

CODEx ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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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 Republic of Korea, and International Food Additives Council (IFAC))

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.

Changes from the previous proposal in CX/FA 26/56/8 are presented as **bold and underline** for additions.

THE PROPOSAL IS SUBMITTED BY:		Republic of Korea	
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive		Steviol glycosides	
As listed in Class Names and the International Numbering System for Food Additives (CXG 36-1989)			
INS Number		960a, 960b, 960c, 960d	
Functional Class		Sweetener	
As listed in Class Names and the International Numbering System for Food Additives (CXG 36-1989)			
PROPOSED USE(S) OF THE FOOD ADDITIVE ⁽¹⁾:		The proposal for:	
The rows below may be copied as many times as needed.		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⁾
13.6	Food supplements	<u>200 mg/kg</u>	Note 26, 203 & 477 <u>Remove "Note 203 (for use in chewable supplements only.)" from</u>

			the steviol glycosides provision in FC 13.6. Add New Note: Except for use at 2,500 mg/kg in food supplements in solid form not intended to be reconstituted or diluted prior to consumption.
Is the proposal related to a FC with corresponding commodity standards? (if yes indicate the relevant FC) No			
Is the proposal also intended to revise the products covered by the commodity standards? (if yes indicate the relevant 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>		1. Evaluation year: 2019 (87 th JECFA) 2. ADI: 0-4 mg/kg bw (expressed as steviol equivalents) 3. Report: TRS 1020-JECFA87/10 4. 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>		Based on Section 3.2 of the Preamble of the General Standard for Food Additives, the main technological need for the use of steviol glycosides (INS 960a, 960b, 960c, 960d) in food category 13.6 (food supplements) is 3.2(c) 'to improve its organoleptic properties of foods'. An appropriate use of sweeteners is necessary to mask inherent bitterness and other undesirable tastes characteristic of most nutrients and functional ingredients used in food supplements. In addition, sweeteners such as aspartame, neotame, and saccharin are already permitted for use in FC 13.6 (food supplements) in various dosage forms, not limited to chewable forms.	
Safe use of additive: Dietary intake assessment		Table 3 additive: ☐ Yes ☒ No	

	<u>The proposed use levels for steviol glycosides have been assessed with reference to the acceptable daily intake (ADI) established by the Joint FAO/WHO Expert Committee on Food Additives, expressed as steviol equivalents (4 mg/kg bw/day).</u> <u>Using a default adult body weight of 70 kg, the ADI corresponds to 280 mg/day.</u> <u><Data provided by the International Alliance of Dietary/Food Supplement Associations(IADSA)></u> <u>For food supplements in solid dosage forms (e.g. tablets and capsules), assuming a maximum use level of 2,500 mg/kg and a consumption scenario of two units per day (1–2 g per unit), the estimated daily intake is below 5% of the ADI.</u> <u>For liquid food supplements, as well as solid forms requiring reconstitution prior to consumption (e.g. powders or effervescent formats), exposure has been estimated based on a daily serving of 200 mL. At the proposed use levels, the resulting intake represents approximately 14% of the ADI. This level of exposure remains below the ADI.</u> <u>The proposed maximum level for liquid forms (200 mg/L) is consistent with existing provisions for comparable liquid food categories in the Codex General Standard for Food Additives (GSFA).</u> <u>Food supplements are consumed in defined portion sizes with specified conditions of use, typically resulting in significantly lower daily consumption volumes compared to conventional food categories.</u> <u>Based on this, the proposed use levels for steviol glycosides in food supplements do not lead to an exceedance of the ADI under the stated conditions of use.</u>
Justification that the use does not mislead consumer	The use of steviol glycosides would be indicated on the label of the products.

International Food Additives Council (IFAC)

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>		Nisin A	
INS Number		234	
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: ☐ 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)
12.6.1	Emulsified sauces and dips (e.g. mayonnaise, salad dressing, onion dip)	5 mg/kg	Revising an existing provision. We propose to update Note 538 (or create a new Note if more applicable for this FC) to allow flexibility for different levels of oil content in sauce formulations. Note 538 For use in low oil content or refrigerated products only Note 538 Including but not limited to low oil content or refrigerated products
12.6.2	Non-emulsified sauces (e.g. ketchup, cheese sauce, cream sauce, brown gravy)	5 mg/kg	Revising an existing provision. We propose to update Note 538 (or create a new Note if more applicable for this FC) to allow flexibility for different levels of oil content in sauce formulations. Note 538 For use in low oil content or refrigerated products only Note 538 Including but not limited to low oil content or refrigerated products

8.2.2	Heat-treated processed meat, poultry, and game products in whole pieces or cuts	25 mg/kg	Revising an existing provision. We propose to update Note 330 to be clearer. Note 330 Except for use in canned products Note 330 Excluding canned products
Is the proposal related to a FC with corresponding commodity standards? (if yes indicate the relevant FC) No			
Is the proposal also intended to revise the products covered by the commodity standards? (if yes indicate the relevant commodity standards) N/A			
EVALUATION BY JECFA:			
Evaluation by JECFA Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or “not specified”); specifications monograph).		Evaluation year: 2024 ADI: 0-2 mg/kg bw Comments: Based on the available data, JECFA concluded that there is no concern for the induction of antimicrobial resistance, and that the risk of nisin having a disrupting effect on the microbiome of the human gastrointestinal tract is low. The new toxicological information available for this evaluation did not provide any reason to revise the ADI for nisin. JECFA re-affirmed the ADI of 0– 2 mg/kg bw for nisin established by the previous JECFA meeting at the Seventy-seventh meeting, but noted that the critical toxicological studies were conducted with nisin A; JECFA therefore concluded that the ADI applies only to nisin A. Meeting: 99 Specs Code: R Report: TRS 1056-JECFA 99/35 Tox Monograph: FAS 90-JECFA 99/107 Previous Years: 2013, 1968	
JUSTIFICATION:			
Justification for use and technological need 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).		<u>Related to FC 12.6.1 and 12.6.2 and Note 538</u> The definition of “low oil content” in Note 538 is unclear as currently written, leading to ambiguity about its applicability to certain products. We believe the current note, “for use in low oil content only,” is driven by the concern that nisin works in the water phase, not the oil phase, and that high oil or fat reduces nisin’s effectiveness. However, there are now solutions to increase nisin efficacy in both emulsified and non-emulsified sauces, at different oil levels, using various application strategies such as encapsulation technologies to encapsulate nisin and thereby improve its overall efficacy. These technologies have overcome fat-related limitations, enabling the use of	

	nisin in high lipid product applications. Hence, the low oil content restriction is no longer applicable. There are existing products under FC 12.6.1 and 12.6.2, containing oil ranging from 10 to 60% fat and using nisin as a preservative: <table><tr><th>FC</th><th>Example of products containing nisin in market</th><th>Fat %</th></tr><tr><td rowspan="3">12.6.1</td><td>Mayonnaise</td><td>58.7%</td></tr><tr><td>Salad Dressing</td><td>50%</td></tr><tr><td>Caesar Dressing</td><td>33.3%</td></tr><tr><td rowspan="3">12.6.2</td><td>Cheese Sauce</td><td>30%</td></tr><tr><td>Hotpot Dipping Sauce</td><td>20.4%</td></tr><tr><td>Creamy Pesto Sauce</td><td>10%</td></tr></table> <u>Related to FC 8.2.2 and Note 330</u> Notes of the type “Except for use in ...” typically contain additional use level information such as “Except for use in xyz at 50 mg/kg.” The use of Note 330 “Except for use in canned products” in this instance does not make sense and creates confusion. While it was not clearly captured in the CCFA47 report, it was believed there was discussion at the meeting that nisin would not be needed in canned products. Hence a clearer note would have been “Excluding canned products” which is why we are seeking this revision. We don’t find products using nisin under FC 8.2.2.	FC	Example of products containing nisin in market	Fat %	12.6.1	Mayonnaise	58.7%	Salad Dressing	50%	Caesar Dressing	33.3%	12.6.2	Cheese Sauce	30%	Hotpot Dipping Sauce	20.4%	Creamy Pesto Sauce	10%
FC	Example of products containing nisin in market	Fat %																
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Safe use of additive: Dietary intake assessment <i>(as appropriate)</i>	Table 3 additive: ☐ Yes x☐ No (Please provide information on dietary intake assessment below) <u>WHO Technical Report Series 1056</u> There were dietary exposure estimates available for more than 40 countries across all WHO regions. The estimates were based on different types of foods and concentrations. These included GSFA permissions, local permissions or other uses (e.g. proposed use levels; as a processing aid). GSFA permissions include cheeses, processed meats, other dairy products, fine bakery wares, desserts, liquid egg products, salads, soups, sauces and dips.																	

	For all national estimates of dietary exposure to Nisin A considered at the Ninety-ninth meeting, mean estimates ranged up to 0.23 mg/kg bw per day for children and up to 0.07 mg/kg bw per day for adults. Estimates of high dietary exposure ranged up to 0.78 mg/kg bw per day for children and up to 0.23 mg/kg bw per day for adults. Major contributors to dietary exposure were commonly processed meats, cheeses, and fermented milk products. JECFA noted that the dietary exposure estimates for nisin of up to 0.78 mg/kg bw per day for all population subgroups assessed were below the ADI for nisin A, and concluded that dietary exposure to nisin was not of toxicological concern. <u>Related to FC 12.6.1 and 12.6.2 and Note 538</u> A typical serving size of sauces is 30g per day. At the current Nisin A provision of a maximum of 5mg/kg in FC12.6.1 and FC12.6.2, this equates to 0.15mg per serving per day. • For adults (60kg body weight), the exposure would be 0.0025mg/kg bw per day (or 0.125% of the reported 2mg/kg ADI). • For children (15kg body weight), the exposure would be 0.01mg/kg bw per day (or 0.5% of the 2mg/kg ADI). These are low additions to the current dietary exposure rate of 0.23 mg/kg bw per day for adults and 0.78 mg/kg bw per day for children. <u>Related to FC 8.2.2 and Note 330</u> A clearer note to exclude canned products would maintain the dietary exposure rate of 0.23 mg/kg bw per day for adults and 0.78 mg/kg bw per day for children.
Justification that the use does not mislead consumer	The use of nisin A would be declared on product labels.