



## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD ADDITIVES

#### Fifty-first Session

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

Prepared by an Electronic Working Group<sup>1</sup> co- chaired by Iran and Belgium

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 2019/12-FA available on the Codex webpage/Circular Letters 2019: <http://www.codexalimentarius.org/circular-letters/en/>.

#### Background

1. In March 2018 the 50<sup>th</sup> Session of Codex Committee on Food Additives (CCFA50) held in Xiamen, agreed to establish an electronic working group (EWG) open to all members and observers, co- chaired by Iran and Belgium, and working in English only, with the following term of reference:

- (i) Consider the replies to the CL 2018/26-FA requesting proposals for changes and/or additions to the INS list; and prepare a proposal for circulation for comments at Step 3; and
- (ii) Assign an INS number to  $\beta$ - carotene- rich extract from *Dunaliella salina*.

2. In April 2018 the Codex Secretariat distributed CL 2018/26-FA, all members and observers were invited to respond by 15 September 2018 (proposals for changes, addition and deletion to the INS list).

#### The Electronic Working Group

3. In 26<sup>th</sup> May 2018, the Codex Secretariat distributed a kick-off message containing an invitation to members and observers to express interest in participation in the EWG. This invitation contained: the term of reference of the EWG; a general outline of the work of the EWG; and the expected outcome of the work, namely a proposal for changes to the INS list.

4. An outline of the work, a first and second draft were send to the EWG. An attempt has been made to take into account the comments of the EWG.

#### Replies to the circular letters on addition and changes to INS:

5. Comments in response to CL 2018/26-FA were received from the European Union and Senegal.

*Based on the European Union reply:*

6. A request for deletion of the following additives from INS list is to be discussed:

- Red 2G (INS 128)
- Sodium sorbate (INS 201)
- Potassium ascorbate (INS 303)
- Distarch glycerol (INS 1411)

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<sup>1</sup> Members of EWG: Argentina, Belgium, Brazil, Canada, China, Colombia, Egypt, European Union, India, Iran, Ireland, Japan, Kazakhstan, Malaysia, Mexico, Norway, Peru, Republic of Korea, the Russian Federation, Senegal, Spain, the United Kingdom, the United States of America, Association for International Promotion of Gums (AIPG), European Food Emulsifiers Manufacturers Association (EFEMA), EU specialty food ingredients (Formerly ELC), Food Drink Europe (FDE), International Fruit and Vegetable Juice Association (IFU), International Association of Color Manufacturers (IACM), International Council of Beverage Association (ICBA), International Chewing Gum Association (ICGA), International Council of Beverages Association, International Council of Grocery Manufacturers Association (ICGMA), International Organization of the Flavor Industry (IOFI), International Special Dietary Foods Industries (ISDI), Natural Food Colors Association (NATCOL), the Calorie Control Council (CCC), the Food Industry Asia (FIA), the International Alliance of Dietary/Food Supplement Associations (IADSA) and the International Food Additives Council (IFAC)

#### Justification for deletion of Red 2G and discussion

7. The European Food Safety Authority (EFSA) re-evaluated safety of Red 2G (INS 128) in 2007 and concluded that it would be prudent to regard Red 2G as being of safety concern since it is extensively metabolized to aniline which should be considered as a carcinogen for which a genotoxic mechanism cannot be excluded.

8. There are no provisions for Red 2G in the GSFA. Safety of Red 2G should have been re-evaluated by the Joint Expert Committee on Food Additives (JECFA). However, CCFA50 agreed to remove Red 2G (INS 128) from the priority list of substances for evaluation by JECFA since no confirmation of data availability had been provided and noted that the specification and the ADI for Red 2G would be withdrawn (REP18/FA, paragraph 130). Based on the lack of the interest to provide the data it can be assumed that the additive is not commercially manufactured or used.

9. If it is not legally on the market and as it is not in GSFA, it can be deleted now from the INS list. As a health issue has been raised, there is an argument to consider to delete the substance from the INS.

#### Justification for deletion of sodium sorbate and discussion

10. The EFSA in 2015 took note of the available positive genotoxicity data on sodium sorbate reported by the scientific committee on food. Sodium sorbate is not authorized any more in the EU. In 2015, CL 2015/9-FA requesting information on the commercial use of sodium sorbate, received a reply from Colombia and from Malaysia, informing on national authorizations as well as on commercial use.

11. There are no codex specifications for sodium sorbate. CCFA49 agreed to retain sodium sorbate (INS 201) on the priority list for evaluation by JECFA, but because of lack of data, the CCFA50 agreed to remove sodium sorbate from the priority list. CCFA50 noted that relevant provisions of sodium sorbate in both the GSFA and relevant commodity standards would be revoked (REP18/FA, paragraph 132, 134(iv)). Based on the lack of the interest to provide the data it was assumed by the European Union that the additive is not commercially manufactured or used.

#### Justification for deletion of potassium ascorbate and discussion

12. There are no provisions for potassium ascorbate (INS 303) in the GSFA, no specifications established, neither potassium ascorbate is on the JECFA priority list. The Member States of the European Union are not aware of any use of this substance as an additive, thus suggest deleting the substance from CXG 36-1989 unless the evidence of its commercial use as an additive is provided.

13. Potassium ascorbate has been removed from the GSFA in 2015 due to lack of specifications and no commitment for the JECFA priority list.

#### Justification for deletion of distarch glycerol and discussion

14. There are no provisions for distarch glycerol (INS 1411) in the GSFA, no specifications established (see list of codex specifications for food additives (CAC/MISC 6-2018)), neither distarch glycerol is on the JECFA priority list. The Member States of the European Union are not aware of any use of this substance as an additive, thus suggest deleting the substance from CXG 36-1989 unless the evidence of its commercial use as an additive is provided.

#### General discussion on the EU proposal

15. It was to be investigated whether these four additives are still commercially manufactured or used. The USA indicated commercial use of all four food additives and suggested it is premature to delete the INS numbers. The International Numbering System for Food Additives (INS) is intended as a harmonized naming system for food additives. The question was raised whether there are countries in which the use is still authorized. In Russia, sodium sorbate (INS 201) and potassium ascorbate (INS 303) are still legally used. In the USA sodium sorbate (INS 201) is still authorized and used. Hence sodium sorbate and potassium ascorbate should not be deleted from INS. 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. The EWG supported the proposal in the annex.

*Based on Senegal reply:*

Justification for addition the functional class of carrier for basic methacrylate copolymer and discussion

16. The INS currently associates the functional class of “Glazing agent” with the additive basic methacrylate copolymer (Methacrylate copolymer, basic; INS 1205). Senegal requested that the CCFA add the functional class of “Carrier” and the technological purposes of “carrier” and “encapsulating agent” to basic methacrylate copolymer, with the following justification. It has been demonstrated that micronutrient encapsulation in basic methacrylate copolymer allows for the rapid, complete release of micronutrients from the polymer coating when immersed in simulated gastric fluid (SGF) at 37°C, but the absence of their release in water at room temperature or at 100°C for 2 hours. Furthermore, the encapsulation has been shown to protect micronutrients from degradation due to light and humidity exposure during storage.

17. At its 86<sup>th</sup> meeting in Geneva, 12-21 June, 2018, JECFA established an ADI “not specified” for basic methacrylate copolymer. JECFA concluded that the use of BMC that complies with the specifications established at the current meeting is not of safety concern when the food additive is used as a coating or glazing agent for solid food supplements and for foods for special medical purposes and micronutrient encapsulation for food fortification.

**Assign an INS number to  $\beta$ - carotene- rich extract from *Dunaliella salina*:**

18. The first proposal of the co- chairs of the EWG was:

Name:  $\beta$ - carotene-rich extract from *Dunaliella salina*

INS: 160a (v)

Functional class: colour

Technological purpose: colour

19. It was noted that the FAO JECFA secretariat clarified that the JECFA specification was different from Carotene (Algae) (INS 160a(iv)) which was not covered by  $\beta$ - Carotene- rich extract from *Dunaliella salina* (REP 18/FA, paragraph 21).

20. There are no adopted codex specifications for carotene (algae) and this additive is not in the GSFA either. According to information of industry, INS 160a(iv) with the specifications of carotene (algae) is not on the market any more. The EU specifications (in regulation 231/2012) for E160a (iv) algal carotenes are more similar to the new specifications for  $\beta$ - carotene- rich extract from *Dunaliella salina* than to the JECFA specifications for INS 160a(iv) carotenes (algae).

21. Hence the proposal is made to reuse the INS number 160a(iv) for the new specifications and to stop using it for the old specifications, similar to a change in specifications, combined with a change of name.

22. A consequential change should be made to the list of codex specifications for food additives CXM 6-2018, to include the new INS number for the adopted specifications of  $\beta$ - carotene- rich extract from *Dunaliella salina*.

**Conclusion and recommendations:**

23. The EWG recommends CCFA to consider the changes and/ or additions/ deletions to the INS list as presented in tables 1, 2 and 3, as well as consequential changes to the list of specifications presented in table 4. There are no consequential changes for the GSFA.

24. 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.

**Final remark from the co-chairs**

25. While finalizing the report of the EWG, the co-Chairs noted that, although there are no adopted provisions for Red 2G (INS 128) in the GSFA, there are, however, provisions in the steps procedure. According to the decision of CCFA50 that “Proposals for deletion of INS entries cannot be submitted to this circular letter if there are existing provisions (adopted or in the Step Process) for the additive in the *General Standard for Food Additives* (CODEX STAN 192-1995).” (Appendix XII, part B of REP18/FA), the proposal for deletion might have to be reconsidered, unless the provisions in the steps procedure are discontinued too in line with the announced withdrawal of the ADI (REP18/FA, paragraph 130).

26. However due to time-constraint, the proposal for deletion of red 2G could not be sent back for consideration by the EWG.

**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**. Text in ~~strikethrough~~ is to be deleted.

**Table 1: New or additional functional class or technological purpose**

INS No.	Name of food additive	Functional class	Technological purpose
1205	Methacrylate copolymer, basic	Glazing agent	<i>glazing agent</i>
		<b><u>Carrier</u></b>	<b><u>carrier</u></b>
			<b><u>encapsulating agent</u></b>

**Table 2: Change of name**

INS No.	Name of Food Additive	Functional class	Technological Purpose
160a(iv)	Carotenes, <del>beta-</del> , algae <b><u>β- carotene- rich extract from <i>Dunaliella salina</i></u></b>	Colour	<i>colour</i>

**Table 3: Substances to be deleted**

INS No.	Name of Food Additive	Functional class	Technological Purpose
<del>128</del>	<del>Red 2 G</del>	<del>Colour</del>	<del>colour</del>
<del>1411</del>	<del>Distarch glycerol</del>	<del>Emulsifier</del>	<del>emulsifier</del>
		<del>Stabilizer</del>	<del>stabilizer</del>
		<del>Thickener</del>	<del>binder</del> <del>thickener</del>

**Table 4: Consequential changes in the List of Codex Specifications for Food Additives  
(CXM 6-2018)**

FOOD ADDITIVE	ADDITIF ALIMENTAIRE	ADITIVO ALIMENTARIO	INS No.	Year of adoption
Red 2G	Rouge 2G	Rojo 2G	<del>128</del>	1987; (2003)
β-Carotene-rich extract from <i>Dunaliella salina</i>	Extrait riche en β-Carotène de <i>Dunaliella salina</i>	Extracto de <i>Dunaliella salina</i> rico en betacarotenos	<b><u>160a(iv)</u></b>	2018