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World Health Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifty-third Session

ALIGNMENT OF THE FOOD ADDITIVE PROVISIONS OF COMMODITY STANDARDS: REPORT OF THE EWG ON ALIGNMENT

(Comments of the European Union, Kenya, Rwanda, Senegal, South Africa, Thailand and ISDI)

European Union

European Union Competence
European Union Vote

The European Union (EU) would like to thank Australia, the United States of America and Japan for chairing the electronic Working Group (EWG) and preparing CX/FA 23/53/6, which addresses in 348 pages various matters related to the alignment of the food additive provisions of commodity standards with the GSFA.

The EU supports the alignment and its general underlying principle to respect the intentions of the commodity standards and the scope of the provisions listed therein.

The EU has the following comments

Appendix 1, Annex 1

Issue 1

The EU supports the development of Table 3 (T3) notes to the GSFA as suggested by the US. The EU considers that the suggested approach (Option 2) improves clarity of the GSFA while capturing the intentions and specificities of the provisions for standardised products.

The EU takes note of the discussion on the use of notes referring to the appropriate functional class (in relation to Table 1&2 as well as Table 3 provisions). The EU observes that the chair suggests considering such notes on a case-by-case basis (item 7 and 8 'Use of notes to limit provisions to certain function classes' in Annex 3), subject to a justification and support, whilst recognising that the comments expressed by Canada and others on this issue *'can be considered further by the Committee noting the large amount of current work alignment still needs to undertaken*'.

The EU supports further reflection on this issue to assure that any relevant information on the use of food additives in standardised products, including the information on the relevant functional classes, is appropriately captured in the GSFA.

Issue 2

The EU takes note of the difficulties encountered in aligning CXS 288 with the GSFA. The EU observes that CXS 288 clearly covers recombined and reconstituted cream, however, there is no specific reference to such products in the descriptors of FC 01.4 and its subcategories (Annex B to the GSFA). The EU further observes that GSFA Annex C refers to reconstituted and recombined products only in relation with FC 01.4.1. Therefore, the EU seeks a clarification for the proposed reference to recombined and reconstituted cream in FC 01.4.2 and 01.4.3 in GSFA Annex C.

The EU recalls the work carried out in the past on the FC 01.1 and its subcategories triggered by recombined and reconstituted fluid milks related to specificities concerning the use of certain food additives in those products. The EU takes note of the clarification provided by IDF that with respect to FC 01.4.1 there is a need only for limited use of food additives.

The EU could accept the proposed changes to GSFA Annex C and GSFA Annex B (only in FC 01.4) as editorial, only if it is demonstrated that recombined and reconstituted cream is already covered by all sub-categories of FC 01.4 and therefore the scope of the 01.4 subcategories is not altered. At the same time, it needs to be confirmed that there is no impact on the food additive provisions.

As regards the proposed update of the descriptor of FC 01.4.3 (item 11, Annex 3), the EU considers that it is out of the mandate of the Alignment EWG and that it should be subject to a new work should such amendment be pursued.

Issue 3 & 6

The EU recognises the important role of the Codex commodity committees to appraise and justify the technological need for the use of food additives in commodities under their purview. On the other hand, CCFA is responsible for considering the safety of the food additive provisions deemed justified by the commodity committees.

It is a good CCFA practice to establish numerical maximum use levels for additives with numerical ADIs. The EU supports that this practice is also followed for the commodity standards food additive provisions for which deviations from this principle have been identified in the alignment exercise.

The EU supports that the respective provisions for INS 405 (propylene glycol alginate), INS 636 (maltol), INS 637 (ethyl maltol) and INS 100(i) (curcumin) are referred to the EWG on the GSFA to seek the appropriate MLs.

Issue 7

The EU supports that the EWG on Alignment passes the question of whether INS 500(iii) has the functional class of stabiliser and thickener to the EWG on INS.

Issue 8

The EU supports the minor amendment as outlined in issue 8.

Appendix 6 – Amendment of the Procedural Manual (PM)

The EU takes note of the proposed new text for the PM updating the section on '*Relations Between Commodity Committees and General Subject Committees*' as regards food additive provisions.

The EU understands the importance of avoiding divergence of food additive provisions between the GSFA and Commodity Standards, however, the EU does not currently support an amendment of the PM due to the concerns outlined below.

The EU is of the view that further discussions on the need for updating the PM are required before considering concrete amendments of the PM. In view of these discussions, the EU would appreciate information on concrete examples where amendments suggested to the aligned commodity standards led to divergences. The EU also notes that CCFA52 endorsed the "*Guideline Document on Avoiding Future Divergence of Food Additive Provisions in the GSFA with Commodity Standards*" in order to prevent any future divergence, which was communicated to the active commodity committees and published as an Information Document on the Codex website. The EU is of the view that experience on the implementation of this Guideline would be useful before considering amendments of the PM.

Finally, the EU would like to point out that, should amendments of the PM be further considered, CCGP, that is in charge of examining general and procedural matters, could be tasked to carry out this work that is relevant for CCFA, the Commodity Committees, as well as General Subject Committees and Regional Committees when considering the development of Commodity standards.

Kenya

Alignment of the food additive provisions of commodity standards: CX/FA 23/53/6

Key issues and questions requiring consideration by the Committee:

Issue 1: To expand the general USA proposal of Table 3 notes to also consider them to identify the specific function class consistent with aligning the provision in the commodity standard. However, this would only be on a case-by-case basis if there are a variety of possible functional classes and if justified and supported.

Comment: Kenya does not support the general inclusion of the footnotes and proposes the inclusion of the notes to be on a case-by-case basis, based on the commodity, intended use, and intended outcome.

Justification: Alignment is a continuous process, and each entry should be considered individually.

Issue 3: What MLs for INS 405 (propylene glycol alginate), INS 636 (maltol) and INS 637 (ethyl maltol) are appropriate to align CXS 243 with the GSFA? Is this outside the scope of Alignment, like the consideration of ML for curcumin (INS 100(i)), but needs to be considered by another process?

Kenya's Comment: This work is outside the TOR of this committee and proposes that it is carried out by INS.

Rwanda

AGENDA ITEM	Section or Paragraph	Nature of comment (Indicate whether technical or editorial)	Comment/Proposed Changes	Rationale
Agenda item 4b	Alignment of the food additive provisions of commodity standards: Report of the EWG on Alignment, CX/FA 23/53/6	technical	Rwanda supports the proposed amendments to the Procedural Manual text to ensure misalignment of food additive provisions does not occur once the full alignment of the food additive provisions between the Commodity Standards and the GSFA have been completed.	There needs to be alignment on additives between the Commodity Standards and GSFA and there cannot be different limits for additives.

Senegal

Contexte : Le GTE sur l'alignement est chargé de veiller à ce qu'il n'y ait pas de conflit entre les dispositions relatives aux additifs des normes de produits et celles de la NGAA. C'est la décision du CCFA d'assurer l'harmonisation complète des dispositions et d'élaborer des stratégies pour s'assurer que ce décalage ne se reproduise pas à l'avenir. L'une des stratégies consiste à proposer des révisions/modifications du manuel de procédures afin d'assurer la pleine participation du CCFA. Les modifications procédurales ont déjà été telles que toutes les dispositions relatives aux additifs alimentaires sont envoyées au CCFA à l'étape 5 pour approbation, étape au cours de laquelle l'uniformité est examinée.

a) Réponses aux principaux problèmes et questions appelant un examen par le Comité, comme indiqué à l'annexe 1 de l'appendice 1 du document (CX/FA 23/53/6)

- ***Question 1 : Proposition de notes du tableau 3 pour les prendre également en compte afin d'identifier la classe de fonction spécifique compatible avec l'harmonisation de la disposition des normes de produit.***

Position : Le Sénégal ne soutient pas cette approche relative à l'inclusion de la classe de fonctions dans la NGAA.

Justification : Il s'agit d'introduire une nouvelle approche de l'inclusion de la classe de fonctions dans la NGAA, contrairement à la procédure actuelle. Un nouveau projet de travail visant à réviser la procédure doit être lancé pour examen.

- ***Question 2 : Les Recommandations du GTE sur l'alignement visant à modifier les noms et les descripteurs de la FC 01.4 et des sous-catégories 01.4.1, 01.4.2 et 01.4.3 proposées soient présentées au CCFA pour un examen plus approfondi et éventuellement pour de nouveaux travaux.***

Position : Le Sénégal appuie l'amendement et demande des éclaircissements sur la procédure à suivre pour sa mise en œuvre.

Justification : La modification de la classe fonctionnelle (FC) a des implications sur les produits et l'application de la NGAA en général, d'où la nécessité d'études par le Comité. Une décision sera également prise sur la question de savoir si ce GTE sera approprié pour diriger la révision des catégories.

- ***Question 3 : Quelles LM pour les SIN 405 (alginate de propylène glycol), SIN 636 (maltol) et SIN 637 (maltol éthylique) sont appropriées pour aligner le CXS 243 avec la NGAA et si cela est en dehors du mandat du GTE ?***

Position : L'établissement du LM va au-delà du processus d'harmonisation. Le Comité sur l'alignement doit simplement identifier les anomalies et le rapporter en plénière du comité.

Justification : L'établissement de LM nécessite la contribution du JECFA pour la réévaluation de l'innocuité ou l'établissement de données sur les niveaux d'utilisation.

- ***Question 4 : Changement du nom des adipates en acide adipique.***

Position : Le Sénégal appuie le changement de nom proposé.

Justification : Le changement de nom permettra d'assurer la cohérence des normes Codex puisque le CXG 36 (SIN) utilise déjà le terme comme c'est le cas avec d'autres textes du Codex.

- ***Question 5 : Est-il approprié que le GTE sur l'alignement recommande la suppression des dispositions relatives aux additifs alimentaires dans les catégories d'aliments pertinentes dans la NGAA lorsqu'il n'y a que des notes XS.***

Position : Le Sénégal ne soutient pas cette approche.

Justification : Le GTE devrait identifier les additifs alimentaires concernés et informer la plénière pour une prise de décision. L'élimination ou l'inclusion d'additifs alimentaires dans la NGAA revient au CCFA en tant que comité.

Une telle décision peut également nécessiter la contribution d'autres groupes de travail tels que celui sur la NGAA ou même des comités de produits, le cas échéant.

- ***Question 7 :***

Il est suggéré que le GTE sur l'alignement passe au GTE sur le SIN (via la session) la question à savoir si l'additif alimentaire sesquicarbonate de sodium (SIN 500(iii)) a la classe fonctionnelle de stabilisant et d'épaississant, pour laquelle il est répertorié dans CXS 253-2006, mais pas dans CXG 36- 1989,. Voir annexe 3, point 51

Position : Le Sénégal propose que cette question soit effectivement renvoyée au GTE sur leSIN pour fournir une justification technologique.

Justification : Le référentiel principal pour fournir une justification technologique, le CXG 36-1989, n'a pas décrit de classe fonctionnelle de stabilisant et d'épaississant pour le sesquicarbonate de sodium.

b) Appendice 3 (Amendements proposés aux dispositions relatives aux additifs alimentaires des normes de produit du Codex pour le lait et les produits laitiers (CCMMP) en raison de l'harmonisation avec la NGAA), Appendice 4 (Amendements proposées aux tableaux 1, 2 et 3 de la NGAA concernant l'harmonisation des normes de produit du Codex pour le lait et les produits laitiers (CCMMP), Appendice 5 (liste complète des modifications apportées à la NGAA en raison de l'introduction des notes du tableau 3 découlant de la CCFA51, CCFA52 et harmonisation proposée du CCFA53 du CCMMP).

Position : Le Sénégal appuie l'adoption des alignements proposés dans les Appendices 3, 4 et 5. Le Sénégal soutient également les propositions du GTE telles qu'inscrites au niveau des appendices 7, 9 et 10.

Justification : nécessité de cohérence dans les textes du Codex.

South Africa

South Africa supports the proposed amendments to the procedural manual text.

Rationale: The amendment will ensure that the misalignment of food additive provisions does not occur once the full alignment of the food additive provisions between the commodity standards and the GSFA has been completed.

Thailand

Thailand would like to thank Australia and the United States of America and Japan for leading the electronic Working Group (eWG) on the alignment of the food additive provisions of the commodity standards with the GSFA.

We are pleased to provide our specific comments on Appendices 7 and 9 as follows:

Appendix 7: Proposed amendments to the food additive provisions of the codex commodity standards for processed fruits and vegetables (CCPFV) and Tables 1, 2 and 3 of the GSFA relating to CCPFV

Regarding the alignment of the food additive provisions of Standard for Chili sauce (CXS 306-2011) and Standard for Mango Chutney (CXS 160-1987) and relevant provisions of the GSFA, we would like to point out that the 29th session of the CCPFV has revised the food additive provisions of these standards and has already provided the information to the 52nd of the CCFA in CX/FA 21/52/5. However, the alignment work has been conducted by using the previous version of the standards. We, therefore, would like to propose that the new food additive sections of the CCPFV standards contained in CX/FA 21/52/5 (Annex I, III and IV) should be taken into consideration in the alignment work.

For example, in case of the alignment of the Standard for Mango Chutney (CXS 160-1987), the CCPFV29 has observed the food additives provision in GSFA and considered to allow the use of certain classes of food additives (e.g., colours) that are already allowed in food category 04.1.2.6 of GSFA in food conforming to CXS 160-1987 (see CX/PFV 20/29/5, Para 7). However, the functional class of colours is not listed in the proposed amendments to the food additive section of CXS 160-1987 and Note XS160 is proposed to add to the relevant GSFA provisions for colours additives, excluding their use in the Commodity Standard. Hence, it seems that there are some inconsistencies between the new food additive sections of the CCPFV standards as outlined in CX/PFV 20/29/5 and CX/FA 21/52/5, and the alignment work.

Appendix 9: The alignment of the seven CCNFSDU commodity standards, including the Guideline for the Ready to Use Therapeutic Foods (RUTF)

Inclusion of food additives provisions listed in the Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children (CXG 10-1979)

Regarding the alignment of the Standard for Infant formula and formulas for special medical purposes intended for infants (CXS 72-1981), Standard for Processed cereal based foods for infants and children (CXS 74-1981), Standard for Follow-up formula (CXS 156-1987) and Guidelines for Ready to use therapeutic foods (CXG 95-2022) with the GSFA, these Commodity Standards allow the use of the food additives listed in CXG 10-1979 Part D (including; gum arabic, silicon dioxide, amorphous, mannitol, starch sodium octenyl succinate and sodium ascorbate) as a nutrient carrier. From our point of view, theses food additives are not allowed to add directly to the food, but rather as the result of carry-over from a raw material or other ingredient. We, therefore, propose to add Note 65 "as a result of carryover from nutrient preparations" to the above-mentioned food additives provisions in order to make it clearer and to capture the specific allowance of these Commodity Standards.

Alignment of the Standard for Follow-up formula (CXS 156-1987) with the GSFA

Bases on information provided by the 42nd session of the CCNFSDU to the 53rd of the CCFA in Agenda Item 2 "Matters Referred by the Codex Alimentarius Commission and other subsidiary bodies" (CX/FA 23/53/2, para 21) that the CCNFSDU42 has revised food additive sections of CXS 156-1987. We would like to propose that the revised food additive sections of CXS 156-1987 as presented in REP22/NFSDU (Appendix IV) should be further taken into consideration in the alignment work.

ISDI (International Special Dietary Foods Industries)

ISDI would like to thank the chair of the Alignment Electronic Working group for their work on aligning the commodity standards in Food Category 13 with the provisions in the GSFA. We recognize the complexity of this work, and despite this complexity we believe that Electronic Working Group has succeeded in bringing a strong proposal to this meeting for discussion.

ISDI has provided comments throughout the process that have been reflected in the Report of the EWG on Alignment (CX/FA 23/53/6). In addition, ISDI would like to highlight some of the comments there, and to provide additional context that may aid in the discussion during the Physical Working Group and the Plenary.

Chair's Proposal: To replace the ML units of mg/kg to mg/L for FC 13.1 and subcategories in the GSFA to better align with the relevant commodity standards

ISDI supports the proposal of the chair's proposal that the Maximum Level (ML) for the provisions in these food categories should be expressed as mg/L in order to both align with the provisions in the commodity standards, and to reflect how these products are consumed.

The commodity standards that correspond with Food Categories 13.1.1, 13.1.2, and 13.1.3 all express their additive provisions "as-fed" with units of g/100 mL, therefore it would be more harmonized to express the maximum use levels with the unit "mg/L" within the GSFA. ISDI believes this change in unit would be highly beneficial in ensuring aligned interpretations of the provisions.

ISDI notes that this recommendation is currently captured through Note U (Maximum use level is expressed as mg additive/L of food), and that it is not possible to make such specific changes to the GSFA database. ISDI believes modifying the unit in the GSFA table in the Max Level column would be a more effective way of indicating the appropriate unit (see example below). However, while we understand there may be technological challenges to updating the GSFA to accommodate this suggestion, ISDI requests clarity as to whether the GSFA itself could be updated in this manner, which would still be beneficial.

Food Category No. 13.1.1 Infant formulae

Additive	INS	Year Adopted	Max Level	Notes
ACETYLATED DISTARCH PHOSPHATE	1414	2014	5000 ~~mg/kg~~ mg/L	72, 150, 284 & 292
ASCORBYL ESTERS	304, 305	2019	10 ~~mg/kg~~ mg/L	72 & 187

Chair's Proposal: Unchanged, replace note 72 with Note 381 in FC 13.1.1, FC 13.1.2, and FC 13.1.3.

ISDI appreciates the ongoing discussion on this point, and would like to take this opportunity to restate our position that inclusion of Note 381 (or Note 72) is unnecessary for the products covered by FC 13.1.1, FC 13.1.2, and FC 13.1.3. Furthermore, use of Note 381 (or Note 72) for products in these food categories, but not others within food category 13, has led to confusion in the interpretation of the provisions.

Section 6 of the preamble of the GSFA states that “Unless otherwise specified, maximum use level for additives in Tables 1 and 2 are set on the final product as consumed.” Therefore, whether products are sold as liquids ready for consumption, powders that require reconstitution prior to consumption, or in both formats, an additive provision should be interpreted to be applied “as consumed” in the absence of a Note, as in these cases the provision within Section 6 of the preamble would guide interpretation.

If the committee aligns to maintaining Note 381 (or Note 72) for the provisions within FC 13.1.1, FC 13.1.2, and FC 13.1.3, ISDI believes it would be beneficial for the Committee to reaffirm that any provisions within the GSFA should be interpreted as being applied to the products as consumed, as noted in Section 6 of the preamble. ISDI believes this would aid in the future interpretation of provisions both within other food categories in category 13, but also for products in other food categories in which products are sold in different formats (e.g. liquid ready to consume, powder requiring reconstitution, concentrated liquid).

Chair’s proposal: Unchanged: (1) Maintain Notes 55, 240, 316, 319 and 320 to capture the intent of the commodity standards (same as 2nd circular proposal); (2) If a commodity standard has already had the limitation notes for a nutrient in food additive section, notes which limit the amount for the nutrient are added to food additives containing the nutrient including for FC 13.1.3 (3) Amend Note 55 as proposed above.

ISDI supports proposal (3) of the three proposals but would like to clarify further on proposals (1) and (2).

In relation to proposal (1), ISDI supports retaining the existing Notes 55, 240, 316, 319, and 320 in FC 13.1.1 and FC 13.1.2. Our concern is that not all additives that contribute nutrients for which there is a limit have a corresponding Note. This could lead to confusion as to whether the presence or absence of the Note has some different effect on interpretation.

For example, in FC 13.1.2, the current EWG proposals include:

Additive	INS	Max level	Notes	Step/Year Adopted	Recommendation
Sodium carbonate	500(i)	GMP	~~72~~, 316, **381, U**	2015	Endorse
Potassium carbonate	501(i)	GMP	~~72~~, **381, U**	2013	Endorse

72: On the ready-to-eat basis

316: Within the limit for sodium specified in the Codex Standard for Follow-up Formulae (CODEX STAN 156-1987): singly or in combination with other sodium containing additives.

381: As consumed

U: Maximum use level is expressed as mg additive/L of food.

Both sodium and potassium have limits in CXS 156-1987 in section 3.2.6:

	Amounts per 100 available calories		Amounts per 100 available kilojoules	
	Minimum	Maximum	Minimum	Maximum
3.2.6 Minerals				
Sodium (Na)	20 mg	85 mg	5 mg	21 mg
Potassium (K)	80 mg	N.S.[2]	20 mg	N.S.[2]
Chloride (Cl)	55 mg	N.S.[2]	14 mg	N.S.[2]
Calcium (Ca)[5]	90 mg	N.S.[2]	22 mg	N.S.[2]
Phosphorus (P)[6]	60 mg	N.S.[2]	14 mg	N.S.[2]
Magnesium (Mg)	6 mg	N.S.[7]	1.4 mg	N.S.[2]
Iron (Fe)	1 mg	2 mg	0.25 mg	0.50 mg
Iodine (I)	5 µg	N.S.[2]	1.2 µg	N.S.[2]
Zinc (Zn)	0.5 mg	N.S.[2]	0.12 mg	N.S.[2]

Only sodium carbonate has a Note relating to the sodium limit in the GSFA based on the proposals. However, only through reading the commodity standard would show that both sodium carbonate and potassium carbonate would be subject to the nutrient limit in CXS 156-1987.

Given the stated purpose of alignment is to make the GSFA the single reference point for additives, the lack of a Note regarding potassium limits in the GSFA would hinder achieving this outcome.

In relation to proposal (2), we disagree that Notes 55 and D72 should remain for FC 13.1.3 because the Note is contrary to provisions in CXS 72-1981.

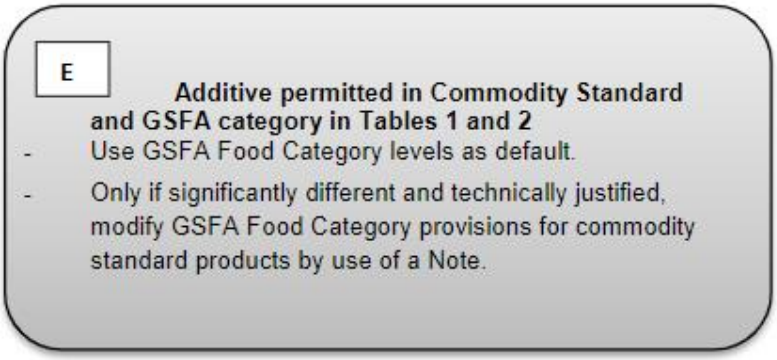
These two Notes read:

> Note 55: Within the limits for sodium, calcium, and potassium specified in the Standard for Infant Formula and Formulas for Special **Medical**~~Dietary~~ Purposes Intended for Infants (**CXS**~~CODEX STAN~~ 72-1981): singly or in combination with other sodium, calcium, and/or potassium salts.
>
> Note D72: Within the limits for sodium, potassium and phosphorus specified in the Standard for Infant Formula and Formula for Special Dietary Purposes Intended for Infants (CXS 72-1981)

When these Notes are attached to FC 13.1.3 food additives, they suggest that products covered by FC 13.1.3 have a sodium, calcium, potassium, and/or phosphorus limit in CXS 72-1981. However, that is not the case and these Notes could confuse the reader. CXS 72-1981 states in Part B, section 3.1.3 (emphasis added):

> The energy content and nutrient composition of Formula for Special Medical Purposes intended for infants shall be based on the requirements for infant formula as given in sections A 3.1.2 and A 3.1.3, ***except for the compositional provisions*** which must be modified to meet the special nutritional requirements arising from the disease(s), disorder(s) or medical condition(s) for whose dietary management the product is specifically formulated, labelled and presented.

We refer also to the CCFA information document on alignment, in particular box E of the flow diagram:



FC 13.1.3 has a one-to-one relationship to formula for special medical purposes intended for infants and CXS 72-1981 clearly exempts such products from the compositional provisions. Therefore, based on box E, there is a significantly different level in the commodity standard (i.e. no compositional limit) to what is in the GSFA and this should be reflected by use of a Note – or in this case, the deletion of Notes 55 and D72 for FC 13.1.3.