

CODEx ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



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Organization

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Agenda Item 5(b)

CX/FA 25/55/8
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx COMMITTEE ON FOOD ADDITIVES

Fifty-fifth Session

GENERAL STANDARD FOR FOOD ADDITIVES (GSFA): PROPOSALS FOR NEW AND/OR REVISION OF FOOD ADDITIVE PROVISIONS (REPLIES TO CL 2024/58-FA)

(Submitted by China, South Africa, International Food Additives Council (IFAC), International Special Dietary Foods Industries (ISDI))

China

THE PROPOSAL IS SUBMITTED BY:		China	
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Glycerol	
INS Number		422	
Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Humectant, Thickener	
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⁾
Propose to add the codex standard number 249-2006 (CXS 249-2006) into Column 5 of table 3 for the food additive "Glycerol".			
INS No	Additive	Functional Class	Year Adopted
Specific allowance in the following commodity standards			
422	Glycerol	Humectant, Thickener	1999
CS 87-1981, CS 253-2006 (see functional class table and footnote), CS 249-2006			
Is the proposal related to a FC with corresponding commodity standards?			

(if yes indicate the relevant FC)	
Is the proposal also intended to revise the products covered by the commodity standards? (if yes indicate the relevant commodity standards) 06.4.3 CODEX STAN 249-2006 Standard for Instant Noodles	
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: 2002 ADI: not specified (1976) https://apps.who.int/food-additives-contaminants-jecfa-database/Home/Chemical/1565
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>	Glycerol could interact with emulsifiers added into instant noodles, thereby enhancing the emulsifying function. Additionally Glycerol could improve the water retention and anti-aging properties of flour-based products, enhances their resistance to freezing. And also glycerol has the capability to reduce the water activity of the emulsion oil products which could avoid the microbial contaminations and eventually protect instant noodle products.
Safe use of additive: Dietary intake assessment (as appropriate)	Table 3 additive: ☒ Yes ☐ No (Please provide information on dietary intake assessment below)
Justification that the use does not mislead consume	The presence of glycerol would be declared on product labels

THE PROPOSAL IS SUBMITTED BY:	China
IDENTITY OF THE FOOD ADDITIVE:	
Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>	NA
INS Number	NA
Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>	NA
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 CategoryNo. (²)	Food Category Name (²)	Maximum Use Level (³)	Comments (⁴)
Propose to amend the explanatory note to the table 3 of GSFA, proposal as the following: - If the text indicates that "only certain Table 3 food additives (as indicated in Table 3) <u>with or without specific functional classes</u>" are permitted for use in foods covered by the commodity standard, then the user may refer to column 5 of Table 3 where the commodity standard number will be listed for the particular Table 3 food additives that are permitted for use in the commodity standard.			
Is the proposal related to a FC with corresponding commodity standards? <i>(if yes indicate the relevant FC)</i>			
Is the proposal also intended to revise the products covered by the commodity standards? <i>(if yes indicate the relevant commodity standards)</i> NA			
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>		NA	
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>		NA	
Safe use of additive: Dietary intake assessment <i>(as appropriate)</i>		Table 3 additive: NA ☐ Yes ☐ No (Please provide information on dietary intake assessment below)	
Justification that the use does not mislead consume		NA	

Propose to amend the explanatory note to the table 3 of GSFA:

Explanatory Note: Determining the Use of Table 3 Additives in Foods Covered by Commodity Standards based on the Revised Approach - If a commodity standard covers the use of foods in food categories that are contained in the Annex to Table 3, then Table 3 does not apply to the commodity standard. - All food additive permissions for foods covered by food categories listed in the Annex to Table 3 must be listed in Tables 1 and 2 of the GSFA. - If a commodity standard covers a food category that is not listed in the Annex to Table 3, then the user

should refer to the “References to Commodity Standards for GSFA Table 3 Additives” section of Table 3.

- If the section specific to the commodity standard indicates that all Table 3 additives are permitted for use in foods covered by the standard, then any food additives listed in Table 3 may be used in foods covered by the standard.
- If the text indicates that only Table 3 additives with specific functional classes may be used (e.g. acidity regulator), then any Table 3 additive listing the noted functional class in column 3 of Table 3 may be used in foods covered by the commodity standard.
- If the text indicates that “only certain Table 3 food additives (as indicated in Table 3) **with or without specific functional classes**” are permitted for use in foods covered by the commodity standard, then the user may refer to column 5 of Table 3 where the commodity standard number will be listed for the particular Table 3 food additives that are permitted for use in the commodity standard.

The current explanatory notes cover 3 scenarios for the use of Table 3 food additives in Commodity Standard:

- all Table 3 additives are permitted for use in foods covered by the commodity standard.
- only Table 3 additives with specific functional classes may be used.
- only certain Table 3 food additives (as indicated in Table 3) are permitted.

However, there is another scenario that is not included in the explanatory note, i.e. “only certain Table 3 food additives **with specific functional classes** are permitted”.

This missing scenario could lead to a misunderstanding that any Table 3 additive listing the noted functional class in column 3 of Table 3 may be used in foods covered by the commodity standard. However, the correct interpretation is that only the particular Table 3 food additives are permitted for use in the commodity standard which the commodity standard number is listed in the column 5 of Table 3.

Example I: The use of Table 3 food additives in FC 01.6.2.1 for Cheeses in Brine (CXS 208-1999) and the Generals Standard for Cheese (CXS 283-1978).

In the References to commodity standards for GSFA table 3 additives" in FC 01.6.2.1 for Cheeses in Brine (CXS 208-1999) and the Generals Standard for Cheese (CXS 283-1978). It states "Only certain acidity regulators, anticaking agents, colours and preservatives in Table 3 (as indicated in Table 3) are acceptable for use in foods conforming to CXS 283-1978, and only certain acidity regulators in Table 3 (as indicated in table 3) are acceptable for use in foods conforming to CXS 208-1999." It could lead to a wrong interpretation that Table 3 food additives with specific function class “acidity regulators, anticaking agents, colours and preservatives” could be allowed to use in food conforming to CXS 283-1978, and Table 3 food additives with specific function class “acidity regulators” could be used in foods conforming to CXS 208-1999.

However, as checking the version of CXS 283-1978 and CXS 208-1999 before Alignment, it states as following:

GENERAL STANDARD FOR CHEESE (CODEX STAN 283-1978)

4. FOOD ADDITIVES

Only those food additives listed below may be used and only within the limits specified.

Unripened cheeses

As listed in the Codex Standard for Unripened Cheese Including Fresh Cheese.

Cheeses in Brine

As listed in the Codex Standard for Cheeses in Brine (CODEX STAN 208-1999).

Ripened cheeses, including mould ripened cheeses

Additives not listed below but provided for in Codex individual standards for varieties of ripened cheeses may also be used for similar types of cheese within the limits specified within those standards.

INS No.	Name	Maximum Level
Colours		
100	Curcumins (for edible cheese rind)	Limited by GMP
101	Riboflavins	Limited by GMP
120	Carmines (for red marbled cheeses only)	Limited by GMP
140	Chlorophylls (for green marbled cheeses only)	Limited by GMP

141	Chlorophylls and chlorophyllins, copper complexes	15 mg/kg
160a(i)	-Carotenes, <i>beta</i> - (synthetic)	25 mg/kg
160a(ii)	Carotenes, <i>beta</i> -(vegetable)	600 mg/kg
160b(ii)	Annatto extracts, norbixin-based	50 mg/kg
160c	Paprika oleoresins	Limited by GMP
160e	Carotenal, <i>beta</i> -apo-8'-	35 mg/kg
160f	Carotenoic acid, ethyl ester, <i>beta</i> -apo-8'-	35 mg/kg
162	Beet red	Limited by GMP
171	Titanium dioxide	Limited by GMP
Acidity regulators		
170	Calcium carbonates	Limited by GMP
504	Magnesium carbonates	
575	Glucono delta-lactone	
Preservatives		
200	Sorbic acid	3000 mg/kg calculated as sorbic acid
201	Sodium sorbate	
202	Potassium sorbate	
203	Calcium sorbate	
234	Nisin	12.5 mg/kg
239	Hexamethylene tetramine (Provolone only)	25 mg/kg, expressed as formaldehyde
251	Sodium nitrate	50 mg/kg, expressed as NaNO ₃
252	Potassium nitrate	
280	Propionic acid	3000 mg/kg, calculated as propionic acid
281	Sodium propionate	
282	Calcium propionate	
1105	Lysozyme	Limited by GMP
For surface/rind treatment only:		
200	Sorbic acid	1000 m /kg singly or in combination, calculated as sorbic acid
202	Potassium sorbate	
203	Calcium sorbate	
235	Natamycin (Pimaricin)	2 mg/dm ² of surface. Not present in a depth of 5 mm ⁹
Miscellaneous additive		
508	Potassium chloride	Limited by GMP

Sliced, cut, shredded or grated cheese

INS No.	Name	Maximum Level
Anti-caking agents		
460	Cellulose	Limited by GMP
551	Silicon dioxide, amorphous	
552	Calcium silicate	
553	Magnesium silicates	
		10,000 mg/kg singly or in combination. Silicates calculated as silicon dioxide
560	Potassium silicate	
Preservatives		
200	Sorbic acid	1000 mg/kg singly or in combination, calculated as sorbic acid
202	Potassium sorbate	
203	Calcium sorbate	

**GROUP STANDARD FOR CHEESES IN BRINE
(CODEX STAN 208-1999)**

4. FOOD ADDITIVES

Only those food additives listed may be used and only within the limits specified.

INS No	Name of Additive	Maximum Level
Acidity regulators		
270	Lactic acid (L-, D- and DL-)	Limited by GMP
575	Glucono delta-lactone	Limited by GMP

The provisions above indicates that only those food additives listed in the table above are permitted, not all Table 3 additives with function class "acidity regulators, anticaking agents, colours and preservatives" are permitted in CXS 283-1978. And only INS 270 Lactic acid and INS 575 Glucono delta-lactone are permitted in

CXS 208-1999, not all Table 3 food additives with acidity regulator function class are permitted in food conforming to CXS 208-1999.

Example II: The use of Glycerol (Table 3 food additive) in CXS 249-1999 “Standard for instant noodles”.

Glycerol is a Table 3 food additive and has function class “humectant and thickener” listed in column 3.

INS No	Additive	Functional Class	Year Adopted	Specific allowance in the following commodity standards
422	Glycerol	Humectant, Thickener	1999	CS 87-1981, CS 253-2006 (see functional class table and footnote)

In the “Food Additive” section of the CXS 249-1999, it is stated that “only certain Table 3 acidity regulators, antioxidants, colours, emulsifiers, flavour enhancers, humectants, stabilizers, and thickeners as indicated in Table 3 of the General Standard for Food Additives (CXS 192-1995) are acceptable for use in foods conforming to this Standard.” Since there list several food additive function classes, it could lead to a misunderstood that any Table 3 additives with food additive function class “acidity regulators, antioxidants, colours, emulsifiers, flavour enhancers, humectants, stabilizers, and thickeners” listed in column 3 of Table 3 is allowed to be used in instant noodles, for instance, Glycerol could be used in CXS 249-1999. However, since there is a word “certain” in the provision, so the correct interpretation is only the particular Table 3 food additives are permitted for use in instant noodles which the commodity standard number “CXS 249-1999” is listed in the column 5 of Table 3, as the commodity standard number “CXS 249-1999” is not listed in column 5 for Glycerol, so Glycerol is not permitted to be used in instant noodles.

And as checking the version of CXS 249-2006 before Alignment (as following), Glycerol is not permitted in the standard.

**STANDARD FOR INSTANT NOODLES
(CODEX STAN 249-2006)**

4 FOOD ADDITIVES

The use of food additive(s) as well as food additive(s) carry-over shall comply with the maximum level permitted by the *General Standard for Food Additives* (GSFA), CODEX STAN 192-1995. However, until the food additive provisions for the food category 06.4.3 “Pre-cooked pastas and noodles and like products” in the GSFA is finalised, the following listed food additives will apply⁴.

INS No.	Name of Additive	Maximum Level
	Acidity regulators	
260	Acetic acid, glacial	GMP
262(i)	Sodium acetate	GMP
270	Lactic acid (L-, D-, and DL-)	GMP
296	Malic acid (DL-)	GMP
327	Calcium lactate	GMP
330	Citric acid	GMP
331(iii)	Trisodium citrate	GMP
334	Tartaric acid (L(+)-)	7500mg/kg
350(ii)	Sodium malate	GMP
365	Sodium fumarates	GMP
500(i)	Sodium carbonate	GMP
500(ii)	Sodium hydrogen carbonate	GMP
501(i)	Potassium carbonate	GMP
516	Calcium sulphate	GMP
529	Calcium oxide	GMP

	Antioxidants	
300	Ascorbic acid (L-)	GMP
304	Ascorbyl palmitate	500 mg/kg Singly or in combination as ascorbyl stearate
305	Ascorbyl stearate	
306	Mixed tocopherols concentrate	200 mg/kg Singly or in combination
307	Alpha-tocopherol	
310	Propyl gallate	200 mg/kg Singly or in combination expressed as a fat or oil basis
319	Tertiary butylhydroquinone (TBHQ)	
320	Butylated hydroxyanisole (BHA)	
321	Butylated hydroxytoluene (BHT)	
	Colours	
100(i)	Curcumin	500 mg/kg
101(i)	Riboflavin	200 mg/kg Singly or in combination as riboflavin
101(ii)	Riboflavin 5'-phosphate, sodium	
102	Tartrazine	300 mg/kg
110	Sunset yellow FCF	300 mg/kg
120	Carmines	100 mg/kg
123	Amaranth	100 mg/kg
141(i)	Chlorophyll copper complex	100 mg/kg
141(ii)	Chlorophyllin copper complex, sodium and potassium salts	100 mg/kg
143	Fast green FCF	290 mg/kg
150a	Caramel I-plain	GMP
150b	Caramel II - sulfite caramelsulfite	50000 mg/kg
150c	Caramel III-ammonia caramel	50000 mg/kg
150d	Caramel IV-ammonia sulfite caramel	50000 mg/kg
160a(i)	Beta carotene (synthetic)	1200 mg/kg
160a(ii)	Carotenes, Vegetable	1000 mg/kg
160a(ii)	Beta-carotene (Blakeslea trispora)	1000 mg/kg
160e	Beta-apo-carotenal	200 mg/kg
160f	Beta- apo-8'-carotenic acid, methyl or ethyl ester	1000 mg/kg
162	Beet red	GMP
	Flavour Enhancers	
620	Glutamic acid (L(+)-)	GMP
621	Monosodium glutamate, L-	GMP
631	Disodium 5'-inosinate,	GMP
627	Disodium 5'-guanylate	GMP
635	Disodium 5'-ribonucleotides	GMP

	Stabilizers	
170(i)	Calcium carbonate	GMP
406	Agar	GMP
459	Beta-cyclodextrin	1000 mg/kg
	Thickeners	
400	Alginic acid	GMP
401	Sodium Alginate	GMP
410	Carob Bean Gum	GMP
407	Carrageenan and its Na, K, NH ₄ salts (includes furcellaran)	GMP
407a	Processed Eucheuma Seaweed	GMP
412	Guar gum	GMP
414	Gum Arabic (acacia gum)	GMP
415	Xanthan gum	GMP
416	Karaya Gum	GMP
417	Tara Gum	GMP
418	Gellan Gum	GMP
424	Curdlan	GMP
440	Pectins	GMP
466	Sodium carboxymethyl cellulose	GMP
508	Potassium chloride	GMP
1401	Acid treated starch	GMP
1402	Alkaline treated starch	GMP
1403	Bleached starch	GMP
1404	Oxidized Starch	GMP
1405	Starches, enzyme-treated	GMP
1410	Monostarch phosphate	GMP
1412	Distarch phosphate esterified with sodium trimetaphosphate; esterified with phosphorous oxychloride	GMP
1413	Phosphated distarch phosphate	GMP
1414	Acetylated distarch phosphate	GMP
1420	Starch acetate	GMP
1422	Acetylated distarch adipate	GMP
1440	Hydroxypropyl starch	GMP
1442	Hydroxypropyl distarch phosphate	GMP
1450	Starch sodium octenyl succinate	GMP
1451	Acetylated oxidized starch	GMP
	Humectants	
325	Sodium lactate	GMP
339(i)	Monosodium orthophosphate	2000 mg/kg Singly or in combination as phosphorus
339(ii)	Disodium orthophosphate	
339(iii)	Trisodium orthophosphate	
340(i)	Monopotassium orthophosphate	
340(ii)	Dipotassium orthophosphate	
340(iii)	Tripotassium orthophosphate	
341(iii)	Tricalcium orthophosphate	
450(i)	Disodium diphosphate	
450(iii)	Tetrasodium diphosphate	
450(v)	Tetrapotassium diphosphate	
450(vi)	Dicalcium diphosphate	
451(i)	Pentasodium triphosphate	
452(i)	Sodium polyphosphate	
452(ii)	Potassium polyphosphate	
452(iv)	Calcium polyphosphates	
452(v)	Ammonium polyphosphates	
420	Sorbitol and sorbitol syrup	GMP
1520	Propylene glycol	10000 mg/kg
	Emulsifiers	
322	Lecithin	GMP
405	Propylene glycol alginate	5000 mg/kg
430	Polyoxyethylene (8)stearate	5000 mg/kg (dry basis)
431	Polyoxyethylene (40)stearate	Singly or in combination
432	Polyoxyethylene (20)sorbitan monolaurate	5000 mg/kg Singly or in combination as
433	Polyoxyethylene (20)sorbitan monooleate	

434	Polyoxyethylene (20)sorbitan monopalmitate	total polyoxyethylene (20) sorbitan esters
435	Polyoxyethylene (20)sorbitan monostearate	
436	Polyoxyethylene (20)sorbitan tristearate	
471	Mono and di-glycerides of fatty acids	
472e	Diacetyltartaric and fatty acid esters of glycerol	GMP
473	Sucrose esters of fatty acids	10000 mg/kg
475	Polyglycerol esters of fatty acids	2000 mg/kg
476	Polyglycerol esters of interesterified ricinoleic acids	2000 mg/kg
477	Propylene glycol esters of fatty acids	500 mg/kg
481(i)	Sodium stearoyl lactylate	5000 mg/kg (dry basis)
482(i)	Calcium stearoyl lactylate	5000 mg/kg
491	Sorbitan monostearate	5000 mg/kg (dry basis) Singly or in combination
492	Sorbitan tristearate	
493	Sorbitan monolaurate	
495	Sorbitan monopalmitate	
Flour Treatment Agents		
220	Sulphur dioxide	20 mg/kg Singly or in combination as sulphur dioxide
221	Sodium sulfite	
222	Sodium hydrogen sulfite	
223	Sodium metabisulfite	
224	Potassium metabisulfite	
225	Potassium sulfite	
227	Calcium hydrogen sulfite	
228	Potassium bisulfite	
539	Sodium thiosulphate	
Preservatives		
200	Sorbic acid	2000 mg/kg Singly or in combination as Sorbic acid
201	Sodium sorbate	
202	Potassium sorbate	
203	Calcium sorbate	
Anticaking Agent		
900a	Polydimethylsiloxane	50 mg/kg

South Africa

THE PROPOSAL IS SUBMITTED BY:		South Africa	
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>		Potassium sorbate	
INS Number		INS 202	
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⁾
04.1.1.2	Surface-treated fresh fruit	20 mg/kg (ppm)	Add Note 42 (as sorbic acid).
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>	Evaluation year: 1973 ADI: 0 - 25 mg/kg bw Group ADI, as the sum of sorbic acid and calcium, potassium and sodium sorbates (expressed as sorbic acid) Meeting: 17 Specs Code: R (1976) Report: NMRS 53/TRS 539-JECFA 17/18 Tox Monograph: NMRS 53A/FAS 5-JECFA 17/121 Specification: COMPENDIUM ADDENDUM 6/FNP 52 Add.6/115 (1998). R; FAO JECFA Monographs 1 vol.3/157
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>	The GSFA permits preservatives (sulphites) in this food category to preserve the freshness and quality of surface-treated fruits. Potassium sorbate is a widely used food preservative known for its fungicidal or fungistatic properties. It is also used in the post-harvest treatment of citrus fruits to act against spoilage fungi and moulds. The proposed usage level (up to 20 mg/kg) is required to act against some of the major post-harvest spoilage organisms of citrus fruit. When used on surface-treated citrus fruits, it prevents the decay of the fruit, thus enhancing the keeping quality or stability.
Safe use of additive: Dietary intake assessment <i>(as appropriate)</i>	Table 3 additive: ☐ Yes ☒ No (Please provide information on dietary intake assessment below) https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5625
Justification that the use does not mislead consumer	The use of the additive under the proposed maximum usage level is not considered misleading for the consumer. The purpose of potassium sorbate is to prolong the shelf life of the citrus fruit, i.e. solely for preservation rather than to alter the consumer's perception of the product misleadingly.

International Food Additives Council (IFAC)

THE PROPOSAL IS SUBMITTED BY:	International Food Additives Council (IFAC)
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>	Sucrose Esters

INS Number		INS 473: Sucrose esters of fatty acids INS 473a: Sucrose oligoesters, Type I and II INS 474: Sucroglycerides	
Functional Class <i>As listed in Class Names and the International Numbering System for Food Additives (CXG 36-1989)</i>		Glazing agent	
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 ☒ 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⁾
4.1.1.2	Surface-treated fresh fruit.	1,500 mg/kg	Revising an existing provision. We propose to replace Note 454 with Note 453 to enable use of sucrose esters as a glazing agent itself. Note 454 appears to only cover the use of sucrose esters <i>in</i> waxes, coatings, and glazes. Note 454: For use in waxes, coatings or glazes where these surface treatments are allowed for application to the surface of fresh fruit. Note 453: For use as a glaze where such surface treatment is allowed for application to the surface of fresh fruit.
4.2.1.2	Surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds).	1,500 mg/kg	New provision. We propose adding an allowance at 1,500 mg/kg (the same level as allowed in 4.1.1.2) and add Note 455. Note 455: For use as a glaze where such surface treatment is allowed for application to the surface of fresh vegetables, seaweeds or nuts and seeds.
Is the proposal related to a FC with corresponding commodity standards? Yes (if yes indicate the relevant FC) FC 4.1.1.2 and FC 04.2.1.2 have commodity standards for some of the fruits and vegetables therein.			
Is the proposal also intended to revise the products covered by the commodity standards? (if yes indicate the relevant 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>	Evaluation Year: 2020 ADI: 0–30 mg/kg bw Comments: Sucrose esters of fatty acids (INS 473) (SEFs) and sucrose oligoesters (SOEs) types I and II (INS 473a) are used mainly as emulsifiers and stabilizers in food. SEFs are authorized for use in 50 food categories at maximum permitted levels (MPLs) ranging from 200 mg/kg up to 20 000 mg/kg, as specified in the Codex General Standard for Food Additives (GSFA). Meeting: 89 Report: INS 473, INS 473a: Evaluation of certain food additives: eighty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives WHO technical report series; 1027 8 July 2021 https://www.who.int/publications/i/item/9789240030244 INS 474: Evaluation of Certain Food Additives and Contaminants: Forty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives WHO Technical Report Series; 884 1999 http://apps.who.int/iris/bitstream/10665/42142/1/WHO_TRS_884.pdf. Tox Monograph: INS 473, INS 473a: https://www.who.int/publications/i/item/9789240038448 INS 474: https://www.inchem.org/documents/jecfa/jecmono/v040je04.htm Specification: INS 473: https://openknowledge.fao.org/server/api/core/bitstreams/5a7fb0e4-fcd9-43e1-9270-30c84cd98573/content INS 474: https://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/monograph10/additive-445-m10.pdf Previous Years: 1997, 2009, 2017
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>	As sucrose esters are already allowed for use as a food additive in Food Category 4.1.1.2, the health and safety of this group of additives has already been evaluated by JECFA and found to be safe for these food categories at the current maximum use levels. Further, several markets allow the use of INS 473 as a glazing agent on fresh fruits. This proposal is to change the Note associated with the allowance for INS 473 in Food Category 4.1.1.2 to use INS 473 as the glazing agent. Vegetables face the same challenges as fruits with respect to moisture loss and oxidation. INS 473 can be used in Food Category 4.2.1.2 to extend the shelf life and quality of fresh vegetables as a glazing agent.

Safe use of additive: Dietary intake assessment <i>(as appropriate)</i>	Table 3 additive: ☐ Yes ☒ No (Please provide information on dietary intake assessment below) The additional proposed intake from sucrose esters on fresh fruits and vegetables is low (< 2%) based on the data available in the United States National Health and Nutrition Examination Survey (NHANES - 2013-2014) for total aggregated consumption of fruits, vegetables seeds and nuts with an edible peel.
Justification that the use does not mislead consumer	The proposed use described above does not disguise the nature or quality of fresh fruits and vegetables; the use of sucrose esters maintains the quality of fresh produce for longer by slowing moisture loss and oxidation.

Dietary Intake Assessment for Sucrose Esters in F.C. 4.1.1.2 & F.C. 4.2.1.2

JECFA group ADI

In 2010 at the 73rd meeting, Joint Expert Committee on Food Additives (JECFA) established a group acceptable daily intake (ADI) of 0–30 mg/kg bw/day for sucrose monoesters of lauric, palmitic, or stearic acid together with sucrose esters of fatty acids, sucroglycerides, sucrose oligoesters type I and type II (SOEs).¹ This includes INS 473 (sucrose esters of fatty acids), INS 473a (sucrose oligoesters, Type I and Type II), and INS 474 (sucroglycerides).

Estimated Dietary Intake

United States consumer data is used to estimate the dietary intake of both fresh fruits and vegetables treated with sucrose esters. This data is then added to the estimated dietary intake from all food uses for sucrose esters to obtain the cumulative estimated dietary intake, as presented in the 89th report of the JECFA Evaluation of certain food additives.² We note that the JECFA report references the 2019 Codex General Standard on Food Additives (GSFA), in which sucrose esters were not yet permitted in F.C. 4.1.1.2 (Surface-treated fresh fruits). Rather, sucrose esters were adopted for use in F.C. 4.1.1.2 in 2021.

Estimated Dietary Intake from F.C. 4.1.1.2 and F.C. 4.2.1.2

Sucrose esters (INS 473, INS 473a, and INS 474) are already allowed to be used on Food Category (F.C.) 4.1.1.2 (Surface-treated fresh fruits) with Note 454: For use in waxes, coatings or glazes where these surface treatments are allowed for application to the surface of fresh fruit. Sucrose esters are proposed to be used as a coating or glazing agent in F.C. 4.1.1.2 and 4.2.1.2 (Surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds) at a maximum level of 1,500 mg/kg of produce to harmonize the maximum use levels in both F.C. 4.1.1.2 and 4.2.1.2. However, for the purposes of the dietary intake estimate, 170 mg/kg of produce will be used based on use data as a coating on fresh produce. The tables below include calculations that utilize United States consumer data from the 2013-2014 National Health and Nutrition Examination Survey (NHANES). The aggregated absolute consumption of fruits, vegetables, nuts and seeds with edible peels is provided in Table 1. The “mean” is the average of all intake values calculated for individuals within the target population. “N” is the number of participants. The “mean error (SEM)” is the standard deviation of the distribution of mean intake values. The distributions of mean intake values are calculated using bootstrapping. The “P90” is the value of intake below which 90% of the analyzed population falls, and “P90 error” is the standard deviation of the distribution of the 90th percentile intake values. The distributions of P90 intake values are calculated using bootstrapping.

Table 1. Total aggregated absolute consumption of fruits, vegetables, seeds and nuts with an edible peel (2013-2014 NHANES Data)

¹ JECFA, 2010

² WHO, 2021

Population Group	Age (Years)	N	Absolute consumption of edible peel fruits and vegetables, nuts and seeds by Food Consumers* (g/day)			
			Mean	SEM	P90	P90 Error
Children	2-12	1058	92.5	2.1	201	6.3
Adolescents	13-19	564	91.9	3.2	190.6	8.5
Adults	20+	3019	118.2	1.9	252.2	6.2
All	2+	4641	112.3	1.6	234.8	4.4

The Estimated Daily Intake (EDI) of the allowed use of sucrose esters in a coating for F.C. 4.1.1.2 and the proposed use as a coating for F.C. 4.2.1.2 is summarized in Table 2, below. A value of 170 mg/kg of produce is used in these calculations rather than the maximum use limit of sucrose esters in F.C. 4.1.1.2 in the Codex GSFA (1,500 mg/kg) to give an estimate based on current use data.

Table 2. EDI of Sucrose Esters from Total Aggregated Absolute Consumption of Fruits, Vegetables, Seeds, and Nuts with Edible Peels (2013-2014 NHANES data)

Population Group	Age (Years)	Sucrose Esters Use Level (mg/g)	Daily Intake of Sucrose Esters (mg/person/day)		Body Weight (kg)	Daily Intake of a Sucrose Esters (mg/kg bw/day)	
			Mean	P90		Mean	P90
Children	2-12	0.17	15.73	34.17	24	0.66	1.42
Adolescents	13-19	0.17	15.62	32.40	62	0.25	0.52
Adults	20+	0.17	20.09	42.87	81	0.25	0.53
All	2+	0.17	19.09	39.92	65	0.29	0.61

Total Estimated Dietary Exposure to Sucrose Esters

The 89th report of the JECFA Evaluation of certain food additives reported dietary exposure estimates for the sum of INS 473 and INS 473a,³ as replicated in Table 3, below. The maximum permissible level (MPL) of sucrose esters is included for Japan. The dietary exposure estimates for some age groups exceeded the group ADI of 0–30 mg/kg bw/day, where the high dietary exposure estimate of the sum of INS 473 and INS 473a was 112.6 mg/kg bw/day for children aged 3–9 years. However, JECFA acknowledged that the exposure estimates are likely overestimates of the real exposure in Japan, Europe, and the USA. This is predominantly due to the assumptions that all foods that *could* contain INS 473 and INS 473a do in fact contain these food additives, and when INS 473 and INS 473a are used, they are present at the reported use levels. Realistically, other food additives with the same technical functions in food are available. In Japan in 2013, only 15% of all food additives used mainly as emulsifiers were INS 473 and INS 473a. At its 71st meeting, the JECFA noted that INS 473a are expected to account for not more than 10% of the total market share of emulsifiers,⁴ and the European Food Safety Authority (EFSA) noted that data from Mintel's Global New Products Database⁵ showed INS 473 was listed on the labels of only 0.2% of the foods in food categories in which sucrose esters are authorized for use.⁶ JECFA concluded the evaluation with the recommendation that more refined and realistic estimates should be provided to better assess dietary exposure for INS 473 and INS 473a.

Table 3. Estimated Dietary Exposure to the Sum of Sucrose Esters of Fatty Acids and Sucrose

³ WHO, 2021

⁴ WHO, 2010

⁵ The Mintel Global New Products Database is an online database for monitoring new packaged goods introduced to markets globally.

⁶ EFSA, 2018

Oligoesters, Types I and II (from JECFA 89th Report)

Country and levels	Dietary Exposure (mg/kg bw per day) ^a			
	Children ^b		General population ^c	
	Mean	High	Mean	High
Japan				
MPLs	65 ^b	–	23	–
Use level ^d	25	–	9	–
Europe				
Use level ^e				
Brand-loyal scenario	3.0–54.6	11.1–124.3	0.2–54.6	0.8–124.3
Non-brand loyal scenario	1.7–42.7	6.3–112.6	0.1–42.7	0.4–112.6
USA				
Maximum use level ^e		–	9	18

^a High dietary exposure: 95th percentile for Europe and 90th percentile for USA.

^b Children aged 1–6 years in Japan and 1–9 years in Europe.

^c The general population of Europe comprises infants (12 weeks–11 months), toddlers (12–35 months), children (3–9 years), adolescents (10–17 years), adults (18–64 years), and older adults (≥ 65 years); the general population of the USA covers the ages of 2–99 years. The age range of the general population of Japan was not specified.

^d Use levels of sucrose esters of fatty acids (INS 473) and sucrose oligoesters, types I and II (INS 473a) combined.

^e Use levels of sucrose esters of fatty acids (INS 473).

For the JECFA dietary exposure, the Committee considered that the high (95th percentile) dietary exposure for children aged 3–9 years, in the non-brand loyal scenario, was the most suitable for evaluation of dietary exposure to the sum of INS 473 and INS 473a: 112.6 mg/kg bw/day, which the Committee rounded to 113 mg/kg bw/day. The Committee notes that “the non-brand loyal estimate was selected because INS 473 and INS 473a are predominantly used as emulsifiers or stabilizers in foods for which other food additives with the same functions in foods are available, and [INS 473 and INS 473a] are not expected to influence the taste or appearance of foods.” The conservative estimate of 112.6 mg/kg bw/day is applied in the calculations herein.

To estimate the cumulative dietary exposure for sucrose esters from all approved food uses, the JECFA’s conservative estimate for sucrose esters consumption (which considers any food that is allowed to contain sucrose esters does contain sucrose esters, and it is present at the max use levels) is added to the US dietary exposure calculation for the use of sucrose esters in F.C. 4.1.1.2 and F.C. 4.2.1.2. The total cumulative estimated dietary intake (EDI) of sucrose esters is presented in Table 4.

Table 4. Total Estimated Dietary Exposure for Sucrose Esters

Population Group	Age (Years)	Total Sucrose Esters EDI based on Europe non-brand loyal scenario (mg/kg bw/day)*		EDI Increase with Proposed Use in F.C. 4.1.1.2 & F.C. 4.2.1.2	
		Mean	P90	Mean	High
Children	2-12	43.36	114.02	1.53%	1.26%

Adolescents	13-19	–	–	–	–
Adults	20+	–	–	–	–
All	2+	42.99	113.21	0.69%	0.55%

* – The mean value of 42.7 mg/kg bw/day and high (95th percentile) value of 112.6 mg/kg bw/day are used for both children and the general population (“All”), consistent with the Committee’s approach in the 89th Report.⁷

As shown in Table 4, the resulting increase in dietary exposure to sucrose esters for the proposed uses in F.C. 4.1.1.2 and F.C. 4.2.1.2 is low: less than 2% increase for children and less than a 1% increase for the general population. Additionally, similar to the JECFA estimated dietary exposure,⁸ the estimates for use in F.C. 4.1.1.2 and F.C. 4.2.1.2 are extremely conservative because the calculation assumes that sucrose esters are applied as a coating on *all* consumed fresh fruits and vegetables, and that the amount of sucrose esters applied in all instances is the maximum proposed use level of 180 mg/kg of produce.

References

EFSA, 2018. Scientific opinion on the refined exposure assessment of sucrose esters of fatty acids (E 473) from its use as a food additive. EFSA J. 2018;16(1);5087.

JECFA, 2010. The Summary report of the 73rd JECFA meeting, 8 – 17 June 2010. Issued 24 June 2010. JECFA/73/SC, available at: <https://www.fao.org/3/at862e/at862e.pdf>.

WHO (World Health Organization), 2010. Evaluation of certain food additives. Seventy-first report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series, No. 956.

WHO, 2021. Evaluation of certain food additives. Sucrose esters of fatty acids (INS 473) and sucrose oligoesters types I and II (INS 473a). Eighty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). WHO Technical Report Series, 1027, 38–42.

International Special Dietary Foods Industries (ISDI)

THE PROPOSAL IS SUBMITTED BY:		International Special Dietary Foods Industries (ISDI)	
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		All additives in Food Categories 13.2, 13.3, 13.4, 13.5, and 13.6	
INS Number		All additives in Food Categories 13.2, 13.3, 13.4, 13.5, and 13.6	
Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		All additives in Food Categories 13.2, 13.3, 13.4, 13.5, and 13.6	
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)
13.2	Complementary foods for infants and young children		

⁷ WHO, 2021

⁸ WHO, 2021

13.3	Dietetic foods intended for special medical purposes (excluding products of food category 13.1)		Consistent with the ongoing discussion at the EWG on an update to the “as consumed” note for FC 13.1 products, ISDI proposes adding a new note to all additive provisions in the other FC 13 products to align:
13.4	Dietetic formulae for slimming purposes and weight reduction		
13.5	Dietetic foods (e.g. supplementary foods for dietary use) excluding products of food categories 13.1-13.4 and 13.6		
13.6	Food supplements		“Products in food category 13 are available in multiple formats (e.g. liquid ready to consume and powder which requires mixture with water before consumption). In all cases, consistent with the language in Section 6 of the Preamble of the GSFA, the maximum level listed in the GSFA is for the final product as consumed.”

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

CXS 53-1981, CXS 73-1981, CXS 74-1981, CXS 118-1979, CXS 181-1991, CXS 203-1995; CXG 95-2022

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

Yes, products in the following commodity standards will be affected by the proposed change:

53-1981 Special Dietary Foods with Low-Sodium Content, including salt substitutes (special dietary foods with low sodium content)

73-1981 Canned Baby Foods

74-1981 Processed Cereal-Based Foods for Infants and Children

118-1981 Foods for Special Dietary Use for Persons Intolerant to Gluten

181-1991 Formula Foods for Use in Weight Control Diets

203-1995 Formula Foods for Use in Very Low Energy Diets for Weight Reduction

CXG 95-2022 Ready-to-Use Therapeutic Foods

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).

Not applicable

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).

Section 6 of the preamble to the GSFA indicates that “Unless otherwise specified, maximum use levels for additives in Tables 1 and 2 are set on the final product as consumed.”

	Considering the ongoing discussion to replace Note 381 (“As consumed”) in food categories 13.1.1., 13.1.2, and 13.1.3 with a new note indicating that the maximum levels set in the GSFA is for the final product as consumed, it is appropriate to consider the addition of a similar note in all other subcategories of FC 13.0 too, as currently they do not include this Note. This inconsistency in the application of the “as consumed” Note (which is redundant with the clause in Section 6 of the preamble of the GSFA) within the FC 13 products has led to confusion in the interpretation of the maximum use levels. Addition of this note to all provisions across FC 13 would reduce confusion by taking a harmonized approach to all products in this FC.
Safe use of additive: Dietary intake assessment <i>(as appropriate)</i>	Table 3 additive: ☐ Yes ☒ No (Please provide information on dietary intake assessment below)
Justification that the use does not mislead consumer	Not applicable