

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
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Agenda Item 5(b)

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifty-sixth Session

GENERAL STANDARD FOR FOOD ADDITIVES (GSFA) (CXS 192-1995): PROPOSALS FOR NEW AND/OR REVISION OF FOOD ADDITIVE PROVISIONS (REPLIES TO CL 2025/31-FA)

(Comments of Kenya, Republic of Korea, International Association of Color Manufacturers (IACM), International Food Additives Council (IFAC), International Stevia Council (ISC) and International Special Dietary Foods Industries (ISDI))

Kenya

Comment: Kenya welcomes the submissions from Member States and observers, recognizing that they contribute to harmonization of Codex standards and provide clarity for industry and regulators. Kenya looks forward to discussing the proposals.

Republic of Korea

The Republic of Korea would appreciate the support of Members for the proposed revision to the existing provisions in Tables 1 and 2 of the GSFA for steviol glycosides (INS 960a, 960b, 960c, 960d), in order to permit their use not only in chewable forms of food supplements (FC 13.6) but also in powdered and liquid forms.

IACM

Re: Supplementary Information on Additional GSFA Food Categories for Gardenia (Genipin) Blue (INS 165)

IACM is providing supplementary information to support the consideration of proposed GSFA food categories for Gardenia (Genipin) Blue (INS 165).

JECFA Evaluation and Reference Exposure

Gardenia (Genipin) Blue (INS 165) was evaluated by JECFA at its 100th meeting. JECFA established an ADI of 0–7 mg/kg bw/day, expressed on the basis of the Gardenia Blue polymer. For its safety evaluation, JECFA considered the highest estimated dietary exposure, 5.0 mg/kg bw/day for young children, to be appropriate.¹ Key elements of the JECFA evaluation relevant to this proposal are summarized in Table 1.

Table 1. Summary of JECFA Evaluation

Item	JECFA Outcome
Evaluating body	JECFA (100th meeting)
Substance	Gardenia (Genipin) Blue (INS 165)

¹ [Safety evaluation of certain food additives: prepared by the one-hundredth meeting of the Joint FAO/WHO Expert Committee on Food Additives \(JECFA\)](#)

ADI	0–7 mg/kg bw/day
Basis of ADI	Gardenia Blue polymer
Reference exposure	5.0 mg/kg bw/day (young children)

Additional Food Categories Proposed for GSFA

The proposed additions to the GSFA include five food categories that were not included in JECFA's exposure assessment: FC 4.2.2.2, FC 11.4, FC 12.2.2, FC 12.6, FC 14.1.5 and FC 15.1. These food categories were proposed including specific notes that clearly limit the intended application. Therefore, use in these food categories will be restricted to clearly defined products at the lowest level necessary to provide the expected color. On this basis, a substantial increase in overall dietary exposure is not expected to occur. An overview of the proposed additional food categories and their regulatory conditions is provided in Table 2.

Table 2. Proposed Additional GSFA Food Categories

Aspect	Description
Food categories	FC 4.2.2.2, FC 11.4, FC 12.2.2, FC 12.6, FC 14.1.5, FC 15.1
Scope of use	Limited by specific GSFA notes
Level of use	Minimum necessary under GMP
Expected impact on exposure	No substantial increase expected

Supplementary Screening-Level Exposure Estimate

To provide supplementary information for food categories not explicitly reflected in the JECFA exposure assessment, a screening-level dietary exposure estimate was prepared by a coalition of the primary manufacturers of gardenia (genipin) blue, which includes an IACM member company.

The estimate is based on the proposed maximum use levels, assumed consumption amounts and occurrence-adjusted factors reflecting the observed prevalence of blue-colored products within the relevant food categories.

The estimated incremental dietary exposure from the six additional food categories is summarized in Table 3.

Table 3. Incremental Dietary Exposure from Additional Food Categories

Population group	Incremental exposure (mg/kg bw/day)
Child (15 kg)	0.1838–0.2556
Adult (60 kg)	0.0460–0.0639
Nature of estimate	Screening-level, supplementary

For young children, addition of this incremental exposure to the 5.0 mg/kg bw/day exposure considered by JECFA results in a combined exposure of 5.184–5.256 mg/kg bw/day. The relationship between this combined exposure and the established ADI is shown in Table 4.

Table 4. Combined Exposure Relative to the ADI (Young Children)

Item	Value
JECFA reference exposure	5.0 mg/kg bw/day
Incremental exposure	0.184–0.256 mg/kg bw/day
Combined exposure	5.184–5.256 mg/kg bw/day

ADI upper bound	7 mg/kg bw/day
Margin to ADI	Maintained

Conclusion

The supplementary screening assessment shows that the additional contribution to dietary exposure from the proposed GSFA food categories is limited and do not materially affect dietary exposure or the resulting safety conclusion as the resulting combined exposure remains below the upper bound of the ADI established by JECFA.

Therefore, the proposed GSFA additions for Gardenia (Genipin) Blue (INS 165), including the additional, note-limited uses, are consistent with the existing JECFA evaluation and should not present any new safety concerns.

Table 5. Screening estimate of incremental dietary exposure from the five additional food categories

Food Category	Proposed maximum use level (mg/kg)	Assumed consumption (g/day)	Occurrence-adjusted additive intake (mg/day)	Incremental exposure: Child, 15 kg (mg/kg bw/day)	Incremental exposure: Adult, 60 kg (mg/kg bw/day)
FC 4.2.2.2	3000	0.4	0.36	0.024	0.006
FC 11.4	400	1–5	0.004–0.020	0.00027–0.00133	0.00007–0.00033
FC 14.1.5	200	100–250	0.600–1.500	0.0400–0.1000	0.0100–0.0250
FC 15.1	200	20–30	0.320–0.480	0.0213–0.0320	0.00533–0.00800
FC 12.2.2	3000	1	1.571	0.1048	0.0262
FC 12.6	500	1	0.262	0.0175	0.00437
Total	—	—	2.757–3.833	0.208–0.280	0.052–0.07
As proportion of ADI	—	—	—	0.30–0.04	0.007–0.01

International Food Additives Council (IFAC)

The International Food Additives Council (IFAC) is responding to the Circular Letter published in April 2025 requesting proposals for new and/or revision of food additive provisions in the General Standard for Food Additives (GSFA). IFAC is a global association representing manufacturers and end-users of food additives. IFAC has NGO Observer status before Codex Alimentarius and appreciates the opportunity to provide the following information.

IFAC is requesting that CCFA consider new food additive provisions for glycolipids (INS 246) for Food Categories 14.1.2 (Fruit and vegetable juices), 14.1.3 (fruit and vegetable nectars), and 14.1.5 (Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding coca). Please find the enclosed Annex 1 and Appendix 1 on Glycolipids with more information.

Annex 1

FORM FOR THE SUBMISSION OF PROPOSALS FOR NEW AND/OR REVISION OF ADOPTED FOOD ADDITIVE PROVISIONS IN THE GSFA

THE PROPOSAL IS SUBMITTED BY:	International Food Additives Council (IFAC), 529 14th Street NW, Suite 1280, Washington, DC 20045, USA
IDENTITY OF THE FOOD ADDITIVE:	
Name of the Additive <i>As listed in Class Names and the International Numbering System for Food Additives (CXG 36-1989)</i>	Glycolipids

INS Number		246	
Functional Class <i>As listed in Class Names and the International Numbering System for Food Additives (CXG 36-1989)</i>		Preservative	
PROPOSED USE(S) OF THE FOOD ADDITIVE ⁽¹⁾: <i>The rows below may be copied as many times as needed.</i>		The proposal for: X a new provision; or ☐ revising an existing provision in Tables 1 and 2 of the GSFA; 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⁾
14.1.2	Fruit and vegetable juices	100 mg/kg	Add: Note XS247 Excluding products conforming to the General Standard for Fruit Juices and Nectars (CXS 247-2005).
14.1.3	Fruit and vegetable nectars	80 mg/kg	Add: Note XS247 Excluding products conforming to the General Standard for Fruit Juices and Nectars (CXS 247-2005).
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	50 mg/kg	
Is the proposal related to a FC with corresponding commodity standards? Yes, CXS 247-2005.			
Is the proposal also intended to revise the products covered by the commodity standards? No			
EVALUATION BY JECFA:			
Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i>		Evaluation year: 2025 ADI: NOT SPECIFIED Comments: A proportion of the glycolipids is hydrolysed by intestinal microflora to their components, namely glucose, xylose, acetate, isovalerate, and long-chain fatty acids, and the remaining unchanged glycolipids are eliminated in the faeces. JECFA further noted that the hydrolysis products are normal components of the human diet. JECFA therefore established an ADI "not specified" for glycolipids. Intake: JECFA noted the high dietary exposure estimates of 3.3 mg/kg/bw per day for children aged 2–5 years in the USA and 1.3 mg/kg/bw per day for adults in Europe. JECFA concluded that these dietary exposure estimates did not raise any safety concerns. Meeting: 100	

	Specs Code: N Report: TRS 1058-JECFA 100/35 Tox Monograph: FAS 91-JECFA 100/143 Specification: FAO Combined Compendium of Food Additive Specifications
JUSTIFICATION:	
Justification for use and technological need <i>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).</i>	Glycolipids is intended for addition to beverages as an antimicrobial agent used to preserve food by preventing growth of microorganisms and subsequent spoilage. The prominent antifungal effect against common yeasts and molds makes glycolipids particularly useful as a naturally derived preserving agent to prevent spoilage of beverages. Thus, glycolipids can be used to prolong shelf life and guarantee the microbiological quality of beverages, making it a versatile alternative or complement to other techniques like heat treatment, which may be attributed with loss of nutritional value, vitamin content, or taste. Glycolipids may also substitute current chemical preservatives in beverages, such as sorbic acid, benzoic acid, or sulfites at lower concentrations in use. For example, under identical test conditions (method DIN 58940-8), Minimum Inhibitory Concentrations (MICs) of 3.1 and 7.8 mg/L were determined for glycolipids against <i>Aspergillus niger</i> in SDB (Sabouraud Dextrose Broth) medium (pH 5.6) or clear apple juice medium (pH 3.3), respectively, compared to MICs of 250 mg/L (in SDB) or ≥ 1000 mg/L (in apple juice medium) for sorbic acid and benzoic acid, respectively (supporting details are provided Appendix 1). Since glycolipids is also active against yeast and mold strains which have adapted to current chemical preservatives, it represents an alternative or complement to successfully assure shelf life of beverages. Glycolipids is known to have good activity against Gram-positive bacteria (including spoilage organisms like <i>Bacillus cereus</i> (MIC 12.5 mg/L [Appendix 1]) or <i>Listeria</i> spp. (MIC 25-50 mg/L [Appendix 1]) but weak or no activity against Gram-negative bacteria. Additional data and figures illustrating the antimicrobial activity of glycolipids and its application as an antimicrobial preservative in beverages are provided in Appendix 1.

	Glycolipids is a Generally Recognized as Safe (GRAS) food ingredient in the United States (as per 21 CFR §170.30)(FDA, 2018; FDA, 2023)² with authorized use as an antimicrobial preservative in select non-alcoholic beverages (including juices, nectars and tea/herbal infusion). Glycolipids (E 246) has regulatory approvals for use as a preservative in juices, nectars and tea/herbal infusion in Canada,³ Mexico,⁴ and Australia/New Zealand.⁵ The use in tea and herbal infusion concentrates is approved in the European Union (EU) and EU member states,⁶ Iceland, Lichtenstein, Norway, Switzerland, Turkey,⁷ and Israel.⁸ The safe use of glycolipids has been evaluated by multiple scientific and regulatory bodies including the United States (U.S.) Food and Drug Administration (FDA, 2018),¹ Health Canada (2021),⁹ European Food Safety Authority (EFSA, 2021),¹⁰ Food Standards Australia New Zealand (FSANZ, 2020),¹¹ and Joint FAO/WHO Expert Committee on Food Additives (JECFA).¹²
Safe use of additive: Dietary intake assessment (as appropriate)	Table 3 additive: X Yes, recommendation for Glycolipids to be included in Table 3 (see agenda item 3(a) CX/FA 26/56/3 Add.1).
Justification that the use does not mislead consumer	Glycolipids (INS 246) must be labeled as a food additive functional class preservative in the ingredient list. Therefore, the consumer has full transparency about the use of glycolipids in the beverage.

- ⁽¹⁾ For proposed revisions of adopted provisions, the current adopted provision should be provided, with deletions noted in ~~strikethrough~~ text, and changes or additions noted in **bold** font.
- ⁽²⁾ Food category number and name, as listed in Annex B of the GSFA.
- ⁽³⁾ For consistency, the maximum use level should be reported on the same basis as the ADI. A numerical use level should be provided for a food additive assigned a numerical ADI. GMP or a numerical use level may be provided for a food additive assigned a non-numerical ADI (e.g. “not-specified”).
- ⁽⁴⁾ Comments on specific restrictions on the use of the food additive to be included as Notes (e.g. limitation of use to specific products in a food category).

² GRN 740. FDA No Questions letters dated May 17, 2018, August 25, 2023 and September 13, 2025.

https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=740&sort=GRN_No&order=DESC&startrow=1&type=basic&search=740.

³ [List of Permitted Preservatives](#) (Part 2 & 3), effective date: 2022-06-10.

⁴ Comisión Federal Para La Protección Contra Riesgos Sanitarios Official Notice No. COFEPRIS-CEMAR-223300EL753730-2022, December 13 19, 2023.

⁵ [Amendment No. 198](#) to Food Standards Code as gazetted in Australia (No. FSC 139, 26 March 2021) and published in the New Zealand Gazette.

⁶ [Regulation \(EC\) No 1333/2008](#) of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2002, p.8), [Commission Regulation \(EU\) No 231/2012](#) of 9 March 2012 for the food additives listed in Annexes II and III of Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 083, 22.03.2012, p.1).

⁷ [Türk Gıda Kodeksi Gıda Katkı Maddeleri Yönetmeliği](#) 13 October 2023.

⁸ State of Israel – Ministry of Health: [Decision 561669323](#) - Update of the list of food additives Glycolipids E246 of December 10 2023. Effective by 10 February 2024, State of Israel – Ministry of Health: [Decision 627891924](#) - Update of the list of food additives Glycolipids E246 of October 01 2024. Effective by 01 November 2024.

⁹ <https://www.canada.ca/en/health-canada/services/food-nutrition/public-involvement-partnerships/notice-proposal-long-chain-glycolipids-dacryopinax-spathularia/document.html>.

¹⁰ <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6609>.

¹¹ <https://www.foodstandards.gov.au/sites/default/files/food-standards-code/applications/Documents/A1180%20SD1%20at%20Approval.pdf>.

¹² <https://iris.who.int/server/api/core/bitstreams/cc932452-c2fd-43d0-8ee9-16cf86a79bfc/content>.

Efficacy Data for Glycolipids (AM-1)

1. Introduction

Glycolipids (hereinafter referred to as “AM-1”) are a mixture of glycolipids with antimicrobial properties. Its prominent antifungal effect makes AM-1 in particular useful as a **naturally derived preserving agent to prevent spoilage of beverages by common yeasts and molds**. Thus, AM-1 can substitute for frequently used chemical preservatives like benzoic acid, sorbic acid, or sulfites.

2. Microbial spoilage of beverages

A number of organisms are responsible for spoiling a variety of beverages materials, including cold-filled beverages. Most beverages have an acidic pH value, favoring the growth of fungi including yeasts and molds.

Typical spoilage yeasts in beverages include the genera *Saccharomyces*, *Zygosaccharomyces*, *Candida* and *Dekkera*. In particular yeasts of the genus *Zygosaccharomyces* have had a long history as spoilage yeasts within the food industry. This is due mainly to the fact that these species can grow in the presence of high sucrose, ethanol, acetic acid, sorbic acid, benzoic acid, and sulfur dioxide concentrations (which are some of the commonly used preservatives).

Typical spoilage molds in beverages include the genera *Penicillium*, *Aspergillus* and *Brettanomyces*. Further, heat resistant mold spores of *Byssoschlamys*, its anamorphic (asexual) stages *Paecilomyces*, and *Neosartorya* spp. can survive pasteurization and may spoil hot-filled products, including carbonated beverages, sport drinks, and teas.

Also certain pathogenic bacteria are known to spoil beverages, e.g. *Bacillus cereus* or certain lactic acid bacteria. These are known to tolerate the acidic environment found in the beverage. Their growth is sometimes difficult to prevent, requiring the use of (ultra) high temperature treatment or other physical methods in combination with chemical preservative systems.

3. Limitations of currently used chemical preservatives

Current preservation systems for acidic, shelf-stable, carbonated and non-carbonated beverages, e.g. soft drinks, generally rely on weak acid preservatives (i.e., benzoic and/or sorbic acid and their salts). Benzoic and sorbic acids inhibit growth of yeasts, molds, and bacteria with some exceptions and limitations.

The weak acids in beverages exist in equilibrium between their dissociated and non-dissociated forms, which is dependent on the dissociation constant of the acid (pKa) and the beverage's pH. The pKa for benzoic acid is 4.19 and the pKa of sorbic acid is 4.76. A beverage pH below the pKa of the involved acid pushes the equilibrium towards the non-dissociated form, which is the antimicrobially active form. Therefore, weak acid preservatives are only effective in the low pH range.

Further, genetic adaptation of microorganisms is of growing concern also in the beverage industry (Piper, 2001; Stratford, 2013). Certain yeast strains identified as *Zygosaccharomyces bailii*, *Z. bisporus*, *Candida krusei*, and *Saccharomyces cerevisiae* have developed specific genes that enable them to resist the weak acid preservatives and grow (Mira, 2013). The levels of weak acids necessary to overcome this adaptation are often far beyond regulatory limits on use levels. Therefore, spoilage of preserved teas, juice-containing beverages, and carbonated beverages is due to preservative-adapted microorganisms.

Another intrinsic disadvantage of benzoic and sorbic acid is the fact that these organic acids have a taste impact on the beverage, as their typical use level is rather high (100 ppm and above). This off-taste is usually undesired and needs to be considered during development and refinement of the beverage composition, e.g. by masking this taste effect with added flavors.

4. Minimum Inhibitory Concentrations (MICs) of AM-1 against spoilage organisms

AM-1 exhibits excellent antimicrobial activity against relevant spoilage organisms, as shown by the Minimum Inhibitory Concentrations (MICs). MIC values for AM-1 are much lower than those of the benchmarks sorbic acid and benzoic acid tested in parallel, allowing for low use levels in finished beverages to achieve the desired technical effect.

Generally, AM-1 has

- Very potent activity against yeast and mold
- Good activity against Gram-positive bacteria

- Weak or no activity against Gram-negative bacteria

MIC values were obtained using the micro-dilution method according to DIN 58940-8. Incubation was done in clear flat-bottom 96-well plates at 28 °C. MIC values were determined as the minimum concentration without visible growth (or detectable turbidity using a photometer). Inoculum concentration was adjusted to ca. 1×10^5 cells/ml as determined by viable cell count. For comparison, sodium benzoate and potassium sorbate were tested in parallel to AM-1. Concentrations in [mg/l] for the benchmarks are corrected to the corresponding free carboxylic acids.

MIC [mg/l]			
<i>Saccharomyces cerevisiae</i>	3.1	250	250
<i>Aspergillus niger</i>	3.1	250	250
<i>Zygosaccharomyces bailii</i>	<3.9	>1000	>1000
<i>Dekkera bruxeliensis</i>	<3.9	1000	250
<i>Aspergillus niger</i>	7.8	1000	>1000
<i>Byssoschlamys fulva</i>	<3.9	500	500

SDB = Sabouraud Dextrose Broth

MIC values of AM-1 against further spoilage bacteria, yeasts, and molds:

Category	Taxonomy	MIC [mg/l]
Bacteria	<i>Bacillus cereus</i> (ATCC11778)	12.5
	<i>Bacillus subtilis</i> (ATCC6633)	1.6
	<i>Propionibacterium acnes</i> (ATCC6919)	60
	<i>Clostridium perfringens</i> (ATCC13124)	60
	<i>Clostridium sporogenes</i> (ATCC3584)	50
	<i>Enterococcus faecalis</i> (ATCC19433)	50
	<i>Listeria welshimeri</i> (DSM15452)	25
	<i>Listeria monocytogenes</i> (ATCC19111)	50
	<i>Lactobacillus plantarum</i> (DSM12028)	25
	<i>Leuconostoc mesenteroides</i> (ATCC 8293)	6.3
	<i>Staphylococcus aureus</i> (ATCC6538)	25
Molds	<i>Aspergillus fumigatus</i> (ATCC1028)	20
	<i>Aspergillus niger</i> (ATCC16404)	6.3
	<i>Byssoschlamys fulva</i> (DSM62097)	3.1
	<i>Mucor plumbeus</i> (MUCL49355)	6.3
	<i>Talaromyces luteus</i> (CBS348.51)	<3.9
	<i>Dekkera bruxellensis</i> (DSM70726)	6.3
	<i>Dekkera naardenensis</i> (DSM70743)	12.5
Yeasts	<i>Saccharomyces cerevisiae</i> (MUCL 53497)	12.5
	<i>Zygosaccharomyces bailii</i> (DSM70492)	3.1
	<i>Zygosaccharomyces bailii</i> (ATCC 60484)	25
	<i>Zygosaccharomyces bisporus</i> (ATCC 52407)	3.1
	<i>Zygosaccharomyces bisporus</i> (DSM70415)	12.5
	<i>Zygosaccharomyces florentinus</i> (DSM70506)	6.3
	<i>Zygosaccharomyces rouxii</i> (NCYC381)	6.3
	<i>Candida albicans</i> (ATCC10231)	12.5

5. Application data for AM-1 in beverages

Application data for AM-1 were successfully determined in more than 150 commercially available beverages, proving the applicability of AM-1 in different beverage matrices.

Tests were designed as antimicrobial challenge tests, using the following test organisms:

Yeasts

Saccharomyces cerevisiae

Zygosaccharomyces rouxii

Zygosaccharomyces bailii

Molds

Aspergillus niger

Byssoschlamys nivea

Penicillium roqueforti

AM-1 was added to the non-preserved beverages, usually as certain volume of a 10 mg/l stock solution in water. The beverage was mixed thoroughly to assure homogenous dissolution of AM-1. Then, the test organisms depicted above were added either as yeast mixture or mold mixture. In both cases, the initial inoculum was ca. 100 cfu/ml as proven by viable cell count at test start. Incubation was done at ambient temperature for three months and included benchmark controls (preserved with either benzoic or sorbic acid) and growth controls (i.e. the non-preserved beverage).

In case of flasks, tests were carried out in the original container without protection from light. In case of cans, Tetra-Pak® or other non-closable containers, the beverages were filled into sterile glass bottles before start of the test and protected against light during the test, as would have been the case in the original container.

Readout was done visually on a regular basis and – after three months – by determination of the viable cell count (cfu/ml) using the spread or pour plate method with SDB or OSA agar.

Results show that the minimum effective concentration of AM-1 depends on the nature of the beverage and can be summarized for each beverage category as follows:

Beverage category	Typical AM-1 use level [mg/l]
Carbonated soft drinks (CSD)	Cola or citrus-type, incl. concentrates: 3 – 10 10% juice, turbid: 10 – 25
Fruit drinks	Clear fruit drinks: 3 – 5 10% juice, turbid: 5 – 25 spritzer, nectar, other turbid fruit drinks: 25 – 80
Teas	Clear 3 – 10 With juice content: 10 – 50
Enhanced waters	2 – 25
Energy drinks	10 – 50
Sport drinks	3 – 50
Juice	Clear juices: 5 – 10 turbid, apple: 25 turbid, other: 50 – 100

Within a specific beverage category, the needed amount of AM-1 depends on pH value (low pH beverages need less AM-1), turbidity (low turbidity beverages need less AM-1) and carbonization (non-carbonated beverages need slightly higher AM-1 levels).

For comparison: under identical test conditions, required concentrations of benzoate and sorbate are above regulatory limits to pass the test (ca. 600 – 1200 mg/l for benzoic acid; ca. 600 – 900 mg/l for sorbic acid).

Example:

AM-1 was added to commercially obtained fruit drink “Capri Sun Multivitamin” containing 12% juice and no declared preservative. AM-1 was applied at 10 mg/l use level. Without AM-1, rapid spoilage was observed within a few days, while AM-1 treated beverages were without microbial growth until the end of the test after 3 months. Sorbate and benzoate treated comparisons needed 1000 ppm each to pass the test while 500 ppm samples failed.

Example:

Preservation of 6 citrus-type carbonated soft drinks



AM-1 was applied to 6 different citrus-type carbonated soft drinks at **3 (clear) to 10 (turbid)** ppm use level. Despite inoculation with mold or yeast mixtures, no microbial growth occurred during the three month test period. Without preservative, yeasts and molds grew visibly within 7- 14 days.

6. Comparison of antimicrobial efficacy of AM-1 with sorbate and benzoate

Efficacy against benzoate- and/or sorbate-tolerant spoilage yeasts:

Test of specific microorganisms (isolates from the beverage industry) with resistance/adaptation against sorbate and benzoate showed that, most likely due to a unique mode of action, no cross-resistance to existing preservative solutions exists for AM-1.

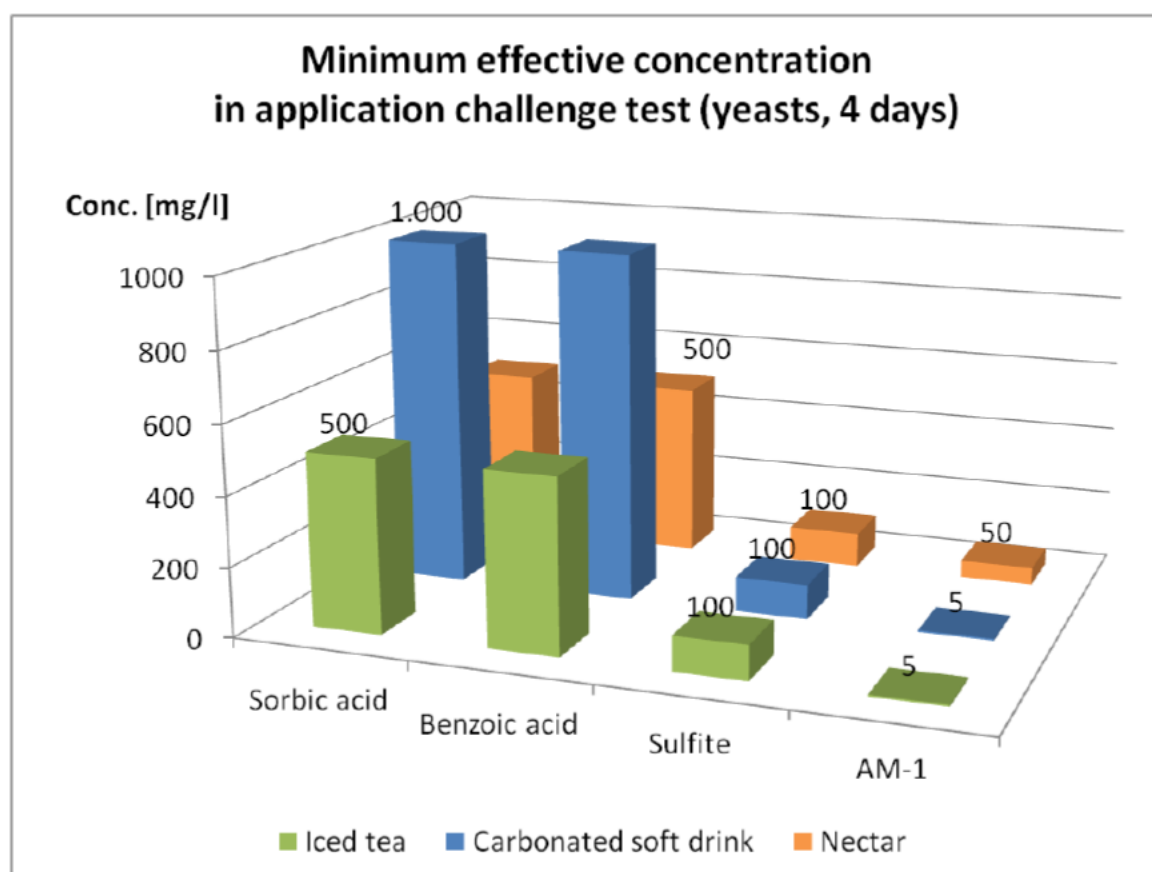
Example: *Saccharomyces cerevisiae* strain FU74037 was isolated as a sorbate- and benzoate-tolerant strain from a commercial carbonated soft drink. The MIC value at pH 3.6 against AM-1 was found to be **3.1 mg/l**, while 200 mg/l benzoate or sorbate could not completely inhibit growth of this organism.

Comparison of 4-day MIC data in selected beverages:

Four selected commercial beverages (bought from hot fill in Germany, i.e. non-preserved) were subjected to an antimicrobial challenge test as outlined in Section 5, but – deviating from the described protocol – with incubation at 28 °C for four days. Then, viable cell counts were determined using the streaking plate method on SDB agar plates.

Table: MIC values after 4 days in [mg/l] in selected beverages

	Carbonated soft drink		Nectar		Orange juice		Iced tea	
Preservative	yeasts	molds	yeasts	molds	yeasts	molds	yeasts	molds
Sorbic acid	1000	250	500	250	500	250	500	250
Benzoic acid	1000	100	500	100	2000	100	500	500
Metabisulfite	100	100	100	100	500	100	100	100
AM-1	5	5	50	25	100	50	5	3



7. References

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- Stadler, M., Bitzer, J., Köpcke, B., Reinhardt, K., Moldenhauer, J. (2012) Long chain glycolipids useful to avoid perishing or microbial contamination of materials. WO2012/167920A1.

International Stevia Council (ISC)

THE PROPOSAL IS SUBMITTED BY:	International Stevia Council
IDENTITY OF THE FOOD ADDITIVE:	
Name of the Additive <i>As listed in Class Names and the International Numbering System for Food Additives (CXG 36-1989)</i>	Steviol Glycosides
INS Number	960

Functional Class <i>As listed in Class Names and the International Numbering System for Food Additives (CXG 36-1989)</i>		Sweetener	
PROPOSED USE(S) OF THE FOOD ADDITIVE ⁽¹⁾: <i>The rows below may be copied as many times as needed.</i>		The proposal for: ☐ a new provision; or ☐ revising an existing provision in Tables 1 and 2 of the GSFA; 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 (no change)	Request for the deletion of Note XS243.
01.7	Dairy-based desserts	330 mg/kg (no change)	Request for the deletion of Note XS243.
12.5	Soups and broths	50 mg/kg (no change)	Request for the deletion of Note XS117.
12.6.2	Non-emulsified sauces	350 mg/kg (no change)	Request for the deletion of Note XS206.
12.6.4	Clear sauces	350 mg/kg (no change)	Request for the deletion of Note XS302.
Is the proposal related to a FC with corresponding commodity standards? Yes. Food categories 01.1.4 and 01.7 correspond to products covered by the Standard for Fermented Milks (CXS 243-2003). Yes: - Food category 12.5 → Standard for Bouillons and Consommés (CXS 117-1981), - Food category 12.6.2 → Standard for Chili Sauce (CXS 206-2023) - Food category 12.6.4 → Standard for Fish Sauce (CXS 302-2011).			
Is the proposal also intended to revise the products covered by the commodity standards? No. However, CXS 243-2003 should be updated (through the Codex Committee on Milk and Milk Products (CCMMP)) to explicitly list Steviol glycosides among sweeteners acceptable in flavored versions of "fermented milks and drinks based on fermented milk" and "fermented milks heat treated after fermentation and drinks based on fermented milk heat treated after fermentation". Steviol glycosides were not added to the list of sweeteners in the Standard likely due to the fact that the CCMMP was not operating when Steviol glycosides were introduced into the GSFA. No. The relevant commodity standards CXS 117-1981, CXS 206-2023 and CXS 302-2011 already allow for the use of steviol glycosides in accordance with the GSFA. This proposal is not intended to modify those standards, but to remove residual XS notes in the GSFA that create an unintended consistency between the GSFA and the existing provisions of the commodity standards.			
EVALUATION BY JECFA:			

Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or “not specified”); specifications monograph).</i>	Last JECFA evaluation: 2023, 96 th Meeting ADI: 0-4 mg/kg bw Monograph 31 (2023)
JUSTIFICATION:	
Justification for use and technological need <i>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).</i>	Steviol glycosides provide sweetness without addition in energy reduced or no-added-sugar fermented dairy products and serve the same technological function as other sweeteners already permitted under CXS 243-2003. Removing Note XS243 restores coherence between the GSFA and CXS243 for flavored fermented milks. Sweeteners such as steviol glycosides serve a technological function in soups, broths and sauces by supporting reduced-sugar or energy-reduced formulations. Sweeteners, including steviol glycosides, already perform this technological function in these food categories under the GSFA. Removing XS Notes 117, 206 and 302 in the corresponding food categories mentioned above restores consistency between the GSFA and commodity standards that already recognize this technological role.
Safe use of additive: Dietary intake assessment <i>(as appropriate)</i>	Table 3 additive: ☐ Yes ☐ No (Please provide information on dietary intake assessment below) This proposal for deletion of Note XS243 from these food categories does not result in new exposure as maximum use levels remain unchanged. Steviol glycosides have been used in food categories 01.1.4 (Flavored fluid milk drinks) and 01.7 (Dairy-based desserts) prior to the introduction of Note XS243. The note was added in 2017 to 01.1.4, and to 01.7 in 2024. Therefore, their use in these categories predates both the 2017 and 2024 note additions and does not represent a new use or result in any additional exposure beyond long-standing historical use. The proposal of deletion of Notes XS 117, 206 and 302 from the corresponding food categories as mentioned above does not result in new exposure. Steviol glycosides are already permitted in food categories 12.5, 12.6.2 and 12.6.4 under the GSFA.
Justification that the use does not mislead consumer	The function of Steviol glycosides as a sweetener is clearly declared on product labelling, ensuring transparency for consumers. The use of Steviol glycosides in flavored fermented milks does not mislead consumers as it would align with permitted use of sweeteners in flavored products under CXS 243-2003 in general. The function of Steviol glycosides as a sweetener is clearly declared on product labelling, ensuring transparency for consumers. The use of sweeteners such as steviol glycosides in soups, broths and sauces does not mislead consumers either as the function of sweeteners is well understood in these products,

	their use is consistent with existing Codex commodity standards and sweeteners are required to be declared on product labelling in accordance with Codex provision, ensuring transparency.
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- (1) For proposed revisions of adopted provisions, the current adopted provision should be provided, with deletions noted in ~~strike through~~ text, and changes or additions noted in **bold** font.
- (2) Food category number and name, as listed in Annex B of the GSFA.
- (3) For consistency, the maximum use level should be reported on the same basis as the ADI. A numerical use level should be provided for a food additive assigned a numerical ADI. GMP or a numerical use level may be provided for a food additive assigned a non-numerical ADI (e.g. “not- specified”).
- (4) Comments on specific restrictions on the use of the food additive to be included as Notes (e.g. limitation of use to specific products in a food category).

ISDI

Background:

Full specifications were prepared for four (4) food additives: i) Gardenia (Genipin) Blue (INS 165), ii) low-acyl clarified Gellan gum (INS 418(ii)), iii) Glycolipids (INS 246), iv) Thaumatin II.

ISDI Comments

ISDI believes that after the adoption of full specifications for low-acyl clarified Gellan gum (INS 418(ii)), the provisions for use in Category 13.1.3 should be adopted. Therefore ISDI would like to propose the following amendments:

Proposed amendment to Table 1 of the GSFA

GELLAN GUM:			
INS: 418(ii) Functional class: Gelling agent, Stabilizer, Thickener			
Food Category No	Food Category	Max level	Notes
13.1.3	Formulae for special medical purposes for infants	50 mg/kg	192, 376, 551

Note 192: For use in liquid products only.

Note 376: For use in hydrolyzed protein and/or amino acid based infant formula only.

Note 551: Maximum use level is expressed as mg additive/L of food.

Proposed amendment to Table 2 of the GSFA

Food category 13.1.3 Formulae for special medical purposes for infants:			
Additive	INS	Max level	Notes
Low acyl clarified gellan gum	418(ii)	50 mg/kg	192, 376, 551

Note 192: For use in liquid products only.

Note 376: For use in hydrolyzed protein and/or amino acid based infant formula only.

Note 551: Maximum use level is expressed as mg additive/L of food.

Rationale:

Prior to CCFA56, low acyl clarified gellan gum (INS 418(ii)) has already completed the critical requirements for adoption of the provisions to tables 1 and 2:

- The 87th meeting of JECFA concluded that the “the use of gellan gum in FSMPs and liquid fortification products for addition to human milk or infant formula at a maximum level of 50 mg/L in the fed product indicates low risk for the health of infants, including preterm infants, and that its proposed use is therefore of no safety concern”. ([Eighty-seventh meeting of the Joint FAO/WHO Expert Committee on Food Additives](#) ISBN: 978-92-4-121029-4)
- CCNFSDU43 ([REP23/NFSDU](#) Para. 78 concluded that “the proposed use of low-acyl clarified gellan gum (INS 418) as a thickener and stabilizer in formulas for special medical purposes intended for infants at 5 mg/100 ml limited to hydrolyzed protein and/or amino acid-based liquid formula was technologically justified”.
- 100th meeting of JECFA prepared Full specifications low acyl clarified gellan gum (INS 418(ii)). ([Compendium of food additive specifications](#), Joint FAO/WHO Expert Committee on Food Additives, One hundredth Meeting, Rome, 10–19 June 2025)

Furthermore, CCFA53 ([REP23/FA](#), Para. 142) concluded that “the safety evaluation for infants under the age of 12 weeks had already been completed and the only outstanding issue was the specification for the gellan gum, low acyl clarified”.

Therefore, now that the specifications for low acyl clarified gellan gum (INS 418(ii)) have been finalized, it should proceed for adoption in FC 13.1.3.