CODEX ALIMENTARIUS COMMISSION ${f E}$







Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.net Agenda Item 5(d) CX/FA 12/44/10

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD ADDITIVES

Forty-fourth Session

Hangzhou, China, 12-16 March 2012

PROVISIONS FOR ALUMINIUM-CONTAINING FOOD ADDITIVES OF THE GSFA

Prepared by an electronic Working Group led by Brazil, with the assistance of Argentina, Canada, European Union, Japan, Thailand, The United States of America, CEFIC, CIAA, IAI, ICGA, ICGMA, IDF and IFAC.

Background

- The 42nd Session of the Codex Committee on Food Additives (CCFA), agreed to establish an electronic Working Group (eWG) on aluminium-containing food additives, hosted by Brazil, tasked to revise the maximum use levels (MLs) for five aluminium-containing food additives included in the General Standard for Food Additives (GSFA): sodium aluminium phosphates (acidic and basic) (INS 541(i), (ii)), aluminium ammonium sulfate (INS 523), sodium aluminosilicate (INS 554), calcium aluminium silicate (INS 556), and aluminium silicate (INS 559) based upon information submitted by eWG members. The purpose of this work is to ensure that their maximum use levels are numeric and expressed on an aluminium basis, consistent with the JECFA PTWI¹.
- In its 43rd Session, the CCFA agreed to revoke or discontinue work on all non-numerical provisions for aluminium-containing food additives in the GSFA², and to recommend the 34th Session of the Commission to revoke the provisions for sodium aluminosilicate (INS 554), calcium aluminium silicate (INS 556) and aluminium silicate (INS 559) in Table 3 of the GSFA³, since all provisions for aluminiumcontaining food additives should be numerical.
- The Committee agreed to reestablish an eWG, led by Brazil, open to all Members and Observers and working in English only, to revise the compilation of provisions and proposals attached to CX/FA 11/43/10 and make recommendations for the adoption, discontinuation or revocation, including those for new uses, at its 44th Session⁴.
- The work was based on the Report of the eWG in CX/FA 11/43/10, FA/43 CRD 14, FA/43 INF/01 Appendix I, II and III and the decisions of the 43rd Session of the CCFA.
- To fulfill the task of the eWG, adherence to the Procedures for consideration of entry and review of food additive provisions in the General Standard for Food Additives (GSFA)⁵ is necessary, in particular for the technological justification. Section 3.2 of the Preamble to the GSFA establishes the criteria for justifying the use of a food additive.
- 6. The following approaches have guided the elaboration of the eWG recommendations:
 - Provisions for which both justification and numeric MLs were provided are recommended for adoption. Changes are presented as underlined text;
 - Provisions for which different ML proposals were submitted by participants are recommended for further discussion within the CCFA, since there was no consensus during the discussion on the eWG;

ALINORM REP11/FA, Appendices IV and V

ALINORM 10/33/12, paras. 78-83

ALINORM REP11/FA, Appendix IV

ALINORM REP11/FA, para 91

Procedural Manual, twentieth edition. SECTION II: ELABORATION OF CODEX STANDARDS AND RELATED TEXTS, page 57

- Proposals for new uses are recommended for circulation at Step 3;
- Provisions for which both justification and numeric MLs were not provided are recommended for discontinuation or revocation. Since the purpose of the present work is to revise the existing provisions, in light of the revised PTWI by JECFA, the use of <u>all</u> aluminium-containing food additives should be justified;
- Provisions for which only proposals to discontinue or revoke were received are recommended for discontinuation or revocation;
- Submissions for sodium aluminium phosphates should always specify the INS number (541i/ 541ii) intended for each food category;
- All proposed MLs expressed "as compound" were converted to the "as Al" reporting basis according to the information presented in Annex 1;
- Whenever INS 554, 556 and/or 559 are authorized for use in the same food category, Note 174 (Singly or in combination: sodium aluminosilicate (INS 554), calcium aluminium silicate (INS 556), and aluminium silicate (INS 559)) should be added to such provisions in the GSFA.

Recommendation 1

Only numerical MLs should be set for aluminium-containing food additives. All MLs should be reported on an "as aluminium" basis only and to include Note 6 ("As aluminium") accordingly.

Recommendation 2

When more than one molecular formula is identified for an aluminium-containing food additive, the conversion shall take the average percentage of Al amongst the molecular formulas. The average values lead to lower MLs expressed as aluminium. The more conservative approach is in line with the revision and establishment of a revised PTWI by JECFA (2011) of 2mg/kg b.w. A table of possible molecular formulas and percentages of aluminium to convert the MLs from compound to Al basis is presented in Annex 1.

Recommendation 3

To revise Note 174 ("Singly or in combination: sodium aluminium silicate (INS 554), calcium aluminium silicate (INS 556), and aluminium silicate (INS 559)") in the GSFA, in order to reflect the INS 554 name: "sodium aluminosilicate".

Revised Note 174: Singly or in combination: <u>sodium aluminosilicate</u> (INS 554), calcium aluminium silicate (INS 556), and aluminium silicate (INS 559).

Recommendation 4: The eWG recommends <u>adoption</u> of the following aluminium-containing food additives provisions:

ALUMINIUM AMMONIUM SULFATE (INS 523)

Function: firming agent, stabilizer

1 director.	nrming agent, stabilizer		ı	1	T	
Food Cat. No.	Food Category	Max Level	Notes	Step/ Year Adopted	Proposed Levels/ Basis	Comments
04.2.2.3	Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds in vinegar, oil, brine, or soybean sauce	500 mg/kg 785 mg/kg	6 ⁶	3	315 mg/kg as Al (as firming agent for eggplants in brine) 785 mg/kg as Al (for perilla in brine to retain colour)	Japan (1) Eggplants in brine 5,250 mg/kg (as dodecahydrate) 2,850 mg/kg (as anhydride) 315 mg/kg (as Al) (2) Perilla in brine 13,150 mg/kg (as dodecahydrate) 7,150 mg/kg (as anhydride) 785 mg/kg (as Al) Functional class: Colour retention agent. Aluminium reacts with natural colour of eggplant or perilla and becomes stable complex, which retains colour. Japan's response to the comments by members: Eggplants in brine are included in the Codex Standard on pickled fruits and vegetables (STAN 260-2007) and the food additive provision of aluminium ammonium sulfate is under discussions at CCPFV. EU (technological need questioned in salt containing vegetables; not
					e discontinued	authorized in any of crossed reference Codex standardized foods with 4.2.2.3 of GSFA according to Annex C of GSFA (STAN 66-1981 on table olives, STAN 038-1981 on edible fungi; STAN 115-1981 on pickled cucumbers; STAN 260-2007 on pickled fruits and vegetables)
06.4.1	Fresh pastas and noodles and like products	4 70 mg/kg <u>300 mg/kg</u>	6	3	300 mg/kg as Al	Japan 1. New Levels/Basis "kuzukiri" and "harusame" 5,000 mg/kg (as dodecahydrate) 300 mg/kg (as Al) 2. Justification Functional class: Firming agent Aluminium ammonium sulfate reacts with proteins in flours and

⁶ Note 6 As aluminium

Recommendation 4: The eWG recommends <u>adoption</u> of the following aluminium-containing food additives provisions:

ALUMINIUM AMMONIUM SULFATE (INS 523)

Function: firming agent, stabilizer

Food Cat. No.	Food Category	Max Level	Notes	Step/ Year Adopted	Proposed Levels/ Basis	Comments
						enhances hard texture of noodles. The use of food additive in this category is limited to Japanese traditional starch noodles such as "kuzukiri" and "harusame" only.
					Be discontinued	Thailand
					De discontinued	EU (strongly opposes in fresh pasta; technological need requested)
07.1.2	Crackers, excluding sweet crackers	10000 mg/kg 500 mg/kg	29 ⁷ <u>6</u>	3	500 mg/kg as Al	Japan 1. New Levels/Basis crackers and ice-cream cones 8,300 mg/kg (as dodecahydrate) 500 mg/kg (as Al) 2. Justification Functional class: Raising agent Aluminium ammonium sulfate reacts with sodium hydrogen carbonate and generates carbon dioxide to inflate crackers and ice-cream corns. Japan will provide its comment in response to CL 2011/7 to add technological purpose on Aluminium ammonium sulfate. 3. Japan's response to the comments by members Japan will provide its comment in response to CL 2011/7 to add technological purpose on Aluminium ammonium sulfate.
					Be discontinued	EU (technological need questioned; INS 523 is not recognized as "raising agent" according to CAC/GL 36-1989, only stabilizer/ firming agent).
07.1.3	Other ordinary bakery products (e.g., bagels, pita, English muffins)	10000 mg/kg 500 mg/kg	29 <u>6</u>	3	500 mg/kg as Al	Japan 1. New Levels/Basis American biscuit 8,300 mg/kg (as dodecahydrate) 500 mg/kg (as Al) 2. Justification

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⁷ Note 29 Reporting basis not specified

Recommendation 4: The eWG recommends <u>adoption</u> of the following aluminium-containing food additives provisions:

ALUMINIUM AMMONIUM SULFATE (INS 523)

Tunction	unction: firming agent, stabilizer									
Food Cat. No.	Food Category	Max Level	Notes	Step/ Year Adopted	Proposed Levels/ Basis	Comments				
						Functional class: Raising agent Aluminium ammonium sulfate reacts with sodium hydrogen carbonate and generates carbon dioxide to inflate American biscuits.				
07.1.5	Steamed breads and buns	10000 mg/kg 40 mg/kg	29 6	3	40 mg/kg as Al (for steam bread)	Japan 1. New Levels/Basis Steamed breads 650 mg/kg (as dodecahydrate) 40 mg/kg (as Al) 2. Justification Functional class: Raising agent Aluminium ammonium sulfate reacts with sodium hydrogen carbonate (NaHCO ₃) and generates carbon dioxide to inflate steam bread. 3. Japan's response to the comments by members Japan will provide its comment in response to CL 2011/7 to add technological purpose on Aluminium ammonium sulfate.				
					Be discontinued	Thailand EU (technological need questioned; INS 523 is not recognized as "raising agent" according to CAC/GL 36-1989, only stabilizer / firming agent; the EU comments provided to 7.1.4 apply here too)				
07.1.6	Mixes for bread and ordinary bakery wares	10000 mg/kg 40 mg/kg	6	3	40 mg/kg as Al (for steam bread)	Japan 1. New Levels/Basis Steamed breads 650 mg/kg (as dodecahydrate) 40 mg/kg (as Al) 2. Justification Functional class: Raising agent Aluminium ammonium sulfate reacts with sodium hydrogen carbonate (NaHCO ₃) and generates carbon dioxide to inflate steam bread. 3. Japan's response to the comments by members Japan will provide its comment in response to CL 2011/7 to add				

Recommendation 4: The eWG recommends <u>adoption</u> of the following aluminium-containing food additives provisions:

ALUMINIUM AMMONIUM SULFATE (INS 523)

Food Cat. No.	Food Category	Max Level	Notes	Step/ Year Adopted	Proposed Levels/ Basis	Comments
						technological purpose on Aluminium ammonium sulfate.
					Be discontinued	EU (technological need questioned; INS 523 is not recognized as "raising agent" according to CAC/GL 36-1989, only stabilizer / firming agent)
					-	Brazil questions technological need
09.2.4	Cooked and/or fried fish and fish products, including mollusks, crustaceans, and echinoderms	200 mg/kg	6	2001	200 mg/kg as Al (60 mg/kg as Al for boiled octopus, 200 mg/kg as Al for "tsukudani")	Japan (as firming agent in boiled octopus; as stabilizer in cooked fish products boiled down in soy sauce "tsukudani")
					Be revoked	EU (technological need questioned)
15.1	Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	500 mg/kg 228 mg/kg	6	3	228 mg/kg as Al	Japan 1. New Proposed Levels/Basis Wafer sand 3,800 mg/kg (as dodecahydrate) 228 mg/kg (as Al) 2. Justification Functional class: Raising agent Aluminium ammonium sulfate reacts with sodium hydrogen carbonate (NaHCO ₃) and generates carbon dioxide to inflate wafer. 3. Japan's response to the comments by members Japan will provide its comment in response to CL 2011/7 to add technological purpose on Aluminium ammonium sulfate.
					Be discontinued	Thailand EU (technological need questioned; INS 523 is not recognized as "raising agent" according to CAC/GL 36-1989, only stabilizer/firming agent)

Recommendation 4: The eWG recommends <u>adoption</u> of the following aluminium-containing food additives provisions:

5. SODIUM ALUMINOSILICATE (INS 554) 8

runction.	unction, anticaking agent									
Food Cat. No.	Food Category	Max Level	Notes	Step/ Year Adopted	Proposed Levels/ Basis	Comments				
					20000 mg/kg (not specified)	Mexico				
					1140 mg/kg as Al	IFAC (needed for anticaking)				
					1140 mg/kg as Al	EUSalt (proposed ML based on technological perspective and not a feasible level to guarantee the proper functionality in the salt; levels used in practice are <30.000mg/kg salt, as Al compound and not as Al)				
12.1.1	Salt	20000 mg/kg 1710 mg/kg	6, <u>174</u> °	3	1710 mg/kg as Al	IDF (Used to improve the flow of the very fine salt used in some salting machines to allow its homogenous distribution on the cheese. There is no suitable substitute identified to date. The maximum level of INS 554 in the cheese concerned has been estimated as 23 mg/kg (based on 20000mg/kg of the compound, eg 1140 mg of aluminium in the salt, with a 2 % total salt level in the cheese). This unique requirement for the use of one of the aluminium-containing food additives in only a limited number of cheese varieties (those that are dry salted, where salting machines are used) should not contribute any significant amount to the PTWI of aluminium. We realize that the presence of INS 554 in the cheese from this use is probably due to its being used as a processing aid, rather than of its use as a food additive as such, as it has no subsequent technological function on/in the cheese itself; alternatively its presence would be covered by the carry-over principle if it use is permitted in the salt used for this purpose. Hence we support its use in salt for this purpose. We note from the eWG paper that EUSalt states that a level of < 30,000 mg/kg, expressed as the compound, is required in the salt and using the conversion factors in the paper, this would be equivalent to an ML of 1710 mg/kg as Al. We could support this level, if the suppliers believe it is necessary for the technological function outlined above.				
					860 mg/kg as Al	Canada (ML reported by food industries as an anticaking agent). Based on data from Canada's Total Diet Study (TDS), the levels of aluminium measured in table salt would not be expected to significantly contribute				

⁸ The USA notes that sodium aluminosilicate is regulated for use in food in general in the USA at levels up to 1140 mg/kg food as aluminium, in accordance with good manufacturing practices.

⁹ **Note 174** Singly or in combination: sodium aluminosilicate (INS 554), calcium aluminium silicate (INS 556), and aluminium silicate (INS 559).

Recommendation 4: The eWG recommends <u>adoption</u> of the following aluminium-containing food additives provisions:

5. SODIUM ALUMINOSILICATE (INS 554) 8

Function: anticaking agent

Food Cat. No.	Food Category	Max Level	Notes	Step/ Year Adopted	Proposed Levels Basis	Comments
						to total aluminium intake. http://www.hc-sc.gc.ca/fn-an/surveill/total-diet/concentration/index-eng.php Based on industry reports, sodium aluminosilicate might not necessarily be used in retail table salt.
					Be discontinued	EU (for safety reason, EU recommends to discontinue the work on this staple food which is consumed on a daily basis; on the basis of the ML of 1.15 mg/g salt, and adult of 60kg reaches the ADI by consuming 7g salt/day; therefore, there is a significant exposure of aluminium that can come from salt also)

Recommendation 4: The eWG recommends <u>adoption</u> of the following aluminium-containing food additives provisions:

CALCIUM ALUMINIUM SILICATE (INS 556)

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments
			6. 174		20000 mg/kg (not specified)	Mexico
		20000			-	Canada - Based on data from Canada's Total Diet Study (TDS), the levels of aluminium measured in table salt would not be expected to significantly contribute to total aluminium intake. http://www.hc-sc.gc.ca/fn-an/surveill/total-diet/concentration/index-eng.php
12.1.1	Salt	20000 mg/kg <u>530 mg/kg</u>		3	530 mg/kg (as Al)	USA (This level is necessary to achieve the intended technical effect. While the USA agrees with the statement that salt is a staple food, the USA notes that the potential intake of aluminum from the use of calcium aluminum silicate in salt would not significantly contribute to the overall intake of aluminum. The USA does not have any safety concerns regarding this use. Additionally, the USA notes that the GSFA contains provisions for the use of several other anticaking agents (e.g., calcium carbonate, sodium carbonate, talc) in salt. Therefore, a salt manufacturer has a choice of anticaking agents, so it is reasonable

Recommendation 4: The eWG recommends <u>adoption</u> of the following aluminium-containing food additives provisions:

CALCIUM ALUMINIUM SILICATE (INS 556)

Function: anticaking agent

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments
						to expect that not all salt will contain calcium aluminium silicate as an anticaking agent. This would further reduce the contribution of calcium aluminum silicate in salt to the overall intake of aluminium.)
					Be discontinued	EU (for safety reason, EU recommends to discontinue the work on this kind of staple food which is consumed on a daily basis).

Recommendation 5: The eWG recommends <u>further discussion</u> on the following aluminium-containing food additives provisions:

SODIUM ALUMINIUM PHOSPHATES

SODIUM ALUMINIUM PHOSPHATE, ACIDIC (INS 541(i))

SODIUM ALUMINIUM PHOSPHATE, BASIC (INS 541(ii))

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments
					450 mg/kg as Al	IFAC (INS 541ii for emulsification and stabilization)
01.6.1	Unripened cheese	670 mg/kg	6	3	Be discontinued C d E	Brazil (Codex Standard 221-2001 - CODEX GROUP STANDARD FOR UNRIPENED CHEESE INCLUDING FRESH CHEESE includes an ML of 1540mg/kg for several phosphates, singly or in combination expressed as phosphorus. Since many other thickeners and stabilizers are assigned for this food category, Brazil supports the discontinuation of this provision for sodium aluminium phosphate).
						CEFIC – there is no technological need, therefore, no further discussion is needed
						EU (not authorized in STAN 273-1968 on cottage cheese, STAN 275-1993 on cream cheese; EU questions technological need for unripened cheese which do not present rind; alternatives like silicon dioxide, calcium silicate, magnesium silicates or potassium silicate can be used).
		35000 mg/kg	29	6	2000 mg/kg as Al	IFAC (INS 541ii for emulsification and stabilization)
01.6.4	Processed cheese				1750 mg/kg as Al	Canada (ML of INS 541ii reported by food industries as an emulsifier)
					Be discontinued	Brazil (alternative food additives with similar functions may be

Recommendation 5: The eWG recommends <u>further discussion</u> on the following aluminium-containing food additives provisions:

SODIUM ALUMINIUM PHOSPHATES

SODIUM ALUMINIUM PHOSPHATE, ACIDIC (INS 541(i))

SODIUM ALUMINIUM PHOSPHATE, BASIC (INS 541(ii))

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments
						adequate).
						EU (EFSA has highlighted that dairy products, in particular cheese, are the main contributor of aluminium; because of safety concern, EU recommends to discontinue work on this category).
					1000 mg/kg as Al	Brazil – ML for INS 541i reported by food industry and authorized in some kinds of flours, which are mixed with some kinds of food additives, including raising agents. These "mixed flours" are available to consumers in the market.
	Flours				60 mg/kg as Al	Indonesia (ML established based on consumption and PTDI of 1mg/kg bw/d; ML proposed by Codex exceeds PTWI of Al - 7mg/kg bw/wk)
		45000 mg/kg	29	6	1600 mg/kg as Al	IFAC (INS 541i as raising agent)
06.2.1					Be discontinued	EU (technological need questioned; flour is a staple foodstuff widely consumed which contributes substantially to the daily intake; not authorized in any commodity standards related to flours (STAN 152-1985 on wheat flour, STAN 170-1989 on pearl millet, STAN 173-1989 on sorghum flour, STAN 176-1989 for edible cassava flour, STAN 178-1991 for durum wheat semolina and durum wheat flour)
						CEFIC – there is no technological need in flours in general – only for self-raising flours it make sense, but there is no official standard available. Therefore no further discussion is needed.
					96 mg/kg as Al	Indonesia (ML established based on consumption and PTDI of 1mg/kg bw/d; ML proposed by Codex exceeds PTWI of Al - 7mg/kg bw/wk)
06.6	Batters (e.g., for breading or batters for fish or	1600 mg/kg	6	6	1600 mg/kg as Al	IFAC (INS 541i as raising agent; 2% SALP in batter is required to fulfill its technological function as a raising agent)
	poultry)				1000 mg/kg as Al	CEFIC - INS 541i as raising agent
					2340 mg/kg as Al	Canada (ML of INS 541i reported by food industries as food industries)
07.1	Bread and ordinary	2000 mg/kg	6	6	1000 mg/kg as Al	Brazil - ML for INS 541i reported by food industry as raising agent, necessary in association with sodium bicarbonate in the dough to obtain

Recommendation 5: The eWG recommends <u>further discussion</u> on the following aluminium-containing food additives provisions:

SODIUM ALUMINIUM PHOSPHATES

SODIUM ALUMINIUM PHOSPHATE, ACIDIC (INS 541(i))

SODIUM ALUMINIUM PHOSPHATE, BASIC (INS 541(ii))

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments
	bakery wares					the desired effect in the final products.
					10000 mg/kg as Al	Mexico
					1600 mg/kg as Al	IFAC (level for 541i; functions as a raising agent in this category)
					900 mg/kg as Al	ICGMA (to achieve intended function; INS 541I is used as leavening/raising agent to help with dough/texture formation in baking mixes for bread (FC 7.1.1) and pizza crust (FC 7.1.6), for example)
					2340 mg/kg as Al	Canada (ML of INS 541i reported by food industries as leavening agent)
					Be discontinued	EU (the 67th JECFA highlighted cereal products as main contributor of aluminium; the recent EFSA opinion (2008) on aluminium shared JECFA conclusions, spotted cereal and cereal products as main food contributors, and concluded that the EU population could exceed the newly revised PTWI; there is a safety ground to discontinue work on this category, which is widely consumed, on a daily basis, in large quantities)
						Thailand
					1000 mg/kg as Al	Brazil - ML for INS 541i reported by food industry as raising agent, necessary in association with sodium bicarbonate in the dough to obtain the desired effect in the final products.
					1600 mg/kg as Al	IFAC (level for 541i; functions as a raising agent in this category)
07.2.1	Cakes, cookies and pies (e.g., fruit-filled or custard types)	2000 mg/kg	6	6	170 mg/kg as Al	ICGMA (to achieve intended function; INS 541i is used as leavening/raising agent to help with dough/texture formation in cookies and pop-tarts)
	Castala Gpos)				980 mg/kg as Al	Canada (ML of INS 541i reported by food industries as a leavening agent)
					Be discontinued	EU (fine bakery wares are widely consumed by children; as JECFA indicated explicitly that children exceed the PTWI, EU strongly opposes continuation of work on this category)

Recommendation 5: The eWG recommends <u>further discussion</u> on the following aluminium-containing food additives provisions:

SODIUM ALUMINIUM PHOSPHATES

SODIUM ALUMINIUM PHOSPHATE, ACIDIC (INS 541(i))

SODIUM ALUMINIUM PHOSPHATE, BASIC (INS 541(ii))

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments
						Thailand
					1000 mg/kg as Al	Brazil - ML for INS 541i reported by food industry as raising agent, necessary in association with sodium bicarbonate in the dough to obtain the desired effect in the final products.
					10000 mg/kg as Al	Mexico
	Other fine bakery				1600 mg/kg as Al	IFAC (level for 541i; functions as a raising agent in this category)
07.2.2	products (e.g., doughnuts, sweet rolls, scones, and muffins)	2000 mg/kg	6	6	900 mg/kg as Al	ICGMA (to achieve intended function; INS 541i is used as leavening/raising agent to help with dough/texture formation in muffins, french toast, filled sweet rolls, waffles, cinnabon, pancakes, and baked wafers)
					980 mg/kg as Al	Canada (ML reported for 541i by food industries as leavening agent)
					Be discontinued	EU (the use of 1000mg/kg may raise intake concern; at the proposed ML of 1000mg/kg, only one muffin/scone consumed is sufficient to reach the PTWI (20mg Al/week) for children of 20kg)
			29	6	1000 mg/kg as Al	Brazil - ML for INS 541i reported by food industry as raising agent, necessary in association with sodium bicarbonate in the dough to obtain the desired effect in the final products.
					1600 mg/kg as Al	IFAC (INS 541i as raising agent)
07.2.3	Mixes for fine bakery wares (e.g., cakes, pancakes)	15300 mg/kg			900 mg/kg as Al	ICGMA (to achieve intended function; INS 541i is used as leavening/raising agent to help with dough/texture formation in baking mixes for muffins, cakes, pancakes, for example)
					2340 mg/kg as Al	Canada (ML for 541i reported by food industries as leavening agent)
					Be discontinued	EU (fine bakery wares are widely consumed by children; as JECFA indicated explicitly that children exceed the PTWI, EU strongly opposes continuation of work on this category)
	Frozen processed				-	Brazil questions technological need
08.3.3	comminuted meat, poultry, and game	360 mg/kg	6	3	470 mg/kg as Al	IFAC (INS 541i - Phosphate is needed in this category as a raising agent for the battered portion of the product. Its use is critical for many

Recommendation 5: The eWG recommends <u>further discussion</u> on the following aluminium-containing food additives provisions:

SODIUM ALUMINIUM PHOSPHATES

SODIUM ALUMINIUM PHOSPHATE, ACIDIC (INS 541(i))

SODIUM ALUMINIUM PHOSPHATE, BASIC (INS 541(ii))

Functions: acidity regulator, emulsifier, raising agent, stabilizer, thickening agent

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments
	products					of the foods in this category, including chicken fingers and chicken nuggets. Sodium Aluminium Phosphate is already permitted in category 6.6, Batters, so to be transparent and consistent within the food categories, we recommend it be allowed for use in this category)
					Be discontinued	EU (aluminium based food additives are not authorized in any CC relevant to a food category similar to 8.3.3, the food category 8.3.2: STAN 088-1981 on canned corned beef; not authorized in STAN 089-1981 on luncheon meat, STAN 098-1981 on cooked cured chopped meat; EU questions the rational to authorize aluminium-containing food additives in 08.3.3 and why the frozen process requires the use of aluminium)
					-	Brazil questions technological need
					1000mg/kg as Al (calculated on the batter coating only)	CEFIC – INS 541i as the SALP is permitted to use in batters (food category 06.6), the use should also be permitted in food category 09.2.2
	Frozen battered fish, fish fillets, and fish products,				10000 mg/kg (not specified)	Mexico
09.2.2	including mollusks, crustaceans, and echinoderms 190 mg/kg 6 & 41 ¹⁰	6	780 mg/kg as Al	IFAC (INS 541i Sodium Aluminium Phosphate is needed in this category as a raising agent for the battered portion of the product. Its use is critical for many of the foods in this category. Sodium Aluminium Phosphate is already permitted in category 6.6, Batters, so to be transparent and consistent within the food categories, we recommend it be allowed for use in this category.)		
					Be discontinued	EU (technological need questioned)
	Fried fish and fish				-	Brazil questions technological need
09.2.4.3	products, including mollusks, crustaceans, and echinoderms	600 mg/kg	6	3	780 mg/kg as Al	IFAC (INS 541i Sodium Aluminium Phosphate is needed is this category as a raising agent for the battered portion of the product. Its use is critical for many of the foods in this category. Sodium

¹⁰ **Note 41** Use in breading or batter coatings only

Recommendation 5: The eWG recommends <u>further discussion</u> on the following aluminium-containing food additives provisions:

SODIUM ALUMINIUM PHOSPHATES

SODIUM ALUMINIUM PHOSPHATE, ACIDIC (INS 541(i))

SODIUM ALUMINIUM PHOSPHATE, BASIC (INS 541(ii))

Functions: acidity regulator, emulsifier, raising agent, stabilizer, thickening agent

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments
						Aluminum Phosphate is already permitted in category 6.6, Batters, so to be transparent and consistent within the food categories, we recommend it be allowed for use in this category.)
					Be discontinued	EU (technological need questioned)
12.6.3	Mixes for sauces and gravies	2000 mg/kg	6 &127	6	120 mg/kg as Al	IFAC (for INS 541ii as emulsifier and stabilizer, especially for cheese sauces)
	Composite foods - foods			6	15 mg/kg as Al for INS 541i 120 mg/kg as Al for INS 541ii	IFAC (Sodium Aluminium Phosphate is needed in this category, which includes frozen dinners, often composed of battered and frozen fish or chicken. To be consistent and consistent within the food categories, IFAC recommends Sodium Aluminium Phosphate be allowed for use in this category.)
16.0	that could not be placed in categories 01 - 15	190 mg/kg	6			Thailand
	entegories of - 13				Be discontinued	EU (opposes any proposal in this category as long as there is no clear food category identified for which a technological need is demonstrated; category 16.0 should not be seen as a way for authorising by default food additives in a wide range of non identified compound foods)

Recommendation 5: The eWG recommends <u>further discussion</u> on the following aluminium-containing food additives provisions:

5. SODIUM ALUMINOSILICATE (INS 554) 11

Function: anticaking agent

Step/Year Proposed Levels/ **Food Food Category Max Level** Notes **Comments** Cat. No. Adopted **Basis** IFAC (levels for INS 554 (Na₂0:Al₂O₃:13SiO₂)) (needed for Dairy-based drinks, 1140 mg/kg as Al anticaking) 01.1.2 flavoured and/or 20000 mg/kg 6 3 fermented (e.g., chocolate 1140 mg/kg as Al **IDF**

11 The USA notes that sodium aluminosilicate is regulated for use in food in general in the USA at levels up to 1140 mg/kg food as aluminium, in accordance with good manufacturing practices.

Recommendation 5: The eWG recommends <u>further discussion</u> on the following aluminium-containing food additives provisions:

5. SODIUM ALUMINOSILICATE (INS 554) 11

Function: anticaking agent

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments
	milk, cocoa, eggnog,				57 mg/kg as Al	ICGMA (used in dry mix hot chocolate)
	drinking yoghurt, whey- based drinks)					Thailand
					Be discontinued	EU (INS 554 is not authorized in Codex STAN 243-2003 for fermented milks)
					1140 mg/kg as Al	IFAC (needed for anticaking)
					1140 mg/kg as Al	IDF
01.2	Condensed milk and	20000 m a/ka	4	2	570 mg/kg as Al	ICGMA (for beverage whiteners (FC 1.3.2) including non-dairy creamer powder, coffee whitener powder)
01.3	analogues (plain)	20000 mg/kg	6	3	Be discontinued	EU (not authorized in any CC relevant to sub cat.01.3: a) 01.3.2: STAN 250-2006 on blend of evaporated skimmed milk, STAN 252-2006 on blend of sweetened condensed milk, b) 01.3.1: STAN 281-1971 on evaporated milk, STAN 282-1971 on sweetened condensed milk; therefore the technological need is question in the general heading 01.3)
01.4.4	C	20000 //	(2	1140 mg/kg as Al	IFAC (needed for anticaking)
01.4.4	Cream analogues	20000 mg/kg	6	3	1140 mg/kg as Al	IDF
					1140 mg/kg as Al	IFAC (needed for anticaking)
					570 mg/kg as Al	IDF (as authorized in the Codex Standard 207)
	Milk powder and cream				570 mg/kg as Al	ICGMA - for milk/cream powder analogues (e.g., soy oil powder) and 5000 mg/kg as compound for dairy-based creamers (e.g., milk powder and cream powder)
01.5	powder and powder analogues (plain)	10000 mg/kg	6 & 174	3	Be discontinued	Brazil (Codex Standard 207-1999 CODEX STANDARD FOR MILK POWDERS AND CREAM POWDER includes the provision of several anticaking agents with the ML10000 mg/kg singly or in combination. As there are alternative substitutes, Brazil supports the discontinuation of this provision)
					860 mg/kg as Al	Canada (ML reported by food industries as an anticaking agent)
01.6.2.1	Ripened cheese, includes	10000 mg/kg	6, 174 & 177 ¹²	3	1140 mg/kg as Al	IFAC (needed for anticaking)

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¹² Note 177 For use in sliced, cut, shredded, or grated cheese only.

Recommendation 5: The eWG recommends <u>further discussion</u> on the following aluminium-containing food additives provisions:

5. SODIUM ALUMINOSILICATE (INS 554) 11

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments
	rind				570 mg/kg as Al	IDF (as authorized in the Codex Standard 283) anticaking agent in shredded cheese
					Be discontinued	Brazil (Codex Standard 283-1978 CODEX GENERAL STANDARD FOR CHEESE includes silicates as anticaking agents with the ML of 10000mg/kg, singly or in combination. As there are alternative substitutes, Brazil supports the discontinuation of this provision)
					Be discontinued	EU (EFSA has highlighted that dairy products, in particular cheese, are among the main contributors of aluminium, at least in EU; because of safety concern, EU recommends to discontinue work on this category; substitutes are used by the EU industry)
	Cheese powder (for reconstitution; e.g., for cheese sauces)				1140 mg/kg as Al	IFAC (needed for anticaking)
			6 & 174	3	570 mg/kg as Al	IDF
01.6.2.3		10000 mg/kg			1425 mg/kg as Al	ICGMA (used as anti-caking agent that helps prevent components from adhering to each other; to ensure flow ability for the cheese powder and to prevent clumping)
					1140 mg/kg as Al	Canada (ML reported by food industries as an anticaking agent)
		10000 mg/kg	6, 174 & 177	3	1140 mg/kg as Al	IFAC (needed for anticaking)
					570 mg/kg as Al	IDF (technological justification as anticaking agent for sliced, cut, shredded and grated cheese)
01.6.4	Processed cheese				860 mg/kg (as Al)	Canada (ML reported by food industries as an anticaking agent in shredded grated cheese). Canada questions whether this use in grated/shredded cheese should be captured under "Processed cheese"? According to the GSFA, such mechanical treatment (i.e. cutting, grating, shredding, etc. of cheese) would not fall under the processed cheese category but would be included under 01.6.2 (Ripened cheese).
					1140 mg/kg as Al	IFAC (needed for anticaking)
01.6.5	Cheese analogues	10000 mg/kg	6, 174 & 177	3	570 mg/kg as Al	IDF (technological justification as anticaking agent for sliced, cut, shredded and grated cheese)
	Liquid whey and whey				1140 mg/kg as Al	IFAC (needed for anticaking)
01.8.1	products, excluding whey cheeses 20000 mg/kg	6	3	1140 mg/kg as Al	IDF	

Recommendation 5: The eWG recommends <u>further discussion</u> on the following aluminium-containing food additives provisions:

5. SODIUM ALUMINOSILICATE (INS 554) 11

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments
01.8.2	Dried whey and whey products, excluding whey cheeses	10000 mg/kg	6 & 174	3	1140 mg/kg as Al	IFAC (needed for anticaking)
04.2.2.2	Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	20000 mg/kg	6	3	1140 mg/kg as Al	IFAC (needed for anticaking)
	Batters (e.g., for breading				GMP	Mexico
06.6	or batters for fish or	20000 mg/kg	6	3	1140 mg/kg as Al	IFAC
	poultry)				80 mg/kg as Al	Canada (ML reported by food industries as an anticaking agent)
	Mixes for bread and ordinary bakery wares		6 & 174	3	GMP	Mexico
		10000 mg/kg			1140 mg/kg as Al	IFAC (needed for anticaking)
07.1.6					342 mg/kg as Al	ICGMA (use levels range from 0.1-0.6% (6000 mg/kg on the basis of whole compound or 342 mg/kg as Al) to prevent clumping and ensure flow ability)
					1140 mg/kg as Al	Canada (ML reported by food industries as an anticaking agent)
					GMP	Mexico
					1140 mg/kg as Al	IFAC (needed for anticaking)
	Mixes for fine bakery				1140 mg/kg as Al	ICGMA (to ensure flow ability and prevent clumping)
07.2.3	wares (e.g., cakes, pancakes)	10000 mg/kg	6	3	1140 mg/kg	Canada (ML reported by food industries as an anticaking agent)
	pancakes)				Be discontinued	EU (for safety reason; JECFA already spotted that children are a subcategory at risk with regard to the exposure to aluminum; fine bakery wares are widely consumed by children)
	D 1				1140 mg/kg as Al	IFAC (needed for anticaking)
11.1.2	Powdered sugar, powdered dextrose	10000 mg/kg	6 & 174	3	794 mg/kg as Al	CEFS (Note 56 "Provided starch is not present" should be added)
	*				Be discontinued	Brazil (CODEX STANDARD FOR SUGARS - CODEX STAN 212-

Recommendation 5: The eWG recommends <u>further discussion</u> on the following aluminium-containing food additives provisions:

5. SODIUM ALUMINOSILICATE (INS 554) 11

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments
						1999 includes silicates as anticaking agents. As there are alternative substitutes, Brazil supports the discontinuation of this provision)
						EU (due to safety concern, the EU intend to revisit its current authorization on aluminum based food additives in sugar and to withdraw this authorization; sugar is a staple foodstuff which is widely consumed on a daily basis)
					1140 mg/kg as Al	IFAC (needed for anticaking)
12.1.2	Salt Substitutes	10000 mg/kg	6, <u>174</u>		Be discontinued	EU (for safety reason, EU recommends to discontinue the work on this staple food which is consumed on a daily basis)
		120 mg/kg	6	3	1140 mg/kg as Al	IFAC (needed for anticaking)
					Be discontinued	Thailand
						Brazil (if the use is in seasonings for snacks, then the provision for food category 12.2.2 is enough)
15.1	Snacks- potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)					Canada (if the use is in seasonings for snacks, then the provision for food category 12.2.2 is enough. Notes that such use could also possibly be captured under the provision for salt (12.1.1) since industry has reported the use of 554 as an anti-caking agent in the salt component of some seasonings for snack foods in this food category).
					114mg/kg as Al	ICGMA (snacks frequently have seasoning mixtures applied to them to create new flavors of products; these seasonings must flow to properly adhere to the product; INS 554 is needed as anticaking agent in these seasonings to prevent components from adhering to each other and then not adhering to the snack product).

Recommendation 5: The eWG recommends <u>further discussion</u> on the following aluminium-containing food additives provisions:

CALCIUM ALUMINIUM SILICATE (INS 556)

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments
01.5	Milk powder and cream powder and powder analogues (plain)	10000 mg/kg	6 & 174	3	265 mg/kg as Al	IDF (as authorized in the Codex Standard 283)
					265 mg/kg as Al	IDF
01.6.1	Unripened cheese	10000 mg/kg	6 & 174	3	Be discontinued	EU (not authorized in STAN 273-1968 on cottage cheese, STAN 275-1993 on cream cheese; EU questions technological need for unripened cheese which do not present rind; alternatives like silicon dioxide, calcium silicate, magnesium silicates or potassium silicate can be used).
					265 mg/kg as Al	IDF
01.6.2.1	Ripened cheese, includes rind	10000 mg/kg	6, 174 & 177 ¹³	3	Be discontinued	EU (the recent EFSA opinion on aluminium (2008) shared the conclusion of JECFA and highlighted that dairy products, in particular cheese, are among the main contributor of aluminium; because of safety concern, EU recommends to discontinue work on this category; substitutes are used by the EU industry)
01.6.2.3	Cheese powder (for reconstitution; e.g., for cheese sauces)	10000 mg/kg	6 & 174	3	265 mg/kg as Al	IDF
					265 mg/kg as Al	IDF
01.6.4	Processed cheese	10000 mg/kg	6, 174 & 177	3	Be discontinued	EU (EFSA has highlighted that dairy products, in particular cheese, are among the main contributor of aluminium; because of safety concern, EU recommends to discontinue work on this category)
01.6.5	Cheese analogues	10000 mg/kg	6, 174 & 177	3	265 mg/kg as Al	IDF (should be consistent with other cheese standards)
01.8.2	Dried whey and whey products, excluding whey cheeses	265 mg/kg	6 & 174	3	7 mg/kg as Al	IDF
11.1.2	Powdered sugar, powdered dextrose	15000 mg/kg	6, 56 ¹⁴	3	265 mg/kg as Al	CEFS (proposes this ML in line with EU in dried powdered stuffs, including sugars; Note 174 "Singly or in combination: sodium aluminium silicate (INS 554), calcium aluminium silicate (INS 556), and aluminium silicate (INS 559) should be added).

Note 177 For use in sliced, cut, shredded, or grated cheese only
 Note 56 Provided starch is not present

Recommendation 5: The eWG recommends <u>further discussion</u> on the following aluminium-containing food additives provisions:

CALCIUM ALUMINIUM SILICATE (INS 556)

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments
					Be discontinued	EU (due to safety concern, the EU intend to revisit its current authorization on aluminum based food additives in sugar and to withdraw this authorization; sugar is a staple foodstuff which is widely consumed on a daily basis).
12.2.2	Seasonings and condiments	30000 mg/kg	6 & 174	3	875 mg/kg as Al	Brazil - ML reported by food industry necessary to prevent clumping and improving flow ability. The use of sodium aluminum silicate is justified by its round molecular structure, which allows the flow of less crystallized seasonings and condiments along the production site. Therefore, it is not possible the substitute this food additive, but it may be used in combination with other anticaking agents, such as silicate dioxide.
					1140 mg/kg as Al	IFAC (needed for anticaking)
					1710 mg/kg as Al	ICGMA (used as anticaking agent in seasonings to prevent clumping and improving flow ability)
		10000 mg/kg	6 & 174	3	570 mg/kg as Al	Brazil - necessary to prevent clumping in highly hygroscopic products.
					1150 mg/kg as Al	IFAC (needed for anticaking)
12.5.2	Mixes for soups and broths				570 mg/kg as Al	ICGMA (used as anticaking agent in these mixes to prevent clumping and improving flow ability)
					Be discontinued	EU (not authorized in STAN 117-1981 on bouillon and consommés; calcium phosphates are used as anticaking agents)
					570 mg/kg as Al	Brazil - necessary to prevent clumping in highly hygroscopic products.
					1150 mg/kg as Al	IFAC (needed for anticaking)
12.6.3	Mixes for sauces and gravies	10000 mg/kg	6 & 174	3	1140 mg/kg as Al	ICGMA (used as anticaking agent in these mixes to prevent clumping and improving flow ability)
	giunto				Be discontinued	EU (does not support this new proposal on aluminium while PTWI is already exceeded and JECFA recommends to restrict the conditions of its use)

Recommendation 5: The eWG recommends the <u>further discussion</u> of the following aluminium-containing food additives provisions:

2. ALUMINIUM SILICATE (INS 559)

Food	Food Category	Max Level	Notes	Step/ Year	Proposed Levels/	Comments
Cat. No.				Adopted	Basis	
01.5	Milk powder and cream powder and powder analogues (plain)	10000 mg/kg	6 & 174	3	3000 mg/kg as Al	IDF (as authorized in the Codex Standard 207)
					3000 mg/kg as Al	IDF (as authorized in the Codex Standard 221-2001 for sliced, cut, shredded and grated products only (surface treatment)
						India
01.6.1	Unripened cheese	10000 mg/kg	6	3	Be discontinued	EU (not authorized in STAN 273-1968 on cottage cheese, STAN 275-1993 on cream cheese; EU questions technological need for unripened cheese which do not present rind; alternatives like silicon dioxide, calcium silicate, magnesium silicates, or potassium silicate can be used)
	Ripened cheese, includes rind	10000 mg/kg	6, 174 & 177		3000 mg/kg as Al	IDF (as authorized in the Codex Standard 283)
						India
01.6.2.1				3	Be discontinued	EU (EFSA has highlighted that dairy products, in particular cheese, are among the main contributor of aluminium; because of safety concern, EU recommends to discontinue work on this category; substitutes are used by the EU industry)
01.6.2.3	Cheese powder (for reconstitution; e.g., for cheese sauces)	10000 mg/kg	6 & 174	3	3000 mg/kg as Al	IDF
			6, 174 & 177		3000 mg/kg as Al	IDF (technological justification as anticaking agent for sliced, cut, shredded and grated cheese)
01.6.4	Processed cheese	10000 mg/kg		3	Be discontinued	EU (EFSA has highlighted that dairy products, in particular cheese, are among the main contributor of aluminium; because of safety concern, EU recommends to discontinue work on this category)
01.6.5	Cheese analogues	10000 mg/kg	6, 174 & 177	3	3000 mg/kg as Al	IDF (technological justification as anticaking agent for sliced, cut, shredded and grated cheese)

Recommendation 6: The eWG recommends the <u>circulation for comments at step 3</u> of the following new proposed provisions for aluminium-containing food additives:

ALUMINIUM AMMONIUM SULFATE (INS 523)

Food Cat. No.	Food Category	Max Level	Notes	Step/ Year Adopted	Proposed Levels/ Basis	Comments
06.4.2	Dried pastas and noodles and like products		<u>6</u>		300 mg/kg as Al	Japan 1. New Levels/Basis "kuzukiri", "harusame" 5,000 mg/kg (as dodecahydrate) 300 mg/kg (as Al) 2. Justification Functional class: Firming agent Aluminium ammonium sulfate reacts with proteins in flours and enhances hard texture of noodles. The use of this additive in this category is limited to Japanese traditional starch noodles.
				_	Be discontinued	Thailand
					Be discontinued	EU (does not support this new proposal on aluminium while PTWI is already exceeded and JECFA recommends to restrict the conditions of its use)
<u>06.6</u>	Batters (e.g., for breading or batters for fish or poultry)		<u>6</u>		165 mg/kg as Al (batter for tempura and deep fry)	Japan) 1. New Levels/Basis (1) Batter for tempura and deep fry 2,700 mg/kg (as dodecahydrate) 165 mg/kg (as Al) 2. Justification Functional class: Raising agent Aluminium ammonium sulfate reacts with sodium hydrogen carbonate (NaHCO ₃) and generates carbon dioxide to inflate batter. Aluminium ammonium sulfate acts slowly and its effects holds long, which contributes to the softness of batter. The desired effect cannot be obtained by the use of other food additives.
					Be discontinued	EU (opposes any new proposal on aluminium while PTWI is already exceeded and JECFA recommends to restrict the conditions of its use; technological need is questioned)

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Recommendation 6: The eWG recommends the <u>circulation for comments at step 3</u> of the following new proposed provisions for aluminium-containing food additives:

ALUMINIUM AMMONIUM SULFATE (INS 523)

Food Cat. No.	Food Category	Max Level	Notes	Step/ Year Adopted	Proposed Levels/ Basis	Comments
07.2.1	Cakes, cookies and pies (e.g., fruit-filled or custard types)		<u>6</u>		96 mg/kg as Al	Japan (1) New Levels/Basis Cookies 1,600 mg/kg (as dodecahydrate) 96 mg/kg (as Al) (2) Justification Functional class: Raising agent Aluminium ammonium sulfate reacts with sodium hydrogen carbonate (NaHCO ₃) and generates carbon dioxide to inflate cookies.
07.2.2	Other fine bakery products (e.g., doughnuts, sweet rolls, scones, and muffins)		<u>6</u>		165 mg/kg as Al	Japan (1) New Proposed Levels/Basis (i) Sweet rolls 2,750 mg/kg (as dodecahydrate) 165 mg/kg (as Al) (ii) Cones for ice cream 1,900 mg/kg (as dodecahydrate) 114 mg/kg (as Al) (iii) Breads containing sweet bean paste ("anpan") 17 mg/kg (as dodecahydrate) 1 mg/kg (as dodecahydrate) 1 mg/kg (as Al) (2) Justification (i) and (ii) Functional class: Raising agent Aluminium ammonium sulfate reacts with sodium hydrogen carbonate (NaHCO ₃) and generates carbon dioxide to inflate sweet rolls and cones for ice cream. (3) Justification (iii) Functional class: Colour retention agent Cochineal extract used in bean paste as colour reacts with protein from bean paste, which damages the function of cochineal extract. Aluminium ammonium sulfate reacts with cochineal extract and becomes stable complex, which inhibits reacting with protein.

Recommendation 6: The eWG recommends the <u>circulation for comments at step 3</u> of the following new proposed provisions for aluminium-containing food additives:

ALUMINIUM AMMONIUM SULFATE (INS 523)

runction.	firming agent, stabilized	l	T		1	
Food Cat. No.	Food Category	Max Level	Notes	Step/ Year Adopted	Proposed Levels/ Basis	Comments
						(4) Japan's response to the comments by members
						Japan will provide its comment in response to CL 2011/7 to add technological purpose on Aluminium ammonium sulfate.
						Japan 1. Food Category No. 07.2.3
						1. Food Category No. 07.2.3 (1) New Levels/Basis
						Cake mix
						16,200 mg/kg (as dodecahydrate)
	Mixes for fine bakery wares (e.g., cakes, pancakes)					980 mg/kg (as Al)
07.2.3			<u>6</u>		980 mg/kg as Al	(2) Justification
			_			Functional class: Raising agent
						Aluminium ammonium sulfate reacts with sodium hydrogen carbonate (NaHCO ₃) and generates carbon dioxide to inflate cake.
						2. Japan's response to the comments by members
						Japan will provide its comment in response to CL 2011/7 to add technological purpose on Aluminium ammonium sulfate.
						Japan
						1. New Levels/Basis
						Fresh sea urchins
						4,400 mg/kg (as anhydride)
						500 mg/kg (as Al)
						2. Justification
00.4.6	Fresh mollusks,				500 mg/kg as Al	Functional class: Firming agent
<u>09.1.2</u>	crustaceans and echinoderms		<u>6</u>			(1) To keep tissue firm by protein denaturation of sea urchins.
	ecimodernis					(2) To keep tissue fresh by inhibition of growing microorganism.
						3. Japan's response to the comments by members
						No codex standards are existed for sea urchins. We believe that the use of aluminium ammonium sulfate should be authorized by our justification as above.
					Be discontinued	EU (technological need questioned; INS 523 is not recognized as "raising agent" according to CAC/GL 36-1989, only stabilizer / firming

Recommendation 6: The eWG recommends the <u>circulation for comments at step 3</u> of the following new proposed provisions for aluminium-containing food additives:

ALUMINIUM AMMONIUM SULFATE (INS 523)

Food Cat. No.	Food Category	Max Level	Notes	Step/ Year Adopted	Proposed Levels/ Basis	Comments
						agent).
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	<u>6</u>	<u>6</u>	600mg/kg as Al (for salted jellyfishes)	Japan 1. New Levels/Basis Salted jellyfishes 10,000 mg/kg (as dodecahydrate) 600 mg/kg (as Al) 2. Justification Functional class: Firming agent (1) To keep tissue firm by protein denaturation of fresh sea urchins. (2) To keep tissue fresh by inhibition of growing microorganism. 3. Japan's response to the comments by members No Codex Standards are existed for salted jelly fishes. We believe that the use of aluminium ammonium sulfate should be authorized by our justification as above.	
					Be discontinued	EU (technological need questioned; not authorized in any CC relevant for 09.2.5: STAN 222-2001 on crackers from marine and freshwater fish, STAN 236-2003 on dried salted anchovies, STAN 189-1993 on dried shark fins, STAN 244-2004 on salted atlantic herring, STAN 167-1989 on salted fish and dried salted fish).
12.4	<u>Mustards</u>		<u>6</u>		732 mg/kg as Al	Japan. 1. New Levels/Basis Mustards 12,290 mg/kg (as dodecahydrate) 732 mg/kg (as Al) 2. Justification Functional class: Acidity regulator Allyl isothiocyanate which makes mustards spicy is resolved by an enzyme in mustard itself. Aluminium ammonium sulfate adjusts pH of the product to inhibit activation of the enzyme. The use of aluminium ammonium sulfate does not affect the original flavour of mustards.

Recommendation 6: The eWG recommends the <u>circulation for comments at step 3</u> of the following new proposed provisions for aluminium-containing food additives:

5. SODIUM ALUMINOSILICATE (INS 554) 15

Function: anticaking agent

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments
<u>05.3</u>	Chewing gum		6 & 174		100 mg/kg	ICGA (new proposed use - aluminium containing additives are technologically used singly or in combination in chewing gum processes and in some (but not all) recipes and may result in a presence at the surface of final chewing gum product. Likewise, in some regions, they may also be used as anticaking agents (i.e. in compressed chewing gum in the EU). The quantity used in these cases is limited to what is strictly necessary to achieve the technological effect, according to the quantum satis principle, as these additives are generally regulated at GMP level at national level. Maximum use levels which were reported do not exceed more than 100 ppm expressed on an Aluminium basis. No reference to Footnote 3 (surface treatment only) is suggested as some products subject to international trade may contain such additives in the gum part of the product (therefore not absorbed).

Recommendation 6: The eWG recommends the <u>circulation for comments at step 3</u> of the following new proposed provisions for aluminium-containing food additives:

3. CALCIUM ALUMINIUM SILICATE (INS 556)

Function: anticaking agent

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments				
05.3	Chewing gum		6 & 174		100 mg/kg	ICGA (new proposed use - aluminium containing additives are technologically used singly or in combination in chewing gum processes and in some (but not all) recipes and may result in a presence at the surface of final chewing gum product. Likewise, in some regions, they may also be used as anticaking agents (i.e. in compressed chewing gum in the EU). The quantity used in these cases is limited to what is strictly necessary to achieve the technological effect, according to the quantum satis principle, as these additives are generally regulated at GMP level at national level. Maximum use levels which were reported				

¹⁵ The USA notes that sodium aluminosilicate is regulated for use in food in general in the USA at levels up to 550 mg/kg food as aluminium, in accordance with good manufacturing practices. However, the USA has no data on actual use levels of this additive in specific food categories.

Recommendation 6: The eWG recommends the <u>circulation for comments at step 3</u> of the following new proposed provisions for aluminium-containing food additives:

3. CALCIUM ALUMINIUM SILICATE (INS 556)

Function: anticaking agent

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments
						do not exceed more than 100 ppm expressed on an Aluminium basis. No reference to Footnote 3 (surface treatment only) is suggested as some products subject to international trade may contain such additives in the gum part of the product (therefore not absorbed).

Recommendation 6: The eWG recommends the <u>circulation for comments at step 3</u> of the following new proposed provisions for aluminium-containing food additives:

2. ALUMINIUM SILICATE (INS 559)

Food Cat. No.	Food Category	Max Level	Notes	Step/ Year Adopted	Proposed Levels/ Basis	Comments
<u>05.3</u>	Chewing gum		<u>6 & 174</u>		100 mg/kg	ICGA (new proposed use - aluminium containing additives are technologically used singly or in combination in chewing gum processes and in some (but not all) recipes and may result in a presence at the surface of final chewing gum product. Likewise, in some regions, they may also be used as anticaking agents (i.e. in compressed chewing gum in the EU). The quantity used in these cases is limited to what is strictly necessary to achieve the technological effect, according to the quantum satis principle, as these additives are generally regulated at GMP level at national level. Maximum use levels which were reported do not exceed more than 100 ppm expressed on an Aluminium basis. No reference to Footnote 3 (surface treatment only) is suggested as some products subject to international trade may contain such additives in the gum part of the product (therefore not absorbed).

1. ALUMINIUM AMMONIUM SULFATE (INS 523)

	Tirming agent, stabilizer	1	1	1		T
Food Cat. No.	Food Category	Max Level	Notes	Step/ Year Adopted	Proposed Levels/ Basis	Comments
	Dairy-based drinks, flavoured and/or fermented					EU (INS 523 is not authorized in Codex STAN 243-2003 for fermented milks; dairy-based products are widely consumed by children)
01.1.2	(e.g., chocolate milk, cocoa, eggnog, drinking yoghurt,	350 mg/kg	6	3	Be discontinued	Japan
	whey-based drinks)					Thailand
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	150 mg/kg	6	3	Be discontinued	EU (no technological justification provided; INS 523 is not authorized in Codex STAN 243-2003 for fermented milks; dairy-based desserts are widely consumed by children and as JECFA indicated explicitly that children exceed the PTWI, EU strongly opposes continuation of work on this category)
	yoghuriy					Japan
						Thailand
04.2.2.3	Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds in vinegar, oil, brine, or soybean sauce	35 mg/kg	6	2003	Be revoked	Japan
04127	C I IC '	200 //		2001	D 1.1	EU (technological need requested)
04.1.2.7	Candied fruit	200 mg/kg	6	2001	Be revoked	Japan
	Vegetable (including mushrooms and fungi, roots and tubers, pulses and					EU (technological need requested; not authorized in STAN 057-1981 on processed tomato concentrates, STAN 259R-1981 on Tehena, STAN 295R-2009 on ginseng products)
04.2.2.6	legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5	200 mg/kg	6	2001	Be revoked	Japan
04.2.2.7	Fermented vegetable (including mushrooms and fungi, roots and tubers,	500 mg/kg	6	3	Be discontinued	EU (technological need requested; not authorized in any of crossed reference Codex standardized foods with 4.2.2.7 of GSFA according to Annex C of GSFA: STAN 151-1985 on Gari, STAN 223-2001 on

1. ALUMINIUM AMMONIUM SULFATE (INS 523)

Food Cat. No.	Food Category	Max Level	Notes	Step/ Year Adopted	Proposed Levels/ Basis	Comments
	pulses and legumes, and aloe vera) and seaweed					Kimchi, STAN 294R-2009 on Gochujang, STAN 038-1981 on edible fungi, STAN 260-2007 on pickled fruits and vegetables)
	products, excluding fermented soybean products of food categories 06.8.6, 06.8.7, 12.9.1, 12.9.2.1 and 12.9.2.3					Japan
06.2	Flours and starches (including soybean powder)	500 mg/kg	6	3	Be discontinued	EU (JECFA pointed out that "high aluminium content of cereal products and in particular of ordinary baked goods may be of special importance in a number of countries since they constitute staple food and may therefore be consumed regularly in large quantity"; there is a safety concern and cereals/cereal products may be considered as a main contributor already; Al is not authorized in any commodity standards related to flours (STAN 152-1985 on wheat flour, STAN 170-1989 on pearl millet, STAN 173-1989 on sorghum flour, STAN176-1989 for edible cassava flour, STAN 178-1991 for durum wheat semolina and durum wheat flour).
						Japan
07.1.4	Bread-type products, including bread stuffing and	10000 mg/kg	29	4	Be discontinued	EU (for safety reason, considering the 67th JECFA and EFSA 2008 conclusions)
	bread crumbs					Japan
					Withdraws proposal	Japan
	Fine bakery wares (sweet,			3		Thailand
07.2	salty, savoury) and mixes	10000 mg/kg	29		Be discontinued	EU (technological need questioned; INS 523 is not recognized as "raising agent" according to CAC/GL 36-1989, only stabilizer / firming agent)
					-	Brazil questions technological need
08.3.2	Heat-treated processed comminuted meat, poultry, and game products	5 mg/kg	6	3	Be discontinued	EU (technological need questioned; not authorized in any CC relevant for 8.3.2: STAN 088-1981 on canned corned beef, STAN 089-1981 on luncheon meat, STAN 098-1981 on cooked cured chopped meat)
						Japan

1. ALUMINIUM AMMONIUM SULFATE (INS 523)

Food Cat. No.	Food Category	Max Level	Notes	Step/ Year Adopted	Proposed Levels/ Basis	Comments				
					-	Brazil questions technological need				
09.2	Processed fish and fish products, including mollusks, crustaceans, and echinoderms	1500 mg/kg	6	3	Be discontinued	EU (technological need questioned; not authorized in any CC relevant for 09.2.1: STAN 165-1989 on quick frozen blocks of fish fillets, STAN 190-1995 on quick frozen fish fillets, STAN 095-1981 on quick frozen lobsters)				
					Withdraws proposal	Japan				
	Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	1500 mg/kg	6	3	-	Brazil questions technological need				
09.3					Be discontinued	EU (technological need questioned)				
09.5					Withdraws proposal	Japan				
10.2	Egg products	30 mg/kg	6	2001	Be discontinued	Japan				
10.4	Egg-based desserts (e.g., custard)	380 mg/kg	6	2003	Be revoked	EU (technological need questioned; desserts are widely consumed by children and as JECFA indicated explicitly PTWI is exceeded by children, EU strongly oppose continuation of work on this category)				
						Japan				
	Herbs, spices, seasonings					EU (technological need questioned)				
12.2	and condiments (e.g., seasoning for instant noodles)	500 mg/kg	6	3	Be discontinued	Japan				

Recommendation 7: The eWG recommends the <u>revocation/discontinuation</u> of the following aluminium-containing food additives provisions:

4. SODIUM ALUMINIUM PHOSPHATES 16

SODIUM ALUMINIUM PHOSPHATE, ACIDIC (INS 541(i))

SODIUM ALUMINIUM PHOSPHATE, BASIC (INS 541(ii))

Functions: acidity regulator, emulsifier, raising agent, stabilizer, thickening agent

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments
					-	Brazil questions technological need
					120 mg/kg (as Al)	Indonesia (ML established based on consumption and PTDI of 1mg/kg bw/d; ML proposed by Codex exceeds PTWI of Al - 7mg/kg bw/wk)
	Dainy hazad dagganta (a a				10000 mg/kg (not specified)	Mexico
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	2000 mg/kg	6	6	2000 mg/kg (120 mg/kg as Al)	IFAC (INS 541ii for emulsification and stabilization)
						Thailand
					Be discontinued	EU (INS 523 is not authorized in Codex STAN 243-2003 for fermented milks; dairy based desserts are widely consumed by children and as JECFA indicated explicitly that children exceed the PTWI, EU strongly opposes continuation of work on this category)
		2000 mg/kg	6	6	-	Brazil questions technological need
	Fat-based desserts				120 mg/kg (as Al)	Indonesia (ML established based on consumption and PTDI of 1mg/kg bw/d; ML proposed by Codex exceeds PTWI of Al - 7mg/kg bw/wk)
02.4	excluding dairy-based dessert products of food				2000 mg/kg (120 mg/kg as Al)	IFAC (INS 541ii for emulsification and stabilization)
	category 01.7				Be discontinued	EU (questions technological need; desserts are widely consumed by children and as JECFA indicated explicitly that children exceed the PTWI, EU strongly opposes continuation of work on this category)
					-	Brazil questions technological need
04.1.2.9	Fruit-based desserts, including fruit-flavoured	2000 mg/kg	6	6	2000 mg/kg (170 mg/kg as Al)	IFAC (INS 541i for emulsification and stabilization)
0111219	water-based desserts				Be discontinued	E U (questions technological need; desserts are widely consumed by children and as JECFA indicated explicitly that children exceed the PTWI, EU strongly opposes continuation of work on this category)

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¹⁶ The USA notes that sodium aluminium phosphates are regulated for use in food in general in the USA, in accordance with good manufacturing practices.

Recommendation 7: The eWG recommends the <u>revocation/discontinuation</u> of the following aluminium-containing food additives provisions:

4. SODIUM ALUMINIUM PHOSPHATES ¹⁶

SODIUM ALUMINIUM PHOSPHATE, ACIDIC (INS 541(i))

SODIUM ALUMINIUM PHOSPHATE, BASIC (INS 541(ii))

Functions: acidity regulator, emulsifier, raising agent, stabilizer, thickening agent

Food Cat. No.	Food Category	Max Level	Notes Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments
- Cut. 110.				ruopicu	-	Brazil questions technological need
					2000 mg/kg (120 mg/kg as Al)	IFAC (INS 541ii for emulsification and stabilization)
						Thailand
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	2000 mg/kg	6 & 72 ¹⁷	6	Be discontinued	EU (technological need questioned; cocoa-based dessert are widely consumed by children and as JECFA indicated explicitly that children exceed the PTWI, EU strongly opposes continuation of work on this category; not authorized in CC relevant to 05.1.1: STAN 141-1983 on cocoa mass; alternatives can be used for cocoa powders like magnesium/calcium silicate, tricalcium phosphate, silicon dioxide)
	Confectionery including	hard and soft candy, nougats, etc other than food categories 05.1, 05.3 and 350 mg/kg 29 3			-	Brazil questions technological need
					2000 mg/kg (120 mg/kg as Al)	IFAC (INS 541ii for emulsification and stabilization)
05.2	nougats, etc other than food categories 05.1, 05.3 and 05.4		3	Be discontinued	EU (JECFA raised a safety concern over the exceedance of the PTWI for aluminium by a large extent by some population groups, and spotted explicitly children, who regularly consume foods containing aluminium; the recent EFSA opinion on aluminium shared this conclusion)	
						IFAC
06.2	Flours and starches (including soybean powder)	3600 mg/kg	6	3	Be discontinued	EU (technological need questioned; flour is a staple foodstuff widely consumed which contributes substantially to the daily intake; not authorized in any commodity standards related to flours (STAN 152-1985 on wheat flour, STAN 170-1989 on pearl millet, STAN 173-1989 on sorghum flour, STAN 176-1989 for edible cassava flour, STAN 178-1991 for durum wheat semolina and durum wheat flour)
06.5	Cereal and starch based	2000 mg/kg	6	6	-	Brazil questions technological need
00.5	desserts (e.g., rice pudding,		6		2000 mg/kg (170	IFAC (INS 541i as acidity regulator, thickening agent and raising

¹⁷ **Note 72** Ready-to-eat basis

Recommendation 7: The eWG recommends the <u>revocation/discontinuation</u> of the following aluminium-containing food additives provisions:

4. SODIUM ALUMINIUM PHOSPHATES 16

SODIUM ALUMINIUM PHOSPHATE, ACIDIC (INS 541(i))

SODIUM ALUMINIUM PHOSPHATE, BASIC (INS 541(ii))

Functions: acidity regulator, emulsifier, raising agent, stabilizer, thickening agent

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments
	tapioca pudding)				mg/kg as Al)	agent)
						Thailand
					Be discontinued	EU (desserts are widely consumed by children and as JECFA indicated explicitly PTWI is exceeded by children, EU strongly oppose continuation of work on this category)
				6	-	Brazil questions technological need
10.4	Egg-based desserts (e.g., custard)	2000 mg/kg	6		Be discontinued	EU (technological need questioned; desserts are widely consumed by children and as JECFA indicated explicitly PTWI is exceeded by children, EU strongly oppose continuation of work on this category)
12.5.2	Mixes for soups and broths	2000 mg/kg	6 & 127 ¹⁸	6	2000 mg/kg (170 mg/kg as Al)	IFAC (INS 541i for emulsification and stabilization)
12.3.2					Be discontinued	EU (not authorized in STAN 117-1981 on bouillon and consommés; calcium phosphates are used as anticaking agents)

Recommendation 7: The eWG recommends the <u>revocation/discontinuation</u> of the following aluminium-containing food additives provisions:

SODIUM ALUMINOSILICATE (INS 554)

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments
01.8.2	Dried whey and whey products, excluding whey cheeses	10000 mg/kg		2006	570 mg/kg (as Al) 20000 mg/kg (1150 mg/kg as Al)	Brazil – conversion of the adopted ML to AL basis IFAC (needed for anticaking)
06.3	Breakfast cereals,	20000 mg/kg	6	3	GMP	Mexico

¹⁸ **Note 127** As served to the consumer

SODIUM ALUMINOSILICATE (INS 554)

Food	anticaking agent			Step/Year	Proposed Levels/	
Cat. No.	Food Category	Max Level	Notes	Adopted	Basis	Comments
	including rolled oats				20000 mg/kg (1150 mg/kg as Al)	IFAC (needed for anticaking)
					Be discontinued	EU (JECFA raised a safety concern over the exceedance of the PTWI for aluminium by a large extent by some population groups, and spotted explicitly children, who regularly consume foods containing aluminium; the recent EFSA opinion on aluminium shared this conclusion; EU recommends to discontinue the work on this category which is particularly consumed by children)
					GMP	Mexico
06.4.3	Pre-cooked pastas and noodles and like products	20000 mg/kg	6	3	20000 mg/kg (1150 mg/kg as Al)	IFAC (needed for anticaking)
	noodies and like products				D 11 41 1	Thailand
					Be discontinued	EU (no technological need in pre-cooked pasta)
					GMP	Mexico
					20000 mg/kg (1150 mg/kg as Al)	IFAC (needed for anticaking)
	Cereal and starch based					Thailand
06.5	desserts (e.g., rice pudding, tapioca pudding)	20000 mg/kg	6	3	Be discontinued	EU (JECFA raised a safety concern over the exceedance of the PTWI for aluminium by a large extent by some population groups, and spotted explicitly children, who regularly consume foods containing aluminium; the recent EFSA opinion on aluminium shared this conclusion; EU recommends to discontinue the work on this category which is particularly consumed by children)
14.1.4.3	Concentrates (liquid or solid) for water-based	10000 mg/kg	6 & 174	3	20000 mg/kg (1150 mg/kg as Al)	IFAC (needed for anticaking)
	flavoured drinks				5000 mg/kg (no	India

SODIUM ALUMINOSILICATE (INS 554)

Function: anticaking agent

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments	
					reporting basis)		
					Be discontinued	EU (strongly opposes to authorize aluminium in flavoured drinks; a child of 20kg reaches the PTWI by consuming around 2.85mg Al/day; at the ML of 1.15 mg Al/g of drink, few ml of drink are sufficient for the child to reach the PTWI)	
						ICBA (would agree to discontinue the draft provision since there are alternative anticaking agents available and commonly used in powdered drinks)	

Recommendation 7: The eWG recommends the <u>revocation/discontinuation</u> of the following aluminium-containing food additives provisions:

3. CALCIUM ALUMINIUM SILICATE (INS 556)

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments	
						Thailand	
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	10000 mg/kg	6 & 174	3	Be discontinued	EU (INS 523 is not authorized in Codex STAN 243-2003 for fermented milks; dairy based desserts are widely consumed by children and as JECFA indicated explicitly that children exceed the PTWI, EU strongly opposes continuation of work on this category).	
01.8.2	Dried whey and whey products, excluding whey cheeses	10000 mg/kg		2006			
					GMP	Mexico	
07.1.6	Mixes for bread and ordinary bakery wares	10000 mg/kg	6 & 174	3	Be discontinued	EU (for safety reason; JECFA highlighted the high aluminium content of cereal products which are considered as staple food in a number of countries and consumed regularly in large quantity; the recent EFSA opinion (2008) on aluminium shared JECFA conclusions, spotted cereal and cereal products as main food contributors, and concluded that the EU population could exceed the newly revised PTWI)	

3. CALCIUM ALUMINIUM SILICATE (INS 556)

Function: anticaking agent

Food Cat. No.	Food Category	Max Level	Notes	Step/Year Adopted	Proposed Levels/ Basis	Comments	
					GMP	Mexico	
07.2.3	Mixes for fine bakery wares (e.g., cakes, pancakes)	10000 mg/kg	6 & 174	3	Be discontinued	EU (for safety reason; JECFA highlighted the high aluminium content of cereal products which are considered as staple food in a number of countries and consumed regularly in large quantity; the recent EFSA opinion (2008) on aluminium shared JECFA conclusions, spotted cereal and cereal products as main food contributors, and concluded that the EU population could exceed the newly revised PTWI)	
11.1.2	Powdered sugar, powdered dextrose	15000 mg/kg	56	2006			
12.1.2	Salt substitutes	10000 mg/kg		6			
12.2.2	Seasonings and condiments	30000 mg/kg	6 & 174	3	GMP	Mexico	
12.5.2	Mixes for soups and broths	10000 mg/kg	6 & 174	3	Be discontinued	EU (not authorized in STAN 117-1981 on bouillon and consommés calcium phosphates are used as anticaking agents)	
12.6.3	Mixes for sauces and gravies	10000 mg/kg	6 & 174	3	Be discontinued	EU (does not support this new proposal on aluminium while PTWI is already exceeded and JECFA recommends to restrict the conditions of its use)	

Recommendation 7: The eWG recommends the <u>revocation/discontinuation</u> of the following aluminium-containing food additives provisions:

2. ALUMINIUM SILICATE (INS 559)

Food Cat. No.	Food Category	Max Level	Notes	Step/ Year Adopted	Proposed Levels/ Basis	Comments	
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	10000 mg/kg	6 & 174	3	Be discontinued	EU (INS 523 is not authorized in Codex STAN 243-2003 for fermented milks; dairy based desserts are widely consumed by children and as JECFA indicated explicitly that children exceed the PTWI, EU strongly oppose continuation of work on this category) Thailand	
01.8.2	Dried whey and whey products, excluding whey	10000 mg/kg	6 & 174	3			

Recommendation 7: The eWG recommends the <u>revocation/discontinuation</u> of the following aluminium-containing food additives provisions:

2. ALUMINIUM SILICATE (INS 559)

Food Cat. No.	Food Category	Max Level	Notes	Step/ Year Adopted	Proposed Levels/ Basis	Comments	
	cheeses						
01.8.2	Dried whey and whey products, excluding whey cheeses	10000 mg/kg		2006			
					GMP	Mexico	
07.1.6	Mixes for bread and bakery wares	10000 mg/kg	6 & 174	3	Be discontinued	EU (for safety reason; JECFA highlighted the high aluminium content of cereal products which are considered as staple food in a number of countries and consumed regularly in large quantity; the recent EFSA opinion (2008) on aluminium shared JECFA conclusions, spotted cereal and cereal products as main food contributors, and concluded that the EU population could exceed the newly revised PTWI)	
					GMP	Mexico	
07.2.3	Mixes for fine bakery wares (e.g., cakes, pancakes)	10000 mg/kg	6 & 174	3	Be discontinued	EU (for safety reason; JECFA highlighted the high aluminium content of cereal products which are considered as staple food in a number of countries and consumed regularly in large quantity; the recent EFSA opinion (2008) on aluminium shared JECFA conclusions, spotted cereal and cereal products as main food contributors, and concluded that the EU population could exceed the newly revised PTWI)	
12.1.1	Salt	10000 mg/kg	6	3	Be discontinued EU (for safety reason, EU recommends to discontinue the work on t kind of staple food which is consumed on a daily basis)		
12.1.2	Salt Substitutes	10000 mg/kg		6			
12.2.2	Seasonings and condiments	30000 mg/kg	6 & 174	3	GMP	Mexico	
12.5.2	Mixes for soups and broths	10000 mg/kg	6 & 174	3	Be discontinued	EU (not authorized in STAN 117-1981 on bouillon and consommés; calcium phosphates are used as anticaking agents)	
12.6.3	Mixes for sauces and gravies	10000 mg/kg	6 & 174	3	Be discontinued	EU (opposes any new proposal without robust justification on aluminium while PTWI is already exceeded and JECFA recommends to restrict the conditions of use of aluminium)	

 $\underline{\text{ANNEX 1}}$ Information to convert the MLs for aluminium-containing food additives into Al basis:

INS	Name	Molecular Formula	Molecular Weight		(%Al)	Reference
	Sodium	$Na_3Al_2H_{15}(PO_4)_8$	897.82	6.0%	To convert to Al basis, multiply ML as	JECFA/FCC
541i	aluminium phosphate, acid	NaAl ₃ H ₁₄ (PO ₄) ₈ ·4H ₂ O	949.88	8.5%	compound by 0.089 (highest percentage of Al) OR by	JECFA/FCC
		NaAl ₃ H ₁₄ (PO ₄) ₈ .2H ₂ 0	913.85	8.9% 0.078 (average)		FCC
541ii	Sodium aluminium phosphate, basic	Na $_8$ Al $_2$ (OH) $_2$ (PO $_4$) $_4$ Product for which specification was developed contains 30% NaH $_2$ PO $_4$		8.3% To convert to Al basis, multiply ML as compound by 0.7 (since the product contains 70% of the compound) and then by 0.083		JECFA/FCC
554	Sodium aluminosilicate	Na ₂ O:Al ₂ O ₃ :SiO ₂ molar ratios of approximately 1:1:13 Na.[(AlO ₂)x(SiO ₂)y].zH ₂ O	284-2190	5,7% To convert to Al basis, multiply ML as compound by 0.057		FCC EFSA (2008)
	Aluminium silicate	Al ₂ SiO ₅	162	33%	To convert to Al basis, multiply ML as	NNT (2000) Scientific
559				20.9%	compound by 0.380 (highest percentage of Al) OR by	Database Gateway (Cambridge)
		$Al_6O_{13}Si_2$	426	38%	0.300 (average)	
556	Calcium aluminium silicate	Al ₂ Ca ₂ O ₁₅ Si ₅ CaAl ₂ Si ₂ O ₈ Ca ₂ Al ₂ SiO ₇ Not less than 44% and not more than 50% of silicon dioxide (SiO ₂) Not less than 3% and not more than 5% of aluminium oxide (Al ₂ O ₃) Not less than 32% and not more than 38% of calcium oxide (CaO) Not less than 0.5% and not more than 4% of sodium oxide (Na ₂ O)	426 38% 0.300 (average) 514.5 10.5% 278 19-20% 274 2.65% To convert to Al basis, multiply ML as compound		Chemical Book ¹⁹	
		AlNH ₄ (SO ₄) ₂ ·12H ₂ O	453.32	6%	To convert	JECFA
523	Aluminium ammonium sulfate	AlNH ₄ (SO ₄) ₂	237.15	to Al basis, multiply ML as compound by 0.060		"Japan's Specifications and Standards for Food Additives"

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 $^{^{19} \} NTP \ (p.\ 2\ of\ Report\ and\ p.\ 16\ of\ the\ \textit{pdf}\ document:\ \underline{http://ntp.niehs.nih.gov/ntp/htdocs/Chem_Background/ExSumpdf/Aluminum.pdf})$