CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



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Agenda Item 6

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifty-second Session

PROPOSED DRAFT REVISION TO THE INTERNATIONAL NUMBERING SYSTEM (INS) FOR FOOD ADDITIVES (CXG 36-1989)

Prepared by an electronic Working Group chaired by Belgium and co-chaired by Iran

Codex members and Observers wishing to submit comments at Step 3 on the proposed changes and/or addition to the International Numbering System for Food Additives (Annex 1) should do so as instructed in CL 2019/117-FA available on the Codex webpage/Circular Letters 2019: http://www.codexalimentarius.org/circular-letters/en/.

BACKGROUND

1. The 51th session of the Codex Committee on Food Additives (CCFA51)¹ held in Jinan, China from 25 to 29 March 2019 agreed to establish an electronic Working Group (EWG), chaired by Belgium, open to all members and observers and working in English only, to consider:

a. Replies to the CL on addition and changes to the INS; and preparing a proposal for circulation for comments at Step 3;

b. Including the functional class of "Antioxidant" and the technological purpose of "antioxidant synergist" for tricalcium citrate (INS 333(iii)) and tripotassium citrate (INS 332(ii)), and consider including the technological purpose of "antioxidant synergist" for lecithin (INS 322(i));

c. The appropriateness of including the functional class of "Flour treatment agent" for magnesium carbonate (INS 504(i));

d. Whether lecithin (INS 322(i)) and sodium ascorbate (INS 301) have the functional class of "Flour treatment agent" in products conforming to CXS 152-1985 (Standard for Wheat Flour) - or should the functional class for lecithin be that of an "Emulsifier";

e. To assign an INS number to fungal amylase from Aspergillus niger and consider including the functional class and technological purpose of "flour treatment agent"; and

f. The establishment of a mechanism to keep track of deleted INS numbers.

2. CCEXEC77² noted that Iran would be a co-chair for the EWG.

DISCUSSIONS IN THE ELECTRONIC WORKING GROUP

3. In April 2019, the Codex Secretariat distributed CL 2019/39-FA, all members and observers were invited to respond by 15 September 2019 (proposals for changes, addition and deletion to the INS list).

4. On 3rd July 2019, the Codex Secretariat distributed a kick-off message containing an invitation to members and observers to express interest in participation in the EWG. The EWG used the online platform, and the following members and observers registered: Australia, Belgium, Brazil, Colombia, Egypt, Iran, Iraq, Japan, Malaysia, Mexico, Norway, Peru, Romania, Singapore, United Kingdom, USA, ESFI, FIA, ICGA, IFAC, IOFI, ISDI, OIV.

¹ REP19/FA para. 149

² REP19/EXEC2, para. 18

A. Replies to the circular letter on addition and changes to INS

Isomalt (hydrogenated isomaltulose) (INS 953)

5. EU Specialty Food Ingredients requests to add the functional class of "flavour enhancer" and technological purpose of "flavour enhancer" for isomalt (hydrogenated isomaltulose) (INS 953) with the following justification:

"Besides its technological functions as anticaking agent, bulking agent, glazing agent, stabilizer, sweetener and thickener, isomalt is well known and used in food industry for its flavour enhancing and taste masking effects. It considerably contributes to an improved taste profile." Brazil suggested the technological purpose of flavour synergist rather than flavour enhancer for isomalt (hydrogenated isomaltulose), based on the referred effects in combination with other sweeteners.

• Riboflavin from Ashbya gossypii

6. EU Specialty Food Ingredients requests to add a new entry for INS 101(iv) riboflavin from *Ashbya gossypii*, with the functional class colour and technological purpose colour, as the substance is on the priority list for evaluation by JECFA³. According to EU Specialty Food Ingredients, riboflavin from *Ashbya gossypii* is marketed as food color and nutrient source in over 60 countries in the world and for many years. Riboflavin is authorized according to generic specifications without specifying the route of manufacturing, like in the EU, Canada, US and many countries in Europe, Asia-Pacific and South America. Due to the introduction of a product-specific authorization of the different riboflavin types in the GSFA in recent years and riboflavin from *Ashbya gossypii* not listed in the GSFA, in 2020 an evaluation by JECFA is scheduled to get this important riboflavin source listed in the GSFA.

7. It is logic to support the number 101(iv) for the next riboflavin in the INS. JECFA might propose another name and it might be premature to set a Codex name if not requested for national reasons. Additives produced with genetically modified microorganism (GMM) usually receive more detailed names including the wording "expressed in". The principles for changes/additions to Section 3 of the *Class Names and International Numbering System* (CXG 36-1989) states "Since the INS is an open list, requests for the inclusion of new additives may be made by Codex members that authorize the additive for use in that country and for which an INS number is needed." There was no clear request from a Member State.

B. Including the functional class of "Antioxidant" and the technological purpose of "antioxidant synergist" for tricalcium citrate (INS 333(iii) and tripotassium citrate (INS 332(ii)), and consider including the technological purpose of "antioxidant synergist" for lecithin (INS 322(i))

8. The questions on citrates arose from the discussions in CCFO⁴ on standards for fats and oils. CCFO requested CCFA to consider updating CXG 36-1989 to include the technological purpose "antioxidant synergist" to lecithin (INS 322(i)); tricalcium citrate (INS 333(iii)); and tripotassium citrate (INS 332(ii)).

• Lecithin (INS 322(i))

9. For lecithin (INS 322(i)), the function of antioxidant is already recognized in CXG 36-1989. The main antioxidant action of lecithin is as a synergist with other primary antioxidants, such as α -tocopherol, by delaying the oxidative breakdown of these primary antioxidants; and the synergistic effect appears to be enhanced by the presence of ascorbic acid and citric acid. Therefore, the inclusion of the technological purpose antioxidant synergist is justified.

• Tricalcium citrate (INS 333(iii)) and tripotassium citrate (INS 332(ii))

10. For tricalcium citrate (INS 333(iii)) and tripotassium citrate (INS 332(ii)), the function of sequestrant is already listed in the CXG 36-1989. The mode of action of these food additives in the oil would be metal complexation, which would increase the product shelf life by avoiding oxidation. Considering that antioxidant is a food additive "which prolongs the shelf-life of foods by protecting against deterioration caused by oxidation", if they play sequestrant function in the oil, they comply with the antioxidant definition. For citric acid (INS 330), the functional class and technological purpose of antioxidant are already listed and the salts may have similar functions. It's acceptable for most members of the EWG to include the functional class of "Antioxidant" and the technological purpose of "antioxidant synergist" for tricalcium citrate (INS 333(iii) and tripotassium citrate (INS 332(ii)).

³ REP19/FA, Appendix X

⁴ CX/FA 19/51/2 Add.2

C. The appropriateness of including the functional class of "Flour treatment agent" for magnesium carbonate (INS 504(i))

11. This question arises from the work on the GSFA, as there is a draft provision for magnesium carbonate in food category 06.2.1 (Flours), which is on hold awaiting the outcome of the INS discussion. CRD2 of CCFA51 mentions the technological justification for the use of magnesium carbonate as a flour treatment agent was provided.

12. This substance is not known to most of the members of the EWG to be a flour treatment agent, but magnesium carbonate is affirmed as Generally Recognized as Safe (GRAS) in the USA for use as a flour treating agent in 21 CFR 184.1425 (Magnesium carbonate). Hence the inclusion of the functional class of "Flour treatment agent" for Magnesium carbonate (INS 504(i)) is supported.

D. Whether lecithin (INS 322(i)) and sodium ascorbate (INS 301) have the functional class of "Flour treatment agent" in products conforming to CXS 152-1985 (Standard for–Wheat Flour) - or should the functional class for lecithin be that of an "Emulsifier"

Lecithin (INS 322(i))

13. These questions arise from the discussion on alignment of the *standard for wheat flour* (CXS 152-1985) with the GSFA in CCFA51 (comments from Canada). In the standard for wheat flour, lecithin and sodium ascorbate are listed under the title of flour treatment agents since 1985. However, it is believed that lecithin was included in 2014 in the GSFA in the food category 6.2.1. (Flours) as an emulsifier. Until now, the functional class of flour treatment agent is not assigned to lecithin in the INS.

14. Is there an overlap between the definitions of emulsifier and flour treatment agent, as defined in the INS (CXG 36-1989)? In the EU, the definition of the functional class of flour treatment agent is excluding emulsifiers. Is this interpreted the same way in Codex Alimentarius? Lecithin is used in flour for its emulsifying properties as well as for other properties such as improvement of dough condition (handling properties), bread volume improvement, delaying staleness and improving crumb scores. The functionality of lecithin is a combination of several aspects: It works as a lubricant, surface active component, interacts with gluten etc. This results in better water absorption, fat dispersion, better extensibility and dough elasticity, thus contributes to overall better machineability. By definition, flour treatment agents are added to flour or dough to improve its baking quality. Therefore, the inclusion of the functional class flour treatment agent is justified.

Sodium ascorbate (INS 301)

15. Ascorbic acid (INS 300) already has the functional class of flour treatment agent. Now the request is to do the same for sodium ascorbate (INS 301). Does the salt play the same function? As ascorbic acid has the function of flour treatment agent, this suggests that the sodium salt of ascorbic acid might also be suitable to serve the same technological function.

E. To assign an INS number to fungal amylase from *Aspergillus niger* and consider including the functional class and technological purpose of "flour treatment agent"

16. This question arises from the discussion on alignment of the standard for wheat flour with the GSFA.

17. All amylases which are already included in the INS standard have the functional class and technological purpose of flour treatment agent. They are all listed under 1100 amylases. The next number is 1100(vii). As fungal amylase from *Aspergillus niger* was included in the standard for wheat flour, this might indicate it is or was used a flour treatment agent. There was no new information about the technological purpose/functional class.

18. In Brazil, amylases are recognized as flour treatment agents and listed in the legislation under INS 1100, but only if the substance has previously been evaluated by JEFCA and has a published monograph. The enzyme is on the JECFA priority list.

F. The establishment of a mechanism to keep track of deleted INS numbers

19. If a substance is deleted from the INS, it is recommended to carefully consider the reuse of the number for another additive, taking into account the former use of the number for another food additive, to avoid confusion.

20. An overview could be kept of deleted names and numbers including the year of deletion. In addition, the re-use of numbers could also be kept in the overview, to make it clear which numbers are already re-used for another food additive. It was suggested to keep such document separate from CXG 36-1989 as an information document, to be reviewed each year and updated in case there is a change.

21. A first draft of such document is presented in annex 2. There was some discussion in the EWG on the format of the overview. The proposal to include columns with functional class and technological purpose is more difficult for deletions from many years ago. Many times, there were name changes, sometimes related to changes in specifications/definitions. It is probably easier to keep track of all name and number changes than to clarify all those changes. If re-use is very close to a name change, it could be listed as name change.

22. It was also proposed in the EWG to develop a set of criteria for reusing the deleted INS numbers. Otherwise, we run the risk of randomly re-assigning INS numbers which will further add to confusion. One such criteria could be: the deleted INS number can only be re-assigned to another food additive if it belongs to the same functional class as the deleted one. A good example would be carotenes, *beta*, algae (INS 160a(iv)) which was deleted and the INS number reused for beta-carotene-rich extract from *Dunaliella salina*. Both food additives belong to the same functional class - colour.

23. Some delegations proposed to keep omitted names and numbers in the INS list with the year of omission. However, then they are not deleted from the Codex document and it might look like a document full of track change. A solution could be to list deleted and re-used INS numbers in a table at the end of CXG 36-1989. In such case it is more important only to list the major deletions and re-use and not every change.

CONCLUSION AND RECOMMENDATIONS

24. The EWG recommends CCFA to consider the changes and/or additions/deletions to the INS list as presented in the annex 1.

25. The EWG recommends CCFA to consider it is premature to include the following proposals in the INS, and to wait for the JECFA assessment and proposal for a name:

- a. INS 101(iv) Riboflavin from *Ashbya gossypii*, with the functional class "Colour" and technological purpose "colour"
- b. INS 1100(vii) Fungal amylase from *Aspergillus niger*, with the functional class "Flour treatment agent" and technological purpose "flour treatment agent"
- 26. The EWG recommends CCFA to reflect on
- a. the format of the overview of deleted INS numbers and names including an overview of re-used numbers;
- b. the approach to deal with the information, either in a separate information document or within CXG 36-1989 in a table at the end;
- c. the question to which extent changes of names and changes of numbers are to be included

27. The EWG recommends the next EWG would continue working on a mechanism to keep track of deleted INS numbers taking into account the discussions on paragraph 26 (A partial overview is presented in annex 2).

Proposed changes and/or additions to the INS (at Step 3)

The INS list in numerical order is proposed to be updated for some food additives as listed. The changes and additions are highlighted with **bold/ underlined font**.

INS No.	Name of food additive	Functional class	Technological purpose
201	Sodium apparbata	Antioxidant	Antioxidant
301	Socium ascorbate	Flour treatment agent	flour treatment agent
322(i)	Lecithin	Antioxidant Emulsifier <u>Flour treatment agent</u>	antioxidant <u>antioxidant synergist</u> emulsifier <u>flour treatment agent</u>
		Acidity regulator	acidity regulator
332(ii)	Tripotassium citrate	Antioxidant Emulsifying salt Sequestrant Stabilizer	<u>antioxidant synergist</u> emulsifying salt sequestrant stabilizer
333(iii)	Tricalcium citrate	Acidity regulator	acidity regulator
		Antioxidant Emulsifying salt Firming agent Sequestrant Stabilizer	<u>antioxidant synergist</u> emulsifying salt firming agent sequestrant stabilizer
504(i)	Magnesium carbonate	Acidity regulator Anticaking agent Color retention agent Flour treatment agent	acidity regulator anticaking agent color retention agent <u>flour treatment agent</u>
953	Isomalt (Hydrogenated isomaltulose)	Anticaking agent Bulking agent <u>Flavour enhancer</u> Glazing agent Stabilizer Sweetener Thickener	anticaking agent bulking agent <u>flavour enhancer</u> <u>flavour synergist</u> glazing agent stabilizer sweetener texturizing agent

Format of tables keeping track of deleted INS-numbers

Information document/table on INS for deleted and re-used numbers

[including changes of names or numbers]

Changes and additions are indicated in **bold**; deletions strikethrough.

Remark: It was difficult to prepare the tables in a consistent way and hence the current information is rather a historical overview of the last ten years, to support the discussion on the establishment of a mechanism to keep track of deleted INS numbers.

2019

The names and numbers of food additives deleted from the INS-list

INS No.	Name of Food Additive	Functional class	Technological	Year
			purpose	
128	Red 2G	Colour	colour	Deleted in 2019
160a(iv)	Carotenes, beta, algae	Colour	colour	Deleted in 2019
1411	Distarch glycerol	Emulsifier	emulsifier	Deleted in 2019
		Stabiliser	stabilizer	
		Thickener	binder	
			thickener	

Re-use of INS-numbers which were deleted

INS No.	Name of food additive	Functional class	Technological	Year of re-use
			purpose	
160a(iv)	β-carotene-rich extract	colour	colour	Adopted in 2019
	from <i>Dunaliella salina</i>			

2018

For the INS number 960 steviol glycosides (linked to specifications for steviol glycosides from Stevia *rebaudiana* Bertoni), a change of number to 960a and a change of name was decided. The INS number 960 was re-used to become a parent number. Another specification was added with number 960b(i) as well as the sub-parent 960b.

INS No.	Name of Food Additive	Functional Class	Technological Purpose
960	Steviol glycosides	Sweetener	Sweetener
960a	Steviol glycosides from <i>Stevia rebaudiana</i> Bertoni (Steviol glycosides from Stevia)	Sweetener	sweetener
960b	Steviol glycosides from fermentation		
960b(i)	Rebaudioside A from multiple gene donors expressed in <i>Yarrowia lipolytica</i>	Sweetener	sweetener

2017

No deletion or re-use or change of name

2016

The name of the additive for INS 1101(i) was changed from "protease" to "protease from Aspergillus oryzae Var."

INS No.	Name of Food Additive	Functional Class	Technological Purpose
1101(i)	Protease	Flour treatment agent	flour treatment agent
		Flavour enhancer	flavour enhancer

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Protease	from	Aspergillus	Stabilizer	stabilizer
oryzae Var				

2015

The name of INS 451 (iii) was corrected : Sodium potassium trisphospate triphosphate

2014

It was proposed to ensure harmonization between the names and functional classes used in the INS and the GSFA that six amylases with unique names in Table 3 of the GSFA are all associated with the same name (Amylases) and same INS number (INS 1100) in the INS. It has been proposed by USA the more specific names for the amylases used in the GSFA should be incorporated into the INS to allow for harmonization with the GSFA. Therefore, the Roman subclasses were chosen to identify the six amylases.

INS No.	Name of Food Additive	Functional Class	Technological Purpose
102	Tartrazine	Colour	Colour
<u>1100</u>	Amylases	Flour treatment agent	flour treatment agent
<u>1100 (i)</u>	alpha-Amylase from	Flour treatment agent	flour treatment agent
	<u>Aspergillus oryzae var.</u>		_
<u>1100 (ii)</u>	alpha-Amylase from	Flour treatment agent	flour treatment agent
	<u>Bacillus</u>		
	stearothermophilus		
<u>1100 (iii)</u>	alpha-Amylase from	Flour treatment agent	flour treatment agent
	Bacillus subtilis		
<u>1100 (iv)</u>	alpha-Amylase from	Flour treatment agent	flour treatment agent
	Bacillus megaterium		
	expressed in Bacillus		
	<u>subtilis</u>		
<u>1100 (v)</u>	alpha-Amylase from	Flour treatment agent	<u>flour treatment agent</u>
	<u>Bacillus</u>		
	stearothermophilus		
	expressed in Bacillus		
	subtilis		
<u>1100 (vi)</u>	Carbohydrase from	Flour treatment agent	flour treatment agent
	<u>Bacillus licheniformis</u>		

2013

The Committee noted that 76th JECFA had prepared a new specifications monograph for mineral oil, medium and low viscosity, class I (INS 905e) and agreed to change the name of this food additive to mineral oil, medium viscosity.

INS No.	Name of Food Additive	Functional Class	Technological Purpose
905e	Mineral oil, medium and low viscosity, class I Mineral oil, medium viscosity	Glazing agent	glazing agent sealing agent

2012

When INS 160c(ii) was introduced, INS 160c changed into 160c(i). For INS 173 and 180 the names of INS did not match with JECFA and were corrected to match the JECFA name: Aluminium to aluminium powder. Lithol Rupine BK to Lithol Rubine BK. For INS 124, it was decided not to delete the synonym cochineal red A and hence not to align with JECFA.

Withdrawal from the INS: Potassium bromate (INS 924a) and calcium bromate (INS 924b).

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INS No.	Name of Food Additive	Functional Class	Technological Purpose
160c 160c(i)	Paprika oleoresin		colour
173	Aluminium Aluminium powder		surface colourant
180	Lithol Rupine BK Lithol rubine BK		colour
4 52(vi) 451(iii)	Sodium potassium tripolyphosphate Sodium potassium		acidity regulator emulsifier moisture-retention agent
	triphosphate		raising agent sequestrant stabilizer

INS No.	Name of Food Additive
924a	Potassium bromate
924b	calcium bromate

2011

INS No.	Name of Food Additive	Technological Purpose
150a	Caramel I – plain (Caustic caramel) caramel	colour
150b	Caramel II – caustic sulfite process caramel	colour
150c	Caramel III – ammonia process caramel	colour
150d	Caramel IV – sulfite ammonia process caramel	colour
414a	Octenyl succinic acid (OSA) modified gum arabic	emulsifier
423		

Re-use of INS-numbers which were deleted

INS No.	Name of food additive	Comments
514	Sodium sulfates	Re-introduced as parent additives in 2011
		after deletion in 2009
515	Potassium sulfates	Re-introduced as parent additives in 2011
		after deletion in 2009

2010

INS No.	Name of Food Additive	
101(iii)	Riboflavin (Bacillus subtilis)	
	Riboflavin from Bacillus subtilis	
343(i)	Monomagnesium phosphate	
	Magnesium dihydrogen phosphate	
445	Glycerol ester of wood rosin	
	Glycerol esters of rosin	
445	Glycerol ester of wood rosin	
445(iii)		
904	Shellac	
	Shellac, bleached	

INS No.	Name of Food Additive	Proposed new name
140	Chlorophyll	Chlorophylls
150a	Caramel I - plain	Caramel I – plain (Caustic caramel)
160f	Carotenoic acid, methyl or ethyl ester, β-	Carotenoic acid, ethyl ester, β-apo-8'-
	apo-8'-	
181	Tannins, food grade	Tannic acid (Tannins)
235	Pimaricin (Natamycin)	Natamycin (Pimaricin)
315	Isoascorbic acid (Erythorbic acid)	Erythorbic acid (Isoascorbic acid)
316	Sodium isoascorbate	Sodium erythorbate (Sodium
		isoascorbate)
335(ii)	Disodium tartrate	Sodium L(+)-tartrate
337	Potassium sodium tartrate	Potassium sodium L(+)-tartrate
338	Orthophosphoric acid	Phosphoric acid
339(i)	Monosodium orthophosphate	Sodium dihydrogen phosphate
339(ii)	Disodium orthophosphate	Disodium hydrogen phosphate
339(iii)	Trisodium orthophosphate	Trisodium phosphate
340(i)	Monopotassium orthophosphate	Potassium dihydrogen phosphate
340(ii)	Dipotassium orthophosphate	Dipotassium hydrogen phosphate
340(iii)	Tripotassium orthophosphate	Tripotassium phosphate
341(i)	Monocalcium orthophosphate	Calcium dihydrogen phosphate
341(ii)	Dicalcium orthophosphate	Calcium hydrogen phosphate
341(iii)	Tricalcium orthophosphate	Tricalcium phosphate
342(i)	Monoammonium orthophosphate	Ammonium dihydrogen phosphate
342(ii)	Diammonium orthophosphate	Diammonium hydrogen phosphate
343(i)	Monomagnesium orthophosphate	Monomagnesium phosphate
343(ii)	Dimagnesium orthophosphate	Magnesium hydrogen phosphate
343(iii)	Trimagnesium orthophosphate	Trimagnesium phosphate
350(i)	Sodium hydrogen malate	Sodium hydrogen DL-malate
350(ii)	Sodium malate	Sodium DL-malate
407	Carrageenan and its ammonium, calcium,	Carrageenan
	magnesium, potassium and sodium salts	5
	(includes furcellaran)	
445	Glycerol esters of wood rosin	Glycerol ester of wood rosin
460(i)	Microcrystalline cellulose	Microcrystalline cellulose (Cellulose
		gel)
479	Thermally oxidized soya bean oil with mono-	Thermally oxidized soya bean oil
	and di- glycerides of fatty acids	interacted with mono- and diglycerides
		of fatty acids
504(ii)	Magnesium hydrogen carbonate	Magnesium hydroxide carbonate
514	Sodium sulfates	
514(i)		Sodium sulfate
514(ii)		Sodium hydrogen sulfate
515	Potassium sulfates	
515(i)		Potassium sulfate
515(ii)		Potassium hydrogen sulfate
542	Bone phosphate (essentially calcium	Bone phosphate
	phosphate, tribasic)	
553(i)	Magnesium silicate	Magnesium silicate (Synthetic)
621	Monosodium glutamate	Monosodium L-glutamate
622	Monopotassium glutamate	Monopotassium L-glutamate
623	Calcium glutamate (D,L-)	Calcium di-L-glutamate
624	Monoammonium glutamate	Monoammonium L-glutamate
625	Magnesium glutamate	Magnesium di-L-glutamate
630	Inosinic acid	5'-Inosinic acid

CX/FA 20/52/11 10 Dipotassium 5'-inosinate 632 Potassium inosinate 905b Petrolatum (Petroleum jelly) Petroleum jelly (Petrolatum) 907 Hydrogenated poly-decenes Hydrogenated poly-1-decene 952(iii) Potassium cyclamate Isomalt (Isomaltitol) Isomalt (Hydrogenated isomaltulose) 953 1200 Polydextroses A, N Polydextroses

Proposed criteria for re-use of INS-numbers:

The deleted INS number can only be re-assigned to another food additive if it belongs to the same functional class as the deleted one.