

CODEx ALIMENTARIUS COMMISSION

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Food and Agriculture
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World Health
Organization

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Agenda Item 6

CX/FA 21/52/11¹
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx COMMITTEE ON FOOD ADDITIVES

Fifty-second Session

PROPOSED DRAFT REVISION TO THE CLASS NAMES AND 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 2021/1-FA available on the Codex webpage/Circular Letters 2021: <http://www.codexalimentarius.org/circular-letters/en/>.

BACKGROUND

1. The 51th session of the Codex Committee on Food Additives (CCFA51)² 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 2019/39-FA 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. CCEXEC77³ noted that Iran would be a co-chair for the EWG. In 2020, CCFA52 could not be held as scheduled due to the pandemic period. Based on the comments received in response to CL 2020/34-FA, it was decided that the INS EWG would continue working and take up the following additional tasks:

- Consider the issues highlighted in document CX/FA 20/52/11 add1; and
- Consider the replies to CL 2020/35-FA “requests for addition and changes to the INS”; and preparing a proposal for circulation for comments at Step 3

¹ This document is an updated version of CX/FA 20/52/11

² REP19/FA para. 149

³ REP19/EXEC2, para. 18

3. Comments on CX/FA 20/52/11 were requested in CL 2019/117-FA. Those comments were compiled in CX/FA 20/52/11 add1 stating that EU and Malaysia expressed their support to the proposals included in CX/FA 20/52/11. The EUMS supported keeping the overview of deleted INS numbers and names, including an overview of re-used numbers, as a separate information document that shall be updated when CXG 36-1989 is changed. The EUMS supported that the information on the functional classes and technological purposes is retained in the information document together with the year of deletion. The EUMS also agree with a careful re-use of the numbers that the system in which certain range of numbers corresponds to a particular functional class(es) is maintained (e.g. INS No 100-199 for colours).

DISCUSSIONS IN THE ELECTRONIC WORKING GROUP

4. 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). In June 2020, the Codex Secretariat distributed CL 2020/35-FA, all Members and Observers were invited to respond by 15 September 2020.

5. On 3 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.

6. On 12 August 2020, the Codex Secretariat distributed a notification of the continuation of the EWG for the Revision of the *Class Names and the International Numbering System for Food Additives* (INS) (CXG36-1989) containing an invitation to Codex Members and Observers that are not already registered for this EWG to register. The following Members and Observers reacted: Chile, European Union, Hungary, Republic of Korea, New Zealand, AMFEP, ECOWAS, ICA, ISC and USP.

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

- Isomalt (hydrogenated isomaltulose) (INS 953) (Comments in response to CL 2019/39-FA)

7. 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.”

8. 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* (Comments in response to CL 2019/39-FA)

9. 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 JECFA⁴. 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 yet, in 2020 an evaluation by JECFA is scheduled to get this important riboflavin source listed in the GSFA.

⁴ REP19/FA, Appendix X

10. 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 summary report of the 89th JECFA meeting in June 2020 reported that, because of time constraints, the assessments of safety and dietary exposure were not completed and specifications will be published at a later point. 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.

- Jagua (genipin-glycine) blue (Comments in response to CL 2020/35-FA)

11. Colombia submitted the request for addition of the food additive Jagua (genipin-glycine) blue with the functional class of colour. The 89th meeting of JECFA established an ADI in 2020 for Jagua blue. A point of discussion can be whether the name should be ‘Jagua blue’ or ‘Jagua (genipin-glycine) blue’ or keeping both options together in the name including a synonym in ‘Jagua (genipin-glycine) blue (Jagua blue)’, as is mentioned in the summary report of JECFA. Columbia proposes the INS number 183. The EWG supported the original proposal.

- Butterfly pea flower extract (Comments in response to CL 2020/35-FA)

12. The IACM (International Association of Color Manufacturers) requests the addition of the colour ‘butterfly pea flower extract’. IACM included information that this colour is reviewed for use in the USA, is approved for use in Thailand, and as an allowed anthocyanin in Canada. As the colour contains anthocyanins as the principle colouring component, it was suggested that it be assigned a number under INS 163. It is logic to choose INS 163 (xi) as the next anthocyanin.

- Steviol Glycosides (Comments in response to CL 2020/35-FA)

13. The ISC (International Stevia Council) proposes new INS numbers 960c for Enzyme Modified Steviol Glycosides and 960d for Enzyme Modified Glucosylated Steviol Glycosides. JECFA prepared revised specifications for steviol glycosides with four annexes.

14. It is not clear why the name for 960d would not be simplified to ‘glucosylated steviol glycosides’. The information of ISC on authorizations in countries, do not refer to the names proposed here, but to approvals for bioconversion and for glycosylation. ISC refers to ‘glycosylated’ and to ‘glucosylated’, as if it is the same. As JECFA uses to the more specific ‘glucosylated’, this term is the appropriate choice .

15. A preference for the wording “enzymatically produced steviol glycosides” and “enzymatically produced glucosylated steviol glycosides” was expressed by one Member Organisation in the EWG. Others preferred the names put forward by JECFA as the appropriate choice (960c Enzyme Modified Steviol Glycosides and 960d Enzyme Modified Glucosylated Steviol Glycosides), or the shortened name for 960d suggested by the Chair of the EWG (Glucosylated Steviol Glycosides).

16. ISC requested to add the functional class and technological purpose of sweetener not only for the newly proposed INS 960c and 960d but also for the INS 960b Steviol glycosides from fermentation. These proposals were supported by the EWG.

17. Some presumptions were made about deleting INS 960b(i) Rebaudioside A from multiple gene donors expressed in *Yarrowia lipolytica*. However, criteria for deletion, as listed in CL 2020/35-FA, are not fulfilled, especially as this additive is in the GSFA.

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)) (Request from CCFA51)

18. The questions on citrates arose from the discussions in CCFO⁵ 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)).

⁵ CX/FA 19/51/2 Add.2

- Lecithin (INS 322(i))

19. 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))

20. 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)).

C. The appropriateness of including the functional class of “Flour treatment agent” for magnesium carbonate (INS 504(i)) (Request from CCFA51)

21. 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.

22. 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” (Request from CCFA51)

- Lecithin (INS 322(i))

23. 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.

24. 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)

25. 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” (Request from CCFA51)

26. This question arises from the discussion on alignment of the standard for wheat flour with the GSFA.
27. All amylases which are already included in CXG 36-1989 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.
28. 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 (Request from CCFA51)

29. 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.
30. 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.
31. 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. Sometimes re-use is very close to a name change.
32. 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.
33. 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.
34. Another option, proposed by the chair and co-chair, is to update the 'Information document/table on INS for deleted and re-used numbers' each year as an information table in the report of the electronic working group.

CONCLUSION AND RECOMMENDATIONS

35. The EWG recommends CCFA to consider the changes and/or additions/deletions to the INS list as presented in the annex I. CCFA can consider discussing alternative names suggested in paragraphs 14 and 15.
36. 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"
37. The EWG recommends CCFA to discuss annex II in order 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 or as a continuous annex of future reports of the EWG;
 - c. the question to which extent changes of names and changes of numbers are to be included
38. The EWG recommends the next EWGs would update or continue working on an information table to keep track of deleted INS numbers.

**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
<u>163(xi)</u>	<u>Butterfly Pea Flower Extract</u>	<u>Colour</u>	<u>Colour</u>
<u>183</u>	<u>Jagua (genipin-glycine) blue</u>	<u>Colour</u>	<u>Colour</u>
301	Sodium ascorbate	Antioxidant <u>Flour treatment agent</u>	<i>Antioxidant</i> <u>flour treatment agent</u>
322(i)	Lecithin	Antioxidant Emulsifier <u>Flour treatment agent</u>	<i>antioxidant</i> <u>antioxidant synergist</u> <i>emulsifier</i> <u>flour treatment agent</u>
332(ii)	Tripotassium citrate	Acidity regulator <u>Antioxidant</u> Emulsifying salt Sequestrant Stabilizer	<i>acidity regulator</i> <u>antioxidant synergist</u> <i>emulsifying salt</i> <i>sequestrant</i> <i>stabilizer</i>
333(iii)	Tricalcium citrate	Acidity regulator <u>Antioxidant</u> Emulsifying salt Firming agent Sequestrant Stabilizer	<i>acidity regulator</i> <u>antioxidant synergist</u> <i>emulsifying salt</i> <i>firming agent</i> <i>sequestrant</i> <i>stabilizer</i>
504(i)	Magnesium carbonate	Acidity regulator Anticaking agent Color retention agent <u>Flour treatment agent</u>	<i>acidity regulator</i> <i>anticaking agent</i> <i>color retention agent</i> <u>flour treatment agent</u>
953	Isomalt (Hydrogenated isomaltulose)	Anticaking agent Bulking agent <u>Flavour enhancer</u> Glazing agent Stabilizer Sweetener Thickener	<i>anticaking agent</i> <i>bulking agent</i> <u>flavour enhancer</u> <u>flavour synergist</u> <i>glazing agent</i> <i>stabilizer</i> <i>sweetener</i> <i>texturizing agent</i>
960b	Steviol glycosides from fermentation	<u>Sweetener</u>	<u>sweetener</u>

<u>960c</u>	<u>Enzyme modified steviol glycosides</u>	<u>Sweetener</u>	<u>sweetener</u>
<u>960d</u>	<u>Enzyme modified glucosylated steviol glycosides</u>	<u>Sweetener</u>	<u>sweetener</u>

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

In order of INS number

Name changes of food additives are not included in this list.

INS N°	Name of Food Additive	Functional class	Comments
128	Red 2G	colour	Deleted in 2019
160a(iv)	Carotenes, beta, algae	colour	In 2019, this number was deleted and re-used for β -carotene-rich extract from <i>Dunaliella salina</i>
163(i)	Anthocyanins	colour	Deleted in 2008 as it repeated the parent name 163 anthocyanins
164	Saffron	colour	Deleted in 1992; this number has been re-used for the colour Gardenia yellow in 2001
306	Mixed tocopherols concentrate	antioxidant	Deleted in 2007 to assign a new number 307b under the umbrella of 307 tocopherols
307	Tocopherol, alpha	antioxidant	In 2007, this number changed to umbrella number 307 tocopherols, when 307a d-alpha tocopherol concentrate and 307c dl-alpha tocopherol were introduced.
414a	Octenyl succinic acid (OSA) modified gum arabic	emulsifier	In 2011, the additive received another number 423
445i	Glyceryl abietate	Emulsifier, stabiliser	Deleted in 1990; this number 445(i) has been re-used in 2010 for glycerol ester of gum rosin
445ii	Ester gum	Emulsifier, stabilizer	Deleted in 1990; this number 445(ii) has been re-used in 2010 for glycerol ester of tall oil rosin
452(vi)	Sodium potassium tripolyphosphate	Acidity regulator, emulsifier, moisture retention agent, raising agent, sequestrant, stabilizer	In 2012, the INS number of this food additive was changed to another INS number (451(iii)) and the number 452(vi) was re-used the same year for sodium potassium hexametaphosphate
472f	Mixed tartaric, acetic and fatty acid esters of glycerol	Emulsifier, stabilizer, sequestrant	Deleted in 2005
498	Cross-Linked Sodium Carboxymethyl-Cellulose	Stabilizer, binder	Deleted in 2008 because it was a duplication of 466
907	Refined wax	Release agent	Deleted in 1990; this number has been re-used for the glazing agent hydrogenated poly-1-decenes in 1996
924a	Potassium bromate	Flour treatment agent	Deleted in 2012
924b	Calcium bromate	Flour treatment agent	Deleted in 2012
930	Monoisopropyl citrate	Preservative	Deleted in 1990, when this number was re-used for the flour treatment agent calcium peroxide
943	butane	propellant	Replaced in 1990 by 943a butane when 943b isobutane was added
952(iii)	Potassium cyclamate	sweetener	Deleted in 2009

960	stevioside	sweetener	Deleted in 2005 for immediate re-use for steviol glycosides
962	D-tagatose	sweetener	In 2004, D-tagatose was allocated a new INS number of 963 to re-use number 962 for acesulfame-aspartame salt to align with the EU number
1411	Distarch glycerol	Emulsifier, stabiliser, thickener	Deleted in 2019
1420	Starch acetate esterified with acetic anhydride	Thickener	In 2006, 1420 and 1421 were combined to 1420 starch acetate'
1421	Starch acetate esterified with vinyl acetate	Thickener	
1423	Acetylated Distarch Glycerol	Stabilizer, Thickener	Deleted in 2007 as these additives are no longer manufactured
1443	Hydroxypropyl Distarch Glycerol	Stabilizer, Thickener	

Proposed criteria for re-use of INS-numbers:

1. 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.