to conform to food labelling requirements for food additives in the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) |

**Food Drink Europe**

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| **THE PROPOSAL IS SUBMITTED BY:** | FoodDrinkEurope | | |
| **IDENTITY OF THE FOOD ADDITIVE:** | | | |
| **Name of the Additive**<br>*As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989* | Sucralose | | |
| **INS Number** | 955 | | |
| **Functional Class**<br>*As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989* | Sweetener | | |
| **PROPOSED USE(S) OF THE FOOD ADDITIVE ([1]):**<br>*The rows below may be copied as many times as needed.*<br>**Existing Authorisation in GSFA**<br>**Table One**<br>**Category 7.2 Fine Bakery Wares**<br>**Sucralose 955 2008 700 mg/kg Notes 161 & 165** | The proposal for:<br>☐ a new provision; or<br>**X** revising an existing provision in Tables 1 and 2 of the GSFA; or<br>☐ revising an existing provision in Table 3 of the GSFA (skip to "Is the proposal intended to revise products covered by the commodity standard"). | | |
| **Food Category No. ([2])** | **Food Category Name ([2])** | **Maximum Use Level ([3])** | **Comments ([4])** |
| 07.2 | Fine Bakery Wares | 700 mg/kg | A new Note to be added "wafer paper only" |
| **Is the proposal related to a FC with corresponding commodity standards?**<br>(*if yes indicate the relevant FC*)<br>No | | | |
| **Is the proposal also intended to revise the products covered by the commodity standards?**<br>(*if yes indicate the relevant commodity standards*)<br>No | | | |
| **EVALUATION BY JECFA:** | | | |
| **Evaluation by JECFA**<br>*Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).* | *Evaluation Year: 1990*<br>*ADI: 0-15mg/kg bw*<br>*Meeting: 37*<br>*Specs Code: R (1993)*<br>*Report: TRS 806-JECFA37/21*<br>*Tox Monograph: FAS 28-JECFA 37/219*<br>*Specification: Compendium Addendum 12/FNP 52 Add. 12/68 (Metals Limits) 2004. R;*<br>*FAO JECFA Monographs 1 vol. 3/439*<br>*2001, Compendium Addendum 9/FNP 52 Add.9/192 (Metals Limits)*<br>*1993, Compendium Addendum 2/FNP 52 Add.2/119. R*<br>*1990, Compendium/1531. R*<br>*1988, TRS 776-JECFA 33/20, FNP 38-JECFA 33/255, FAS 24-JECFA 33/45. 0-3.5 (Temporary). TE. N,T* | | |
| **JUSTIFICATION:** | | | |

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| **Justification for use and technological need**<br>*Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).* | *A baking process with sugar is in the case of wafer papers technically not possible because the sugar will stick during the baking process to the baking plates.*<br>*Therefore, in the case of wafer papers no alternative to Sweeteners. Sucralose is most suitable sweetener for wafer paper.* |
| **Safe use of additive: Dietary intake assessment** (*as appropriate*) | Table 3 additive:<br>☐ Yes<br>**X** No (Please provide information on dietary intake assessment below)<br>Wafer papers are absolute niche products and as a conclusion it can be stated that in the group of adults and children the ADI is not likely to be exceeded even for so called high-level consumers. |
| **Justification that the use does not mislead consumer** | *There are no sugar sweetened wafer papers on the market. Furthermore, the use of Sucralose is mentioned explicitly on the labelling.* |

**Part B: Replies to CL 2020/36-FA**

**Colombia**

Colombia, in response to circular letter CL 2020/36- FA, presents the information required for the inclusion of the food additive Jagua (Genipin-Glycine) Blue in the GSFA.

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| **THE PROPOSAL IS SUBMITTED BY:** | Ecoflora Cares |
| **IDENTITY OF THE FOOD ADDITIVE:** | |
| **Name of the Additive**<br>*As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989* | Jagua (Genipin-Glycine) Blue<br>**Synonims:** Jenipapo (genipapo) , Blue jenipapo (genipapo blue) , Azul de jagua (jagua blue), Azul de huito (huito blue), Huito, Jagua |
| **INS Number** | INS N 183 was requested according to CL 2020/35-FA |
| **Functional Class**<br>*As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989* | Colour |

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| **PROPOSED USE(S) OF THE FOOD ADDITIVE ([1]):**<br>*The rows below may be copied as many times as needed.* | The proposal for:<br>■ a new provision; or<br>☐ revising an existing provision in Tables 1 and 2 of the GSFA; or<br>☐ revising an existing provision in Table 3 of the GSFA (skip to "Is the proposal intended to revise products covered by the commodity standard"). |

| Food Category No. ([2]) | Food Category Name ([2]) | Maximum Use Level ([3]) | Comments ([4]) |
|---|---|---|---|
| 01.1 | Fluid Milk and Milk Products<br>Subcategory: 01.1.4 Flavored Fluid Milk Drink | Blue [(b)] 0.04%<br>Green [(b)], purple, brown 0.021% | Food type: flavored milk<br>[(b)] Color use is seasonal |
| 04.1 | Fruit<br>Subcategory: 04.1.2.8 Fruit preparations, including pulp, purees, fruit toppings and coconut milk | Blue [(b)] 0.04%<br>Green [(b)], purple [(b)], brown [(b)], 0.021% | Food type: flavored milk substitutes<br>[(b)] Color use is seasonal |
| 06.8 | Soybean products (excluding soybean-based seasonings and condiments of food category | Blue [(b)] 0.04%<br>Green [(b)], purple [(b)], brown [(b)], 0.021% | Food type: flavored milk substitutes<br>[(b)] Color use is seasonal |

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| | 12.9)<br>Subcategory: 06.8.1 Soybean-based beverages | | |
| 01.2 | Fermented milks (plain)<br>(subcategory 01.2.1 Fermented milks (plain) | Blue 0.03%<br>Green, purple, brown 0.016% | Food type: yogurt, regular and Greek including non dairy products |
| 01.7 | Dairy-based desserts | Blue 0.10%<br>Green, purple, brown 0.053% | Food type: ice cream and frozen including milk shake<br>dairy |
| 01.7 | Dairy-based desserts | Blue NA(*)<br>Green (b), purple (b), brown 0.021% | Food type: pudding<br>(b) Color use is seasonal<br>NA(*) Not applicable; color not intended. |
| 03.0 | Edible ices, including sherbet and sorbet | Blue 0.03%<br>Green, purple, brown 0.016% | Food type: ice, sorbets |
| 06.3 | Breakfast cereals, including rolled oats | Blue 0.5%<br>Green, purple, brown 0.290% | Food type: Ready to eat cereals |
| 15.0 | Ready-to-eat savouries:<br>(Subcategory 15.1 Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)) | Blue NA(*)<br>Green, brown 0.154% (color in the seasoning) | Food type: potato chips flavored<br>NA(*) Not applicable; color not intended. |
| 15.0 | Ready-to-eat savouries:<br>(Subcategory 15.1 Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes) | Blue 0.3%<br>Green, brown 0.154% | Food type: tortilla, corn, other chips |
| 05.0 | Confectionery<br>Subcategory: 05.1.4 Cocoa and chocolate products | Blue 0.2%<br>Green, purple, brown 0.103% | Food type: candy containing chocolate. Intended use corresponds to the portion of candy that put contain Jagua Blue |
| 05.0 | Confectionery<br>Subcategory:<br>05.2.1 Hard candy<br>05.2.2 Soft candy<br>05.2.3 Nougats and marzipans | Blue 0.2%<br>Green, purple, brown 0.103% | Intended use corresponds to the portion of candy that put contain Jagua Blue |
| 05.0 | Confectionery<br>Subcategory:<br>05.3 Chewing gum | Blue 0.2%<br>Green, purple, brown 0.103% | Food type: Chewing gum |
| 14.1 | Non-alcoholic ("soft") beverages<br>Subcategory:<br>14.1.3 Fruit and vegetable nectars | Blue 0.02%<br>Green, purple, brown 0.011% | Food type: Fruit based drinks (including fruit flavored drinks) |
| 13.0 | Foodstuffs intended for particular nutritional uses | Blue NA<br>Green, purple, brown 0.016% | Food type: Nutritional beverages (RTE and powders) |
| 04.1 | Fruit<br>Subcategory: 14.1.2.1 Fruit juice | Blue NA<br>Green, purple 0.016% | Food type: Smoothie type |
| 01.6 | Cheese and analogues<br>01.6.1 Unripened cheese: | Blue NA<br>Green, purple, brown 0.011% | Food type: Cream cheese |
| 05.4 | Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces | Blue 0.03%<br>Green, purple, brown 0.016% | Food type: Icing and frosting |
| 04.1 | Fruit<br>Subcategory 04.1.2.5 Jams, jellies, marmalades | Blue 0.03%<br>Green, purple, brown 0.016% | Food type: fruit toppings, fillings and jams |

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| **Is the proposal related to a FC with corresponding commodity standards?**<br>No | |
| **Is the proposal also intended to revise the products covered by the commodity standards?**<br>No | |
| **EVALUATION BY JECFA:** | |
| **Evaluation by JECFA**<br>*Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).* | |
| **JUSTIFICATION:** | |
| **Justification for use and technological need**<br>*Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).* | |
| **Safe use of additive: Dietary intake assessment** (*as appropriate*) | Table 3 additive:<br>☐ Yes<br>☐ No (Please provide information on dietary intake assessment below) |
| **Justification that the use does not mislead consumer** | |

**International Stevia Council (ISC)**

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| ISC respectfully proposes the revision of GSFA by replacing the existing entry for food additive 960b Steviol Glycosides from Fermentation and by adding entries for 960c Enzyme Modified Steviol Glycosides (Enzymatically Produced Steviol Glycosides) and INS 960d Enzyme Modified Glucosylated Steviol Glycosides (Glucosylated Steviol Glycosides). | **International Stevia Council – ISC**<br>Contact Person:<br>Maria Teresa Scardigli - Executive Director<br>ISC Global Office:<br>Avenue de Tervuren 188A<br>1150 Brussels - Belgium<br>Tel: +32497597221<br>e-mail: GlobalOffice@internationalsteviacouncil.org |
| **IDENTITY OF THE FOOD ADDITIVE:** | |
| **Name of the Additive**<br>*As listed in Class Names and the International Numbering System (INS) - CXG 36-1989* | Steviol Glycosides from Fermentation<br>**General Comment:** All steviol glycoside-related submissions request that a streamlined approach be applied to all these additives by adding all to the Group Header Steviol Glycosides, as they are all covered under the same group ADI.<br>**Note 1:** this submission is linked to the form submitted for Enzyme Modified Steviol Glycosides (Enzymatically Produced Steviol Glycosides) and the form submitted for Enzyme Modified Glucosylated Steviol Glycosides (Glucosylated Steviol Glycosides).<br>**Note 2:** JECFA approved the monograph for Steviol Glycosides from Fermentation at its 87th meeting at its meeting in June 2019 – this monograph has to be adopted by CODEX and CCFA 52 will consider to adopt the final INS classification. |

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| | **Note 3:** Consistent with past practice, only this name as reflected in the JECFA specification naming should be used in the INS and would serve to update and replace the existing INS entry 'Rebaudioside A from multiple gene donors expressed in Yarowia lipolytica.' The detailed qualification associated with fermentation is (and would be) easily retrievable from the JECFA specification. |
| **INS Number** | 960b<br>**Note 1:** JECFA approved the monograph for Steviol Glycosides from Fermentation at its 87th meeting – this monograph has to be adopted by CODEX and CCFA 52 will consider to adopt the final INS classification.<br>**Note 2:** The INS number 960b serves to update and replace the existing entry 'INS 960b(i)' based upon the JECFA review and approval of the Framework for Steviol Glycosides at its 87th meeting in June 2019 . |
| **Functional Class**<br>*As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989* | Sweetener |

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| **PROPOSED USE(S) OF THE FOOD ADDITIVE ([1]):** *The rows below may be copied as many times as needed.* | The proposal for:<br>☐ a new provision; or<br>**x revising all existing provisions in Tables 1 and 2 of the GSFA,** by revising the group header for Steviol Glycosides to eliminate INS 960b i) and replace it with INS 960b; or<br>☐ revising an existing provision in Table 3 of the GSFA (skip to "Is the proposal intended to revise products covered by the commodity standard"). |

| **Food Category No. ([2])** | **Food Category Name ([2])** | **Maximum Use Level ([3])** | **Comments ([4])** |
|---|---|---|---|
| 01.1.4 | Flavoured fluid milk drinks | 200 mg/kg | 26 & XS243 |
| 01.5.2 | Milk and cream powder analogues | 330 mg/kg | 26 & 201 |
| 01.7 | Dairy-based desserts (e.g. pudding, fruit or flavoured yoghurt) | 330 mg/kg | 26 |
| 02.4 | Fat-based desserts excluding dairy-based dessert products of food category 01.7 | 330 mg/kg | 26 |
| 03.0 | Edible ices, including sherbet and sorbet | 270 mg/kg | 26 |
| 04.1.2.3 | Fruit in vinegar, oil, or brine | 100 mg/kg | 26 |
| 04.1.2.4 | Canned or bottled (pasteurized) fruit | 330 mg/kg | 26 & XS319 |
| 04.1.2.5 | Jams, jellies, marmelades | 360 mg/kg | 26 |
| 04.1.2.6 | Fruit-based spreads (e.g. chutney) excluding products of food category 04.1.2.5 | 330 mg/kg | 26 |

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| 04.1.2.7 | Candied fruit | 40 mg/kg | 26 |
| 04.1.2.8 | Fruit preparations, including pulp, purees, fruit toppings and coconut milk | 330 mg/kg | 26 |
| 04.1.2.9 | Fruit-based desserts, including fruit-flavoured water-based desserts | 350 mg/kg | 26 |
| 04.1.2.10 | Fermented fruit products | 115 mg/kg | 26 |
| 04.1.2.11 | Fruit fillings for pastries | 330 mg/kg | 26 |
| 04.1.2.12 | Cooked fruit | 40 mg/kg | 26 |
| 04.2.2.2 | Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds | 40 mg/kg | 26 |
| 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 soybean sauce | 330 mg/kg | 26 |
| 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 | 70 mg/kg | 26 |
| 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) | 330 mg/kg | 26 |
| 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 | 165 mg/kg | 26 |

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| 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 categories 06.8.6, 06.8.7, 12.9.1, 12.9.2.1 and 12.9.2.3 | 200 mg/kg | 26 |
| 04.2.2.8 | Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds | 40 mg/kg | 26 |
| 05.2 | Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4 | 700 mg/kg | 26, 199 & XS309R |
| 05.3 | Chewing gum | 3,500 mg/kg | 26 |
| 06.3 | Breakfast cereals, including rolled oats | 350 mg/kg | 26 |
| 06.5 | Cereal and starch based desserts (e.g. rice pudding, tapioca pudding) | 165 mg/kg | 26 |
| 06.8.1 | Soybean-based beverages | 200 mg/kg | 26 |
| 08.3.2 | Heat-treated processed comminuted meat, poultry, and game products | 100","mg/kg | 26, 202, XS88, XS89 & XS98 |
| 09.3.1 | Fish and fish products, including mollusks, crustaceans, and echinoderms, marinated and/or in jelly | 100 mg/kg | 26 & 144 |
| 09.3.2 | Fish and fish products, including mollusks, crustaceans, and echinoderms, pickled and/or in brine | 165 mg/kg | 26 |
| 09.3.3 | Salmon substitutes, caviar, and other fish roe products | 100 mg/kg | 26 & XS291 |
| 09.4 | Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms | 100 mg/kg | 26, XS3, XS37, XS70, XS90, XS94 & XS119 |

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| 10.4 | Egg-based desserts (e.g. custard) | 330 mg/kg | 26 |
| 11.6 | Table-top sweeteners, including those containing high-intensity sweeteners | GMP | 26 |
| 12.2.2 | Seasonings and condiments | 30 mg/kg | 26 |
| 12.4 | Mustards | 130 mg/kg | 26 |
| 12.5 | Soups and broths | 50 mg/kg | 26 & XS117 |
| 12.6.1 | Emulsified sauces and dips (e.g. mayonnaise, salad dressing, onion dip) | 350 mg/kg | 26 |
| 12.6.2 | Non-emulsified sauces (e.g. ketchup, cheese sauce, cream sauce, brown gravy) | 350 mg/kg | 26 |
| 12.6.3 | Mixes for sauces and gravies | 350 mg/kg | 26 & 127 |
| 12.6.4 | Clear sauces (e.g. fish sauce) | 350 mg/kg | 26 & XS302 |
| 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 | 115 mg/kg | 26 |
| 12.9.2.1 | Fermented soybean sauce | 30 mg/kg | 26 |
| 12.9.2.2 | Non-fermented soybean sauce | 165 mg/kg | 26 |
| 12.9.2.3 | Other soybean sauces | 165 mg/kg | 26 |
| 13.3 | Dietetic foods intended for special medical purposes (excluding products of food category 13.1) | 350 mg/kg | 26 |
| 13.4 | Dietetic formulae for slimming purposes and weight reduction | 270 mg/kg | 26 |
| 13.5 | Dietetic foods (e.g. supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6 | 660 mg/kg | 26, 198 & 294 |
| 13.6 | Food supplements | 2,500 mg/kg | 26 & 203 |
| 14.1.3 | Fruit and vegetable nectars | 200 mg/kg | 26 |

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| 14.1.4 | Water-based flavoured drinks, including ""sport,"" ""energy,"" or ""electrolyte"" drinks and particulated drinks | 200 mg/kg | 26 |
| 14.1.5 | Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa | 200 mg/kg | 26 & 160 |
| 14.2.7 | Aromatized alcoholic beverages (e.g. beer, wine and spirituous cooler-type beverages, low alcoholic refreshers) | 200 mg/kg | 26 |
| 15.0 | Ready-to-eat savouries | 170 mg/kg | 26 |

**Is the proposal related to a FC with corresponding commodity standards?**

(*if yes indicate the relevant FC*)

This submission requests revisions to the current Group Header for Steviol Glycosides. Commodity standards have already been considered under each provision for steviol glycosides under the Group Header when they have been adopted or during the alignment exercise.

**Is the proposal also intended to revise the products covered by the commodity standards?**

(*if yes indicate the relevant commodity standards*)

This submission requests revisions to the current Group Header for Steviol Glycosides. Commodity standards have already been considered under each provision for steviol glycosides under the Group Header when they have been adopted or during the alignment exercise.

**EVALUATION BY JECFA:**

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| **Evaluation by JECFA**<br>*Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).* | JECFA Evaluation:<br>• 87th meeting, from 4 to 13 June 2019<br>• "At the present meeting, the Committee determined that no safety issues exist for steviol glycosides produced by any one of these methods resulting in products with ≥95% steviol glycosides as per existing specifications. The Committee indicated that the ADI of 0–4 mg/kg bw established at the sixty-ninth meeting of JECFA for steviol glycosides (expressed as steviol) (Annex 1, reference 190) applies to steviol glycosides produced by the four methods indicated in the annexes of the specifications monograph produced at the current meeting." *(Reference to page 11 of the Evaluation of certain food additives (87th report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series No.1020, 2019).* ADI of 0–4 mg/kg bw, expressed as steviol equivalents<br>• JECFA Monograph 23 |

**JUSTIFICATION:**

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| **Justification for use and technological need**<br>*Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health* | Steviol glycosides are high-intensity sweeteners with sweetness potency ranging between 200 and 350 times higher than the one of sucrose. Providing zero calories, they are used for reduction or replacement of sugars in reduced-calorie or no-sugar-added products in many food and beverage categories and have been shown to not interfere with glucose homeostasis. |

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| *risk, serves a technological function).* | A revision to the current GSFA as per this submission is justified because the production through fermentation allow the safe production of products with higher quantities of the minor steviol glycosides typically present in the stevia leaf.<br><br>These minor steviol glycosides offer more options to formulate products with differing sensory profiles. These are better tasting and have better sensory profiles than more common steviol glycosides, allowing manufacturers to better customize steviol glycosides' blends used in products to meet consumers' expectations. These minor steviol glycosides also give manufacturers a greater array of options for sugar reduction and enable a further reduction of sugars in several food and beverages applications, up to between 50 to 100% sucrose replacements. |
| **Safe use of additive: Dietary intake assessment** (*as appropriate*) | Table 3 additive:<br><br>☐ Yes<br><br>**X No** (Please provide information on dietary intake assessment below):<br><br>JECFA performed the Assessment of dietary exposure for steviol glycosides at its 69th meeting where the Committee established an ADI for steviol glycosides of 0– 4 mg/kg bw expressed as steviol (Evaluation of certain food additives, Sixty-ninth report of JECFA - WHO Technical Report Series, No. 952, 2009). A re-evaluation of the dietary intake assessment was carried out by JECFA in 2016 (Evaluation of certain food additives, Eighty-second report of JECFA - WHO Technical Report Series No. 1000, 2016) and the ADI of 0–4 mg/kg bw, expressed as steviol, was confirmed.<br><br>This submission is not asking for changes in the categories or use levels to the provisions of steviol glycosides in GSFA – All the provisions indicated above are already existing provisions, which have already been adopted. Therefore the JECFA dietary intake assessment outcome in 2016 is to be considered appropriate. |
| **Justification that the use does not mislead consumer** | Steviol glycosides – likes all the sweeteners - are labelled on the ingredient list (i.e., name and/or the recognized numerical identification together with the functional class of "sweetener") in accordance with the general standard for the labelling of prepackaged foods (CODEX STAN 1-1985). This labelling requirement ensures the consumer is not misled.<br><br>The INS classification with the alphabetical suffix enables differentiation between production technologies for steviol glycosides. |

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| **THE PROPOSAL IS SUBMITTED BY:** | **International Stevia Council – ISC**<br>Contact Person:<br>Maria Teresa Scardigli - Executive Director<br>ISC Global Office:<br>Avenue de Tervuren 188A<br>1150 Brussels - Belgium<br>Tel: +32497597221<br>e-mail: GlobalOffice@internationalsteviacouncil.org |
| **IDENTITY OF THE FOOD ADDITIVE:** | |
| **Name of the Additive**<br><br>*As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989* | Enzyme Modified Steviol Glycosides (Enzymatically Produced Steviol Glycosides)<br><br>**General Comment:** All steviol glycoside-related submissions request that a streamlined approach be applied to all these additives by adding all to the Group Header Steviol Glycosides, as they are all covered under the same group ADI. |

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| | **Note 1:** this submission is linked to the form submitted for Steviol Glycosides from Fermentation and the form submitted for Enzyme Modified Glucosylated Steviol Glycosides (Glucosylated Steviol Glycosides)<br><br>**Note 2:** JECFA approved the monograph for Enzyme Modified Steviol Glycosides at its 87th meeting in June 2019 – This monograph has to be adopted by CODEX and CCFA 52 will consider to adopt the final INS classification.<br><br>**Note 3:** Consistent with past practice, the name as reflected in the JECFA specification naming or as per above, should be used in the INS. |
| **INS Number** | 960c<br><br>**Note:** JECFA approved the monograph for Enzyme Modified Steviol Glycosides at its 87th meeting – this monograph has to be adopted by CODEX and CCFA 52 will consider to adopt the final INS classification. |
| **Functional Class**<br><br>*As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989* | Sweetener |

**PROPOSED USE(S) OF THE FOOD ADDITIVE ([1]):** *The rows below may be copied as many times as needed.*

The proposal for:
☐ a new provision; or
**X revising all existing provisions in Tables 1 and 2 of the GSFA,** by revising the group header for Steviol Glycosides to include INS 960c; or
☐ revising an existing provision in Table 3 of the GSFA (skip to "Is the proposal intended to revise products covered by the commodity standard").

| **Food Category No. ([2])** | **Food Category Name ([2])** | **Maximum Use Level ([3])** | **Comments ([4])** |
|---|---|---|---|
| 01.1.4 | Flavoured fluid milk drinks | 200 mg/kg | 26 & XS243 |
| 01.5.2 | Milk and cream powder analogues | 330 mg/kg | 26 & 201 |
| 01.7 | Dairy-based desserts (e.g. pudding, fruit or flavoured yoghurt) | 330 mg/kg | 26 |
| 02.4 | Fat-based desserts excluding dairy-based dessert products of food category 01.7 | 330 mg/kg | 26 |
| 03.0 | Edible ices, including sherbet and sorbet | 270 mg/kg | 26 |
| 04.1.2.3 | Fruit in vinegar, oil, or brine | 100 mg/kg | 26 |
| 04.1.2.4 | Canned or bottled (pasteurized) fruit | 330 mg/kg | 26 & XS319 |
| 04.1.2.5 | Jams, jellies, marmelades | 360 mg/kg | 26 |
| 04.1.2.6 | Fruit-based spreads (e.g. chutney) excluding products of food category 04.1.2.5 | 330 mg/kg | 26 |

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| 04.1.2.7 | Candied fruit | 40 mg/kg | 26 |
| 04.1.2.8 | Fruit preparations, including pulp, purees, fruit toppings and coconut milk | 330 mg/kg | 26 |
| 04.1.2.9 | Fruit-based desserts, including fruit-flavoured water-based desserts | 350 mg/kg | 26 |
| 04.1.2.10 | Fermented fruit products | 115 mg/kg | 26 |
| 04.1.2.11 | Fruit fillings for pastries | 330 mg/kg | 26 |
| 04.1.2.12 | Cooked fruit | 40 mg/kg | 26 |
| 04.2.2.2 | Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds | 40 mg/kg | 26 |
| 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 soybean sauce | 330 mg/kg | 26 |
| 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 | 70 mg/kg | 26 |
| 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) | 330 mg/kg | 26 |
| 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 | 165 mg/kg | 26 |
| 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 categories 06.8.6, 06.8.7, 12.9.1, 12.9.2.1 and 12.9.2.3 | 200 mg/kg | 26 |
| 04.2.2.8 | Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds | 40 mg/kg | 26 |

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| 05.2 | Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4 | 700 mg/kg | 26, 199 & XS309R |
| 05.3 | Chewing gum | 3,500 mg/kg | 26 |
| 06.3 | Breakfast cereals, including rolled oats | 350 mg/kg | 26 |
| 06.5 | Cereal and starch based desserts (e.g. rice pudding, tapioca pudding) | 165 mg/kg | 26 |
| 06.8.1 | Soybean-based beverages | 200 mg/kg | 26 |
| 08.3.2 | Heat-treated processed comminuted meat, poultry, and game products | 100","mg/kg | 26, 202, XS88, XS89 & XS98 |
| 09.3.1 | Fish and fish products, including mollusks, crustaceans, and echinoderms, marinated and/or in jelly | 100 mg/kg | 26 & 144 |
| 09.3.2 | Fish and fish products, including mollusks, crustaceans, and echinoderms, pickled and/or in brine | 165 mg/kg | 26 |
| 09.3.3 | Salmon substitutes, caviar, and other fish roe products | 100 mg/kg | 26 & XS291 |
| 09.4 | Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms | 100 mg/kg | 26, XS3, XS37, XS70, XS90, XS94 & XS119 |
| 10.4 | Egg-based desserts (e.g. custard) | 330 mg/kg | 26 |
| 11.6 | Table-top sweeteners, including those containing high-intensity sweeteners | GMP | 26 |
| 12.2.2 | Seasonings and condiments | 30 mg/kg | 26 |
| 12.4 | Mustards | 130 mg/kg | 26 |
| 12.5 | Soups and broths | 50 mg/kg | 26 & XS117 |
| 12.6.1 | Emulsified sauces and dips (e.g. mayonnaise, salad dressing, onion dip) | 350 mg/kg | 26 |
| 12.6.2 | Non-emulsified sauces (e.g. ketchup, cheese sauce, cream sauce, brown gravy) | 350 mg/kg | 26 |
| 12.6.3 | Mixes for sauces and gravies | 350 mg/kg | 26 & 127 |
| 12.6.4 | Clear sauces (e.g. fish sauce) | 350 mg/kg | 26 & XS302 |
| 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 | 115 mg/kg | 26 |
| 12.9.2.1 | Fermented soybean sauce | 30 mg/kg | 26 |

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| 12.9.2.2 | Non-fermented soybean sauce | 165 mg/kg | 26 |
| 12.9.2.3 | Other soybean sauces | 165 mg/kg | 26 |
| 13.3 | Dietetic foods intended for special medical purposes (excluding products of food category 13.1) | 350 mg/kg | 26 |
| 13.4 | Dietetic formulae for slimming purposes and weight reduction | 270 mg/kg | 26 |
| 13.5 | Dietetic foods (e.g. supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6 | 660 mg/kg | 26, 198 & 294 |
| 13.6 | Food supplements | 2,500 mg/kg | 26 & 203 |
| 14.1.3 | Fruit and vegetable nectars | 200 mg/kg | 26 |
| 14.1.4 | Water-based flavoured drinks, including ""sport,"" ""energy,"" or ""electrolyte"" drinks and particulated drinks | 200 mg/kg | 26 |
| 14.1.5 | Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa | 200 mg/kg | 26 & 160 |
| 14.2.7 | Aromatized alcoholic beverages (e.g. beer, wine and spirituous cooler-type beverages, low alcoholic refreshers) | 200 mg/kg | 26 |
| 15.0 | Ready-to-eat savouries | 170 mg/kg | 26 |

**Is the proposal related to a FC with corresponding commodity standards?**

(*if yes indicate the relevant FC*)

This submission requests revisions to the current Group Header for Steviol Glycosides – Commodity standards have already been considered under each provision for steviol glycosides under the Group Header when they have been adopted or during the alignment exercise.

**Is the proposal also intended to revise the products covered by the commodity standards?**

(*if yes indicate the relevant commodity standards*)

This submission requests revisions to the current Group Header for Steviol Glycosides – Commodity standards have already been considered under each provision for steviol glycosides under the Group Header when they have been adopted or during the alignment exercise.

| **EVALUATION BY JECFA:** | |
|---|---|
| **Evaluation by JECFA**<br>*Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).* | JECFA Evaluation:<br>• 87th meeting of JECFA, from 4 to 13 June 2019:<br>• "At the present meeting, the Committee determined that no safety issues exist for steviol glycosides produced by any one of these methods resulting in products with ≥95% steviol glycosides as per existing specifications. The Committee indicated that the ADI of 0–4 mg/kg bw established at the sixty-ninth meeting of JECFA for steviol glycosides (expressed as steviol) (Annex 1, reference 190) applies to steviol glycosides produced by the four methods indicated in the annexes of the specifications monograph produced at the current meeting." *(Reference to page 11 of the Evaluation of certain food additives (87th report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series No.1020, 2019).* ADI of 0–4 mg/kg bw, expressed as steviol equivalents<br>• JECFA Monograph 23 |
| **JUSTIFICATION:** | |
| **Justification for use and technological need**<br>*Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).* | Steviol glycosides are high-intensity sweeteners with sweetness potency ranging between 200 and 350 times higher than the one of sucrose. Providing zero calories, they are used for reduction or replacement of sugars in reduced-calorie or no-sugar-added products in many food and beverage categories and have been shown to not interfere with glucose homeostasis.<br>A revision to the current GSFA as per this submission is justified because enzymatic processes allow the safe production of products with higher quantities of the minor steviol glycosides typically present in the stevia leaf.<br>These minor steviol glycosides offer more options to formulate products with differing sensory profiles. These are better tasting and have better sensory profiles than more common steviol glycosides, allowing manufacturers to better customize steviol glycosides' blends used in products to meet consumers' expectations. These minor steviol glycosides also give manufacturers a greater array of options for sugar reduction and enable a further reduction of sugars in several food and beverages applications, up to between 50 to 100% sucrose replacements. |
| **Safe use of additive: Dietary intake assessment** (*as appropriate*) | Table 3 additive:<br>☐ Yes<br>**X No** (Please provide information on dietary intake assessment below):<br>JECFA performed the Assessment of dietary exposure for steviol glycosides at its 69th meeting where the Committee established an ADI for steviol glycosides of 0– 4 mg/kg bw expressed as steviol (Evaluation of certain food additives, Sixty-ninth report of JECFA - WHO Technical Report Series, No. 952, 2009). A re-evaluation of the dietary intake assessment was carried out by JECFA in 2016 (Evaluation of certain food additives, Eighty-second report of JECFA - WHO Technical Report Series No. 1000, 2016) and the ADI of 0–4 mg/kg bw, expressed as steviol, was confirmed.<br>This submission is not asking for changes in the categories or use levels to the provisions of steviol glycosides in GSFA – All the provisions indicated above are already existing provisions, which have already been adopted. Therefore the JECFA dietary intake assessment outcome in 2016 is to be considered appropriate. |

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| **Justification that the use does not mislead consumer** | Steviol glycosides – likes all the sweeteners - are labelled on the ingredient (i.e. name and/or the recognized numerical identification together with the functional class of "sweetener" in accordance with the general standard for the labelling of prepackaged foods (CODEX STAN 1-1985). This labelling requirement ensures the consumer is not misled.<br><br>The INS classification with the alphabetical suffix enables differentiation between production technologies for steviol glycosides. |

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| **THE PROPOSAL IS SUBMITTED BY:** | **International Stevia Council – ISC**<br>**Contact Person:**<br>**Maria Teresa Scardigli - Executive Director**<br>**ISC Global Office:**<br>**Avenue de Tervuren 188A**<br>**1150 Brussels - Belgium**<br>**Tel: +32497597221**<br>**e-mail: GlobalOffice@internationalsteviacouncil.org** |

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| **IDENTITY OF THE FOOD ADDITIVE:** | |
| **Name of the Additive**<br><br>*As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989* | Enzyme Modified Glucosylated Steviol Glycosides (Glucosylated Steviol Glycosides)<br><br>**General Comment:** All steviol glycoside-related submissions request that a streamlined approach be applied to all these additives by adding all to the Group Header Steviol Glycosides, as they are all covered under the same group ADI.<br><br>**Note 1:** this submission is linked to the form submitted for Steviol Glycosides from Fermentation and the form submitted for Enzyme Modified Steviol Glycosides (Enzymatically Produced Steviol Glycosides).<br><br>**Note 2:** JECFA approved the monograph as tentative at its 87th meeting in June 2019 and the full monograph is expected to be adopted at the JECFA meeting in February 2021 and sent to CCFA 52 for adoption – CCFA 52 will consider to adopt the final INS classification.<br><br>**Note 3:** Consistent with past practice, the name as reflected in the JECFA specification naming or as per above, should be used in the INS. |
| **INS Number** | 960d<br><br>**Note 1:** JECFA approved the monograph as tentative at its 87th meeting in June 2019 and the full monograph is expected to be adopted at the JECFA meeting in February 2021 – the monograph has to be adopted by CODEX and CCFA 52 will consider to adopt the final INS classification |
| **Functional Class**<br><br>*As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989* | Sweetener |

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| **PROPOSED USE(S) OF THE FOOD ADDITIVE ([1]):** *The rows below may be copied as many times as needed.* | The proposal for:<br>☐ a new provision; or<br>☐ **X revising all existing provisions in Tables 1 and 2 of the GSFA, by revising the group header for Steviol Glycosides to include INS 960**; or<br>☐ revising an existing provision in Table 3 of the GSFA (skip to "Is the proposal intended to revise products covered by the commodity standard"). |

| Food Category No. ([2]) | Food Category Name ([2]) | Maximum Use Level ([3]) | Comments ([4]) |
|---|---|---|---|
| 01.1.4 | Flavoured fluid milk drinks | 200 mg/kg | 26 & XS243 |
| 01.5.2 | Milk and cream powder analogues | 330 mg/kg | 26 & 201 |
| 01.7 | Dairy-based desserts (e.g. pudding, fruit or flavoured yoghurt) | 330 mg/kg | 26 |
| 02.4 | Fat-based desserts excluding dairy-based dessert products of food category 01.7 | 330 mg/kg | 26 |
| 03.0 | Edible ices, including sherbet and sorbet | 270 mg/kg | 26 |
| 04.1.2.3 | Fruit in vinegar, oil, or brine | 100 mg/kg | 26 |
| 04.1.2.4 | Canned or bottled (pasteurized) fruit | 330 mg/kg | 26 & XS319 |
| 04.1.2.5 | Jams, jellies, marmelades | 360 mg/kg | 26 |
| 04.1.2.6 | Fruit-based spreads (e.g. chutney) excluding products of food category 04.1.2.5 | 330 mg/kg | 26 |
| 04.1.2.7 | Candied fruit | 40 mg/kg | 26 |
| 04.1.2.8 | Fruit preparations, including pulp, purees, fruit toppings and coconut milk | 330 mg/kg | 26 |
| 04.1.2.9 | Fruit-based desserts, including fruit-flavoured water-based desserts | 350 mg/kg | 26 |
| 04.1.2.10 | Fermented fruit products | 115 mg/kg | 26 |
| 04.1.2.11 | Fruit fillings for pastries | 330 mg/kg | 26 |
| 04.1.2.12 | Cooked fruit | 40 mg/kg | 26 |
| 04.2.2.2 | Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds | 40 mg/kg | 26 |

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| 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 soybean sauce | 330 mg/kg | 26 |
| 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 | 70 mg/kg | 26 |
| 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) | 330 mg/kg | 26 |
| 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 | 165 mg/kg | 26 |
| 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 categories 06.8.6, 06.8.7, 12.9.1, 12.9.2.1 and 12.9.2.3 | 200 mg/kg | 26 |
| 04.2.2.8 | Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds | 40 mg/kg | 26 |

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| 05.2 | Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4 | 700 mg/kg | 26, 199 & XS309R |
| 05.3 | Chewing gum | 3,500 mg/kg | 26 |
| 06.3 | Breakfast cereals, including rolled oats | 350 mg/kg | 26 |
| 06.5 | Cereal and starch based desserts (e.g. rice pudding, tapioca pudding) | 165 mg/kg | 26 |
| 06.8.1 | Soybean-based beverages | 200 mg/kg | 26 |
| 08.3.2 | Heat-treated processed comminuted meat, poultry, and game products | 100","mg/kg | 26, 202, XS88, XS89 & XS98 |
| 09.3.1 | Fish and fish products, including mollusks, crustaceans, and echinoderms, marinated and/or in jelly | 100 mg/kg | 26 & 144 |
| 09.3.2 | Fish and fish products, including mollusks, crustaceans, and echinoderms, pickled and/or in brine | 165 mg/kg | 26 |
| 09.3.3 | Salmon substitutes, caviar, and other fish roe products | 100 mg/kg | 26 & XS291 |
| 09.4 | Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms | 100 mg/kg | 26, XS3, XS37, XS70, XS90, XS94 & XS119 |
| 10.4 | Egg-based desserts (e.g. custard) | 330 mg/kg | 26 |
| 11.6 | Table-top sweeteners, including those containing high-intensity sweeteners | GMP | 26 |
| 12.2.2 | Seasonings and condiments | 30 mg/kg | 26 |
| 12.4 | Mustards | 130 mg/kg | 26 |
| 12.5 | Soups and broths | 50 mg/kg | 26 & XS117 |
| 12.6.1 | Emulsified sauces and dips (e.g. mayonnaise, salad dressing, onion dip) | 350 mg/kg | 26 |

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| 12.6.2 | Non-emulsified sauces (e.g. ketchup, cheese sauce, cream sauce, brown gravy) | 350 mg/kg | 26 |
| 12.6.3 | Mixes for sauces and gravies | 350 mg/kg | 26 & 127 |
| 12.6.4 | Clear sauces (e.g. fish sauce) | 350 mg/kg | 26 & XS302 |
| 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 | 115 mg/kg | 26 |
| 12.9.2.1 | Fermented soybean sauce | 30 mg/kg | 26 |
| 12.9.2.2 | Non-fermented soybean sauce | 165 mg/kg | 26 |
| 12.9.2.3 | Other soybean sauces | 165 mg/kg | 26 |
| 13.3 | Dietetic foods intended for special medical purposes (excluding products of food category 13.1) | 350 mg/kg | 26 |
| 13.4 | Dietetic formulae for slimming purposes and weight reduction | 270 mg/kg | 26 |
| 13.5 | Dietetic foods (e.g. supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6 | 660 mg/kg | 26, 198 & 294 |
| 13.6 | Food supplements | 2,500 mg/kg | 26 & 203 |
| 14.1.3 | Fruit and vegetable nectars | 200 mg/kg | 26 |
| 14.1.4 | Water-based flavoured drinks, including ""sport,"" ""energy,"" or ""electrolyte"" drinks and particulated drinks | 200 mg/kg | 26 |
| 14.1.5 | Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa | 200 mg/kg | 26 & 160 |
| 14.2.7 | Aromatized alcoholic beverages (e.g. beer, wine and spirituous cooler-type beverages, low alcoholic refreshers) | 200 mg/kg | 26 |

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|---|---|---|---|
| 15.0 | Ready-to-eat savouries | 170 mg/kg | 26 |

**Is the proposal related to a FC with corresponding commodity standards?**

(*if yes indicate the relevant FC*)

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| **Evaluation by JECFA**<br>*Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).* | JECFA Evaluation:<br>• 87th meeting of JECFA, from 4 to 13 June 2019<br>  ○ "At the present meeting, the Committee determined that no safety issues exist for steviol glycosides produced by any one of these methods resulting in products with ≥95% steviol glycosides as per existing specifications. The Committee indicated that the ADI of 0–4 mg/kg bw established at the sixty-ninth meeting of JECFA for steviol glycosides (expressed as steviol) (Annex 1, reference 190) applies to steviol glycosides produced by the four methods indicated in the annexes of the specifications monograph produced at the current meeting." *(Reference to page 11 of the Evaluation of certain food additives (87th report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series No.1020, 2019).*<br>• ADI of 0–4 mg/kg bw, expressed as steviol equivalents<br>• JECFA Monograph 23 (tentative with respect to analytical method; expected to be adopted as full at JECFA in February 2021). |

**JUSTIFICATION:**

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|---|---|
| **Justification for use and technological need**<br>*Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).* | Steviol glycosides are high-intensity sweeteners with sweetness potency ranging between 200 and 350 times higher than the one of sucrose. Providing zero calories, they are used for reduction or replacement of sugars in reduced-calorie or no-sugar-added products in many food and beverage categories and have been shown to not interfere with glucose homeostasis.<br>A revision to the current GSFA as per this submission is justified because enzymatic processes allow the safe production of products with higher quantities of the minor steviol glycosides typically present in the stevia leaf.<br>These minor steviol glycosides offer more options to formulate products with differing sensory profiles. These are better tasting and have better sensory profiles than more common steviol glycosides, allowing manufacturers to better customize steviol glycosides' blends used in products to meet consumers' expectations. These minor steviol glycosides also give manufacturers a greater array of options for sugar reduction and enable a further reduction of sugars in several food and beverages applications, up to between 50 to 100% sucrose replacements. |
| **Safe use of additive: Dietary intake assessment** (*as appropriate*) | Table 3 additive:<br>☐ Yes<br>☐ **X No** (Please provide information on dietary intake assessment below): |

| | |
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| | JECFA performed the Assessment of dietary exposure for steviol glycosides at its 69th meeting where the Committee established an ADI for steviol glycosides of 0– 4 mg/kg bw expressed as steviol (Evaluation of certain food additives, Sixty-ninth report of JECFA - WHO Technical Report Series, No. 952, 2009). A re-evaluation of the dietary intake assessment was carried out by JECFA in 2016 (Evaluation of certain food additives, Eighty-second report of JECFA - WHO Technical Report Series No. 1000, 2016) and the ADI of 0–4 mg/kg bw, expressed as steviol, was confirmed.<br><br>This submission is not asking for changes in the categories or use levels to the provisions of steviol glycosides in GSFA – All the provisions indicated above are already existing provisions, which have already been adopted. Therefore the JECFA dietary intake assessment outcome in 2016 is to be considered appropriate. |
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