

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 4a and 4b

CRD 31

Original language only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fiftieth Session

Comments of Japan

Item 4a

Japan would like to submit the following comment on CX/FA 18/50/5.

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Additive class	Heat treated doogh		Un-heat treated doogh	
	Plain	Flavoured	Plain	Flavoured
Packaging gases	-	X	X	X

Japan requests clarification on whether the use of packaging gases in certain types of doogh is technologically justified or not. There are no food additives listed as packaging gases in the standard.

Several food additives with packaging gas function are adopted in Food Categories 01.2.1.1 and 01.1.4 which cover doogh (except plain heat treated doogh) in Table 2 of the GSFA. Table 3 additives can be also used in products covered by FC 01.1.4. If the use of packaging gas is justified and governed by the food additive provisions in the corresponding food categories in the GSFA, a general reference to the GSFA should be added in the standard, following the *Format for Commodity Standards* in the Procedural Manual.

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INS No.	Name of the Food Additive	Maximum Level	ADI	Note
101(i)	Riboflavin, synthetic	300 mg/kg	Group ADI of 0-0.5 mg/kg bw for riboflavin from <i>Bacillus subtilis</i> , synthetic riboflavin and riboflavin-5-phosphate (51st JECFA 1998)	In GSFA FC 01.1.4: 300 mg/kg.
101(ii)	Riboflavin 5'-phosphate, sodium			
102	Tartrazine		0-10 mg/kg bw (82th JECFA, 2016)	

Japan requests clarification on whether the proposed maximum level is set separately for each food additive or “singly or in combination: INS 101(i), INS 101(ii), INS 102”.

Japan also notes that INS 101(i) and 101(ii) share a numerical group ADI, so they should be listed as a group, in accordance with the Codex Procedural Manual.

In addition, Japan notes that riboflavin from *Bacillus subtilis* (INS 101(iii)) also shares a numerical group ADI with INS 101(i) and 101(ii). In Food Category 01.1.4, food additive provisions for INS 101(i), 101(ii) and 101(iii) are already adopted as a group. It is preferable to add INS 101(iii) in the standard to align with the food additive provisions in the GSFA unless any specific reasons are identified. Japan requests clarification on the reason why only INS 101(iii) is not included.

(Rationale)

Twenty-fifth edition of the Procedural Manual states, “food additives that share a numerical group ADI will be considered as a group without further restrictions on the use of individual additives in that group.” (see p. 67 “Consideration of Conditions of Use in the Specific Food Categories” in “Procedures for consideration of the entry and review of food additive provisions in the general standard for food additives”).

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INS No.	Name of the Food Additive	Maximum Level	ADI	Note
120	Carmines	150 mg/kg	Group ADI of 0-5 mg/kg bw for carmines, as ammonium carmine or the equivalent of Ca, K and Na salts (55th JECFA, 2000)	In GSFA FC 01.1.4: 150 mg/kg.
122	Azorubine (Carmoisine)		0-4 mg/kg bw (27th JECFA, 1983)	
124	Ponceau 4R (Cochineal red A)		0-4 mg/kg bw (74th JECFA, 2011)	

Japan requests clarification on whether the proposed maximum level is set separately for each food additive or “singly or in combination: INS 120, INS 122, INS 124”.

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INS No.	Name of the Food Additive	Maximum Level	ADI	Note
141(ii)	Chlorophylls, copper complexes, sodium and potassium salts	500 mg/kg	0-15 mg/kg bw (22nd JECFA, 1978)	In GSFA FC 01.1.4: 50 mg/kg, with Note 190 “Except for use in fermented milk drinks at 500 mg/kg”.

Japan notes that the name of INS 141(ii) is “chlorophyllins, copper complexes, sodium and potassium salts”, not chlorophylls.

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INS No.	Name of the Food Additive	Maximum Level	ADI	Note
163(ii)	Grape skin extract	100 mg/kg	0-2.5 mg/kg bw (26th JECFA, 1982)	In GSFA FC 01.1.4: 100 mg/kg, with Note 402 “For use in products conforming to the Standard for Fermented Milks (CXS 243- 2003) at 100 mg/kg”.
172(i)	Iron oxide, black		0-0.5 mg/kg bw (53rd JECFA, 1999)	
172(ii)	Iron oxide, red			In GSFA FC 01.1.4: 20 mg/kg with Note 402 “For use in products conforming to the Standard for Fermented Milks (CXS 243- 2003) at 100 mg/kg”.
172(iii)	Iron oxide, yellow			

Japan requests clarification on whether the proposed maximum level is set separately for each food additive or “singly or in combination: INS 163(ii), 172(i), 172(ii), 172(iii)”.

Japan also notes that INS 172(i), 172(ii) and 172(iii) share a numerical group ADI, so they should be listed as a group, in accordance with the Codex Procedural Manual.

(Rationale)

Please refer to the rationale for INS 101 Riboflavin, synthetic.

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INS No.	Name of the Food Additive	Maximum Level	ADI	Note
473	Sucrose esters of fatty acids	5000 mg/kg	0-30 mg/kg bw (73rd JECFA, 2010)	In GSFA FC 01.1.4: 5000 mg/kg.

INS No.	Name of the Food Additive	Maximum Level	ADI	Note
474	Sucroglycerides	5000 mg/kg	0-30 mg/kg bw, group ADI for sucrose esters of fatty acids and sucroglycerides (49th JECFA, 1997)	In GSFA FC 01.1.4: 5000 mg/kg.

INS 473 and 474 share a numerical group ADI, so they should be listed as a group, in accordance with the Codex Procedural Manual.

Japan notes that Sucrose oligoesters, type I and type II (INS 473a) also shares a numerical group ADI with INS 473 and 474. In Food Category 01.1.4, food additive provisions for INS 474, 473 and 473a are already adopted with note 348 "Singly or in combination: Sucrose esters of fatty acids (INS 473), sucrose oligoesters, type I and type II (INS 473a) and sucroglycerides (INS 474)". It is preferable to add INS 473a in the standard to align with the food additive provisions in the GSFA unless any specific reasons are identified. Japan requests clarification on the reason why only INS 473a is not included.

(Rationale)

Please refer to the rationale for INS 101 Riboflavin, synthetic.

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INS No.	Name of the Food Additive	Maximum Level	ADI	Note
481(i)	Sodium stearoyl lactylate	10000 mg/kg	0-20 mg/kg bw (17th JECFA, 1973)	In GSFA FC 01.1.4: 1000 mg/kg for stearoyl lactylates.
482(i)	Calcium stearoyl lactylate	10000 mg/kg	0-20 mg/kg bw (17th JECFA, 1973)	

INS 481(i) and 482(i) share a numerical group ADI, so they should be listed as a group, in accordance with the Codex Procedural Manual.

(Rationale)

Please refer to the rationale for INS 101 Riboflavin, synthetic.

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INS No.	Name of the Food Additive	Maximum Level	ADI	Note
636	Maltol	GMP	0-1 mg/kg bw (25th JECFA, 1981)	In GSFA there is no provision in FC 01.1.4.
637	Ethyl maltol	GMP	0-2 mg/kg bw (18th JECFA, 1974)	In GSFA there is no provision in FC 01.1.4.

JECFA assigned numerical ADIs to INS 636 and 637. A numerical use level should be established for each food additive provision unless any justifications for GMP are provided in accordance with the Codex Procedural Manual.

(Rationale)

Twenty-fifth edition of the Procedural Manual states, "For additives with a numerical Acceptable Daily Intake (ADI), a numerical maximum use level for each specified use although for certain cases, a level of GMP may be appropriate" (see p. 63 "Revision" in "Procedures for consideration of the entry and review of food additive provisions in the general standard for food additives")

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INS No.	Name of the Food Additive	Maximum Level	ADI	Note
405	Propylene glycol alginate	GMP	0-70 mg/kg bw (41st JECFA, 1993)	In GSFA FC 01.1.4.: 1300 mg/kg, with Note XS243 "Excluding products conforming to the Standard for Fermented Milks (CXS 243-2003)".

INS No.	Name of the Food Additive	Maximum Level	ADI	Note
				In GSFA FCs 01.2.1.1 and 01.2.1.2: 5000mg/kg.

JECFA assigned a numerical ADI to INS 405. A numerical use level should be provided for this food additive unless any justifications for GMP are provided in accordance with the Codex Procedural Manual.

(Rationale)

Please refer to the rationale for INS 636 Maltol.

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INS No.	Name of the Food Additive	Maximum Level	ADI	Note
950	Acesulfame potassium	350 mg/kg	0-15 mg/kg bw (37th JECFA, 1990)	In GSFA FC 01.1.4: 350 mg/kg.
951	Aspartame	1000 mg/kg	0-40 mg/kg bw (25th JECFA, 1981)	In GSFA FC 01.1.4: 600 mg/kg, with Note 405 "For use in energy-reduced products or products with no added sugar conforming to the Standard for Fermented Milks (CXS 243-2003) at 1000 mg/kg".
962	Aspartame-acesulfame salt	350 mg/kg on an acesulfame potassium equivalent basis	The ADIs for aspartame 0-40 mg/kg bw (25th JECFA, 1981) and 0-15 mg/kg bw for acesulfame K (37th JECFA, 1990) cover the aspartame and acesulfame moieties of the salt.	In GSFA FC 01.1.4: 350 mg/kg.

It is necessary to ensure the combined use of the aspartame-acesulfame salt with aspartame or acesulfame potassium would not lead to exceedance of maximum levels established for these sweeteners. Japan proposes that Note 188 "If used in combination with aspartame-acesulfame salt (INS 962), the combined maximum use level, expressed as acesulfame potassium, should not exceed this level." be added to food additive provision for INS 950 acesulfame potassium, and Note 191 "If used in combination with aspartame-acesulfame salt (INS 962), the combined maximum use level, expressed as aspartame, should not exceed this level." be added to food additive provision for INS 951 aspartame.

(Rationale)

At the 55th meeting of JECFA, "the committee concluded that the aspartame and acesulfame moieties of the salt would be covered by the ADIs for aspartame (0-40 mg/kg of body weight) and acesulfame potassium (0-15 mg/kg of body weight)." (see p. 13 of 55th report of the JECFA)

Item 4b

Japan appreciates the efforts of Australia and the United States of America as Chair and Co-chair in preparing the report of the EWG on Alignment.

Japan would like to provide the following amendments. Addition is in **bold and underlined font** and deletion is in ~~strikethrough font~~.

Appendix 2

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L. Proposed amendments to the food additive provisions of the standard for sturgeon caviar (CXS 291-2010)

4. Food additives

~~Only certain~~ Acidity regulators, antioxidants and preservatives ~~as indicated~~ **listed** in Table 3 of the General Standard for Food Additives (CXS 192-1995) are acceptable for use in foods conforming to this Standard

(Rationale)

Report of the 30th CCFFP states, "The Committee considered whether other additives, especially preservatives could be used, and, noting that Table 3 was applicable to food category 09.3.3, agreed that

acidity regulators, antioxidants and preservatives in Table 3 could be used under conditions of GMP” (see paragraph 54 of ALINORM 10/33/18).

Therefore, CXS 291-2010 does permit all Table 3 additives which have technological function of acidity regulator, antioxidant or preservative, rather than specific Table 3 additives.

Appendix 3

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Monosodium L-glutamate

Monosodium L-glutamate: Functional class: Flavour enhancer INS 621					
Food Cat. No	Food Category	Max level	Notes	Step/Year Adopted	Recommendation
09.2.5	Smoked, dried, fermented and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	GMP	29, 313, XS167, XS189, XS222 , XS236, XS244 & XS311	2015	Adopt

(Rationale)

Note XS222 should be deleted since CXS 222-2001 permits Monosodium L-glutamate at GMP (see REP 16/FFP Appendix VI).

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Phosphates

Phosphates: Functional class: Acidity regulator, Antioxidant, Emulsifier, Emulsifying salt, Firming agent, Flour treatment agent, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener INS 338, 339(i)-(iii), 340(i)-(iii), 341(i)-(iii), 342(i)-(ii), 343(i)-(iii), 450(i)-(iii), (v)-(vii), (xi), 451(i),(ii), 452(i)-(v), 542					
Food Cat. No	Food Category	Max level	Notes	Step/Year Adopted	Recommendation
09.2.5	Smoked, dried, fermented and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	2200 mg/kg	29, 33, & 334, XS167, XS189, XS222 , XS236, XS244 & XS311	2	No action. This provision will be discussed in the GSFA EWG

(Rationale)

The Standard for Crackers from Marine and Freshwater Fish, Crustacean and Molluscan Shellfish (CXS 222-2001) allows the use of specific phosphates (i.e. INS 452 (i)-(v)) as sequestrant at 2200 mg/kg (as phosphorus) singly or in combination.

Note XS 222 should be deleted since CXS 222-2001 permits specific phosphates.

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Food category 09.2.5

Food category 09.2.5 Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms					
Food additive	INS	Maximum level	Step/Year Adopted	Notes	Recommendation
Phosphates	338, 339(i)-(iii), 340(i)-(iii), 341(i)-(iii), 342(i)-(ii), 343(i)-(iii), 450(i)-(iii), (v)-(vii), (ix), 451(i),(ii), 452(i)-(v), 542	2200 mg/kg	2	29, 33 & 314, XS167, XS189, XS222 , XS236, XS244 & XS311	No action. This provision will be discussed in the GSFA EWG

(Rationale)

See the rationale as described about page 51 “Phosphates”.

Page 97**C. Proposed amendments to Table 3 of the GSFA**

INS No	Additive	Functional Class	Year Adopted	Acceptable in foods conforming to the following commodity standards
300	Ascorbic acid, L-	Acidity regulator, Antioxidant, Flour treatment agent, Sequestrant	1999	CS 88-1981, CS 89-1981, CS 96-1981, CS 97-1981, CS 98-1981, CS 117-1981, CS 309R-2011, CS 13-1981, CS 57-1981, CS 319-2015 (acidity regulator in general and as antioxidant in canned pineapple <u>and canned mangoes</u>)

(Rationale)

The use of antioxidants in Table 3 is also technologically justified in Canned mangoes in CXS 319-2015.

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Section 2 of the Annex to Table 3

04.1.2.4	Canned or bottled (pasteurized) fruit
	Acidity regulators listed in Table 3 are acceptable for use in all products conforming to the standard. Antioxidants and firming agents listed in Table 3 are acceptable for use in canned mangoes conforming to the standard. Colours listed in Table 3 are acceptable for use in special holiday pack canned pears conforming to the standard. Only certain Table 3 antifoaming agents and antioxidants (as indicated in Table 3) are acceptable for use in canned pineapples conforming to the standard.
Codex Standard	Certain Canned Fruits (CXS 319-2015)

(Rationale)

Report of 28th CCPFV states, "The Committee agreed to make a general reference to the GSFA and to inform CCFA that polydimethylsiloxane (INS 900a) and ascorbic acid, L- (INS 300) were respectively the only antifoaming agent and only antioxidant agent currently used in canned pineapples. The Committee also agreed to request CCFA to have this reflected in the GSFA for purposes of alignment. The Committee noted that other antifoaming agents and antioxidants for use in canned pineapples should go to the Step procedure for adoption." (see para.47 of REP 17/PFV). CXS 319-2015 does not permit any antifoaming agent listed in Table 3 since Polydimethylsiloxane (INS 900a) is the only antifoaming agent but not listed in Table 3.