CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 6 **CRD22**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-Ninth Session

Macao SAR, China, 20-24 March 2017

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

Comments of Cameroon, El Salvador, Ghana, India, Indonesia, Malaysia, Philippines, Russian Federation, African Union, ICGA and CCC

Cameroon

Les amylases (SIN 1100 i, ii, iii, iv, v, vi), **les protéases** (SIN 1101 i, ii, iii, iv, v, vi), les **lipases** (SIN 1104) ne sont pas justifiées pour un emploi en tant qu''additifs alimentaires puisqu''ils ne font pas partie du champ d'application de la définition des additifs alimentaires. Ces substances n'ont pas d'activité dans l'alimentation finale (farine et produits de boulangerie) parce que le processus de production inclut typiquement l'inactivation thermique de l'enzyme afin d'achever le processus lorsque l'effet désiré est obtenu.

La nisine (SIN 234) et la **pimaricine** (natamycine) (SIN 235) sont des antibiotiques de sorte que les antibiotiques ne pourraient pas être utilisés en tant qu'additifs alimentaires.

Le tréhalose, un sucre disaccharide ne correspond pas à la définition de l'édulcorant dans les catégories fonctionnelles de l'additif alimentaire. Les noms de catégorie et le Système international de numérotation pour les additifs alimentaires (CAC/GL 36-1989) stipule que l'édulcorant est "un additif alimentaire (autre qu'un sucre mono- ou disaccharide), qui confère un goût sucré à un aliment."

Position: Compte tenu des observations faites au sujet des différents additifs alimentaires, nous soutenons les propositions du GTE en ce qui concerne les amylases (SIN 1100 i, ii, iii, iv, v, vi), les protéases (SIN 1101 i, ii, iii, iv, v, vi), les lipases (SIN 1104), la pimaricine et le tréhalose.

Quant à la **nisine**, nous ne soutenons pas le retrait de cet additif de la liste parce que le CAC a adopté cette proposition après une récente évaluation du JECFA en 2013 et le Comité avait approuvé son emploi comme additif alimentaire.

El Salvador

9. Los miembros del GTe hicieron las siguientes propuestas:

- Incluir una nueva entrada para:

- tartrato de hierro, con la clase funcional y la función tecnológica de antiaglutinante.

- trehalosa, con la clase funcional y la función tecnológica de edulcorante, humectante, estabilizador y agente texturizador.

- "colorante de jamaica" y "colorante de sauco", con la clase funcional y la función tecnológica de colorantes.

- lecitina, hidroxilada, como aditivo alimentario con el SIN 322(iii) con la clase funcional de emulsionante y antioxidante y la función tecnológica de emulsionante y antioxidante.

- poliacrilato de sodio, con la clase funcional y la función tecnológica de estabilizador.

- proteasas de *Bacillus amyloliquefaciens*, además de las proteasas de *Bacillus subtilis* (SIN 1101(vi)).

- Añadir clase funcional/función tecnológica a:

- carbonato de sodio (SIN 500(i)), sinergista de sal emulsionante con una nota para limitar su uso sólo a aquellas circunstancias en las que el queso procesado se elabora con zumo de limón.

- sucralosa (SIN 955): acentuador del sabor.

- Eliminar:

- amilasas (SIN 1100 i, ii, iii, iv, v, vi), proteasas (SIN 1101 i, ii, iii, iv, v y vi) y lipasas (SIN, 1104).

- nisina (SIN 234) y pimaricina, natamicina (SIN 235) porque son antibióticos y no se pueden utilizar como aditivos alimentarios.

El Salvador considera que debido a que la *nisina* y *natamisina* son antibióticos naturales y su función de preservante de bacterias *Gram positivas* en alimentos diversos como cárnicos y lácteos no deben sacarse de la lista de aditivos alimentarios.

Ghana

Specific Comments

Ghana does not support the deletion of Nisin (INS 234) from the INS list

Rationale: The CCFA48 endorsed the draft provisions of Nisin (INS 234) and subsequently forwarded for adoption by the CAC39, the CAC has since adopted the proposal. The JECFA's 2013 evaluation of Nisin and recent evaluation by member states concluded that antibiotic resistance was not a concern with regards to the use of Nisin as a food additive

India

Proposed draft changes and/or additions to the INS numbering system have been listed in Annexure 1. India has the following specific comments on these proposals:

Table 2:

1. **Deletion of INS number for Enzymes (amylases (INS 1100 i, ii, iii, iv, v, vi), Proteases (INS 1101 i, ii, iii, iv, v, vi) and Lipases (INS 1104):**

India believes that If enzymes are removed from Codex GSFA, authorization for their use should be available in some other CODEX document, so that the use of enzymes in food products doesn't get dis-allowed due to lack of a specific documentary support in CODEX documents. This problem will be especially severe for the trade involving those countries which are completely dependent on CODEX regulations for such cases.

Also in some cases enzymes are being used as food additives in certain cases in some countries.

Moreover, the safety of these enzymes has already been established and they could be used in broad food categories in accordance with GMP. Hence the safety concerns raised in the CODEX agenda papers seem to be unwarranted, and India would like to suggest that such text is not captured in the final report of CCFA.

Hence India doesn't support deletion of INS numbers for these enzymes.

2. **Deletion of INS number for Nisin (INS 234) and Natamycin (INS 235)**

These food additives are listed in several Food Categories and the consequential deletion of these provisions may create a huge confusion.

Furthermore, No anti microbial resistance concerns were raised by JECFA from the use of Nisin or Natamycin (Pimaricin) as preservatives in food.

Hence India strongly opposes deletion of INS numbers for Nisin and Natamycin.

Indonesia

Comment:

Indonesia supports the deletion of amylases (INS 1100 i, ii, iii, iv, v, vi), proteases (INS 1101 i, ii, iii, iv, v, vi) and lipases (INS 1104) from the INS since those substances have no activity in final products. Those substances are more appropriate to be included as processing aids.

Indonesia also supports the deletion of Natamisin since this substance has antibiotic function.

Malaysia

Table 1: New or additional technological purpose

INS No	Name of Food Additive	Functional class	Technological Purpose	Malaysia's Position
955	Sucralose(Trichlorogalactosucros	Sweetener **Flavour enhancer**	Sweetener **Flavour enhancer**	Malaysia does not support the inclusion of flavour enhancer due to inconsistent with the JECFA specification.

Table 2: Deletion of additive purpose

Malaysia does not support deletion of functional class and technological purpose for amylases (INS 1100 i, ii, iii, iv, v, vi), proteases (INS 1101 i, ii, iii, iv, v, vi), lipases (INS 1104), nisin (INS 234) and pimaricin (INS 235) since the food additives have been assigned safe by JECFA and listed under GSFA.

Philippines

Deletion of Nisin (INS 234) and Pimaricin (INS 235)

Nisin (INS 234) and pimaricin (natamycin) (INS 235) are antibiotics so antibiotics could not be used as food additives. Excluding nisin (INS 234), pimaricin (natamycin) (INS 235) from INS list is one of decisions which could help solve the problem of Antimicrobial Resistance (AMR).

Position:

Philippines does not support the EWG's proposal to delete Nisin (INS 234) from the INS list.

Rationale:

In the Philippines, Nisin is used in processed cheese products as preservative that inhibits growth of spore-former bacteria and there are no other food additives that are economically and technologically practicable for use for a specific purpose for which Nisin is currently used. Furthermore, Nisin has been evaluated by JECFA for its safe use in food and during its 77th meeting, Nisin's acceptable daily intake of 0-2mg/kg body weight was established. Nisin was approved to be used as food antimicrobial preservative and has currently no therapeutic use. There are differences in the antimicrobial mode of action between therapeutic antibiotics and Nisin, so the development of antibiotic resistance is not of concern in relation to use of nisin in food. (EFSA, 2006)

Russian Federation

1. The Russian Federation fully supports removal of amylases (INS 1100 i, ii, iii, iv, v, vi), proteases (INS 1101 i, ii, iii, iv, v, vi), lipases (INS 1104) from the INS list. In Russia, enzyme preparations are allowed for use in the food industry only as processing aids.

2. We ask to support the proposal of the Russian Federation to exclude nisin (INS 234) and pyramycin (natamycin) (INS 235) after safety re-assessment from the list of INS, since these food additives are now recognized as antibiotics. They contribute to the antibiotic resistance which is the most urgent public health issue of the present time.

African Union

Issue: The eWG of the CCFA48 has prepared proposals on draft revision of the INS for food additives. One of the proposals is deletion of Nisin (INS 234) from the INS list.

Position: AU does not support the deletion of Nisin (INS 234) from the INS list.

Rationale: The CCFA48 proposed the draft provisions of Nisin (INS 234) and subsequently forwarded for adoption by the CAC39. The Commission has since adopted the proposal. The JECFA's 2013 evaluation of Nisin and other recent evaluation have concluded that anti-microbial resistance was not a concern with regards to the use of Nisin as a food additive.

International Chewing Gum Association (ICGA)

On behalf of the International Chewing Gum Association (ICGA), we would like to reiterate our support to the proposed addition of "flavor enhancer" as a new functional class and a new technological purpose for sucralose (INS 955), as per the recommendation made by the CCFA49's electronic working group on the INS in its report included in CCFA49's working document CX/FA 17/49/12.

ICGA would also like to share the technological justifications, which has helped convincing the CCFA49's electronic working group on the INS to come to its conclusions and its recommendations for approval by the 49th session of the CCFA (i.e. CCFA49) as presented under CCFA49's agenda item 6.

Justification for the requested INS change in Section 3: new or additional technological purpose

☒ Evidence that the compound has been or is capable of being used effectively for the technological purpose proposed

⦸ A Codex Commodity standard has provisions for the use of the compound

⦸ The JECFA specification monograph lists the technological purpose under the heading "Functional Uses"

☒ A national food authority has permitted such a use

☒ The food industry is currently using a substance for the technological purpose proposed

☒ Other justification, what?

The 28 countries of the European Union[1] and the Codex alimentarius[2] (see summary further below) have already recognized the use of several substances with sweetening properties (i.e. so-called sweeteners) in chewing gum as safe and technologically justified for their other functional class and technological purpose as "flavour enhancers", in addition to their primary uses as "sweeteners" (e.g. neotame, acesulfame K, aspartame, advantame, etc.).

Those food additives, when used as flavour enhancers, do exert a special flavour enhancing effect in chewing gum with certain flavours and they act upon the release time of the sweet taste (exerted by other food ingredients such as sugars or polyols). It has also a positive effect in the release time of flavourings and help taste lasting longer.

The amount used as flavour enhancers is generally substantially lower than the amount used when the food additive (e.g. sucralose) is used as a sweetener (i.e. for its sweetening properties).

Accordingly, the use of these food additives (trivially called "'sweeteners" by reference to their primary function), as "flavour enhancers" does not significantly impact overall exposure.

The proposed addition of such a flavour enhancing functional class and its related technological purpose in the INS is therefore totally justified and supported by strong scientific and technical evidences, already reviewed by various food safety regulators around the world (e.g. the EU and its member States).

As a further piece of background information to the attention of all participants to CCFA49, please find below the status of other food additives which are listed in the International Numbering System (CAC/GL 36 (2016 version))[2], with two functional classes and technological purposes as "*Sweetener*" and as "*Flavour enhancer*".

Food additive name	**INS**	**Functional class** already approved in the Codex alimentarius INS	**Technological purpose** already approved in the Codex alimentarius INS
Acesulfame potassium	950	Sweetener Flavour enhancer	Sweetener Flavour enhancer
Aspartame	951	Sweetener Flavour enhancer	Sweetener Flavour enhancer
Alitame	956	Sweetener Flavour enhancer	Sweetener Flavour enhancer
Thaumatin	957	Sweetener Flavour enhancer	Sweetener Flavour enhancer
Glycyrrhizin	958	Sweetener Flavour enhancer	Sweetener Flavour enhancer
Neotame	961	Sweetener Flavour enhancer	Sweetener Flavour enhancer
Advantame	969	Sweetener Flavour enhancer	Sweetener Flavour enhancer

[1] Commission Regulation (EU) 2016/1776 of 6 October 2016 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sucralose (E 955) as a flavour enhancer in chewing gum with added sugars or polyols (Text with EEA relevance)- *C/2016/6347- OJ L 272, 7.10.2016, p. 2–4. See http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1488874761241&uri=CELEX:32016R1776*

[2] Class Names and the International Numbering System for Food Additives (CAC/GL 36, as modified in 2016). See http://www.fao.org/fao-who-codexalimentarius/standards/list-standards/en/

In summary, the members of ICGA are of the views that there is a strong legal and science-based technological justification to add the functional class "flavour enhancer" and the technological purpose "flavour enhancer" to sucralose (INS 955) in the Codex guidelines on the class names and international numbering system for approval by the 49th session of the CCFA and for future inclusion in the next version of CAC/GL 36, once that CCFA decision is endorsed by the 40th session of the Codex alimentarius Commission.

We remain at the disposal of any delegation attending the CCFA49 to answer any further question they may still have after the review of the above comments.

ICGA would really appreciate to see the above comments included in a Conference Room Document (CRD) to be available in advance to the discussion under Agenda Item 6 of the CCFA49.

Calorie Control Council (CCC)

The Calorie Control Council ("the Council") is an international association representing manufacturers and end users of low- and reduced-calorie foods and beverages, including low-calorie sweeteners. The Council is providing comments on Agenda Item 6 – Proposed Draft Revision to the International Numbering System (INS) for Food Additives (CAC/GL-36-1989) – which will be considered at the upcoming CCFA49 meeting.

The Council supports the proposed addition of "flavor enhancer" as a new functional class and a new technological purpose for sucralose (INS 955). This is in accordance with the recommendation made by the CCFA49's electronic Working Group (eWG) on the INS in its report included in CCFA49's working document CX/FA 17/49/12.

Below are technological justifications used by the INS eWG to reach its conclusions and recommendations for approval by CCFA49 under agenda item 6.

Justification for the requested INS change in Section 3: new or additional technological purpose

- Evidence that the compound has been or is capable of being used effectively for the technological purpose proposed
- A Codex Commodity standard has provisions for the use of the compound
- The JECFA specification monograph lists the technological purpose under the heading "Functional Uses"
- A national food authority has permitted such a use
- The food industry is currently using a substance for the technological purpose proposed
- Other justification,

The 28 countries of the European Union[3] and the Codex Alimentarius[4] have recognized the use of several substances with sweetening properties (sweeteners) in chewing gum as safe and technologically justified for other functional class and technological purposes as "flavour enhancers." This is in addition to their primary uses as "sweeteners" (e.g. neotame, acesulfame K, aspartame, advantame, etc.).

Sweeteners used as flavour enhancers offer special effects in chewing gum. They also act upon the release time of the sweet taste exerted by other food ingredients such as sugars or polyols, which creates a positive effect in the release time of the flavors and helps taste last longer.

The amount of a sweetener used as a flavor enhancer is generally substantially lower than the amount used when it is used as a sweetener for its sweetening properties. The use of sweeteners as "flavour enhancers" does not significantly impact overall exposure.

The addition of a flavor enhancing functional class and its related technological purpose for sucralose in the INS is justified, supported by strong scientific and technical evidence, and has been reviewed by various food safety regulators around the world (e.g. the EU and its member States). Below is further information on the status of other sweeteners listed in the International Numbering System (CAC/GL 36 (2016 version))[2], with two functional classes and technological purposes as "*Sweetener*" and as "*Flavour enhancer.*"

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[3] Commission Regulation (EU) 2016/1776 of 6 October 2016 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sucralose (E 955) as a flavour enhancer in chewing gum with added sugars or polyols (Text with EEA relevance)- *C/2016/6347- OJ L 272, 7.10.2016, p. 2–4. See http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1488874761241&uri=CELEX:32016R1776*

[4] Class Names and the International Numbering System for Food Additives (CAC/GL 36, as modified in 2016). See http://www.fao.org/fao-who-codexalimentarius/standards/list-standards/en/

Food additive name	**INS**	**Functional class** already approved in the Codex Alimentarius INS	**Technological purpose** already approved in the Codex Alimentarius INS
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Glycyrrhizin	958	Sweetener Flavour enhancer	Sweetener Flavour enhancer
Neotame	961	Sweetener Flavour enhancer	Sweetener Flavour enhancer
Advantame	969	Sweetener Flavour enhancer	Sweetener Flavour enhancer

The Council believes there is strong legal and science-based technological justification to add the functional class “flavour enhancer” and the technological purpose “flavour enhancer” to sucralose (INS 955) in the Codex guidelines on the class names and INS. We trust that there will be approval by the 49th session of the CCFA for future inclusion in the next version of CAC/GL 36, once the CCFA decision is endorsed by the 40th session of the Codex Alimentarius Commission.

The Council remains available to answer any further questions after the review of the above comments. We also would like to request that the above comments be included in a Conference Room Document (CRD) to be available in advance to the discussion under Agenda Item 6 of the CCFA49.