CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 6 **CX/FA 16/48/14**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-Eighth Session
Xi'an, China, 14-18 March 2016

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

(Prepared by an electronic Working Group led by Iran[1])

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 **31 January 2016** 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 2015 CCFA47 agreed to establish an electronic Working Group (eWG), open to all members and observers and hosted by Iran, and working in English only, with the following terms of reference:

   (i) Consider the replies to the CL 2015/10-FA requesting proposals for changes and/or additions to the INS list; and prepare a proposal for circulation for comments at Step 3

   (ii) Assign INS numbers for specific proteases for which no corresponding INS has been set (e.g. proteases from *Aspergillus oryzae var*. and from *Streptomyces fradiae*)

2. In May 2015, the Codex Secretariat distributed CL 2015/10-FA inviting proposals for changes, addition (and deletion) to the INS list, by 15 September 2015.

The Electronic Working Group

3. In May 2015, the Codex Secretariat distributed a kick-off message inviting Codex members and observers to express interest in participation in the eWG by 15 June 2015. This invitation contained: the terms 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 20 June 2015 thirteen members, one member organization and fourteen observers had signed up for the eWG and a contact list was established.

5. An outline of the work was distributed to the eWG on 20 June 2015. The deadline for submitting information and comments was the same as that of to the CL 2015/10-FA, i.e.15 September 2015.

6. On 30 September 2015, a compilation of the proposals received was sent to the eWG members for comments by 31 October 2015. Based on the comments received, Iran prepared the final document.

[1] Members of the eWG: Argentina, Brazil, China, Costa Rica, European Union,, Iran, Japan, Malaysia, Netherlands, New Zealand, Norway, Republic of Korea, Russia, United States of America, Association for International Promotion of Gums (AIPG), Calorie Control Council (CCC), Federation of European Specialty Food Ingredients Industries (ELC), European Food Emulsifier Manufacturers Association (EFEMA), International Alliance of Dietary/Food Supplement Associations (IADSA), International Association for the Development of Natural Gums (AIDGUM), international Organization of the Flavor Industry (IOFI), International Association of Color Manufacturers (IACM), International Chewing Gum Association (ICGA), International Dairy Federation (IDF), International Council of Grocery Manufacturers Association (ICGMA), International Food Additives Council (IFAC), Natural Food Colours Association(NATCOL), International Organisation of Vine and Wine (OIV).

Summary of eWG's comments

Modification of an existing INS name or new INS number purpose

Proteases

7. The eWG made an attempt to include all proposed changes, especially the technological purposes in order to list all technological purposes for which the food 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 Codex member that any change to the name of protease (INS (1101(i)) would result in a consequential change to the Tables 1 and 2 on the adopted GSFA provision for protease (INS 1101(i)) in food category 06.2.1 (Flours), as well as to its general listing in Table 3 of the GSFA. These changes may have the effect of limiting the scope of proteases that could be used in the GSFA in association with the adopted provisions. In regard to functional class, it is important to note that the existing listing for "Protease (INS 1101(i))" in CAC/GL 36-1989 is associated with the Technological purposes of "flour treatment agent", "flavour enhancer", and "stabilizer". However, as it was stated correctly by a member, the *Standard for Wheat Flour* (CODEX STAN 152-1985) identifies "Proteolytic enzyme from *Bacillus subtilis*" and "Proteolytic enzyme from *Aspergillus oryzae*" as "enzymes".

9. In addition, JECFA specifications for both "Protease from *Aspergillus oryzae*, var.", and "Protease from *Streptomyces fradiae"* list the functional use as "Enzyme preparation". It should be noted that "enzyme" and "enzyme preparation" are not listed as functional classes or technological purposes in CAC/GL 36-1989. Therefore, the eWG could not reach to conclusion to name functional class and technological purposes which are appropriate to be associated with protease from *Aspergillus oryzae*, var., protease from *Streptomyces fradiae,* and protease from *Bacillus subtili*. It is necessary that eWG propose an appropriate functional class and technological purposes for each of these specific protease in Table 1 of Annex I with clear justification for review of INS working group at CCFA48.

10. It should also be noted that one Codex member requested to change the current INS number of papain from INS 1101(ii) to 1101(iii) and subsequently change INS number of bromelain 1101(iii) to 1101(iv) and ficin from 1101(iv) to INS number 1101(v) in order to put all proteases in sequence. However, this member did not propose a INS number for Protease from *Bacillus subtili.* The eWG did not reach to conclusion if this was a feasible approach. Nonetheless, this approach can be reviewed during to working group of INS at CCFA48.

Red radish colour and purple sweet potato colour

11. Another member and an observer supported the addition of red radish colour and purple sweet potato colour to the INS. These colours are both anthocyanins, and as such it was recommend that new INS numbers are allocated accordingly (i.e. INS 163 sub codes). Both of these colours are allowed for use and widely used in many countries, including China, Republic of Korea and the European Union.

Spirulina extract

12. Two Codex members also proposed INS 134 as suitable INS number for spirulina extract. It was noted that spirulina extract was an increasingly popular naturally derived alternative to synthetic blue colours, and was approved for use in many countries, including the United States of America and many countries in the Asian region such as China, Republic of Korea and Japan.

Proposals for additional technological purposes

Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer (INS 1209)

The addition binder and stabilizer technological purpose to polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer (INS 1209) was proposed because the JECFA specification monograph lists the technological purpose under the heading "Functional Uses".

JECFA has established the new specifications for polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer during its 80th meeting and published it in FAO JECFA Monographs 17 (2015). The 80th JECFA (2015) considered the additive to be of no safety concern for use in food supplements for the functional uses listed in the monograph. JECFA has proposed in its monograph to establish the INS No. 1209 for the graft co-polymer, which is the same number as in the European numbering system.

Conclusion

13. The proposed draft amendments are presented in Annex 1 (Table 1 & 2). Table 1 lists modifications of an existing INS name or new INS number and technological purpose, and Table 2 lists proposals for additional technological purposes.

Annex 1

PROPOSED DRAFT AMENDMENTS TO THE INS

(At Step 3)

International Numbering System for Food Additives, List in numerical order

The INS list in numerical order is proposed to be updated for some food additives as listed in the Table below. The changes are highlighted with **bold/underlined font**.

Table 1: Modification of an existing INS name or new INS number purpose

INS No.	Name of Food Additive in INS	Technological Purpose
134	**Spirulina extract**	**Colour**
163(vii)	**Purple sweet potato colour**	**Colour**
163(viii)	**Red radish colour**	**Colour**
1101(i)	**Protease from *Aspergillus oryzae*, var.**	
1101(v)	**Protease from *Streptomyces fradiae***	
1101(vi)	**Protease from *Bacillus subtilis***	

Table 2: Proposal for additional technological purposes

The new technological purpose are highlighted as **bold/underlined font**.)

INS #	Food Additive	Technological Purpose
1209	Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer	Anticaking agent, **Binder,** Carrier, Glazing agent, **Stabilizer**