

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 5(c)

CX/FA 10/42/7 Add.1  
February 2010

(Original Language Only)

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD ADDITIVES

Forty-second Session

Beijing, China, 15-19 March 2010

#### COMMENTS AND INFORMATION ON THE REPORTING BASIS OF THE PROVISIONS FOR ALUMINIUM CONTAINING FOOD ADDITIVES INCLUDED IN THE GSFA (REPLIES TO CL 2009/10-FA)

The following comments have been received from the following Codex members and observers:

Brazil, India, Indonesia, Iran, EuSalt and ICGA

#### BRAZIL

Brazil has estimated the maximum level of aluminium containing food additives expressed as Al, taking into account their molecular weights and the respective content of aluminium. The figures expressed as Al were then compared to the levels proposed in the ALINORM 08/31/12, Appendix VI. The following comments are based on these data.

When more than one molecular formula were identified for a single INS, the percentage of aluminium in each formula was calculated and the highest percentage was used to convert the proposed maximum level of the aluminium containing food additive (when assumed that the level was expressed as the aluminium salt) to a maximum level expressed as aluminium.

The proposed maximum levels for the provisions with note 6 were considered to be appropriated and no suggestions were made.

It was not considered residues or metabolites of the reactions.

INS	Name	Molecular Formula	Molecular Weight	Al proportion (%Al)	Reference	Solubility
541i	Sodium aluminium phosphate, acid	$\text{Na}_3\text{Al}_2\text{H}_{15}(\text{PO}_4)_8$ $\text{NaAl}_3\text{H}_{14}(\text{PO}_4)_8 \cdot 4\text{H}_2\text{O}$	897.82 949.88	6.0% 8.5%	JECFA FCC	Insoluble in water
541ii	Sodium aluminium phosphate, basic	$\text{Na}_8\text{Al}_2(\text{OH})_2(\text{PO}_4)_4$ Product for which specification was developed contains 30% $\text{NaH}_2\text{PO}_4$	652	8.3%	JECFA FCC	Sodium phosphate moiety is soluble in water; sodium aluminium phosphate moiety is only sparingly soluble in water
554	Sodium aluminosilicate	$\text{Na}_2\text{O}:\text{Al}_2\text{O}_3:\text{SiO}_2$ molar ratios of approximately 1:1:13 $\text{Na}_x[(\text{AlO}_2)_x(\text{SiO}_2)_y] \cdot z\text{H}_2\text{O}$	284-2190	3.5%	FCC EFSA (2008)	Insoluble in water and in alcohol and other organic solvents

559	Aluminium silicate	Al <sub>2</sub> SiO <sub>5</sub> Al <sub>2</sub> O <sub>3</sub> ·2SiO <sub>2</sub> ·2H <sub>2</sub> O Al <sub>6</sub> O <sub>13</sub> Si <sub>2</sub>	162 258 426	33 % 20.9% 38%	NNT (2000) Scientific Database Gateway (Cambridge)	Insoluble in water, ethanol and mineral acids
556	Calcium aluminium silicate	Al <sub>2</sub> Ca <sub>2</sub> O <sub>15</sub> Si <sub>5</sub> CaAl <sub>2</sub> Si <sub>2</sub> O <sub>8</sub> Ca <sub>2</sub> Al <sub>2</sub> SiO <sub>7</sub> Not less than 44% and not more than 50% of silicon dioxide (SiO <sub>2</sub> ) Not less than 3% and not more than 5% of aluminium oxide (Al <sub>2</sub> O <sub>3</sub> ) 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 <sub>2</sub> O)	514.5 278 274	10.5% 19-20% 2.65%	Chemical Book	
523	Aluminium ammonium sulfate	AlNH <sub>4</sub> (SO <sub>4</sub> ) <sub>2</sub> · 12H <sub>2</sub> O	453.32	6%	JECFA	Freely soluble in water
522	Aluminium potassium sulfate	AlK(SO <sub>4</sub> ) <sub>2</sub> · xH <sub>2</sub> O (x = 0 or 12)	258.21 474.38	10.46% 5.7%	JECFA	Freely soluble in water

It is appropriate to consider the possibility of expressing maximum levels for all aluminium containing additives as Al, since concern has been raised by JECFA with regard to the contribution of food additives intake as a source of aluminium in the diet.

### **CALCIUM ALUMINIUM SILICATE**

Calcium Aluminium Silicate INS: 556 (2.65% Al)

Function: Anticaking Agent

Food Cat No.	Food Category	Max Level (mg/kg)	Step / Notes	Comments
01.8.2	Dried whey and whey products, excluding whey	10000	Adopted	It should be 265 mg/kg as Al
06.1	Whole, broken, or flaked grain, including rice	GMP	7	Please provide technological justification
11.1.2	Powdered sugar, powdered dextrose	15000	Adopted (Note 56)	400 mg/kg as Al
12.1.1	Salt	GMP	Adopted	It should be 265 mg/kg as Al
12.1.2	Salt substitutes	10000	7	It should be 265 mg/kg as Al
14.2.3	Grape wines	GMP	7	Technological need?

### **ALUMINIUM AMMONIUM SULPHATE**

Aluminium Ammonium Sulphate INS: 523 (6% Al)

Function: Firming Agent, Raising Agent, Stabilizer

INS List (CAC-GL 36-1989, rev. 2008): stabilizer, firming agent.

Food Cat No.	Food Category	Max Level (mg/kg)	Step / Notes	Comments
06.2.2	Starches	GMP	7 (6 & 26)	It should be 500 mg/kg as Al (06.2)
07.1.2	Crackers, excluding sweet crackers	10000	4 (Note 29)	It should be 600 mg/kg as Al
07.1.3	Other ordinary bakery products (e.g., bagels, pita, English muffins)	10000	4 (Note 29)	It should be 600 mg/kg as Al
07.1.4	Bread-type products, including bread stuffing and bread crumbs	10000	4 (Note 29)	It should be 600 mg/kg as Al
07.1.5	Steamed breads and buns	10000	4 (Note 29)	It should be 600 mg/kg as Al

07.1.6	Mixes for bread and ordinary bakery wares	10000	4 (Note 6)	It should be 600 mg/kg as Al
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	10000	4 (Note 29)	It should be 600 mg/kg as Al
08.3.2	Heat-treated processed comminuted meat, poultry, and game products	5	Note 6	Please provide technological justification
09.2	Processed fish and fish products, including mollusks, crustaceans, and echinoderms	1500	Note 6	Please provide technological justification
09.2.4	Cooked and/or fried fish and fish products, including mollusks, crustaceans, and echinoderms	200	Adopted (Note 6)	Please provide technological justification
09.3	Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	1500	Note 6	Please provide technological justification

## **ALUMINIUM SILICATE**

Aluminium Silicate INS: 559

The proportion of aluminium in silicates can range from 20.9 to 38% depending on the molecular formula of the salt. We have used the average value of 30% to calculate the maximum levels for this additive (expressed as Al).

INS	Name	Molecular Formular	Molecular Weight	Al proportion (%Al)	Reference
559	Aluminium silicate	$Al_2SiO_5$	162	33 %	NNT (2000) Scientific Database Gateway (Cambridge)
		$Al_2O_3 \cdot 2SiO_2 \cdot 2H_2O$	258	20.9 %	
		$Al_6O_{13}Si_2$	426	38 %	

Function: **Adjuvant**, Anticaking Agent

Food Cat No.	Food Category	Max Level (mg/kg)	Step / Notes	Comments
01.8.2	Dried whey and whey products, excluding whey cheeses	10000	Adopted	It should be 3000 mg/kg as Al
06.1	Whole, broken, or flaked grain, including rice	GMP	7	No information available in Brazil
12.1.2	Salt substitutes	10000	7	It should be 3000 mg/kg as Al
12.2.1	Herbs and spices	GMP	4 (Note 51)	For consistency, it should be 3000 mg/kg as Al

## **SODIUM ALUMINIUM PHOSPHATES**

Sodium Aluminium Phosphate-Acidic INS: 541(i)

Sodium Aluminium Phosphate-Basic INS: 541(ii) (**8.5 % Al**)

Function: Acidity Regulator, Emulsifier, Raising Agent, Stabilizer, Thickener

INS List (CAC/GL 36-1989, rev. 2008): acidity regulator, emulsifier, raising agent.

Brazil suggests that the functional classes listed under the food additive name and INS in the GSFA be updated to be consistent with the current functions included in the INS list.

Food Cat No.	Food Category	Max Level (mg/kg)	Step / Notes	Comments
01.6.4	Processed cheese	35000	7 (Note 29)	It should be 2975 mg/kg (as Al)
01.7	Dairy-based desserts (pudding, fruit or flavoured yoghurt)	2000	7 (Note 6)	Please specify the technological function performed by the additive in this food category.
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	2000	7 (Note 6)	Please specify the technological function performed by the additive in this food category.
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	2000	7 (Note 6)	Please specify the technological function performed by the additive in this food category.

05.1.1	Cocoa mixes (powders) and cocoa mass/cake	2000	7 (Notes 6 & 72)	Please specify the technological function performed by the additive in this food category.
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4	350	4 (Note 29)	Please specify the technological function performed by the additive in this food category.
06.2.1	Flours	45000	7 (Note 29)	Considering the maximum content of Al in the salt, the level should be 3825 mg/kg (as Al). According to the Brazilian industry, the actual use of INS 541i in this food category is 1000 mg/kg as Al.
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	2000	7 (Note 6)	Please specify the technological function performed by the additive in this food category.
07.1	Breads and ordinary bakery wares	2000	6 (Note 6)	According to the Brazilian industry, the actual use of INS 541i in this food category is 1000 mg/kg as Al.
07.2.1	Cakes, cookies and pies (e.g., fruit-filled or custard types)	2000	6 (Note 6)	According to the Brazilian industry, the actual use of INS 541i in this food category is 1000 mg/kg as Al.
07.2.2	Other fine bakery products (e.g., doughnuts, sweet rolls, scones, and muffins)	2000	6 (Note 6)	According to the Brazilian industry, the actual use of INS 541i in this food category is 1000 mg/kg as Al.
07.2.3	Mixes for fine bakery wares (e.g., cakes, pancakes)	15300	7 (Note 29)	Considering the maximum content of Al in the salt, the level should be 1300 mg/kg (as Al). According to the Brazilian industry, the actual use of INS 541i in this food category is 1000 mg/kg as Al.
08.3.3	Frozen processed comminuted meat, poultry, and game products	360	Note 6	Please specify the technological function performed by the additive in this food category.
09.2.2	Frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	190	7 (Notes 6 & 41)	Please specify the technological function performed by the additive in this food category.
09.2.4.3	Fried fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	600	Note 6	Please specify the technological function performed by the additive in this food category.
10.4	Egg-based desserts (e.g., custard)	2000	7 (Note 6)	Please specify the technological function performed by the additive in this food category.

### **SODIUM ALUMINOSILICATE**

Sodium Aluminosilicate INS: 554 (3.5% Al)

Function: Anticaking Agent

Food Cat No.	Food Category	Max Level (mg/kg)	Step / Notes	Comments
01.8.2	Dried whey and whey products, excluding whey cheeses	10000	Adopted	It should be 350 mg/kg as Al
06.1	Whole, broken, or flaked grain, including rice	GMP	7	Is this substance used as a food additive or processing aid? What is the technological need?
11.1.2	Powdered sugar, powdered dextrose	15000	Adopted (Note 56)	It should be 525 mg/kg as Al
12.1.1	Salt	Not informed	Adopted	It should be 350 mg/kg as Al
12.1.2	Salt substitutes	10000	7	It should be 350 mg/kg as Al
12.2.2	Seasonings and condiments	30000	3 (Notes 6 and 174)	According to the Brazilian industry, the current use of INS 554 in this food category is <u>875</u> mg/kg (as Al).
12.5.2	Mixes for soups and broths	10000	3 (Notes 6 and 174)	Brazil suggests the maximum level of <u>350</u> mg/kg (as Al).

12.6.3	Mixes for sauces and gravies	10000	3 (Notes 6 and 174)	Brazil suggests the maximum level of <u>350 mg/kg</u> (as Al).
--------	------------------------------	-------	------------------------	--

### CALCIUM ALUMINIUM SILICATE

Calcium aluminium silicate INS: 556

Function: anticaking agent

Food Cat No.	Food Category	Max Level (mg/kg)	Step	Comments
06.1	Whole, broken, or flaked grain, including rice	GMP	6	Is this substance used as a food additive or processing aid? What is the technological need?

### **INDIA**

Under the Food categories 1.6.1, 1.6.2.1 - In relation to the dairy products, the only aluminum containing food additive, from amongst those listed in the Circular Letter, allowed under the Indian food law is aluminum silicate in cheese/sliced/cut/shredded cheese, which includes ripened and unripened cheese, at a level of 10,000 mg/kg on whole aluminum silicate basis.

### **INDONESIA**

Indonesia would like to submit comments on the request for information on the reporting basis of the provisions for aluminium containing food additives, as follow:

### SODIUM ALUMINIUM PHOSPHATE

Food Cat No.	Food Category	Max Level (mg/kg)	Notes	Step	Asumption of Daily exposure of Al
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	2000 <b>120</b>	6	6	Asumption consumption : 100 g Body weight : 60 kg $\frac{2000 \text{ mg/kg} \times 0.1 \text{ kg} \times 100 \%}{1 \text{ mg/kg} \times 60 \text{ kg}}$ = 333,33%
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	2000 <b>120</b>	6	6	Asumption consumption : 100 g Body weight : 60 kg $\frac{2000 \text{ mg/kg} \times 0.1 \text{ kg} \times 100 \%}{1 \text{ mg/kg} \times 60 \text{ kg}}$ = 333,33%
06.2.1	Flours	45000 <b>60</b>	29	6	Molecular weight of sodium aluminium phosphate = 898 Molecular weight of aluminium = 54 Maximum level as aluminium : $\frac{54}{898} \times 45000 \text{ mg/kg} = 2706 \text{ mg/kg}$ Asumption consumption : 100 g Body weight : 60 kg $\frac{2706 \text{ mg/kg} \times 0.1 \text{ kg} \times 100 \%}{1 \text{ mg/kg} \times 60 \text{ kg}}$ = 451 %
06.6	Batters (e.g., for breading or batters for fish or poultry)	1600 <b>96</b>	6	6	Asumption consumption : 5 g Body weight : 60 kg $\frac{1600 \text{ mg/kg} \times 0.05 \text{ kg} \times 100 \%}{1 \text{ mg/kg} \times 60 \text{ kg}}$ = 133%

Indonesia proposes aluminium as reporting basis for provision of Sodium aluminium phosphates and to include Note 6 (“as aluminium”) accordingly and also proposes the maximum level above since the maximum level proposed by Codex is exceed the PTWI of aluminium.

Rationale:

Aluminium is toxic metal having PTWI of 7 mg/kg bw/week which is equivalent to the PTDI 1 mg/kg bw/day. Our maximum level was established by taking into account this PTDI and asumption of consumption. Within the proposed maximum level above could meet the technological function.

**IRAN**

Since Aluminium compound is unsafe to health and causes Alzheimer diseases. Therefore we recommend the re-assessment of its compounds for ADI and the need to use it in food products .

**EUSALT**

The European salt producers would like to comment on provisions related to Sodium Alumino silicate INS 554 function anti caking agent. In this related to food category number 12.1.1 – salt, 2 maximum levels of Sodium Alumino silicate are indicated. One being GMP and one 20.000mg/kg.

The position of EuSalt is to have the establishment of GMP as maximum level for Sodium Alumino silicate. The maximum level of 20.000 mg/kg is from a technological perspective not a feasible level to guarantee the proper functionality in the salt. Levels used in practice are <30.000mg/kg salt. We do not have further comments on the levels proposed for INS 556 and INS 559. We understand that the levels expressed are expressed as aluminium compound and not as aluminium.

**ICGA(International Chewing Gum Association)**

Food Additive	Food additive INS	Max Level	Notes	Step	Reporting basis(to be filled by ICGA)
Aluminium Silicate	559	GMP 100 ppm	3, 6 & 174	3	ICGA would like to stress that 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 such cases is limited to what is strictly necessary to achieve the technological effect, according to the <i>quantum satis</i> 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. Should the CCFA decide to change the GMP level to a numerical maximum level, ICGA would appreciate that 100 ppm expressed as Aluminium be given due consideration. In order to reflect various legal statuses, we would further suggest deleting the reference to Footnote 3 (i.e. surface treatment only), as some products subject to international trade may contain such additives in the gum part of the product (therefore not absorbed).
Calcium Aluminium Silicate	556	GMP 100 ppm	3, 6 & 174	3	ICGA would like to stress that 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 such cases is limited to what is strictly necessary to achieve the technological effect, according to the <i>quantum satis</i> 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. Should the CCFA decide to change the GMP level to a numerical maximum level, ICGA would appreciate that 100 ppm expressed as Aluminium be given due consideration. In order to reflect various legal statuses, we would further suggest deleting the reference to Footnote 3 (i.e. surface treatment only), as some products subject to international trade may contain such additives in the gum part of the product (therefore not absorbed).

Sodium Aluminosilicate	554	GMP 100 ppm	3, 6 & 174	3	<p>ICGA would like to stress that 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 such cases is limited to what is strictly necessary to achieve the technological effect, according to the <i>quantum satis</i> 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. Should the CCFA decide to change the GMP level to a numerical maximum level, ICGA would appreciate that 100 ppm expressed as Aluminium be given due consideration. In order to reflect various legal statuses, we would further suggest deleting the reference to Footnote 3 (i.e. surface treatment only), as some products subject to international trade may contain such additives in the gum part of the product (therefore not absorbed).</p>
------------------------	-----	----------------	------------	---	---