



**Food and Agriculture
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Agenda Item 5(b)

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

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RECOMMENDATIONS FOR PROVISIONS FOR ALUMINIUM CONTAINING FOOD ADDITIVES OF THE GSFA

Prepared by an electronic Working Group lead by the United States of America, with the assistance of Argentina, Australia, Brazil, the European Union, Japan, Netherlands, Spain, Thailand, EuSalt, IACM, ICGA, ICGMA, IDF and IFAC

Background

1. 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 (MLs) are numeric and expressed on an aluminium basis, consistent with the provisional tolerable weekly intake (PTWI) assigned by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)¹.
2. The 43rd Session of the CCFA agreed to revoke or discontinue work on all provisions with non-numerical maximum use levels for aluminium-containing food additives in the GSFA², and to recommend that the 34th Session of the Codex Alimentarius Commission (CAC) 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 aluminium-containing food additives should have a numerical ML.
3. The 43rd Session of the CCFA agreed to re-establish an eWG, led by Brazil, to revise the compilation of provisions and proposals in CX/FA 11/43/10, and to make recommendations for the adoption, discontinuation, or revocation, of these provisions, including those for new uses, at its 44th Session⁴.
4. The 44th Session of the CCFA agreed to revoke or discontinue work on all provisions recommended for revocation or discontinuation in CX/FA 12/44/10, with the exception of specific provisions for aluminium ammonium sulfate (INS 523) and sodium aluminosilicate (INS 554).⁵ The CCFA also agreed to re-establish an eWG, led by the United States of America, to continue work on the remaining Recommendations 4 (adopt), 5 (discuss further), and 6 (circulated for comment) in CX/FA 12/44/10.⁶

Working Document

5. This document contains proposals on the existing draft and proposed draft provisions for aluminium-containing food additives in the GSFA, as well as new provisions recommended for circulation at step 3 in CX/FA 12/44/10. To provide context for these recommendations, this document also summarizes comments provided in CX/FA 12/44/10, with corrections as noted in CX/FA 12/44/10 Add. 1, as well as comments made by the current eWG. This document also includes the specific provisions and proposed MLs for aluminium ammonium sulfate (INS 523) and sodium aluminosilicate (INS 554) discussed in REP 12/FA.⁵

¹ ALINORM 10/33/12, paras. 78-83.

² REP11/FA, Appendices IV and V.

³ REP11/FA, Appendix IV.

⁴ REP11/FA, para. 91.

⁵ REP12/FA, para. 104.

⁶ REP 12/FA, para.133.

6. The proposals in this document are grouped by food additive, and sorted into the five following eWG recommendations: Recommendation 1) Discontinue; Recommendation 2) Adopt; Recommendation 3) Discuss further; Recommendation 4) Circulate for comment; and Recommendation 5) Stop work. The same recommendation number is always associated with the same recommendation action (e.g., Recommendation 1 will always be “Discontinue”). However, it is important to note that not all recommendations will be associated with every additive. As an example, there is no “Recommendation 3: Discuss further” for the additive Aluminium ammonium sulfate (INS 523), because there were no provisions that the eWG recommended for further discussion.

7. The eWG proposal for each provision is indicated in underlined font. In cases where the proposal differs from the draft or proposed draft provision currently in the GSFA, the eWG proposal is indicated in **bold, underlined** font and the provision currently in the GSFA is indicated in ~~strike through~~ font. The current status of each provision within the step process is indicated in the “step” column. For those provisions recommended for circulation at step 3 in CX/FA 12/44/10, the corresponding field in the “step” column is left blank.

8. The proposals in this document are based upon a consensus approach, taking into account comments presented in CX/FA 12/44/10 and comments by members of the current eWG. These recommendations are based on a “weight of evidence” approach; that is, comments containing justifications were given more weight than comments with no supporting justification. The following criteria were also considered:

- For consistency with the decisions of the 44th CCFA, only numerical MLs reported on an “as aluminium” basis (i.e., including Note 6 (“As aluminium.”)) were considered. eWG members were asked to consider the average percentage of aluminum among the molecular formulas when more than one molecular formula is identified for an aluminium-containing additive.⁷
- The need to further reduce the use and MLs of aluminium-containing food additives, and to seek alternatives to these food additives.⁸
- Adherence to the *Procedures for consideration of entry and review of food additive provisions in the General Standard for Food Additives* (GSFA)⁹, in particular, in providing technological justification. Section 3.2 of the Preamble to the GSFA establishes the criteria for justifying the use of a food additive. Comments containing only a proposed ML with no justification were given low priority. Since the purpose of the present work is to revise the existing provisions in light of the revised PTWI (2 mg/kg body weight, 74th JECFA), the use of all aluminium-containing food additives should be justified.
- Whenever there is a provision for sodium aluminium silicate (INS 554), calcium aluminium silicate (INS 556) and/or aluminium silicate (INS 559) in the same food category, Note 174 (“Singly or in combination: sodium aluminium silicate (INS 554), calcium aluminium silicate (INS 556), and aluminium silicate (INS 559).”) should be included.
- Submissions for sodium aluminium phosphates (INS 541(i), 541(ii)) should specify the particular additive (i.e., sodium aluminium phosphate, acidic (INS 541(i)), or sodium aluminium phosphate, basic (INS 541(ii))), as appropriate, for each food category.

9. General comments from eWG members on aluminium-containing food additives are presented in Appendix 1 to this document. Proposals on specific provisions for aluminium-containing food additives are presented in Appendix 2.

⁷ REP 12/FA, para. 102.

⁸ REP 12/FA, para. 103.

⁹ Procedural Manual, 20th Ed., Section II: Elaboration of Codex Standards and Related Texts, p. 57.

Appendix 1: General Comments by eWG Members

European Union (EU):

The EU welcomes the work on aluminium-containing food additives based on the recommendation to decrease their use to the extent possible (REP 11/FA, paragraph 79). In the EU the conditions of use and the use levels for aluminium-containing food additives were already revised. In this exercise the provisions for INS 556 calcium aluminium silicate and INS 559 aluminium silicate were revoked since these substances can be replaced by other food additives (e.g. INS 551 silicon dioxide, INS 552 calcium silicate and INS 553(i) magnesium silicate, synthetic). The EU recommends that CCFA follows the same approach.

As highlighted by JECFA (74th Report, p. 15) major contributors to exposure estimates were cereals and cereal-based food products (20–90%). It was also noted that high levels of the actual uses of aluminium-containing food additives were reported in these foodstuffs, in particular for sodium aluminosilicate (INS 554) and sodium aluminium phosphate acidic (INS 541(i)). Therefore, CCFA should be very prudent on provisions related to cereals and cereal-based food products and avoid the use of aluminium-containing food additives where possible. The same principle should apply also to other staple foodstuffs.

As a follow-up to the current exercise other sources of aluminium as regards the use of food additives should be examined. Specifically it relates to aluminium lakes of colouring matters and specifications revision of food additives contaminated with aluminium (e.g. INS 341 calcium phosphates, INS 450 diphosphates and INS 333 calcium citrate).

The Netherlands:

As indicated in the first circular, the focus of this work should be on further reducing the use and MLs of aluminium-containing food additives, and to seek alternatives for these food additives. Consequently, we suggest that in cases where Codex Members propose different MLs, the lowest instead of the highest ML would be used as starting point for the discussion in the working group.

In addition, calciumaluminumsilicate (INS 556) and aluminumsilicate (INS 559) can possibly be replaced by other food additives [for instance silicon dioxide (INS 551), calcium silicate (INS 552) and magnesium silicate (INS 553 (i))]. Therefore, we would suggest that alternatives will be considered to replace INS 556 and INS 559 for the respective applications.

For the remaining food additives (INS 523, 554, 541(i) and 541 (ii)) we recommend to discontinue the work in staple and other highly consumed foods for safety reasons. The use levels proposed for these foods will easily result in regular exposures above the PTWI.

The PTWI for aluminium is 2 mg/kg bw/week. This corresponds to 30 mg/week for a 15 kg child and 120 mg/week for a 60 kg adult. In the table below, it is indicated how much of a food can be consumed per week at use levels of 50, 500 and 5000 mg/kg food before the PTWI is exceeded:

Maximum use level (mg/kg as Al)	Weekly portion that corresponds with 100% of PTWI	
	Child (15 kg)	Adult (60 kg)
50	600	2400
500	60	240
5000	6	24

For foods that are consumed in amounts of approximately 10 g/day or 60 g/week or more by children, a maximum use level of 500 mg/kg as Al already leads to an exposure at the level of the PTWI. It will be obvious that there will also be exposure to aluminium from other foods containing aluminium-containing food additives and from natural occurrence in food. We therefore recommend to discontinue the work on proposals related to processed, ripened and unripened cheese, flours, batters, bread and ordinary bakery wares, cake cookies and pies, other fine bakery products and mixes for fine bakery wares.

Thailand:

We generally support the decrease of the use of aluminium-containing food additive and also the alternative food additive if it is possible. We also think that all proposed MLs for aluminium-containing food additives of the GSFA should take into account technological justification and safety concern including the intake of aluminium from aluminium-containing food additive that may exceed PTWI. In case the technological needs for the aluminium-containing food additives have been reported by several countries, we would like to support the lowest ML.

Besides, we recommend that the provisions for aluminium-containing food additives in the commodity standards such as CODEX STAN 251-2006 (Blend of Skimmed Milk and Vegetable Fat in Powdered Form), CODEX STAN 263-1966 (Cheddar), CODEX STAN 207-1999 (Milk Powders and Cream Powders), CODEX

STAN 283-1978 (Cheese), should be revised since the PTWI by JECFA is changed from 7 mg/kg b.w. to 2 mg/kg b.w.

The United States of America (USA):

Sodium aluminosilicate (INS 554): 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 (Note 6), in accordance with good manufacturing practices (GMP). However, the USA has no data on numerical use levels of this additive in specific food categories.

Use of food additives in batters in food categories 08.3.3, 09.2.2, and 09.2.4.3: The USA notes that Recommendation 5 (further discussion) of the first circular contains a provision for sodium aluminium phosphates (INS 541(i),(ii)) in food category 06.6 (Batters (e.g., for breading or batters for fish or poultry)), but also includes provisions in food categories 08.3.3 (Frozen processed comminuted meat, poultry, and game products), 09.2.2 (Frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms), and 09.2.4.3 (Fried fish and fish products, including mollusks, crustaceans, and echinoderms), where justification is given for the use of sodium aluminium phosphates as raising agents in the battered portion of these foods. The USA is of the opinion that the use of food additives in the batter portion of foods is best captured in food category 06.6 (Batters (e.g., for breading or batters for fish or poultry)), rather than in the food category for the finished battered product, which could include a note restricting the use of the additive to the batter portion only (i.e., Note 41 (“Use in breading and batter coatings only.”)). As such, the USA supports the provision for the use of sodium aluminium phosphates in food category 06.6 (Batters (e.g., for breading or batters for fish or poultry)) at a maximum use level of 1600 mg/kg as aluminium (Note 6), and recommends that the work on the provisions in food categories 08.3.3 (Frozen processed comminuted meat, poultry, and game products), 09.2.2 (Frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms), and 09.2.4.3 (Fried fish and fish products, including mollusks, crustaceans, and echinoderms) be discontinued.

The USA also notes the food additives sections of some commodity standards list specific additives for use in the breading or batter coating of the food, for example, the *Codex Standard for Quick Frozen Fish Sticks (Fish Fingers), Fish Portions and Fish Fillets – Breaded or in Batter* (CODEX STAN 166-1989). It is the opinion of the USA that the integration of food additive provisions listed in commodity standards for use in breading or batter coatings is not within the terms of reference for this eWG, and should instead be addressed by the Codex Committee on Food Additives as part of the integration of the commodity standards into the GSFA.

European Salt Producers Association (EuSalt):

For the use of Sodium Aluminosilicate (INS 554) in Food Category 12/1/1 (Salt): After consultations with the technical experts on the different reference units we have used in presenting the previous EuSalt comments and keeping in line with the decisions of the 44th CCFA, to only report numerical maximum levels (MLs) reported on an “as aluminium” basis, EuSalt has reconsidered the previous introductions and proposes to have a level set as MLs: 1.000 mg/kg as Al in salt. This level is based on the technological requirements for using E554 in salting the crust of specific cheeses” à pâte molle “. These soft cheeses have the growth of a crust and require a homogeneous diffusion of salt on this crust. With this homogeneous diffusion it will achieve an equal formation of this crust. To obtain this equal spreading the specific ultra-fine salt used in this processing of the cheese requires E554 as an anti-caking agent. There are no alternatives yet available that provides similar technical properties. Taking into considerations the health concerns and comments from the delegations, we confirm our aim to adhere to the highest safety standard. In this respect we provide the available ingestion figures of salt, which are in line with those provided in the comments of IDF. However as this concern specific cheeses, the levels provided are overestimations of the real consumption through this salt. The salt containing E554 is only used for this specific topical use on the cheese. The level of E554 in salt is less than 1% (so inferior to 10.000mg/kg salt). This means a dose of 1000mg/kg Al in salt. Taking into consideration a typical salination of the cheese to a maximum dosage of 2% in the cheese; it leads to a use of 200mg/kg E554 in cheese, so an Al-level of maximum 20mg/kg cheese, so it would not contribute to a major consumption in the overall consumption and limits the safety concern.

The International Aluminium Institute (IAI):

We propose, as have others, that wherever the levels of aluminium in food additives would not be expected to contribute significantly to total aluminium intake, the use of the additive material in question be accepted.

International Chewing Gum Association (ICGA):

We fully agree with your initial proposal to adopt a maximum level of 100 mg/kg for each INS 554, 556 and 559 in food category 5.3 Chewing gum, expressed as Aluminium and singly or in combination. We further suggest this eWG to consider as appropriate to recommend these three provisions to be proposed for

advancement at step 5/8 by the forthcoming 45th session of FCCFA, with the added notes 6 (“As aluminium”) and 174 (“Singly or in combination: sodium aluminium silicate (INS 554), calcium aluminium silicate (INS 556), and aluminium silicate (INS 559)”). Indeed, these provisions deem to replace the longstanding GMP levels which have been approved and in force in Table 3 (and therefore authorized in chewing gum) from 1995 to 2011 by the Codex community.

As reported in the Background section of the First Circular document sent to the present electronic Working Group, the 43rd session of the CCFA Committee (March 2011) agreed to ask Codex members and observers to provide comments on numerical values expressed on an aluminium basis through an electronic working group led by Brazil for all revoked provisions (i.e. those which were included in the draft GSFA at the time but also all those which were covered by the GMP use level as previously listed in the Table 3 of the adopted GSFA). In that context, ICGA provided comprehensive technical comments, which were reported in CX/FA 12/44/10 and presented at the 44th session of CCFA (March 2012). ICGA former comments have been reported at the end of this First Circular document under *Recommendation 6* but one exception: these use levels are not “*new proposed uses*” as proposed by ICGA *per se*. These use levels correspond rather to a summary of the maximum use levels reported by ICGA members to us for products in international trade. Therefore they can be considered as the former “GMP levels”, when these three food additives were duly included in the adopted Table 3 of published GSFA and therefore were duly authorized for use at these GMP levels in chewing gum from 1995 to 2011 by the Codex community.

International Food Additives Council (IFAC):

As a general comment, we stress the importance of establishing maximum levels (MLs) for aluminium-containing additives at levels above the minimum level required for the ingredient to be used effectively to achieve a desired technical effect. We strongly urge the eWG to reject the suggestion that using or even starting with the “lowest” level proposed is a feasible option. This type of approach has no scientific basis and will ensure that many MLs are established below thresholds that allow these substances to be used effectively. We reiterate our belief that all MLs should be science-based and encourage the eWG to consider all perspectives shared by eWG members on MLs.

The International Dairy Federation (IDF):

Though IDF normally supports the provisions for food additives that have been included and are technologically justified in the corresponding Codex milk product commodity standards (e.g. the use of the aluminium-containing food additives which act as anti-caking agents), in this case we would not oppose the deletion of the provisions for these additives in the various milk product related food categories, in light of the efforts to reduce their levels of use.

In most circumstances the availability of alternative food additives with similar functions should be adequate in these circumstances (e.g. the other silicates and other anti-caking agents and permitted ingredients). Indeed we should like to point out that the dairy industry has tended to replace these food additives with other alternatives on a voluntary basis in recent years.

There is one particular use for which we would request retention of the use of one of these additives however; that is in the case of the requirement for and use of **INS 554 (aluminosilicates)** in **salt** (FC 12.1.1) used in the dry salting of certain varieties of cheese.

Technological Justification:

In this case **INS 554** is 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.

Appendix 2:Proposals for Specific Provisions for Aluminium-Containing Additives**ALUMINIUM AMMONIUM SULFATE (INS 523)**

Recommendation 1 - Aluminium ammonium sulfate (INS 523)					
The eWG recommends that the 45 th CCFA discontinue the following food additive provisions for Aluminium ammonium sulfate in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
06.2	Flours and starches (including soybean powder)	100 mg/kg	6	3	EU, Japan, Netherlands, Spain, Singapore: Support discontinuation
07.1.2	Crackers, excluding sweet crackers	10000 mg/kg	29 ¹⁰	3	EU: Discontinue Japan: Supports adoption at 500 mg/kg with Note 6. Aluminium ammonium sulfate acts as a raising agent by reacting with sodium hydrogen carbonate and generating carbon dioxide to inflate crackers and ice-cream cones. Industry reports that Aluminium ammonium sulfate acts slowly and keeps on acting during heat processing. No other raising agents can perform such effects. Netherlands: Discontinue: use in staple food may result in intake over PTWI. Singapore: appears to be used as an acid in leavening system. Alternatives such as potassium tartrate and glucono delta-lactone may serve same purpose. If alternatives are suitable, provision should be discontinued. Spain: Discontinue - several raising agents authorized in this category. It would not be appropriated to add a functional class to this product given the JECFA recommendation. Thailand: Discontinue: using national food consumption data, we found that the intake of young children (3-6 years old) were likely to exceed the PTWI (116-205% PTWI) from the consumption of these products.
07.1.3	Other ordinary bakery products (e.g., bagels, pita, English muffins)	10000 mg/kg	29	3	EU: Discontinue Japan: Supports adoption at 500 mg/kg with Note 6. Aluminium ammonium sulfate acts as a raising agent by reacting with sodium hydrogen carbonate and generating carbon dioxide to inflate dough of biscuits. Industry reports that Aluminium ammonium sulfate acts slowly and keeps on acting during heat processing. No other raising agents can perform such effects. Netherlands: Discontinue: use in staple food may result in intake over PTWI. Singapore: Appears to be used as an acid in leavening system. Alternatives such as potassium tartrate and glucono delta-lactone may serve same purpose. If alternatives are suitable, provision should be discontinued. Spain: Discontinue, several raising agents authorized in this category. It would not be appropriated to add a functional class to this product
07.1.4	Bread-type products, including bread stuffing and bread crumbs	100 mg/kg	6, 29	3	EU, Japan, Netherlands, Singapore, Spain, Thailand: Support discontinuation
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	100 mg/kg	6, 29	3	EU, Japan, Netherlands, Singapore, Spain, Thailand: Support discontinuation
09.2	Processed fish and fish products, including mollusks, crustaceans, and echinoderms	100 mg/kg	6	3	EU, Japan, Netherlands, Singapore, Spain,: Support discontinuation

¹⁰ **Note 29** Reporting basis not specified

Recommendation 1 - Aluminium ammonium sulfate (INS 523)					
The eWG recommends that the 45 th CCFA discontinue the following food additive provisions for Aluminium ammonium sulfate in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
09.3	Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	100 mg/kg	6	3	EU, Japan, Netherlands, Singapore, Spain: Support discontinuation
15.1	Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	500 mg/kg	6	3	EU, Spain, Thailand: Support discontinuation Japan: Withdraw previous proposal, industry indicates that there are no valid reasons.

Recommendation 2 - Aluminium ammonium sulfate (INS 523)					
The eWG recommends that the 45 th CCFA adopt the following food additive provisions for Aluminium ammonium sulfate in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	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 520 mg/kg	6 ¹¹ , New note: <u>“Except for use in perilla in brine at 780 mg/kg”</u>	3	Brazil: Suggest new note: “for eggplants and perilla in brine only.” Note that other products in this food category correspond to commodity standards, which do not allow use of this additive. EU: Excessive max level – for children the consumption of only 5.5 g/d or 38 g/w would lead to PTWI Japan: Aluminium ammonium sulfate is used to retain colour. Industry reports that other colour retention agents do not act sufficiently since natural colour of vegetable is lost during processing. Industry has been searching for a substitute for Aluminium containing food additives, however, currently the desired effect cannot be obtained by the use of other food additives. Note that aluminium ammonium sulfate is used not only in eggplants and perilla in brine, but also other type of products categorized in food category 4.2.2.3. Spain: Can other colour retention agents be used? Support new note suggested by Brazil.
06.4.1	Fresh pastas and noodles and like products	470 mg/kg 300 mg/kg	6, New note: <u>“For use in starch noodles only”</u>	3	EU: - staple food for certain consumers - for children the consumption of only 14 g/d or 100 g/w would lead to PTWI. Are the products in question traded internationally (do they have to be included to CODEX?) If yes, it can be restricted to " <i>kuzukiri and harusame only</i> " Japan: Aluminium ammonium sulfate serves as a firming agent. It reacts with proteins in flours and enhances hard texture of noodles, allowing them to keep their shape during boiling process. The use of food additive in this category is limited to Japanese traditional starch noodles such as " <i>kuzukiri</i> " and " <i>harusame</i> " only. According to industry, they have been searching for a substitute for Aluminium-containing food additives, however, the desired effect cannot be obtained by the use of other additives. Netherlands: Reconsider maximum use level. This maximum use level could contribute significantly to the total exposure to aluminium. A consumption of 100 g/week by a child and 400 g/week by an adult would fill up the PTWI. Spain: agree with proposal Thailand: Support proposal with new note.
07.1.5	Steamed breads and buns	40000	29, 6,	3	EU: discontinue – alternative raising agents available

¹¹ **Note 6** As aluminium

Recommendation 2 - Aluminium ammonium sulfate (INS 523)					
The eWG recommends that the 45 th CCFA adopt the following food additive provisions for Aluminium ammonium sulfate in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
		mg/kg 40 mg/kg	New Note: “For use as a raising agent”		Japan: Aluminium ammonium sulfate acts as raising agent. It reacts with sodium hydrogen carbonate (NaHCO ₃) and generates carbon dioxide to inflate steam bread. Aluminium ammonium sulfate acts slowly and its effects holds long, which contributes to the softness and volume of the products. The industry has been searching for the substitute for Aluminium containing food additives, however, currently the desired effect cannot be obtained by the use of other food additives. Singapore: Appears to be used as an acid in leavening system. Alternatives such as potassium tartrate and glucono delta-lactone may serve same purpose. If alternatives are suitable, provision should be discontinued. Spain : Discontinue, several raising agents authorized in this category. Use information should be provided. Thailand: Supports adoption with note.
07.1.6	Mixes for bread and ordinary bakery wares	10000 mg/kg 40 mg/kg	29, 6, New note: “For use as a raising agent in mixes for steamed breads and buns corresponding to food category 07.1.5”	3	EU: discontinue – alternative raising agents available Japan: Aluminium ammonium sulfate acts as raising agent. It reacts with sodium hydrogen carbonate (NaHCO ₃) and generates carbon dioxide to inflate steam bread. Aluminium ammonium sulfate acts slowly and its effects holds long, which contributes to the softness and volume of the products. The industry has been searching for the substitute for Aluminium containing food additives, however, currently the desired effect cannot be obtained by the use of other food additives. Singapore: appears to be used as an acid in leavening system. Alternatives such as potassium tartrate and glucono delta-lactone may serve same purpose. If alternatives are suitable, provision should be discontinued. Spain : Discontinue, several raising agents authorized in this category. Use information should be provided.
09.2.4	Cooked and/or fried fish and fish products, including mollusks, crustaceans, and echinoderms	200 mg/kg	6	Adopted 2004	Recommend revising currently adopted provision in 09.2.4 to the subcategory 09.2.4.2. Brazil: Questions technological need in food category 09.2.4. Recommends addition of note “For use in tsukudani only” for food category 09.2.4. EU: Revoke provision in 09.2.4. It should be explained why other alternatives are not suitable Japan: Change provision in 09.2.4 to only cover subcategory 9.2.4.2 “Cooked molluscs, crustaceans, and echinoderms” at a maximum use level of 200 mg/kg as Al (Note 6). Justification: Aluminium ammonium sulfate is used as firming agent in boiled molluscs and tsukudani to maintain firmness during processing. Japan does not support use of note “for use in boiled octopus and tsukudani only” for provision in food category 09.2.4.2 because, reported from industry, aluminium ammonium sulfate is used not only in boiled octopus and tsukudani, but also other type of products made from raw materials categorized in food category 9.2.4.2. Spain: Agree with inclusion of new note “For use in boiled molluscs and tsukudani only” for provision in food category 09.2.4. Restrict to food category 09.2.4.2 if technologically justified. Thailand: Revoke provision in 09.2.4. We found that the intake of young children (3-6 years old) were likely to exceed the PTWI (106-141% PTWI)
09.2.4.2	Cooked mollusks, crustaceans, and echinoderms	200 mg/kg	6		

Recommendation 4 - Aluminium ammonium sulfate (INS 523)					
The eWG recommends that the 45 th CCFA Circulate for comments at Step 3 the following food additive provisions for Aluminium ammonium sulfate in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
06.4.2	Dried pastas and noodles and like products	300 mg/kg	6, <u>New Note:</u> "For use in Japanese traditional starch noodles, such as Kuzukiri and Harusame only."		EU does not support - staple food; are these traditional products internationally traded – is the provision in Codex necessary? Japan: Support 300 mg/kg as Al with new note, "For use in Japanese traditional starch noodles, such as Kuzukiri" and "Harusame" only." Industry reported that Aluminium ammonium sulfate acts as firming agent to make starch noodles firm and to keep its shape during boiling process. According to industry, they have been searching the substitute for Aluminium-containing food additives, however, the desired effect cannot be obtained by the use of other additives. Netherlands: A consumption of 100 g/week by a child and 400 g/week by an adult would fill up the PTWI. Singapore: Does not support - Starch noodles (e.g. rice vermicelli or bean vermicelli) are a staple in the Asian diet. Consequently use of INS 523 at the level of 300 mg/kg (as Al) may lead to a dietary exposure to aluminium which is above the PTWI. Thailand: Stop work
06.6	Batters (e.g., for breading or batters for fish or poultry)	160 mg/kg	6, New note "For use in tempura and deep fried products only"		EU: Stop work. 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) Japan: Supports 160 mg/kg with new note. Reported from industry, Aluminium ammonium sulfate acts slowly and its effects holds long, which contributes to the crispness of batter. The industry has been searching for the substitute for Aluminium containing food additives, however, currently the desired effect cannot be obtained by the use of other food additives.
07.2.3	Mixes for fine bakery wares (e.g., cakes, pancakes)	980 mg/kg	6		EU: Stop work – excessive ML – intake concerns Japan: Reported from industry, Aluminium ammonium sulfate acts slowly and its effects holds long, which contributes to the softness of the products. The industry has been searching for the substitute for Aluminium containing food additives, however, currently the desired effect cannot be obtained by the use of other food additives. Netherlands: safety concerns due to high intake in staple food. A consumption of 31 g/week by a child and 122 g/week by an adult would fill up the PTWI. Singapore: are there suitable, non-Al containing additives which would serve the intended use? If so, Stop work Spain: Stop work, wide consumption, several other rising agents allowed in this FC, should not add tech function to additive.
09.1.2	Fresh mollusks, crustaceans and echinoderms	500 mg/kg	6, New note "For use in sea urchins only"		Japan: Functional class: Firming agent. Justification: 1) To keep tissue firm by protein denaturation of sea urchins; 2) To keep tissue fresh by inhibition of growing microorganism. 3) 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 Spain: firming agents in this FC could mislead the consumer, limit to use in sea urchins only.
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	600 mg/kg	6, New note: "For use in salted jellyfishes only"		EU: Technological need questioned Japan: Used in salted jelly fish as a firming agent to maintain firmness, no codex standard covers this use. Spain: Support with new note for use in salted jellyfishes only

Recommendation 4 - Aluminium ammonium sulfate (INS 523)					
The eWG recommends that the 45 th CCFA Circulate for comments at Step 3 the following food additive provisions for Aluminium ammonium sulfate in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
12.4	Mustards	720 mg/kg	6		Japan: Aluminium ammonium sulfate is used to keep mustard spicy by adjusting pH. Reported from industry, if other acidity regulators are used for the substitute for aluminium ammonium sulfate, they make mustard sour. However, consumer prefers spicy mustard to sour one. The industry has been searching for the substitute for Aluminium containing food additives, however, currently the desired effect cannot be obtained by the use of other food additives. Spain: Stop work, do not add functional class to additive, several acidity regulators in Table 3 could be used instead.

Recommendation 5 - Aluminium ammonium sulfate (INS 523)					
The eWG recommends that the 45 th CCFA Stop work the following food additive provisions for Aluminium ammonium sulfate in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
07.2.1	Cakes, cookies and pies (e.g., fruit-filled or custard types)	96 mg/kg	6		Japan: Withdraws proposal Netherland, Singapore, Spain: Stop work
07.2.2	Other fine bakery products (e.g., doughnuts, sweet rolls, scones, and muffins)	170 mg/kg	6		Japan: Withdraws proposal Netherland, Singapore, Spain: Stop work

SODIUM ALUMINIUM PHOSPHATES (ACIDIC AND BASIC) (INS 541(i), (ii))¹²

Recommendation 1 - Sodium aluminium phosphates (acidic and basic) (INS 541(i), (ii))					
The eWG recommends that the 45 th CCFA discontinue the following food additive provisions for Sodium aluminium phosphates in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
01.6.1	Unripened cheese	670 mg/kg	6	3	Brazil, EU, Netherlands, Spain, CEFIC, IFAC: discontinue
08.3.3	Frozen processed comminuted meat, poultry, and game products	360 mg/kg	6	3	EU, Netherlands, Spain supports discontinuation Singapore: Discontinue – use in batters is captured in FC 06.6 IFAC: 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, 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 at 470 mg/kg as Al. Should the eWG decide not to list Sodium Aluminium Phosphate in this category to cover the battered portion of the product, we recommend a note be added to this category, referring readers to category 6.6, Batters, where it is permitted, and thus it would be also allowed for use in this category
09.2.2	Frozen battered fish, fish fillets, and fish products,	190 mg/kg	6 & 41 ¹³	6	EU, Netherlands, Spain supports discontinuation Mexico: 10,000 mg/kg as Al

¹² A provision for food category 16.0 (Prepared foods) was discussed in the eWG and recommended for discontinuation. However, upon further review, it was found that this provision was already discontinued at the 44th CCFA (REP 12/FA, para. 112). As a result, a provision for the use of sodium aluminium phosphates in food category 16.0 was included in this document.

¹³ **Note 41** Use in breading or batter coatings only

Recommendation 1 - Sodium aluminium phosphates (acidic and basic) (INS 541(i), (ii))					
The eWG recommends that the 45 th CCFA discontinue the following food additive provisions for Sodium aluminium phosphates in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
	including mollusks, crustaceans, and echinoderms				<p>Singapore: Discontinue – use in batters is captured in FC 06.6</p> <p>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</p> <p>IFAC: 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, 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 at 470 mg/kg as Al. Should the eWG decide not to list Sodium Aluminium Phosphate in this category to cover the battered portion of the product, we recommend a note be added to this category, referring readers to category 6.6, Batters, where it is permitted, and thus it would be also allowed for use in this category</p>
09.2.4.3	Fried fish and fish products, including mollusks, crustaceans, and echinoderms	600 mg/kg	6	3	<p>EU, Netherlands, Spain supports discontinuation</p> <p>Singapore: Discontinue – use in batters is captured in FC 06.6</p> <p>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.)</p>
12.6.3	Mixes for sauces and gravies	2000 mg/kg	6 & 127 ¹⁴	6	<p>EU does not support - no convincing justification provided – it should be explained why other emulsifiers and stabilisers cannot achieve the desired effect</p> <p>IFAC: Support 120 mg/kg as Al. INS 541ii is used as an emulsifier and stabilizer, especially for cheese sauces.</p>

Recommendation 2 - Sodium aluminium phosphates (acidic and basic) (INS 541(i), (ii))					
The eWG recommends that the 45 th CCFA adopt the following food additive provisions for Sodium aluminium phosphates in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
07.1	Bread and ordinary bakery wares	2000 mg/kg 900 mg/kg	6	6	<p>Brazil - ML of 1,000 mg/kg as Al 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.</p> <p>Canada: ML of 2340 mg/kg for INS 541i reported by food industry.</p> <p>EU: Strongly opposes. According to the GSFA Preamble section 1.4 the primary objective of establishing ML for food additives is to ensure that the intake of an additive from ALL its uses does not exceed its ADI. Bread and ordinary bakery wares are staple food - for children the consumption of only 4.2 g/d or 30 g/w would lead to PTWI! Cereal products are the main contributors as indicated by JECFA</p> <p>Mexico: Recommends 10,000 mg/kg as Al.</p> <p>Netherlands, Spain: safety concerns due to high intake in staple food. A consumption of 30 g/week by a child and 120 g/week by an adult would fill up the PTWI.</p> <p>Thailand: supports the ML of 900 mg/kg proposed by ICGMA as it is the lowest ML which has an intentional technological function in the products.</p>

¹⁴ **Note 127** As sold to the consumer.

Recommendation 2 - Sodium aluminium phosphates (acidic and basic) (INS 541(i), (ii))					
The eWG recommends that the 45 th CCFA adopt the following food additive provisions for Sodium aluminium phosphates in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
					<p>ICGMA: Recommend adoption at 900 mg/kg as AI for INS 541i. Additive 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)</p> <p>IFAC: Adopt level of 1600 mg/kg as AI for 541i; functions as a raising agent in this category</p>
07.2.1	Cakes, cookies and pies (e.g., fruit-filled or custard types)	2000 mg/kg 190 mg/kg	6	6	<p>Canada: 980 mg/kg as AI for INS 541i reported by food industry as leavening agent</p> <p>EU: opposes to this generic permission - for children the consumption of only 4.2 g/d or 30 g/w would lead to PTWI –alternatives should cover the need of the vast majority of the products</p> <p>Netherlands, Spain: safety concerns due to high intake in staple food. A consumption of 30 g/week by a child and 120 g/week by an adult would fill up the PTWI.</p> <p>Thailand: Support adoption of 190 mg/kg as AI proposed by ICGMA as it is the lowest ML which has an intentional technological function in the products.</p> <p>ICGMA: Support adoption at 190 mg/kg with Note 6, member companies have looked into possible replacements for INS 541(i) - Potential substitutes have thus far proven to be ineffective, impacting both the taste (metallic), consumer acceptability, and “bake” profile negatively.</p> <p>IFAC: Adopt at 1000 mg/kg with Note 6</p>
07.2.2	Other fine bakery products (e.g., doughnuts, sweet rolls, scones, and muffins)	2000 mg/kg 900 mg/kg	6	6	<p>Brazil: Adopt 1000 mg/kg as AI for INS 541i</p> <p>Canada: 980 mg/kg as AI for INS 541i reported by food industry as leavening agent</p> <p>EU opposes – excessive ML; alternative raising agents should cover the vast majority of the products</p> <p>Mexico: 10,000 mg/kg as AI</p> <p>Netherlands, Spain: safety concerns due to high intake in staple food. A consumption of 30 g/week by a child and 120 g/week by an adult would fill up the PTWI.</p> <p>Thailand: Adopt 900 mg/kg proposed by ICGMA as it is the lowest ML which has an intentional technological function in the products.</p> <p>ICGMA: Adoption at 900 mg/kg as AI 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)</p> <p>IFAC: Adopt at 1600 mg/kg as AI for INS 541i for use as raising agent.</p>
07.2.3	Mixes for fine bakery wares (e.g., cakes, pancakes)	15300 mg/kg 900 mg/kg	29 6	6	<p>Argentina: 1000 mg/kg as AI provided overall intake from all sources does not exceed PTWI – used as raising agent in cakes, muffins, fine bakery mixes to achieve texture and volume</p> <p>Brazil: ML of 1,000 mg/kg as AI 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.</p> <p>Canada: 2340 mg/kg as AI for INS 541i reported by food industry as leavening agent</p> <p>EU opposes – excessive ML; alternative raising agents should cover the vast majority of the products</p> <p>Netherlands, Spain: safety concerns due to high intake in staple food. A consumption of 30 g/week by a child and 120 g/week by an adult would fill up the PTWI.</p> <p>Thailand: Supports 900 mg/kg proposed by ICGMA as it is the lowest ML, which has an intentional technological function in the products.</p> <p>ICGMA: Adoption at 900 mg/kg as AI 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</p>

Recommendation 2 - Sodium aluminium phosphates (acidic and basic) (INS 541(i), (ii))					
The eWG recommends that the 45 th CCFA adopt the following food additive provisions for Sodium aluminium phosphates in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
					IFAC: Adopt at 1600 mg/kg as Al for INS 541i for use as raising agent

Recommendation 3 - Sodium aluminium phosphates (acidic and basic) (INS 541(i), (ii))					
The eWG recommends that the 45 th CCFA discuss further the following food additive provisions for Sodium aluminium phosphates in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
01.6.4	Processed cheese	35000 mg/kg 1600 mg/kg	29 6	6	Brazil: Discontinue, alternative food additives may be adequate. EU, Spain: discontinue - alternatives available; staple food; excessive ML; IDF in its comments on 1 st circular does not object to deletion of all provisions related to dairy products except for use of INS 554 in salt for dry slated cheese. Netherlands: safety concerns due to high intake in staple food. . A consumption of 19 g/week by a child and 75 g/week by an adult would fill up the PTWI. Canada: ML of 1750 mg/kg for INS 541ii reported by food industries as an emulsifier. USA: 1600 mg/kg with note 6 – used as emulsifying agent in pasteurized process cheese IFAC: Supports 1750 mg/kg for INS 541ii for use as emulsifier and stabilizer.
06.2.1	Flours	45000 mg/kg 1600 mg/kg	29 6, <u>New note:</u> <u>“For use</u> <u>in self-</u> <u>rising</u> <u>flour and</u> <u>self-rising</u> <u>cornmeal</u> <u>only”</u>	6	EU: discontinue – according to JECFA cereal and cereals products account for 20-90% contribution to aluminium intake and INS 541 plays an important role; excessive use level – loyal consumers of self-rising flour would exceed the PTWI several times Netherlands: safety concerns due to high intake in staple food. .A consumption of 19 g/week by a child and 75 g/week by an adult would fill up the PTWI. Spain: information on intake from self-rising flour/cornmeal necessary USA: Recommend adoption for INS 541(i) at 1750 mg/k with note 6 and new note “For use in self-rising flour and self-rising corn meal only” Indonesia Recommend 60 mg/kg as aluminium, ML established based on consumption and PTDI of 1mg/kg bw/d; ML proposed by Codex exceeds PTWI of Al - 7mg/kg bw/wk IFAC: adopt at 1600 mg/kg – needed as raising agent in various flours at this level – potentially add note “ for self-raising flour and cornmeal only” 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.
06.6	Batters (e.g., for breading or batters for fish or poultry)	1600 mg/kg	6	6	Brazil: proposed ML is high when compared to most comments listed for this FC. Canada: ML of 2340 mg/kg for INS 541ii reported by food industry. EU: excessive ML; it should be explained why other raising agent are not appropriate Indonesia Recommend 96 mg/kg as aluminium, ML established based on consumption and PTDI of 1mg/kg bw/d; ML proposed by Codex exceeds PTWI of Al - 7mg/kg bw/wk Netherlands: Reconsider maximum use level. This maximum use level could contribute significantly to the total exposure to aluminium. A consumption of 19 g/week by a child and 75 g/week by an adult would fill up the PTWI. USA: Adopt 1600 mg/kg with Note 6. CEFIC: Adopt 1000 mg/kg as raising agent IFAC: 2% SALP (1600 mg/kg as AL) for INS 541(ii) in batter is required to fulfill its technological function as a raising agent

SODIUM ALUMINOSILICATE (INS 554)**Recommendation 1 - Sodium aluminosilicate (INS 554)**

The eWG recommends that the 45th CCFA **discontinue** the following food additive provisions for Sodium aluminosilicate in the GSFA

Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
01.4.4	Cream analogues	20,000 mg/kg	6	3	EU: discontinuation It is important to note that IDF in its comments on 1 st circular does not object to deletion of all provisions related to dairy products; technological justification is not provided; it should be addressed why other anticaking agents are not suitable IFAC: Needed for use as anticaking agent at a level of 1140 mg/kg as Al.
01.6.2.1	Ripened cheese, includes rind	10000 mg/kg	6, 174 & 177 ¹⁵	3	Brazil, EU, Netherlands, Spain: Support discontinuation IDF: 570 mg/kg as Al authorized in CODEX STAN 283 (Codex General Standard for Cheese) for use as an anticaking agent in sliced, cut, shredded or grated cheese.
01.6.4	Processed cheese	10000 mg/kg	6, 174 & 177	3	EU, Netherlands, Spain: Discontinue IFAC: Adopt 860 mg/kg as Al for use as anticaking agent.
01.6.5	Cheese analogues	10000 mg/kg	6, 174 & 177	3	EU: Discontinue. It is important to note that IDF in its comments on 1 st circular does not object to deletion of all provisions related to dairy products; technological justification is not provided; it should be addressed why other anticaking agents are not suitable IFAC: Adopt at 1140 mg/kg as Al
01.8.1	Liquid whey and whey products, excluding whey cheeses	20000 mg/kg	6	3	EU: discontinuation It is important to note that IDF in its comments on 1 st circular does not object to deletion of all provisions related to dairy products; technological justification is not provided; it should be addressed why other anticaking agents are not suitable IFAC: Adopt at 1140 mg/kg as Al
01.8.2	Dried whey and whey products, excluding whey cheeses	570 mg/kg	6 & 174	3	(The adopted provision for food category 01.8.2 is discussed under Recommendation 3 “discuss further”) EU, Netherlands, Spain: Discontinue IFAC: Adopt at 1140 mg/kg as Al
11.1.2	Powdered sugar, powdered dextrose	10000 mg/kg	6 & 174	3	Brazil, EU, Netherlands, Spain: Discontinue CEFS: Recommend 794 mg/kg as Al with inclusion of note “Provided starch is not present.” IFAC: Adopt at 1140 mg/kg as Al
12.1.2	Salt Substitutes	10000 mg/kg	6 & 174	6	EU, Netherlands, Spain: discontinue IFAC: Adopt at 1140 mg/kg as Al

Recommendation 2 - Sodium aluminosilicate (INS 554)

The eWG recommends that the 45th CCFA **adopt** the following food additive provisions for Sodium aluminosilicate in the GSFA

Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	20000 mg/kg 60 mg/kg	6. New note: “For use in dry mix hot chocolate only.”	3	EU: Discontinue. It is important to note that IDF in its comments on 1 st circular does not object to deletion of all provisions related to dairy products; technological justification is not provided; it should be addressed why other anticaking agents are not suitable Netherlands: This maximum use level is anticipated to contribute only marginally to the total exposure to aluminium. Thailand: discontinue ICGMA: Adopt at 57 mg/kg with Note 6, INS 554 - used in dry mix hot chocolate to prevent

¹⁵ **Note 177** For use in sliced, cut, shredded, or grated cheese only.

Recommendation 2 - Sodium aluminosilicate (INS 554)					
The eWG recommends that the 45 th CCFA adopt the following food additive provisions for Sodium aluminosilicate in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
					clumping, Codex Stan 243-2003 addresses liquid products only, not powders. FC 01.1.2 addresses both liquid and powders IFAC: Recommend 1140 mg/kg as AI, needed of use as anticaking agent.
01.5	Milk powder and cream powder and powder analogues (plain)	40000 mg/kg 570 mg/kg	6 & 174	3	Brazil: Discontinue. Alternatives are available. Canada: ML of 860 mg/kg as AI reported by food industry as anticaking agent EU: discontinuation It is important to note that IDF in its comments on 1 st circular does not object to deletion of all provisions related to dairy products; technological justification is not provided; it should be addressed why other anticaking agents are not suitable Spain: alternatives? Thailand: Using national food consumption data the intake of young children (3-6 years old) is likely to exceed the PTWI (1,025% PTWI). However, many countries have reported the technological need for anticaking agent. So we consider that we support the lowest ML (currently 570 mg/kg as AI). ICGMA: 570 mg/kg on the basis of AI are necessary for milk/cream powder analogues (e.g., soy oil powder) and levels of 5,000 mg/kg on the basis of the whole compound are necessary for dairy-based creamers (e.g., milk powder and cream powder) IDF: 570 mg/kg as AI as authorized in CODEX STAN 207 (Codex Standard for Milk Powders and Cream Powders). IFAC: adopt a level of 1140 mg/kg as AI, as this level is needed for anti-caking in milk powder and cream powder and powder analogues (plain).
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 1140 mg/kg	6	3	EU: discontinue – no clear justification provided – it should be clarified why other anticaking agents are not suitable Thailand: Adopt at 1140 mg/kg as AI. IFAC: Adopt at 1140 mg/kg as AI for use as anticaking agent.
06.6	Batters (e.g., for breading or batters for fish or poultry)	20000 mg/kg 80 mg/kg	6	3	Canada: ML of 80 mg/kg as AI recommended by industry. EU: discontinue – no clear justification provided – it should be clarified why other anticaking agents are not suitable Mexico: Recommend GMP IFAC: Supports adoption of 80 mg/kg as AI with note 6.
12.1.1	Salt	20000 mg/kg 1000 mg/kg	6, <u>New note:</u> <u>“For use in salt applied to dry salted cheeses during processing only.”</u>	3	Canada (860 mg/kg is 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 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. 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) Spain: Agree, levels in final product seem less significant EuSalt – 1,000 mg/kg as AL in salt for use in salting the crust of specific cheese ” à pâte molle “.

Recommendation 2 - Sodium aluminosilicate (INS 554)					
The eWG recommends that the 45 th CCFA adopt the following food additive provisions for Sodium aluminosilicate in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
					<p>Taking into consideration a typical salination of the cheese to a maximum dosage of 2% in the cheese; it leads to a use of 200mg/kg E554 in cheese, so an Al-level of maximum 20mg/kg cheese, so it would not contribute to a major consumption in the overall consumption and limits the safety concern.</p> <p>IDF: 1710 mg/kg as Al (1140 mg/kg in salt results in 23 mg/kg in cheese) – used in some salting machines to improve flow of very fine salt to allow its homogenous distribution on the cheese that are dry salted. This use should not contribute to the PTWI of aluminium. There is no identified suitable substitute.</p> <p>IFAC: adopt at 860 mg/kg</p>
12.2.2	Seasonings and condiments	30000 mg/kg 875 mg/kg	6 & 174	3	<p>Brazil – 875 mg/kg as Al reported by food industry as necessary to prevent clumping and improve flow ability. The use of sodium aluminium silicate is justified by its round molecular structure, which allows the flow of less crystallized seasoning and condiments along the production site. Therefore, it is not possible to substitute this food additive, but it may be used in combination with other anticaking agents, such as silicon dioxide.</p> <p>Thailand: Support 875 mg/kg as Al proposed by Brazil as it is the lowest ML which has an intentional technological function in the products.</p> <p>ICGMA: industry has indicated a need for levels up to 1,170 mg/kg as AL for this product</p> <p>IFAC: Supports 875 mg/kg as Al.</p>
12.5.2	Mixes for soups and broths	40000 mg/kg 570 mg/kg	6 & 174	3	<p>Brazil – 570 mg/kg as Al necessary to prevent clumping in highly hygroscopic products.</p> <p>EU: Discontinue. Not authorized in STAN 117-1981 on bouillon and consommés; calcium phosphates are used as anticaking agents</p> <p>Spain: Discontinue, alternatives available for hygroscopic products</p> <p>Thailand: Using national food consumption data the intake of young children (3-6 years old) is likely to exceed the PTWI. However, many countries have reported the technological need for anticaking agent. So we consider that we support the lowest ML (currently 570 mg/kg as Al)</p> <p>ICGMA: 570 mg/kg with Note 6, Bouillons and Consommés, per Stan 117-1981, are thin clear liquids whereas FC 12.5.2. covers not only water-based products but also milk-based products such as cream-based soups, chowders, and bisques and their dried mixes. INS 554 is necessary as anticaking agents in these mixes to prevent clumping and improve flow ability in summer months and humid environments.</p> <p>IFAC: Supports 570 mg/kg as Al.</p>
12.6.3	Mixes for sauces and gravies	40000 mg/kg 570 mg/kg	6 & 174	3	<p>Brazil – 570 mg/kg as Al necessary to prevent clumping in highly hygroscopic products</p> <p>EU – Discontinue. Does not support this new proposal on aluminium while PTWI is already exceeded and JECFA recommends to restrict the conditions of its use</p> <p>ICGMA: industry has indicated a need for levels up to 1,140 mg/kg as AL for this product category</p> <p>IFAC: Supports 570 mg/kg as Al.</p>
15.1	Snacks- potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	420 mg/kg 1140 mg/kg	6	3	<p>Brazil, Canada: If the use is in seasonings for snacks, then the provision for food category 12.2.2 is enough, and the provision in 15.1 can be discontinued</p> <p>EU discontinue – includes cereal products – main contributor; excessive ML</p> <p>Netherlands: safety concerns. A consumption of 26 g/week by a child and 105 g/week by an adult would fill up the PTWI.</p> <p>Thailand: Discontinue</p>

Recommendation 2 - Sodium aluminosilicate (INS 554)					
The eWG recommends that the 45 th CCFA adopt the following food additive provisions for Sodium aluminosilicate in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
					<p>ICGMA: Seasonings must flow adequately to properly adhere to the product. INS 554 is needed as anticaking agent in these seasonings to prevent components from adhering to each other thereby allowing for proper adherence to the snack product. Necessary levels to achieve this function in the snack product are, 1140 on the basis of Al). Provided that adequate levels are endorsed for the Seasonings category FC 12.2.2. (i.e., ~1,700 mg/kg as Al), then provisions for FC 15.1. snacks would not be necessary.</p> <p>IFAC: Supports 1140 mg/kg as Al.</p>

Recommendation 3 - Sodium aluminosilicate (INS 554)					
The eWG recommends that the 45 th CCFA discuss further the following food additive provisions for Sodium aluminosilicate in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
01.3 01.3.2	Condensed milk and analogues (plain) Beverage whiteners	20000 mg/kg 570 mg/kg	6, 6, New note: "For use in powdered beverage whiteners only"	3	<p>Recommend revising current Step 3 provision in food category 01.3 to the subcategory 01.3.2 with a new note limiting use to powdered beverage whiteners only.</p> <p>EU: Discontinue provision in food category 01.3. It is important to note that IDF in its comments on 1st circular does not object to deletion of all provisions related to dairy products; technological justification is not provided; it should be addressed why other antaking agents are not suitable</p> <p>Netherlands: A consumption of 53 g/week by a child and 211 g/week by an adult would fill up the PTWI.</p> <p>Thailand: Discontinue provision in food category 01.3</p> <p>ICGMA: Move to FC 01.3.2, 570 mg/kg with note 6, used in beverage whiteners (e.g., non-dairy creamer powder, Coffee Whitener powder), i.e., FC 1.3.2., to prevent clumping, Scope of FC 1.3.2. in the GSFA addresses NOT ONLY liquid products per Codex STAN 252-2006 and 250-2006, but also POWDERS which are not covered under those commodity standards</p>
01.4.4	Cream analogues	20,000 mg/kg	6	3	<p>EU: discontinuation It is important to note that IDF in its comments on 1st circular does not object to deletion of all provisions related to dairy products; technological justification is not provided; it should be addressed why other anticaking agents are not suitable</p> <p>IFAC: Needed for use as anticaking agent at a level of 1140 mg/kg as Al.</p>
01.6.2.3	Cheese powder (for reconstitution; e.g., for cheese sauces)	40000 mg/kg 1140 mg/kg	6 & 174	3	<p>Canada: ML of 1140 mg/kg as Al reported by industry for use as an anticaking agent.</p> <p>EU: Discontinue. It is important to note that IDF in its comments on 1st circular does not object to deletion of all provisions related to dairy products; technological justification is not provided; it should be addressed why other anticaking agents are not suitable</p> <p>ICGMA: Adopt at 1140 mg/kg as Al. 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)</p> <p>IFAC: Adopt at 1140 mg/kg as Al (anticaking agent)</p>
01.8.2	Dried whey and whey products, excluding whey cheeses	40000 mg/kg 1140 mg/kg	6, 174	2006	<p>Brazil: 570 mg/kg results from conversion of adopted ML to Al basis</p> <p>EU, Netherlands, Spain: Revoke existing provision. It is important to note that IDF in its comments on 1st circular does not object to deletion of all provisions related to dairy products; technological justification is not provided; it should be addressed why other anticaking agents are not suitable</p> <p>IFAC: 1140 mg/kg as Al is necessary as anticaking agent in this FC.</p>

Recommendation 3 - Sodium aluminosilicate (INS 554)					
The eWG recommends that the 45 th CCFA discuss further the following food additive provisions for Sodium aluminosilicate in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
07.1.6	Mixes for bread and ordinary bakery wares	40000 mg/kg 1140 mg/kg	6 & 174	3	Canada: ML of 1140 mg/kg as Al recommended by industry. EU: strongly opposes – staple food; excessive ML; cereal products –main contributors according to JECFA; it should be clarified why other anticaking agents are not suitable Mexico: Recommends GMP. Netherlands, Spain: safety concerns due to high intake in staple food. A consumption of 26 g/week by a child and 105 g/week by an adult would fill up the PTWI. ICGMA and IFAC: Support adoption at 1140 mg/kg
07.2.3	Mixes for fine bakery wares (e.g., cakes, pancakes)	40000 mg/kg 1140 mg/kg	6	3	Canada: ML of 1140 mg/kg as Al recommended by industry. EU: strongly opposes – staple food; excessive ML; cereal products –main contributors according to JECFA; it should be clarified why other anticaking agents are not suitable Mexico: Recommends GMP. Netherlands, Spain: safety concerns due to high intake in staple food. A consumption of 26 g/week by a child and 105 g/week by an adult would fill up the PTWI. ICGMA: Adopt 1140 mg/kg as Al. Speciation of aluminium is an important factor for absorption of Al in humans. Aluminium contained in some additives such as silicates may have much lower bioavailability than some of the more soluble forms of Al compounds thereby not contributing significantly to overall dietary exposure to Al. IFAC: Adopt 1140 mg/kg as Al

Recommendation 4 - Sodium aluminosilicate (INS 554)					
The eWG recommends that the 45 th CCFA Circulate for comment at Step 3 the following food additive provisions for Sodium aluminosilicate in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
05.3	Chewing gum	100 mg/kg	6 & 174		Netherlands: check and see if alternatives can be used ICGA Provision is not a new use but conversion of use previously allowed from GMP provision in Table 3. 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).

CALCIUM ALUMINIUM SILICATE (INS 556)

Recommendation 1 – Calcium aluminium silicate (INS 556)					
The eWG recommends that the 45 th CCFA discontinue the following food additive provisions Calcium aluminium silicates (INS 556) in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments

Recommendation 1 – Calcium aluminium silicate (INS 556)					
The eWG recommends that the 45 th CCFA discontinue the following food additive provisions Calcium aluminium silicates (INS 556) in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
01.6.1	Unripened cheese	10000 mg/kg	6 & 174	3	EU, Netherlands, Spain: Discontinue
01.6.2.1	Ripened cheese, includes rind	10000 mg/kg	6, 174 & 177 ¹⁶	3	EU, Netherlands, Spain: Discontinue
01.6.2.3	Cheese powder (for reconstitution; e.g., for cheese sauces)	10000 mg/kg	6 & 174	3	EU, Netherlands, Spain: Discontinue
01.6.4	Processed cheese	10000 mg/kg	6, 174 & 177	3	EU, Netherlands, Spain: Discontinue
01.6.5	Cheese analogues	10000 mg/kg	6, 174 & 177	3	EU, Netherlands, Spain: Discontinue
01.8.2	Dried whey and whey products, excluding whey cheeses	10000 mg/kg	6, 174 & 177	3	EU, Netherlands, Spain: Discontinue
11.1.2	Powdered sugar, powdered dextrose	15000 mg/kg	6, 56 ¹⁷	3	EU, Netherlands, Spain: Discontinue CEFS: Proposes 265 mg/kg as AI to be in line with EU regulations for dried powdered stuffs, including sugar. Include Note 174

Recommendation 3 – Calcium aluminium silicate (INS 556)					
The eWG recommends that the 45 th CCFA discuss further the following food additive provisions Calcium aluminium silicates (INS 556) in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
01.5	Milk powder and cream powder and powder analogues (plain)	10000 mg/kg 265 mg/kg	6 & 174	3	EU: discontinuation - IDF in its comments on 1 st circular does not object to deletion of all provisions related to dairy products except for use of INS 554 in salt for dry slated cheese. In the EU all provisions of INS 556 revoked – alternatives exist Netherlands, Spain: check if alternatives could be used Thailand: Supports 265 mg/kg as AI.
12.1.1	Salt	20000 mg/kg 530 mg/kg	6, 174	3	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 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 aluminum.) EU: discontinue – whilst EU could accept the specific authorisation (i.e. INS 554 in dry salted cheeses) when there are no alternatives and the permission is linked to the specific product, it does not support this generic request – which could lead to the permanent use if INS 556 in certain salts

¹⁶ **Note 177** For use in sliced, cut, shredded, or grated cheese only

¹⁷ **Note 56** Provided starch is not present

Recommendation 3 – Calcium aluminium silicate (INS 556)					
The eWG recommends that the 45 th CCFA discuss further the following food additive provisions Calcium aluminium silicates (INS 556) in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
					and therefore significant intake of loyal consumers; it should be explained why the alternative anticaking agents could not achieve the intended technical effect Netherlands: check if alternatives available Brazil: Discontinue – there are alternative additives which can fulfil the same tech function in this FC, FC is widely consumed. 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

Recommendation 4 – Calcium aluminium silicate (INS 556)					
The eWG recommends that the 45 th CCFA Circulate for comment at Step 3 the following food additive provisions Calcium aluminium silicates (INS 556) in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
05.3	Chewing gum	100 mg/kg	6 & 174		Spain, Netherlands: check and see if alternatives can be used ICGA: Provision is not a new use but conversion of use previously allowed from GMP provision in Table 3. 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).

ALUMINIUM SILICATE (INS 559)

Recommendation 1 – Aluminium silicate (INS 559)					
The eWG recommends that the 45 th CCFA discontinue the following food additive provisions for Aluminium silicate in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
01.5	Milk powder and cream powder and powder analogues (plain)	10000 mg/kg	6 & 174	3	EU, Netherlands, Spain: Discontinue
01.6.1	Unripened cheese	10000 mg/kg	6	3	EU, Netherlands, Spain: Discontinue
01.6.2.1	Ripened cheese, includes rind	10000 mg/kg	6, 174 & 177	3	EU, Netherlands, Spain: Discontinue India: 3000 mg/kg as Al
01.6.2.3	Cheese powder (for reconstitution; e.g., for cheese sauces)	10000 mg/kg	6 & 174	3	EU, Netherlands, Spain: Discontinue

Recommendation 1 – Aluminium silicate (INS 559)					
The eWG recommends that the 45 th CCFA discontinue the following food additive provisions for Aluminium silicate in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
01.6.4	Processed cheese	10000 mg/kg	6, 174 & 177	3	EU, Netherlands, Spain: Discontinue
01.6.5	Cheese analogues	10000 mg/kg	6, 174 & 177	3	EU, Netherlands, Spain: Discontinue

Recommendation 4 – Aluminium silicate (INS 559)					
The eWG recommends that the 45 th CCFA Circulate for comment at Step 3 the following food additive provisions for Aluminium silicate in the GSFA					
Food Cat. No.	Food Category	Max Level	Notes	Step	Comments
05.3	Chewing gum	100 mg/kg	6 & 174		<p>Spain, Netherlands: check and see if alternatives can be used</p> <p>ICGA: Provision is not a new use but conversion of use previously allowed from GMP provision in Table 3. 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).</p>