



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx COMMITTEE ON FOOD ADDITIVES

Forty-Ninth Session

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

(prepared by an electronic Working Group led by Iran¹)

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments at Step 3 on the proposed changes and/or addition to the International Numbering System for Food Additives (Annex 1) are invited to do so no later than **15 February 2017** as follows: Secretariat, Codex Committee on Food Additives, China National Center for Food Safety Risk Assessment (CFSA), Building 2, No. 37 Guangqu Road, Chaoyang District, Beijing 100022, China, (E-mail: ccfa@cfsa.net.cn), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (E-mail: Codex@fao.org).

Format for submitting comments: In order to facilitate the compilation of comments and prepare a more useful comments document, Members and Observers are requested to provide their comments in word file.

Background

1. In March 2016 the 48th Session of Codex Committee on Food Additives (CCFA48) agreed to establish an electronic working group (EWG) opens to all members and observers and hosted by Iran, and working in English only, with the following term of reference:
 - Consider the replies to the **CL 2016/7-FA** requesting proposals for changes and/or additions to the INS list; and prepare a proposal for circulation for comments at Step 3.
2. In May 2016 the Codex Secretariat distributed CL 2016/7-FA, all members and observers were invited to respond by 15 September 2016 (proposals for changes, addition and deletion to the INS list)

The Electronic Working Group

3. In May 2016, the Codex Secretariat distributed a kick-off message containing an invitation to members and observers to sign up for the EWG by 22 June 2016. 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. By 5 July 2016, 18 members and 11 observers had signed up for the EWG.
5. An outline of the work of the EWG was distributed to the EWG on 21 August 2016. The deadline for submitting information and comments was 15 September 2016 which was later extended to 30 September 2016.
6. By 30 September 2016, comments from 14 members of the EWG were received. Based on the comments received, Iran prepared the final draft.

Summary comments of EWG

¹Members of the EWG: Brazil, China, Costa Rica, Cuba, EU, Iran, Japan, Malaysia, New Zealand, Russia, USA, India, Thailand, Association of Manufacturers and Formulators of Enzyme Products (AMFEP), Calorie Control Council (CCC), Federation of European Specialty Food Ingredients Industries (ELC), International Association of Colour Manufacturers (IACM), International Chewing Gum Association (ICGA), International Dairy Federation (IDF), International Food Additives Council (IFAC), International Sweeteners Association (ISA)

7. An attempt has been made to include all proposed changes, especially as regards the Technological Purposes in order to list all Technological Purposes for which the additive is used according to comments received. The justifications are highlighted in the following paragraphs.

8. It is important to note that any change to INS numbers, food additive names and its encompassing scopes have impact in the GSFA. It was brought to attention of the Chair of INS by a member that any change would result in a consequential change to the Tables 1 and 2 on the adopted GSFA provision, as well as to its general listing in Table 3 of the GSFA.

9. EWG Members made the following proposals:

- Inclusion of a new entry for:
 - Iron tartrate with functional class and technological purpose of anticaking agent.
 - trehalose with technological purpose of sweetener, humectant, stabilizer and texturizing agent.
 - "hibiscus colour" and "elderberry colour" with functional class and technological purpose of colour.
 - lecithin, hydroxylated as a food additive with INS 322(iii) with functional class: emulsifier and antioxidant and technological purpose: emulsifier and antioxidant.
 - Sodium polyacrylate with functional class and technological purpose of stabilizer.
 - proteases from *Bacillus amyloliquefaciens*, in addition to proteases from *Bacillus subtilis* (INS 1101(vi)).
- Addition of functional class/technological purpose to:
 - Sodium carbonate (INS 500(i)) emulsifying salt synergist with a footnote restricting its use to only those circumstances where the processed cheese is made using lemon juice.
 - Sucralose (INS 955): flavour enhancer.
- Deletion of:
 - amylases (INS 1100 i, ii, iii, iv, v, vi) , proteases (INS 1101 i, ii, iii, iv, v, vi) and lipases (INS 1104).
 - nisin (INS 234) and pimaricin, natamycin (INS 235) because they are antibiotics and could not be used as food additives.

EWG Analysis and recommendations

Deletion of amylases (INS 1100 i, ii, iii, iv, v, vi), proteases (INS 1101 i, ii, iii, iv, v, vi) and lipases (INS 1104)

10. Amylases (INS 1100 i, ii, iii, iv, v, vi), proteases (INS 1101 i, ii, iii, iv, v, vi), lipases (INS 1104) are not justified for use as food additives since they fall outside the scope of the definition for food additives. These substances have no activity in final food (flour and bakery products) because the production process typically includes heat inactivation of the enzyme in order to terminate the process when the desired effect is obtained.

11. In compliance with table 3 of GSFA, amylases (INS 1100 i, ii, iii, iv, v, vi), proteases (INS 1101 i, ii, iii, iv, v, vi) and lipases (INS 1104) could be used in broad food categories in accordance with GMP. In some of these FC activity enzymes could be manifested.

12. Amylases (INS 1100 i, ii, iii, iv, v, vi), proteases (INS 1101 i, ii, iii, iv, v, vi) and lipases (INS 1104) are digestive enzymes. They have been broadly used in therapy of digestive tract diseases. However in case of systematic use of digestive enzymes with food there could be imbalance in digestive process:

- Decrease production of endogenic digestive enzyme
- Change of Michaelis constant, from which depend of enzymatic reaction rate in the digestion of food
- Violation allosteric control of enzyme activity
- Hormone imbalance which are for supervising production of digestive enzyme responsible in the human organism.

13. For example, changing quantity of lipase and amylase could lead to imbalance of endocrine function of pancreas and lowering organism tolerance into glucose. It should be noted that:

- As producers of these food additives permitted microorganisms with modified DNA
- Volumes of enzymes production and food produced with help of enzymes are constantly increased.

14. Produced by GM microorganisms enzymes could have different characteristics from enzymes elaborated in digestive tract:

- Another optimum of temperature and pH for enzyme activity
- Different enantiomeres could have different type of enzyme activity.

15. For example, the possibility of negative influence of food additive lipase (in case its use in a higher concentration) showed in:

- WHO Food Additives Series: 71, World Health Organization, Geneva, 2015, p.27-37;
- Safety evaluation of certain food additives World Health Organization, Geneva, 2012.-p.39-51;
- Safety evaluation of certain food additives World Health Organization, Geneva, 2012.-p. 51-63;
- Sixty-first report of the Joint FAO/WHO Expert Committee on Food Additives, WHO 2004, 15-20.

Deletion of nisin (INS 234) and pimaricin (INS 235)

16. Nisin (INS 234) and pimaricin (natamycin) (INS 235) are antibiotics so antibiotics could not be used as food additives. World leaders recognized the need for stronger systems to monitor drug-resistant infections and the volume of antimicrobials used in humans, animals, and crops, as well as increased international cooperation and funding. Countries reaffirmed their commitment to develop national action plans on antimicrobial resistance (AMR), based on the "Global Action Plan on Antimicrobial Resistance" — the blueprint for tackling.

17. AMR developed in 2015 by WHO in coordination with the Food and Agriculture Organization of the United Nations (FAO) and the World Organisation for Animal Health (OIE)

18. Excluding nisin (INS 234), pimaricin (natamycin) (INS 235) from INS list is one of decisions which could help solve the problem of AMR.

Addition of hibiscous colour and elderberry colour

19. Because the new colours (elderberry and hibiscus) are anthocyanins, it is suggested to be sub- codes of anthocyaninns and for clarity and for consistency with existing INS entries, e.g. purple corn colour (INS 163(iv)), red cabbage colour (INS 163(v)) for elderberry colour and hibiscus colour.

Addition of function class for sodium carbonate (INS 500(i)) as an emulsifying salt synergist with a footnote

20. The inclusion of the footnote ("Restricting its use to only those circumstances where the processed cheese is made using lemon juice") in the INS list is unprecedented. Furthermore such a footnote is inappropriate in the INS list. The inclusion of such a note restricting the use of sodium carbonate in a particular food (if it were deemed necessary) is more appropriate in the *General Standard for Food Additives* (GSFA).

Addition of trehalose

21. Trehalose, a disaccharide sugar, does not fit the definition of sweetener in the functional classes of the food additive. The *Class Names and the International Numbering System for Food Additives* (CAC/GL 36-1989) stipulates that sweetener is "a food additive (other than a mono- or disaccharide sugar), which imparts a sweet taste to a food."

Others

22. Harmonizing between E-number and INS list needs wide integration analysis and huge work and in accordance to the opposing views this activity currently remains silent.

Conclusion

23. The proposal for changes and/or additions to the INS list is presented in Annex 1 (Table 1 & 2); with Table 1 new or additional technological purpose and Table 2 deletion of additive purpose.

**Proposed draft 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 in the Table 1 & 2. The changes are highlighted with **bold/underlined font**.

Table 1: New or additional technological purpose

INS No.	Name of Food Additive	Functional class	Technological Purpose
955	Sucralose(Trichlorogalactosucrose)	Sweetener <u>Flavour enhancer</u>	Sweetener <u>Flavour enhancer</u>
163	Anthocyanin		
<u>163(iv)</u>	<u>Elderberry colour</u>	<u>Colour</u>	<u>Colour</u>
<u>163(X)</u>	<u>Hibiscus colour</u>	<u>Colour</u>	<u>Colour</u>
500(i)	Sodium carbonate	<u>Emulsifying salt</u>	<u>Emulsifying salt synergist</u>
<u>534</u>	<u>Iron tartrate</u>	<u>Anticaking agent</u>	<u>Anticaking agent</u>
<u>322(iii)</u>	<u>Lecithin, hydroxylated</u>	<u>Emulsifier</u> <u>Antioxidant</u>	<u>Emulsifier</u> <u>Antioxidant</u>
<u>?</u>	<u>Sodium polyacrylate</u>	<u>Stabilizer</u>	<u>Stabilizer</u>
<u>?</u>	<u>Trehalose</u>	<u>Humectant</u> <u>Stabilizer</u> <u>Texturizing agent</u>	<u>Humectant</u> <u>Stabilizer</u> <u>Texturizing agent</u>

Table 2: Deletion of additive purpose

INS No.	Name of Food Additive	Functional class	Technological Purpose
1100	Amylases		
1100(i)	alpha-amylase from Aspergillus oryzae var.	Flour treatment agent	flour treatment agent
1100(ii)	alpha-amylase from Bacillus stearothermophilus	Flour treatment agent	flour treatment agent
1100(iii)	alpha-amylase from Bacillus subtilis	Flour treatment agent	flour treatment agent
1100(iv)	alpha-amylase from Bacillus megaterium expressed in Bacillus subtilis	Flour treatment agent	flour treatment agent
1100(v)	alpha-amylase from Bacillus stearothermophilus expressed in Bacillus subtilis	Flour treatment agent	flour treatment agent
1100(vi)	Carbohydrase from Bacillus licheniformis	Flour treatment agent	flour treatment agent
1104	Proteases		
1104(i)	Protease from Aspergillus oryzae. Var.	Flour treatment agent Flavour enhancer Stabilizer	flour treatment agent flavour enhancer stabilizer
1104(ii)	Papain	Flavour enhancer Flour treatment agent	flavour enhancer flour treatment agent
1104(iii)	Bromelain	Flavour enhancer Stabilizer Flour treatment agent	flavour enhancer stabilizer flour treatment agent
1104(iv)	Ficin	Flavour enhancer Stabilizer Flour treatment agent	flavour enhancer stabilizer flour treatment agent
1104(v)	Protease from Streptomyces fradiae	Flavour enhancer Stabilizer Flour treatment agent	flavour enhancer stabilizer flour treatment agent
1104(vi)	Protease from Bacillus subtilis	Flavour enhancer Stabilizer	flavour enhancer stabilizer
1104	Lipases	Flavour enhancer	flavour enhancer
234	Nisin	Preservative	Preservative
235	Natamycin(Pimaricin)	Preservative	Preservative