

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

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

Comments at Step 3 of Brazil, Ecuador, Malaysia, United States of America and IDF

BRAZIL

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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	Brazil comments
<u>134</u>	<u>Spirulina extract</u>	<u>Colour</u>	Brazil supports the proposed amendments.
<u>163(vii)</u>	<u>Purple sweet potato colour</u>	<u>Colour</u>	
<u>163(viii)</u>	<u>Red radish colour</u>	<u>Colour</u>	
<u>1101(i)</u>	<u>Protease from <i>Aspergillus oryzae</i>, var.</u>		Brazil considers that in order to maintain consistency with the current CAC/GL 36-1989, the technological purposes "flour treatment agent", "flavor enhancer" and "stabilizer" should be maintained.
<u>1101(v)</u>	<u>Protease from <i>Streptomyces fradiae</i></u>		
<u>1101(vi)</u>	<u>Protease from <i>Bacillus subtilis</i></u>		

Table 2: Proposal for additional technological purposes

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

INS No.	Name of Food Additive in INS	Technological Purpose	Brazil comments
1209	Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer	Anticaking agent, <u>Binder</u> , Carrier, Glazing agent, <u>Stabilizer</u>	Brazil supports the proposed amendments.

ECUADOR

Ecuador considers that in regard to the proposal of protease enzymes (protease from *Aspergillus oryzae*, var., *Streptomycesfradiae*, protease of *Bacillus subtilis*), it needs further review because we do not have enough information about other technological functions besides those already listed in the GSFA.

MALAYSIA

Table 2: Proposal for additional technological purposes

INS	Food Additive	Technological purposes	Comment
1209	Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer 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".	Anticaking agent, Binder , Carrier, Glazing agent, Stabilizer	Malaysia supports the inclusion of binder and stabilizer as technological purpose for Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer INS 1209 because the JECFA specification monograph lists the technological purpose under the heading "Functional Uses"..

UNITED STATES OF AMERICA

Comments on "Table 1: Modification of an existing INS name or new INS number purpose"Colours

The United States supports the inclusion in the INS of the three colours as presented in Table 1 of CX/FA 16/48/14: Spirulina extract (INS 134), Purple sweet potato colour (INS 163(vii)), and Red radish colour (INS 163(viii)).

ProteasesBackground

The request to consider revisions to Protease (INS 1101(i)) first appeared in CX/FA 15/47/2 (paras. 23–24) based on the following text: "It is noted that INS 1101(i) Protease, includes a number of specific proteases for which no corresponding INS has been set and in particular proteases from *Aspergillus oryzae*, var., and from *Streptomyces fradiae*, which are included in the General Standard for Food Additives (GSFA). The Committee is invited to consider assigning INS numbers to these compounds."

There are currently four entries in the INS listed under the "parent" heading Proteases (INS 1101):

INS No.	Name of Food Additive	Functional Class	Technological Purpose
1101	Proteases		
1101(i)	Proteases	Flavour enhancer	Flavour enhancer
1101(ii)	Papain	Flour treatment agent Flavour enhancer Stabilizer	Flour treatment agent Flavour enhancer Stabilizer
1101(iii)	Bromelain	Flour treatment agent Flavour enhancer Stabilizer	Flour treatment agent Flavour enhancer Stabilizer
1101(iv)	Ficin	Flour treatment agent, Flavour enhancer, Stabilizer	Flour treatment agent Flavour enhancer Stabilizer

The additive Protease (INS 1101(i)) is currently adopted in Table 3 of the GSFA, and also has an adopted provision in Tables 1 and 2 of the GSFA (food category 06.2.1 (Flours)).

It is not completely clear which specific proteases are included in the GSFA, as only the "parent" Protease (INS 1101(i)) is listed. While the Joint FAO/WHO Expert Committee on Food Additives (JECFA) has reviewed several proteases, there are only two JECFA specification monographs for proteases that are listed as having INS 1101(i): Protease from *Aspergillus oryzae*, var., and Protease from *Streptomyces fradiae*. Of these two, only Protease from *Aspergillus oryzae*, var. has a JECFA ADI (acceptable daily intake (ADI) Not Specified,

31st JECFA 1987, TRS 759). The ADI for Protease from *Streptomyces fradiae* was withdrawn by JECFA (28th JECFA 1984, TRS 710). It is also important to note that the JECFA specifications for both Protease from *Aspergillus oryzae*, var., and Protease from *Streptomyces fradiae* do not list food additive functional effects, but rather only list the functional use of “Enzyme preparation.” In contrast, the current INS listing for Protease (INS 1101(i)) includes the food additive functional classes of “Flour treatment agent,” “Flavour enhancer,” and “Stabilizer.”

A search of the commodity standards in Annex C of the GSFA (CODEX STAN 192-1995) and the Information Document on Food Additive Provisions in Commodity Standards (FA/48 INF/02) shows that the only commodity standard that corresponds to food category 06.2.1 (which is the only food category in the GSFA with an adopted provision for Protease) and contains provisions for food additives is the *Standard for Wheat Flour* (CODEX STAN 152-1985). CODEX STAN 152-1985 permits the use of the proteases “Proteolytic enzyme from *Bacillus subtilis*” and “Proteolytic enzyme from *Aspergillus oryzae*.” These two proteases are identified as “Enzymes” under the listing of food additives in this standard. While the protease “Proteolytic enzyme from *Aspergillus oryzae*,” as listed in CODEX STAN 152-1985, appears to correspond to Protease from *Aspergillus oryzae*, var. that was reviewed by JECFA, there does not appear to be a direct correlation between any JECFA-reviewed proteases and the other protease listed in CODEX STAN 152-1985 (i.e., “Proteolytic enzyme from *Bacillus subtilis*”).

Comments on Proposals for Protease

Table 1 of CX/FA 16/48/14 proposes revising the name of INS 1101(i) from Protease to Protease from *Aspergillus oryzae*, var., and adding the two new named proteases: Protease from *Streptomyces fradiae* (proposed INS 1101(v)), and Protease from *Bacillus subtilis* (proposed INS 1101(vi)) to the INS.

In general, the United States does not oppose these proposals. However, it is important to note that because the INS is the source of additive names used in the GSFA, any change to the name of Protease (INS (1101(i))) would result in a consequential change to the Tables 1 and 2 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 provision in food category 06.2.1 (Flours) and in Table 3.

In addition, food additive functional classes and technological purposes are not included in the proposal, and therefore would need to be assigned to Protease from *Aspergillus oryzae*, var. (INS 1101(i)), Protease from *Streptomyces fradiae* (INS 1101(v)), and Protease from *Bacillus subtilis* (INS 1101(vi)). It is important to note that the existing listing for Protease (INS 1101(i)) in CAC/GL 26-1989 is associated with the functional classes of “Flour treatment agent,” “Flavour enhancer,” and “Stabilizer.” In contrast, the *Standard for Wheat Flour* (CODEX STAN 152-1985) identifies “Proteolytic enzyme from *Bacillus subtilis*” and “Proteolytic enzyme from *Aspergillus oryzae*” as “Enzymes,” and the JECFA specifications for both “Protease from *Aspergillus oryzae*, var.” and “Protease from *Streptomyces fradiae*” list the functional use of “Enzyme preparation.” It should also be noted that “Enzyme” and “Enzyme preparation” are not listed as food additive functional classes or technological purposes in CAC/GL 36-1989.

The United States does not have information on the appropriate functional classes and technological purposes to assign to Protease from *Aspergillus oryzae*, var. (INS 1101(i)), Protease from *Streptomyces fradiae* (INS 1101(v)), or Protease from *Bacillus subtilis* (INS 1101(vi)). However, the United States welcomes any information in this regard offered by other Codex Members and Observers.

Comments on “Table 2: Proposal for additional technological purposes”

The United States would like to point out what appear to be typographical errors in the listing of “Technological Purposes” for Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer (INS 1209). Table 2 of CX/FA 16/48/14 indicates that INS 1209 currently has associated with it in the INS (CAC/GL 36-1989) the Technological Purposes of “Anticaking agent,” “Glazing agent,” and “Carrier.” However, we note that the 2015 revision of the INS (CAC/GL 36-1989) only lists the functional class and technological purpose of “Glazing agent” for INS 1209. Thus, “Anticaking agent” and “Carrier” should not be associated with INS 1209 in Table 2 of CX/FA 16/48/14.

Table 2 of CX/FA 16/48/14 presents a proposal to add the technological purposes of “Binder” and “Stabilizer” to Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer (INS 1209) based on the recent review of INS 1209 at the 80th JECFA (2015). In conjunction with the review at the 80th JECFA, JECFA recently published a specifications monograph for INS 1209 in FAO JECFA Monographs 17 (2015), which associates the functional uses of “Glazing agent,” “Binder for tablets,” and “Stabilizer” with INS 1209.

The United States supports the inclusion of the functional class and technological purpose of “Stabilizer” with INS 1209 based on the JECFA review. However, the United States cannot support the association of “Binder” with INS 1209 in the INS based on the JECFA functional use of “Binder for tablets,” as these two terms do not

necessarily represent the same function. “Binder” is a technological purpose in the INS, and if it were listed with INS 1209 in the INS, the associated functional class of “Thickener” would also need to be added for INS 1209. We do not believe that this would be appropriate.

In summary, the United States supports the addition of the functional class and technological purpose of “Stabilizer” to the INS listing for Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer (INS 1209), as shown below, (additions shown in **bold text**).

INS No.	Name of Food Additive	Functional Class	Technological Purpose
1209	Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer	Glazing agent, Stabilizer	Glazing agent, Stabilizer

INTERNATIONAL DAIRY FEDERATION (IDF)

IDF requests that the CCFA and the physical Working Group in INS consider Sodium Carbonate (INS 500(i)) to be classified as emulsifying salt synergist (with a note specifying ‘in presence of citric acid’).

Rationale:

The following issue was raised in among IDF experts involved in the Codex draft standard for Processed Cheese, for which the Codex physical Working Group met in December in Uruguay.

Processed Cheese can be made using the Citric acid derived from Lemon juice in conjunction with Sodium Carbonate (as an acidity regulator and as a source of Na⁺ ions). The resulting citrate salt acts as an emulsifier and chelates Ca allowing emulsification to occur with the aid of heat and shear – much the same as if the citrate salts had been added as emulsifying salts. Such products are on the market and are traded, possibly as spreads.

With Sodium Carbonate recognized as an emulsifying salt synergist when used together with lemon juice (in Processed Cheese), the current text would include already existing products, without extending the ‘Processed Cheese’ classification to include some unripened cheeses.