



**Food and Agriculture
Organization of the
United Nations**



**World Health
Organization**

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 6

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx COMMITTEE ON FOOD ADDITIVES

Fifty-fifth Session

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

(Prepared by the 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 2025/02-FA available on the Codex webpage/Circular Letters 2025:

<https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>

INTRODUCTION

1. The International Numbering System for Food Additives (INS) is intended as a harmonised naming system for food additives as an alternative to the use of the specific name, which may be lengthy. Inclusion in the INS does not imply approval by Codex for use as food additives. The list may include those additives that have not been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) or are not included in the *General Standard for Food Additives* (CXS 192-1995). Each year, an electronic working group (EWG) prepares proposals for updating the guidance, based on the terms of reference and the replies of the yearly Circular Letter (CL) requesting proposals for amendments.

TERMS OF REFERENCE

2. The 54th session of the Codex Committee on Food Additives (CCFA54)¹, held from 22 to 26 April 2024, agreed to establish an EWG, chaired by Belgium and co-chaired by Iran, working in English only, to consider:

- i. 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 prepare a proposal for circulation for comments at Step 3;
- ii. deleting azodicarbonamide (INS 927a); and
- iii. assessing the information provided by Chile on phycocyanin produced by bacteria for use as a blue colour, including the authorization in other countries.

PARTICIPATION AND METHODOLOGY

3. In May 2024, the Codex Secretariat distributed CL 2024/57-FA; all Members and Observers were invited to respond by 15 September 2024 in case of requests for proposals for changes and/or additions to the INS list.

4. On 27 August 2024, 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 by e-mail by their Codex contact point and registered also on the platform: Australia, Brazil, Chile, China, Egypt, European Union, Guatemala, Ireland, Nigeria, Norway, Republic of Korea, Russian Federation, Türkiye, USA, EUSFI, FDE, IACM, ICGA, NATCOL, OIV. The Chair posted the replies to the CL on the platform and circulated a first draft to the EWG on the platform, for comments. Contributions were posted in the EWG by Iran, Ireland, USA and NATCOL. The chair and co-chair prepared a second circular

¹ REP 24/FA para. 124

and posted it for comments. Contributions were received from the European Union and NATCOL. Chile provided more information on phycocyanin.

SUMMARY OF DISCUSSION

A. Replies to CL 2024/57-FA on addition and changes to INS

I. Addition of 'Jagua blue' as a synonym of name of INS 183 Jagua (genipin-glycine) blue

5. Colombia requests a change of name of INS 183 Jagua (genipin-glycine) blue in order to add "Jagua blue" as a synonym, referring to JECFA, adding the following justification. Appendix II of the report of CCFA52 consistently associates INS 183 with the name Jagua (genipin-glycine) blue. However, CCFA52 decided to delete the second parentheses (Jagua blue) for the purposes of CXG 36-1989. According to the JECFA Secretariat, the second parentheses "Jagua blue" was for clarity. Colombia believe that deleting this second parentheses will cause confusion for consumers and commercial users of the additive. The name on the INS list is not suitable for labelling purposes. The inclusion of the expression "(genipin-glycine)" in the name is extra, unnecessary information, which instead of giving accurate information to consumers could generate confusion, since it is very technical information, unfriendly to the eyes of consumers. In addition, most of them will not obtain any additional benefit from having this information on the label. The simplification of the name to jagua blue significantly reduces the space needed on the label for the additive. Consumers, trade interests and appropriate regulatory authorities seeking additional information on the identity of jagua blue may refer to the specifications for identity and purity developed by JECFA and adopted by the Codex Alimentarius. The name listed in the INS does not match the names of other related additives. Most of the food additives listed in CXG 36-1989 have concise, consumer-friendly names and do not contain technical information. When it comes to the functional class of colors, most have short, concise names. Exceptions are limited to additives that have subclasses under the main INS number (e.g. caramels (INS 150), carotenes (160a), annatto extracts (160b), lycopenes (160d), luteins (161b), etc.). The Convention for the use of parentheses in the names of food additives listed in CXG 36-1989 is limited to synonyms (e.g. azorubine (carmosine) (INS 122), indigotine (indigo carmine) (INS 132), etc.). In the case of the current name of the additive Jagua Blue, associated with the INS 183, the text between the parentheses "(genipin-glycine)" is not a synonym.

6. Earlier discussions on Jagua blue, including many synonyms, can be found in CX/FA 21/52/11, REP21/FA, CX/FA 23/53/13. The current request is only about adding one synonym (or a change in the name?).

7. Comments on the first circular were received from USA, Iran, Ireland and NATCOL. The EWG noted the following.

- (i) The current name "Jagua (genipin-glycine) blue" is in use as an official name (USA) and needs to remain.
- (ii) The analysis of Colombia is understood. The parentheses in this name, while parentheses are in use in the INS to indicate synonyms, leads to confusion and is an inconsistency in the INS.
- (iii) The name "Jagua blue" is also already in use as an official name (Mexico). There is a general understanding for the need of a simple synonym. The addition of the name "Jagua blue" as a synonym is supported by the EWG.

8. A proposal for the EWG is made to progress with the proposal to add the synonym "Jagua blue". However, it makes sense to consider options to address the misgivings, the confusion and inconsistency about the name which includes parentheses, especially in a situation when a synonym is added between parentheses in the INS:

- (i) To delete the parentheses in the current name and use the parentheses as usual to indicate the synonym: Jagua genipin-glycine blue (Jagua blue)
- (ii) To keep the proposal: Jagua (genipin-glycine) blue (Jagua blue) and to add a clarification, such as the follows:
 - a. The parentheses used in "Jagua (genipin-glycin) blue" are no indication of a synonym. INS 183 has two INS-names: 1) "Jagua (genipin-glycine) blue" and 2) "Jagua blue".
 - b. INS 183 has two INS-names to choose from: 1) "Jagua (genipin-glycine) blue" and the synonym between second parentheses 2) "Jagua blue".
 - either by (c or d or ...)
 - c. Adding the explanation in the Explanatory notes on the layout of the INS (page 2)
 - d. Adding a footnote with the clarification in sections 3 and 4 of the INS.

9. The EWG supports the addition of the synonym without changing the current name. The EWG is in favour of adding a clarification such as 8(ii) a, but there were no strong views as regards the options on how the clarification is captured.

10. After an internal consultation regarding the FAO document editing style, the Codex Secretariat proposes to: i) add a footnote to clarify the exact name and synonym of INS 183; and ii) include an explanation in the Explanatory Notes on the layout of the INS (page 2) to clarify the use of parentheses.

II. Deletion ortho-phenylphenol (INS 231) and sodium ortho-phenylphenol (INS 232).

11. The European Union requests the deletion of ortho-phenylphenol (INS 231) and sodium ortho-phenylphenol (INS 232).

12. CCFA51 discussed the inclusion of ortho-phenylphenol (INS 231) and sodium ortho-phenylphenol (INS 232) in the JECFA priority list in the light of the JECFA recommendation “to re-evaluate the ADIs as some studies indicate that the salt might be more toxic for human health than previously estimated” (see CX/FA 19/51/2 Add.1). CCFA51 included ortho-phenylphenol (INS 231) and sodium ortho-phenylphenol (INS 232) in the priority list; however, indicating that the data availability and data provider need to be confirmed at CCFA52 (REP19/FA, Appendix X). CCFA52 agreed requesting the Codex Secretariat to distribute a CL collecting information on commercial use of ortho-phenylphenol (INS 231) and sodium ortho-phenylphenol (INS 232) in food as preservatives for consideration by CCFA53 in order to make further decisions e.g., whether to include them in the priority list for JECFA’s re-evaluation or delete them from the GSFA (REP21/FA, para 60(iii)). At CCFA53, based on the comments received, the Codex Secretariat informed that ortho-phenylphenol (INS 231) and sodium ortho-phenylphenol (INS 232) were not in use as food additives. CCFA53 agreed to remove ORTHOPHENYLPHENOLS from the GSFA and inform CCPR of this decision (REP23/FA, paras 114-116). In addition, ortho-phenylphenol (INS 231) and sodium ortho-phenylphenol (INS 232) have been removed from the JECFA priority list. In light of the decision made by CCFA53, the EUMS propose removing ortho-phenylphenol (INS 231) and sodium ortho-phenylphenol (INS 232) from CXG 36-1989.

13. Depending on the question whether Members still need inclusion in the INS because of national authorisations, it can be decided to delete or not (yet) delete the additives from the INS.

14. The EWG supported the request for deletion.

III. Inclusion of oxidised polyethylene wax used as a glazing agent

15. The European Union requests inclusion of oxidised polyethylene wax used as a glazing agent. The European Union and its Member States (EUMS) noted that oxidised polyethylene wax, a food additive authorised in the EU since many years ago (1995), is not included in CXG 36-1989. Oxidised polyethylene wax is authorised in the EU (E 914) as a glazing agent for surface treatment of citrus fruit, melons, papaya, mango, avocado and pineapple. The use has been reported by the industry as captured in the scientific opinion of the European Food Safety Authority on the re-evaluation of oxidised polyethylene wax (E 914) as a food additive.² The EUMS propose that oxidised polyethylene wax is included in CXG 36-1989 and that INS 914 is assigned to it. The proposed functional class is “Glazing agent” and the proposed technological purpose is “glazing agent” and “coating agent”.

16. The EWG supported the request for addition.

IV. inclusion of the functional class “Gelling agent” for carob bean gum (INS 410)

17. Peru requests the inclusion of the functional class “Gelling agent” for carob bean gum (INS 410).

18. CCFA54 discussed the proposal of Peru to add the functional class and technological purpose of gelling agent to carob bean gum (INS 410). As CAC47 adopted the change in November 2024, this addition is already decided. No follow up to this request is needed.

V. inclusion of the additional technological function “Flour treatment agents” for lecithin INS 322(i)

19. Peru requests the inclusion of the additional technological function “Flour treatment agents” for lecithin (INS 322(i)).

20. INS 322(i) already has the functional class and technical purpose of flour treatment agent in CXG 36-1989. No follow up to this request is needed.

² <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4145>

B. Deleting azodicarbonamide (INS 927a)

21. Information included in CX/FA 24/54/3 Add.1 was presented in CCFA54 and discussed (REP 24/FA para. 39-44). As proposed by CCFA544, CAC47 deletes this additive from the GSFA because of issues with the safety assessment.

22. Depending on the question whether Members still need inclusion in the INS because of national authorisations, it can be decided to delete or not (yet) the additive from the INS.

23. The EWG noted that there is still national authorisation of azodicarbonamide, and the deletion was hence not supported by everyone. Inclusion in the INS does not imply approval by Codex for use as food additives. The list may include those additives that have not been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) or are not included in the *General Standard for Food Additives* (CXS 192-1995). The INS should not exclude additives that are still permitted for use in Codex countries.

24. It can be recommended to add this point in e.g. 5 years again to the mandate of the EWG on INS to investigate whether the time has come to delete this additive from INS.

C. Assessing the information provided by Chile on phycocyanin produced by bacteria for use as a blue colour, including the authorisation in other countries. (REP 24/FA para. 124)

25. Earlier discussion took place in the former EWG and is to be found in CX/FA 24/54/9. Comments and information were submitted as a reply to CL 2024/23-FA and can be found in CX/FA 24/54/9 Add.1. Other comments were submitted as CRD13, CRD23, CRD25, CRD26, CRD27, CRD28, CRD29 of CCFA54. The report of the in-session working group is available as CCFA54/CRD04. CCFA54 discussed the issues and proposed further work in the EWG (REP24/FA, para 118-121).

26. Chile first informed the chair that investigations were ongoing to compare the bacterial protein to the protein of spirulina in relation to the sequence and to compare the spectrophotometry of the bacterial phycocyanin to the phycocyanin of spirulina. Results might be available in November.

27. At the end of November, Chile specified that they requested to include two food additives: i) phycocyanin from *Bacillus subtilis*, ii) phycocyanin from *Escherichia coli*. Information on production was included. In a bioreactor, a culture of phycocyanin-producing bacteria is grown. Then the following purification steps are done.

- Cell Lysis: A 2% solution of bacterial biomass (*E. coli* or *B. subtilis*) rich in phycocyanin is prepared in a lysis buffer. The biomass in the lysis buffer is processed in a high-pressure homogenizer (HPH) at 1000 bar for 10 minutes, repeating this procedure three times.
- Phycocyanin purification: The total lysed biomass extract is subjected to contaminant removal using a tangential filtration system with the following steps:
 - Tangential filtration with a pore size of 300 kDa: This stage yields two fractions: i) The permeate from the 300 kDa membrane (contains proteins smaller than 300 kDa, rich in phycocyanin) and ii) the retentate that does not pass through the membrane (> 300 kDa, without phycocyanin). The retentate is discarded, and the permeate is used for a second stage of tangential filtration.
 - Tangential filtration with a pore size of 100 kDa: In the second stage of contaminant removal via tangential filtration, a hollow fiber system with a pore size of 100 kDa is used. This process also yields two fractions: i) The retentate (contains proteins larger than 100 kDa, rich in phycocyanin) and ii) the permeate (smaller than 100 kDa, without phycocyanin), which is discarded. The phycocyanin-rich retentate is concentrated to one-tenth of the original volume. Lysis buffer is added to the concentrated retentate, and the sample is reconcentrated to remove smaller molecular contaminants. To achieve this, five times the volume of lysis buffer is added to the permeate volume, and the sample is reconcentrated. This process is repeated three times.
 - Final Contaminant Removal by ATPS: The phycocyanin-rich solution undergoes contaminant removal using an aqueous two-phase system (ATPS). For this, potassium phosphate mono- and dibasic salts are added to the phycocyanin-rich solution at a range of 20–25%, and polyethylene glycol 3350 is added at a final concentration of 5–12%. The solution is vigorously stirred for 10 minutes. Two phases are separated by gravity: the polymeric phase (upper) and the saline phase (lower). The polymeric phase, rich in phycocyanin, is recovered by aspiration

and stored at 4°C until use. The saline phase, containing contaminants and free of phycocyanin, is discarded.

28. Chile provided more information in December. For the safety of phycocyanin from *E.coli*, reference is made to the safety of the unmodified *E.coli* (modification is done by incorporating gene sequences associated with phycocyanin synthesis in *Spirulina* and *Gracilaria*). Chile also referred to the safety of phycocyanin from *spirulina*. Results from the investigation of the colour of the phycocyanin from recombinant *E. coli* and comparison with *spirulina* extract were shared with the EWG. A slight difference was found: the phycocyanin from *E.coli* exhibits a purer blue, which is to be expected as it only contains the purified protein, while *spirulina* extract may contain other pigmented proteins and has a slight magenta tint.

29. The EWG did not have the information needed (e.g. on authorisations in countries) and hence cannot (yet) recommend addition in the INS of i) Phycocyanin from *Bacillus subtilis*, ii) Phycocyanin from *Escherichia coli*.

CONCLUSION AND RECOMMENDATIONS

30. The EWG recommends CCFA55 to:

- (i) consider the additions and deletions to the *Class Names and International Numbering System for Food Additives* (CXG 36-1989) as presented in the Annex, including adding a clarification for INS 183 (see paragraphs 8-10).
 - Update the Information document/table on INS for deleted and re-used numbers with the deletion of INS 231 and INS 232.
 - Find out why ortho-phenylphenol is listed as 2-phenylphenol in the list of flavourings in the *List of Codex specifications for food additives* (CXA 6-2023) and decide whether this entry needs to be deleted.
- (ii) add the point on deletion of azodicarbonamide (INS 927a) again in the mandate of the EWG on INS in a few years time, e.g. in 2030, to investigate whether it still needs to remain included in the INS because of national authorisation(s).

PROPOSED CHANGES, DELETIONS AND/OR ADDITIONS TO THE INS
(at Step 3)

Part 1: Revisions to Sections 3 and 4 of CXG 36-1989

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

INS No.	Name of food additive	Functional class	Technological purpose
183	Jagua (genipin-glycine) blue <u>(Jagua blue)</u> ³	Colour	<i>colour</i>
231	Ortho-phenylphenol	Preservative	<i>preservative</i>
232	Sodium ortho-phenylphenol	Preservative	<i>Preservative</i>
<u>914</u>	<u>Oxidised polyethylene wax</u>	<u>Glazing agent</u>	<u>glazing agent</u> <u>coating agent</u>

Part 2: Revision to Section 1 of CXG 36-1989

The proposed addition of the explanation in the Explanatory notes on the layout of the INS are highlighted with **bold/underlined font**.

1. INTRODUCTION

EXPLANATORY NOTES ON THE LAYOUT OF THE INS

The name of the food additive is sometimes followed by an additional name in parentheses. The parenthetical name is optional, and may be used, when necessary, to indicate another commonly associated name or synonym for the additive, for example INS 235 Natamycin (Pimaricin). Not all synonyms are listed. **A footnote can be used to clarify the use of parentheses**. The name of an additive is sometimes, after a comma, followed by a description of the additive, for example INS 161h(i) Zeaxanthin, synthetic.

³ The parentheses used in “Jagua (genipin-glycin) blue” are no indication of a synonym. INS 183 has two INS-names: 1) “Jagua (genipin-glycine) blue”; and 2) “Jagua blue”.