CODEX ALIMENTARIUS COMMISSION







Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 6

CX/FA 13/45/14 Add.1

February 2013

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD ADDITIVES

Forty-fifth Session

Beijing, China 18-22 March 2013

PROPOSALS FOR CHANGES AND/OR ADDITION TO THE INTERNATIONAL NUMBERING SYSTEM FOR FOOD ADDITIVES

The following comments have been received from the following Codex members and observers

Brazil, Chile, Egypt, European Union, Mexico, New Zealand, Philippines, United States of America, ELC, IDF and USP

BRAZIL

Table 2: Proposal for deletion of technological purposes and related functional classes (deletions are presented in strikethrough font)

The functional class "stabilizer" for INS 508 – Potassium chloride does not apply and should also be removed from the INS list. This food additive is concomitantly used with thickeners and gelling agents (e.g. INS 425 – Konjac gum) as "firming agents" (a food additive, which makes or keeps tissues of fruit or vegetables firm and crisp, or interacts with gelling agents to produce or strengthen a gel1). Therefore, Brazil requests the inclusion of functional class "firming agent" for INS 508.

The fact that certain functional classes are not listed on the JECFA specifications should not be a criterion for removal. Brazil would like to note that this situation is common along the INS list and JECFA does not assess the functionality of food additives.

Table 3: Proposal for additional technological purposes and related functional classes (additions are presented in **bold/underlined font)**

Brazil requests clarification on the inclusion of the following functional classes:

- "Flour treatment agent" for Potassium lactate (INS 326)
- "Dispersing agent" for Citric acid (INS 330)

CHILE

Chile agrees with the document and considers the delivered information very useful for a better arrangement of the additives and their technological functions.

EGYPT

Referring to your document CX/FA 13/45/14 concerning request for proposed changes and/or addition to the International Numbering System for Food Additives.

We would like to inform you that Egypt agrees on the proposed changes to the INS for Food Additives.

EUROPEAN UNION

The European Union and its Member States (EUMS) would like to thank Iran for chairing the electronic Working Group and developing the discussion paper.

The EUMS would like to provide the following comments:

In paragraph 3, it is stated that the paper lists proposals for inclusion of three new food additives. The EUMS would like note that **INS 953 Isomalt** is already listed in CAC/GL 36-1989.

¹ CAC/GL 36-1989

INS 330 Citric acid – the EUMS would like to point out that "dispersing agent" is not recognized as the functional class in CAC/GL 36-1989. "Emulsifier" should be the corresponding functional class for the technological purpose "dispersing agent". The EUMS have some doubts about the use of citric acid as an emulsifier. Therefore, the EUMS are asking for a clarification in this respect.

INS 415 Xanthan gum – the EUMS note that "thickener" should be proposed as the functional class for INS 415 and "bodying agent" as the technological purpose.

MEXICO

Please find attached the Mexican comments (Spanish version) regarding document CX/FA 13/45/14:

DOCUMENT	COMMENTS FROM MEXICO
CX/FA 13/45/14: Proposals for changes and/or additions to the International Numbering System for Food Additives.	Support the proposal to withdraw the functional class and technological function of gelling agent and thickener from Potassium Chloride (INS 508) and Calcium Chloride (INS 509) since they are not recognized in the monograph published by the JECFA, and also to unify the functional classes with those in the Codex General Standard for Food Additives.

NEW ZEALAND

New Zealand would like to thank Iran for the work undertaken by the eWG to prepare a proposal for changes and/or additions to the International Numbering System (INS) list and have the following comments to make:

General Comments

In the 2012 version of CAC/GL 36-1989 the layout of entries in Sections 3 and 4 have been amended to include an extra column headed 'Functional Class'. With this extra column added the Explanatory Notes on the Lay-out of the INS do not align with Section 3 and 4. New Zealand suggest that the Explanatory Notes on the Lay-out of the INS should be reviewed and amended to align with the Lay-out of Sections 3 and 4.

New Zealand considers that additional functional classes/technological purposes entries should be curtailed to those that are given in CAC/GL36-1989 Section 2. If new functional classes/technological purposes are proposed they should be considered for adding to Section 2 prior to being assigned to specific food additive / INS No. entries.

Specific comments

Table 1

Column 1 INS No. should contain only numbers. The '-' should be deleted for 453, 454 and 455.

Table 3

For the entries in column 3 Functional class there is some duplication of entries. A specific functional class should only be entered once, even when there is more than one technological purpose given in column 4. The layout should follow that in the 2012 version of CAC/GL 36-1989. For example the entry for 342(i) should be:

		Raising agent	raising agent
			flour treatment agent
	phosphate	Flour treatment agent	dough conditioner
342(i)	Amonium dihydrogen	Acidity regulator	acidity regulator
INS#	Food additive	Functional class	Technological purpose

The entries in Table 3 relating to 445(i) and 455(iii) appear to have lost the technological purpose density adjustment agent, which is currently listed in 2012 version of CAC/GL 36-1989. Density adjustment agent should be re-instated for these additives.

PHILIPPINES

The Philippines supports the progress of the work. The Philippines favor the use of Food Chemical Codex as another reference point for addition of technological purpose which are those as listed in Section 2 of Class Names and the International Numbering System for Food Additives (CAC/GL 36-1989).

UNITED STATES OF AMERICA

This responds to CX/FA 13/45/14 (November 2012): **Proposals for Changes and/or Addition to the International Numbering System (INS) for Food Additives.** The United States wishes to thank Iran for their hard work and leadership in chairing the electronic working group (eWG) for the INS. The United States appreciates the opportunity to provide the following comments for consideration at the forthcoming 45th Session of the Codex Committee on Food Additives (CCFA).

<u>Comments on "Table 3: Proposal for additional technological purposes and related functional classes"</u>

The United States would like to point out what appear to be typographical errors in the "Notes" column for Calcium sulfate (INS 516) and Potassium aluminium silicate (INS 555) in Table 3 of CX/FA 13/45/14. For both additives, the "Notes" column in Table 3 contains the statement "The addition of technological purposes is requested because they are stated in FCC and requested by one country member." The portion of the statement indicating that the suggested changes to the technological purposes for both additives result from information in the Food Chemicals Codex (FCC) is not accurate. Further information supporting the additional technological purposes and related functional classes is offered below:

- Calcium sulfate (INS 516) A request was made by the United States to add the technological purpose and associated functional class of "Acidity regulator" to Calcium sulfate. Neither the FCC nor the Joint FAO/WHO Expert Committee on Food Additives (JECFA) monographs for Calcium sulfate currently list "Acidity regulator" as a technological purpose for Calcium sulfate. However, in support of the addition of the technological purpose of "Acidity regulator" to Calcium sulfate, the United States noted that: 1) Calcium sulfate is listed as an acidity regulator in the Codex commodity standard for Instant Noodles (CODEX STAN 249-2006); and 2) Calcium sulfate is generally recognized as safe (GRAS) for use in the United States as an acidity regulator (pH control agent; 21 Code of Federal Regulations Part 184.1230).
- Potassium aluminium silicate (INS 555) There currently is no FCC monograph for Potassium aluminium silicate. However, there is a tentative JECFA monograph for Potassium aluminium silicate that associates the technological purpose of "Carrier" with Potassium aluminium silicate.

FEDERATION OF EUROPEAN SPECIALTY FOOD INGREDIENTS INDUSTRIES (ELC)

The ELC would like to thank the e-WG for the work and would like to offer the additional comment:

- addition of the functional class "sweetener" for xylitol (INS 967), as xylitol also has sweetening properties.
- addition of the functional classes "thickener" and "texturizing agent" for maltitols (INS 965), as maltitols
 also have thickening and texturizing properties.

We thank you in advance for considering this request.

INTERNATIONAL DAIRY FEDERATION (IDF)

IDF expresses its appreciation to and acknowledges the good work done by the leadership of Iran in chairing this electronic working group on INS.

General Comments:

At the outset we should like to repeat some comments of a general nature made within the electronic working group.

1. We note the terms of reference of the eWG includes considering the replies to the CL requesting proposals for changes / additions to the INS list and prepare a proposal for circulation for comment at Step 3.

However, GL-36 states in Section 1 that the [technological] purposes listed therein are indicative rather than exhaustive. We also note that Annex 1 to Circular Letter CL 2012/9-FA repeats this point and goes on to state that proposals for the inclusion of new technological purposes should be accompanied by a suitable reference and lists examples of four such references. However other than the four references, there are no criteria established to indicate where additional inclusions would be required or justified, taking into account that the technological purposes listed are just indicative in any event. This

tends to a situation where all such new requested proposals for new technological purposes being listed in Sections 3 and 4 of GL-36.

2. At this time there are 27 functional classes and 86 technological purposes listed in the table in Section 2 of GL-36 and with more and more technological purposes being added and the lists in Sections 3 and 4 thus becoming longer and longer; this would appear to go against the intent that these lists are indicative only and not exhaustive.

THE UNITED STATES PHARMACOPEIAL CONVENTION (USP)

The United States Pharmacopeial Convention (USP) is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. USP publishes its food ingredient standards in the Food Chemicals Codex (FCC). USP's mission is to improve the health of people around the world through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP standards are developed and revised by more than 850 volunteer experts, including international participants, who work with USP at various worldwide sites under strict conflict-of-interest rules.

The USP is herein providing comments pertaining to **CX/FA 13/45/14** where the Food Chemicals Codex (FCC) is referenced in this document with regard to the technological purpose of specific food additives:

• Annex 1, point 4: Specific comments

USP is pleased to clarify that the FCC is an authoritative compendium of internationally recognized standards published by USP for the purity and identity of food ingredients. It features approximately 1,200 monographs, including food-grade chemicals, processing aids, foods (such as vegetable oils, fructose, whey, and amino acids), flavoring agents, vitamins, and functional food ingredients (such as lycopene, olestra, and short chain fructooligosaccharides). Published since 1966, the FCC plays a key role in safeguarding commerce and public health by providing essential criteria and analytical methods to authenticate and determine the quality of food ingredients. FCC standards are beneficial to all players in the food industry. FCC standards are developed through a process of public involvement and substantial interaction between USP and its stakeholders, both domestically and internationally, and include a public comment period in the FCC Forum. FCC standards are approved for publication by the Food Ingredients Expert Committee, composed of independent expert volunteers from science, academia, and industry, and who work under strict conflict-of-interest and confidentiality rules. The FCC is published in the United States, and is available for use, adoption and adaptation worldwide. It is recognized and used worldwide by regulatory agencies, manufacturers, vendors, and other users of food ingredients. It is incorporated into the food laws of various countries, e.g., Canada, Australia, New Zealand, Brazil, most MERCOSUR countries and Israel. Specific FCC standards are incorporated into the food regulations of various countries, including the United States (see, e.g. over 200 FCC standards incorporated by reference in FDA food regulations, 21 CFR Parts 170, 172, 173, 178, 180 and 184). In terms of the technological purpose of specific food additives, FCC includes a Function statement in the Description section of each FCC monograph. FCC publishes these functions for purposes of describing the principal technical effect(s) of the substance in foods or in food on the basis of information provided to USP during the development of these standards. These functions are also reviewed and approved for publication as part of each individual standard approved by USP's Food Ingredients Expert Committee.

Annex 1, Table 3: Proposal for additional technological purposes and related functional classes for citric acid (INS 330); Ammonium dihydrogen phosphate (INS 342(i)); Diammonium hydrogen phosphate (INS 342(ii)); Xanthan gum (INS 415); Sorbitol (INS 420(i)); Sorbitol syrup (INS 420(ii); Mannitol (INS 421); Gelatin (INS 428); Polyoxyethylene (20) sorbitan monolaurate (INS 432); Polyoxyethylene (20) sorbitan monostearate (INS 435); Glycerol ester of gum rosin (INS 445(i)); Isomalt (Hydrogenated isomaltulose (INS 953)

USP supports the addition of these proposed technological purposes on the basis of their inclusion as functions in the corresponding FCC monographs for these food additives.

Annex 1, Table 3: Proposal for additional technological purposes and related functional classes.

USP cannot support the below additions, as they are not supported or addressed in the FCC. None of these proposed additional technological purposes are listed in the FCC monographs corresponding to these additives, so it would be inaccurate to suggest any basis related to the FCC.

INS	Food additive	Functional class	Technological purpose
341(i)	Calcium dihydrogen phosphate	<u>Thickener</u>	Texturizing agent

INS	Food additive	Functional class	Technological purpose
422	Glycerol	<u>Emulsifier</u>	<u>emulsifier</u>
424	Curdlan	<u>Emulsifier</u>	<u>emulsifier</u>
444	Sucrose acetate isobutyrate	<u>Emulsifier</u>	clouding agent
445 (iii)	Glycerol ester of wood rosin	Bulking agent	bulking agent
516	Calcium sulfate	Acidity regulator	acidity regulator

For much the same reasons USP does not support the below additions on the basis of FCC. None of these food additives have corresponding monographs in the FCC, so it would be inaccurate to suggest any basis related to the FCC.

INS	Food additive	Functional class	Technological purpose
427	Cassia gum	<u>Stabilizer</u>	foam stabilizer
		<u>Humectant</u>	moisture retention agent
		<u>Thickener</u>	texturizing agent
555	Potassium aluminum silicate	<u>Carrier</u>	<u>carrier</u>

However, USP would like to emphasize that in furtherance of its continuing public health mission to advance the quality of foods, USP is committed to the continuous updating of the FCC. USP encourages all interested parties in possession of information relevant to existing monographs or information that could lead to new monographs to contact USP with a request to update the FCC. More information can found at: http://www.usp.org/food-ingredients/development-process/food-ingredients-donor-program