

# CODEx ALIMENTARIUS COMMISSION

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Food and Agriculture  
Organization of the  
United Nations



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Agenda Item 6

**CX/FA 24/54/9**  
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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEx COMMITTEE ON FOOD ADDITIVES

#### Fifty-fourth 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<sup>1</sup>

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 2024/23-FA available on the Codex webpage/Circular Letters 2024: <http://www.codexalimentarius.org/circular-letters/en/>.

## BACKGROUND

1. The 53<sup>th</sup> session of the Codex Committee on Food Additives (CCFA53)<sup>2</sup> held from 27 to 31 March 2023 agreed to establish an electronic Working Group (EWG), chaired by Belgium, working in English, to consider:
  - a. replies to a CL requesting proposals for change and/or addition to Section 3 of the Class Names and International Numbering System for Food Additives (CXG 36-1989); and preparing a proposal for circulation for comments at Step 3;
  - b. proposals for the addition of the new additives glycolipids (INS 246) as a preservative, oat lecithin (INS 322a) as an emulsifier and carbomer (INS 1210) as a bulking agent, stabilizer, thickener in the CXG 36-1989 (as mentioned in CX/FA 23/53/13 Add.1);
  - c. the addition of the functional classes of "stabilizer" and "thickener" for sodium sesquicarbonate (INS 500(iii)) (CX/FA 23/53/6);
  - d. the appropriateness of including the functional class of "preservative" for sodium thiosulfate (INS 539) (CX/FA 23/53/6);
  - e. the appropriateness of including the functional class of "carrier" and the technological purpose of "nutrient carrier" for mannitol (INS 421), starch sodium octenyl succinate (INS 1450), and sodium ascorbate (INS 301) (CX/FA 23/53/6); and
  - f. assigning an INS number to low acyl clarified gellan gum (CX/FA 23/FA 23/53/2 Add.2).

## DISCUSSIONS IN THE ELECTRONIC WORKING GROUP

2. In April 2023, the Codex Secretariat distributed CL 2023/45-FA, all Members and Observers were invited to respond by 15 September 2023 (proposals for change and/or addition to the INS list).
3. In June 2023, 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.. The Chair posted the replies to the CL on the platform and circulated a first and a second draft to the EWG on the platform,

<sup>1</sup> Members of the EWG include Australia, Austria, Brazil, China, India, Japan, Kenya, Morocco, Republic of Korea, Russian Federation, Saudi Arabia, Senegal, Turkiye, USA, European Union, EUSFI, FIA, IACM, ICBA, ICGA, IFAC, ISDI, NATCOL

<sup>2</sup> REP 23/FA para. 130 (iii)

for comments. Contributions were posted in the EWG by EU Specialty Food Ingredients, FIA, IACM, IFAC, ISDI, NATCOL.

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

- Addition of phycocyanin produced by bacteria, used as a blue colour
4. Chile requests to add the colour “Phycocyanin” with the following justification (only cited partially):
- The current proposal is based on the scientific experience of a group of specialists from the Interdisciplinary Marine Biotechnology Group (GIBMAR) at the Biotechnology Center and the Department of Food Science and Technology (CyTA), School of Pharmacy, University of Concepción, Chile, who developed a bacterial platform (*B. subtilis* and *E. coli*) for the expression of naturally occurring coloring molecules from macroalgae and microalgae at laboratory and pilot scale.
  - The team is currently executing the StarUp Science (ANID) project SUC220035, "Coloris Biotech: Protein based dyes for the food industry". The technology used is projected in the future as a biological platform for obtaining various high-value functional dyes for the food industry.
  - The current proposal contemplates initiating the procedure to obtain an INS number for the use of phycocyanin as a natural blue colorant, which will allow it to be processed and recognized by Codex. The review of the studies carried out allows to guarantee that it does not generate health problems, and allows, without restrictions, its use as a natural colorant, with proven stability to changes in pH and temperature, with a reduced environmental impact, and feasible to produce on an industrial scale using bacterial models.
  - Phycocyanin is a deep blue colored protein and is present naturally in spirulina extract.
  - We emphasize that the phycocyanin produced in the bacterial models is pure because it does not present traces of carotenoids and chlorophyll as is the case of spirulina extract. On the other hand, this phycocyanin does not present the typical undesirable odor and taste problems that are present in spirulina and spirulina extract.
  - Additionally, this phycocyanin does not contain traces of recombinant DNA of bacterial origin according to EFSA and FDA standards. These aspects constitute a very important technological justification that supports the present proposal.
  - There was evidence (with pictures) that the compound is capable of being used effectively for the technological purpose proposed.
5. The EWG strongly recommends not to include phycocyanin produced by bacteria, for use as a blue colour, as long as there is a lack of proof of authorization, including an official name, in a country. The text of CL 2023/45-FA (requests for the inclusion of new additives may be made by Codex members that authorize the additive for use in that country) as well as earlier discussions on blue microalgae extract of last year need to be taken into account. The name “Phycocyanin” is also not specific enough. Without scientific assessment, it can't be estimated if the colour is similar to that in spirulina extract (INS 134). The question whether the additive should be listed in a subcategory or not is therefore not possible to answer at this point in time.
- Addition of INS 267 buffered vinegar used as a preservative and acidity regulator
6. The European Union requested the addition of buffered vinegar. This additive is included in the European Union list of food additives approved for use in foods in September 2023. The technological need and function were scrutinised. Buffered vinegar is used as an alternative to other authorised preservatives or acidity regulators, in particular to acetic acid and its salts (E / INS 260-263). Buffering increases pH and allows the use as a preservative or acidity regulator in many food categories without impacting the quality of foods. Regulation (EU) 2023/2086 as regards the use of buffered vinegar as a preservative and acidity regulator, includes not only the authorization and conditions of use but also specifications and a reference to the risk assessment.
7. The EWG supported the proposal.

- Inclusion of the functional class “gelling agent” for carob bean gum (INS 410)
8. Peru submitted the request for inclusion of the functional class “gelling agent” for carob bean gum (INS 410), based on the JECFA specifications [monograph 19 of 2016 of JECFA82](https://www.fao.org/documents/card/en/c/ca7513en). <https://www.fao.org/documents/card/en/c/ca7513en> .
9. The EWG supported the proposal.
- Inclusion of the functional class “colour” for calcium sulfate (INS 516)
10. NATCOL requested the inclusion of the functional class “colour” for calcium sulfate (INS 516). Calcium sulphate, and in particular its anhydrous form, is a largely insoluble mineral which when milled to the appropriate particle size exhibits a strong and stable whitening and opacifying effect. In contrast to other TiO<sub>2</sub> alternatives such as calcium carbonate, which is instable at pH levels below 6, and starches which are not temperature stable in low dry substance food and beverage formulations, calcium sulphate is both pH and temperature stable. Therefore, calcium sulphate is a very suitable alternative to replace TiO<sub>2</sub> as a white food colour. This function is however not mentioned in the functional classes in the General Standard for Food Additives (GFSA, CXS 192-1995), which causes irritation of food processers, even though the functional classes are just indicative. To avoid this misunderstanding and to offer the food industry a suitable alternative to TiO<sub>2</sub>, it is requested to include the function as a colour in the functional classes in GSFA. Just for illustrative purposes and to demonstrate the whitening and opacifying ability of INS 516 in a typical application, its effect in emulsified cream bakery filling has been shown to reply to the CL. ANVISA (Brazil) was petitioned to recognise and allow the use of calcium sulphate as food colour in the fall of 2021. Acceptance and approval was granted in January 5, 2023. The food industry has started to use anhydrous calcium sulphate as colour in Europe since the ban of TiO<sub>2</sub> on August 7 2022 in various applications where calcium carbonate or starches do not work due to their technological limitations described above. Turkey and Saudi Arabia have in the meanwhile forbidden the use of TiO<sub>2</sub> and calcium sulphate has been introduced by the food industry for its whitening and opacifying ability since.
11. It can be noted that the JECFA specifications mention that calcium sulfate is white and slightly soluble in water.
12. It was mentioned that calcium sulfate has gained approval for use as a colour in Brazil and approval is pending for the Mercosur region. Therefore, calcium sulfate is capable of being used effectively as a color and industry has begun to use it for this purpose.
13. The EWG supported the proposal.

**B. Proposals for the addition of the new additives glycolipids (INS 246) as a preservative, oat lecithin (INS 322a) as an emulsifier and carbomer (INS 1210) as a bulking agent, stabilizer, thickener in the CXG 36-1989) (as mentioned in CX/FA 23/53/13 Add.1)**

14. In CX/FA 23/53/13 Add.1, the European Union requested the inclusion of a new food additive “glycolipids” used as a preservative and proposed the number INS 246. The technological need and function was scrutinised. Glycolipids acts as a preservative in flavoured drinks, some other non-alcoholic beverages and alcohol free beer and malt beverages. Regulation (EU) 2022/1037 as regards the use of glycolipids as a preservative in beverages, includes not only the authorization and conditions of use but also specifications and a reference to the risk assessment.
15. In CX/FA 23/53/13 Add.1, the European Union requested the inclusion of a new food additive “oat lecithin” as an emulsifier and proposed the number INS 322a, as E322a oat lecithin has been authorized as an emulsifier in the EU. The technological need and function was scrutinised. Oat lecithin acts as an emulsifier and facilitates the manufacturing of cocoa and chocolate products by reducing the viscosity and yield value of chocolate products. Regulation (EU) 2022/1023 as regards the use of oat lecithin in cocoa and chocolate products, includes not only the authorization and conditions of use but also specifications and a reference to the risk assessment.
16. In CX/FA 23/53/13 Add.1, the European Union requested the inclusion of a new food additive “carbomer” as a bulking agent, stabilizer, thickener and proposed the number INS 1210. The technological need and function were scrutinised. Carbomer acts as a bulking agent and stabiliser in solid food supplements and as stabiliser and thickener in liquid food supplements. Regulation (EU) 2023/440 as regards the use of carbomer in food supplements, includes not only the authorization and conditions of use but specifications and a reference to the risk assessment too.

17. The EWG supported the proposals for assigning INS numbers to the three substances, along with their corresponding functional classes and technological purposes.

**C. The addition of the functional classes of “stabilizer” and “thickener” for sodium sesquicarbonate (INS 500(iii)) (CX/FA 23/53/6)**

18. CCFA53 passed on the question of the EWG on Alignment whether the food additive sodium sesquicarbonate (INS 500(iii)) has the functional class of stabiliser and thickener, for which it is listed in CXS 253-2006 (Standard for Dairy Fat Spreads) but not in CXG 36-1989, to the EWG on INS. Therefore, it seemed inappropriate to add INS 500(iii) to Table 3 of the GSFA as part of alignment until the technological justification as stabilizer and thickener is established.

19. CXS 253-2006 mentions “Stabilizers/thickeners” and hence is not fully clear about the function. It can be noted that similar food additives, i.e. the other sodium carbonates INS 500 (i) and INS 500 (ii), already have the functional class and technological purpose of stabilizer and thickener in CXG 36-1989.

20. The EWG agreed to add the functional classes of “stabilizer” and “thickener” for sodium sesquicarbonate (INS 500(iii)) although no more information was available.

**D. The appropriateness of including the functional class of “preservative” for Sodium thiosulfate (INS 539) (CX/FA 23/53/6)**

21. CCFA53 passed the question related to the work on alignment, whether the functional class of “preservative” for sodium thiosulfate, which is mentioned in the *Regional standard for chili sauce* (CXS 306R-2011), can be scrutinized by the EWG on INS.

22. CXS 306R-2011 as well as the GSFA and JECFA include sodium thiosulfate in the group of sulfites.

23. The EWG agreed to include the functional class of “preservative” for Sodium thiosulfate (INS 539).

**E. The appropriateness of including the functional class of “carrier” and the technological purpose of “nutrient carrier” for mannitol (INS 421), starch sodium octenyl succinate (INS 1450), and sodium ascorbate (INS 301) (CX/FA 23/53/6)**

24. The *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CXG 10-1979) permits gum arabic (INS 414), silicon dioxide, amorphous (INS 551), mannitol (INS 421), starch sodium octenyl succinate (INS 1450) and sodium ascorbate (INS 301) as nutrient carriers. However, INS 421, INS 1450 and INS 301 do not have carrier function in the *Class Names and the International Numbering System for Food Additives* (CXG 36-1989). It is suggested that the technological function of INS 301 in nutrient preparations is as an antioxidant (CX/FA 23/53/6, page 269). The technological justification of the food additives listed in CXG 10-1979 relate to their function in the nutrient preparations.

25. The definition of carrier is: A food additive used to dissolve, dilute, disperse or otherwise physically modify a food additive or nutrient without altering its function (and without exerting any technological effect itself) in order to facilitate its handling, application or use of the food additive or nutrient. Hence, the function of antioxidant is not included in the definition of carrier. An additive which is used for its antioxidant effect in the nutrient preparation rather than in a fortified food, and is present in the fortified food by carry-over, is not a carrier. CXG 10-1979 lists Sodium L-ascorbate (in coating of nutrient preparations containing polyunsaturated fatty acids), hence for nutrients which are sensitive to oxidation, for which an antioxidant makes sense. Hence, there are reasons to question that there is a use as carrier.

26. INS 421 Mannitol, which already has the functional classes of anticaking agent and bulking agent, easily fits in a function as nutrient carrier.

27. The EWG did not take a strong position on INS 301. Some members noted that the function of carrier could be added simply on the basis of the advisory list, but noted also that the list of functional classes in CXG 36-1989 is not exhaustive as per Section 1 of the document under “Explanatory Notes on the Lay-Out of the INS”: “The various technological purposes of the food additives are included in the INS in a fourth column. The purposes listed are indicative rather than exhaustive. The technological purposes are grouped under more descriptive functional class titles which are intended to be meaningful to consumers. These are listed in Section 2 along with simple definitions of the function performed.”

28. The EWG supports including the functional class of “carrier” and the technological purpose of “nutrient carrier” for mannitol (INS 421) and starch sodium octenyl succinate (INS 1450).

**F. Assigning an INS number to low acyl clarified gellan gum (CX/FA 23/FA 23/53/2 Add.2)**

29. CCNFSDU43 informed CCFA that the proposed use of low-acyl clarified gellan gum as a thickener and stabilizer in formulas for special medical purposes intended for infants at 5 mg/100 mL limited to hydrolysed protein and/or amino acid-based liquid formula was technologically justified.

30. CCFA53 noted the revision of the *Standard for Follow-Up Formula for Older Infants and Product for Young Children* (CXS 156-1987) with respect to its new structure and food additives provisions and agreed to refer the food additive low-acyl clarified gellan gum to the EWG on Revision of the Class Names and the International Numbering System for Food Additives for assignment of an INS number.

31. Next to INS 418 gellan gum, it was proposed that the EWG assign INS 418 (i) low-acyl clarified gellan gum with the functional class of “thickener” and “stabilizer”, as it has been proposed by CCNFSDU. It was noted it could also be appropriate to include the functional class of gelling agent, copying the functions of gellan gum of which it is a particular kind. The latter proposal was supported by the EWG.

32. An alternative proposal was made by members of the EWG:

INS 418 Gellan

INS 418 (i) gellan gum

INS 418 (ii) Low-acyl clarified gellan gum

33. The alternative proposal can be helpful for the link with specifications. It creates a new parent additive. It would reduce the impact for food companies for the labelling of food the additive INS 418(ii) low-acyl clarified gellan gum, as INS 418(ii) low-acyl clarified gellan gum is until now included in INS 418 gellan gum. It would allow a new short name “gellan” as an option for both INS 418 (i) and INS 418 (ii). A need was mentioned to have a different name for the parent and the specific additive. It was further noted that the simple word ‘gellan’ is the legal name to be used in some Codex Members, such as Switzerland, Germany and Austria (“gellan” is the name in the German version of the EU Regulation). At Codex level, we note that similar food additives with (among others) thickening properties, either have or have not the suffix “gum”. Examples for thickeners the names of which do not contain the suffix “gum” include carrageenan, agar, curdlan, pectins, and others, while the term gum is included in the name for gum arabic, xanthan gum, tragacanth gum, carob bean gum to name a few. What is apparent from these examples, and also when comparing the use of the word “gum” at Codex and in other jurisdictions, is the following: sometimes the word “gum” is used for plant exudates (e.g. gum arabic), other times it is used to denote polysaccharides (e.g. gellan gum), or ground seed endosperm (e.g. carob bean gum). All three understandings of the word “gum” are used in this context not necessarily in a consistent way, neither at Codex nor in other jurisdictions. This in turn supports the proposal that the name “GELLAN” for INS 418 is fully in line with current Codex practice of denoting food additive names.

34. The EWG supported the alternative proposal as described in paragraph 32.

**CONCLUSION AND RECOMMENDATIONS**

35. The EWG recommends CCFA54:

- to consider the additions to the *Class Names and International Numbering System for Food Additives* (CXG 36-1989) as presented in the annex;
- not to include the function of carrier for sodium ascorbate (INS 301) as INS 301 already contains the function of antioxidant and this seems to fit the use in nutrient preparations; and
- not to include phycocyanin produced by bacteria for use as a blue colour until proper authorization, including an official name, is substantiated in a country.

**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 additions are highlighted with **bold/ underlined font**.

INS No.	Name of food additive	Functional class	Technological purpose
<b><u>246</u></b>	<b><u>Glycolipids</u></b>	<b><u>Preservative</u></b>	<b><u>preservative</u></b>
<b><u>267</u></b>	<b><u>Buffered vinegar</u></b>	<b><u>Acidity regulator</u></b>	<b><u>acidity regulator</u></b>
		<b><u>Preservative</u></b>	<b><u>preservative</u></b>
<b><u>322a</u></b>	<b><u>Oat lecithin</u></b>	<b><u>Emulsifier</u></b>	<b><u>emulsifier</u></b>
410	Carob bean gum	Emulsifier	<i>emulsifier</i>
		<b><u>Gelling agent</u></b>	<b><u>gelling agent</u></b>
		Stabilizer	<i>stabilizer</i>
		Thickener	<i>thickener</i>
<b><u>418</u></b>	<b><u>Gellan</u></b>		
418 <b><u>(i)</u></b>	Gellan gum	Gelling agent	<i>gelling agent</i>
		Stabilizer	<i>stabilizer</i>
		Thickener	<i>thickener</i>
<b><u>418(ii)</u></b>	<b><u>Low-acyl clarified gellan gum</u></b>	<b><u>Gelling agent</u></b>	<b><u>gelling agent</u></b>
		<b><u>Stabilizer</u></b>	<b><u>stabilizer</u></b>
		<b><u>Thickener</u></b>	<b><u>thickener</u></b>
421	Mannitol	Anticaking agent	<i>anticaking agent</i>
		Bulking agent	<i>bulking agent</i>
		<b><u>Carrier</u></b>	<b><u>nutrient carrier</u></b>
		Humectant	<i>humectant</i>
		Stabilizer	<i>stabilizer</i>
		Sweetener	<i>sweetener</i>
		Thickener	<i>texturizing agent</i>
500(iii)	Sodium sesquicarbonate	Acidity regulator	<i>acidity regulator</i>
		Anticaking agent	<i>anticaking agent</i>
		Raising agent	<i>raising agent</i>
		<b><u>Stabilizer</u></b>	<b><u>stabilizer</u></b>
		<b><u>Thickener</u></b>	<b><u>thickener</u></b>

516	Calcium sulfate	Acidity regulator	<i>acidity regulator</i>
		<b><u>Colour</u></b>	<b><u>colour</u></b>
		Firming agent	<i>firming agent</i>
		Flour treatment agent	<i>flour treatment agent</i>
		Sequestrant	<i>sequestrant</i>
		Stabilizer	<i>stabilizer</i>
539	Sodium thiosulfate	Antioxidant	<i>antibrowning agent</i> <i>antioxidant</i>
		<b><u>Preservative</u></b>	<b><u>preservative</u></b>
		Sequestrant	<i>sequestrant</i>
<b><u>1210</u></b>	<b><u>Carbomer</u></b>	<b><u>Bulking agent</u></b>	<b><u>bulking agent</u></b>
		<b><u>Stabilizer</u></b>	<b><u>stabilizer</u></b>
		<b><u>Thickener</u></b>	<b><u>thickener</u></b>
1450	Starch sodium octenyl succinate	<b><u>Carrier</u></b>	<b><u>nutrient carrier</u></b>
		Emulsifier	<i>emulsifier</i>
		Stabilizer	<i>stabilizer</i>
		Thickener	<i>binder</i>
			<i>thickener</i>