CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 10 **CX/NFSDU CRD/34**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Fortieth Session

Berlin, Germany

26-30 November 2018

REPORT OF THE IN-SESSION WORKING GROUP ON THE MECHANISM / FRAMEWORK FOR CONSIDERING TECHNOLOGICAL JUSTIFICATION OF FOOD ADDITIVES

The in-session WG was chaired by the European Union. The following delegations participated in its work:

Australia, Austria, Belgium, Canada, Denmark, European Union, Finland, France, Ireland, Japan, New Zealand, Russian Federation, Sweden, Thailand, the Netherlands, United Kingdom, United States of America EU-SFI, GOED, IADSA, ICBA, ICGA, IFAC, IFPRI, IFT, IFU, ISDI, SNE, Codex Secretariat and FAO and WHO JECFA secretariat.

The in-session working group was tasked with the following mandate:

> To review Annex A and Annex B of CX/NFSDU 18/40/11 and, on this basis, make proposals to the Committee regarding
>
> 1) the Process to appraise and justify the technological need for the use of additives in foods subject to CCNFSDU standards and
>
> 2) the CCNFSDU Framework for appraising the technological need of additives
>
> 3) provided a consensus is reached on Recommendations 1 and 2 the in-session working group is invited to appraise the technological need for the proposed use of xanthan gum (INS 415), pectin (INS 440) and gellan gum (INS 418) taking into account the information submitted by the applicant (Annex D of CX/NFSDU 18/40/11) and the discussion in the EWG.

DISCUSSION IN THE IN-SESSION WG

Discussion on Annex A of CX/NFSDU 18/40/11

1. In the beginning of the discussion several procedural questions were raised (e.g. on how the process should be started). It was noted that the current work was triggered by the request for appraising the technological need by CCNFSDU for food additives intended for use in infant formula prior to their inclusion in the JECFA priority list. JECFA secretariat explained that the risk assessment of additives intended for use in infant formula is more resource demanding and thus the confirmation of the technological need prior to the risk assessment is required.

2. A reference was made to CCNFSDU39 that agreed that all foods within the mandate of CCNFSDU should be covered by the Framework and to other situations for which the Framework could be used as outlined in footnote 3 on page 2 of CX/NFSDU 18/40/11, in particular to replying to the inquiries from CCFA on the technological need for food additive provisions intended for use in foods within the CCNFSDU responsibility and to developing food additive sections of CCNFSDU standards.

3. It was noted that the current work is nothing new since the Committee appraised the technological need in the past. However, the intention was to agree on a more formal way on how it should be done.

4. The amendments suggested for the text of the Process were limited to adding the wording "*justification of use*" in the fourth bullet point and addition of the text *"…and the commodity standard is updated if not aligned with the GSFA.*" in the sixth bullet point. The in-session WG agreed with the proposed amendments.

Recommendation 1: the Committee is invited to endorse the Process as outlined in Annex 1 to this report.

Discussion on Annex B of CX/NFSDU 18/40/11

5. The discussion began with the wording [and food ingredients], "standardised, mandate/ scope/ terms of reference" and whether these should be included in part of the "SCOPE". In addition, the question whether the scope of the Framework should apply only to standardised foods or to all foods within the mandate of CCNFSDU was also discussed. Following the exchange of views and several suggestions made the in-session WG agreed with the wording "*The framework applies for the use of additives in foods within the mandate of CCNFSDU*" and the understanding that food ingredients become part of the final foods which should comply with the respective food additive provisions.

6. During the discussion it was noted that foods within the purview of the Committee correspond to the GSFA food category 13 and its sub-categories.

7. The heading of the Q1 was reformulated to "IDENTITY AND INTENDED USE". As a general comment it was suggested to reformulate some questions to sentences which outline what information is needed and that the Committee can appraise the technological need based on this information. The in-session WG agreed with amended Q1.1rev and amended Q1.2. As for Q1.3rev there was a lack of consensus on whether the second sentence should be kept or deleted. The third sentence seems to be redundant in view of the questions in Q2 complex.

8. One in-session WG member asked to align the agreed wording for the scope of the Framework with the title of the Process.

9. In-session WG agreed to merge the questions on the advantage and technological function (functional class(s) into one question so Q2.1 and Q2.3rev was supported. As for the question on misleading more elaborated version (i.e. Q2.2rev) was supported. The in-session WG agreed with Q2.4 and Q2.5, however, for Q2.4 it requested to include the needs (a) through (d) from the GSFA Preamble Section 3.2. in the question as bullet points.

10. One in-session WG member requested further guidance/ clarity on Q2.5 (as regards other economically and technologically practicable means).

11. There was a lack of consensus on the scope of Q3 complex which need to be further discussed. Similarly, a need for a further discussion on Q3.1 and Q3.2rev was indicated. It was noted that some elements from the question Q3.1 were missing.

Recommendation 2: the Committee is invited to endorse the parts of the framework on which consensus was reached by the in-session WG and to further discuss the parts of the framework in the square brackets as outlined in Annex 2 to this report.

Discussion on the technological need for the proposed use of xanthan gum (INS 415), pectin (INS 440) and gellan gum (INS 418)

12. The discussion did not take place due to time constrains.

ANNEX 1

Process to appraise and justify the technological need for the use of additives in foods within the mandate of CCNFSDU

Note: it was suggested to align the text in brackets above with the text on the scope as laid down in Annex B (see the next page)

- CCNFSDU collects requests and information in order to appraise the technological need by using the agreed framework[1].
- CCNFSDU checks the adequacy of the information provided and evaluates it against the criteria/ questions listed in the framework[2].
- The outcome of the assessment is recorded in the report of a CCNFSDU meeting and if CCNFSDU agrees that the proposed use satisfies the established criteria then such use is considered as technologically justified.

The steps which might follow:

For the requests for which the JECFA assessment is envisaged:

- The applicant may then request including the substance in the JECFA priority list following the standard procedure (i.e. replying to the CCFA CL "*Request for information and comments on the priority list of substances proposed for evaluation by JECFA*") and referring to the CCNFSDU report which confirmed the technological need. In particular, section 6 justification of use of the CCFA CL is responded to. Such requests are discussed at CCFA and if appropriate (i.e. the applicant commits to provide the data and the request is supported by a Codex Member) they are included in the JECFA priority list.
- JECFA presents the safety assessment at CCFA and CCFA refers the results to CCNFSDU. Taking into account the outcome of the safety assessment the GSFA (and the commodity standard if not aligned yet with the GSFA) is updated or the matter is further discussed between CCFA and CCNFSDU should questions arise following the JECFA evaluation.

For the requests for which the JECFA assessment is not envisaged:

- Proposals for the use of additives in the CCNFSDU standards are forwarded to CCFA for endorsement and inclusion in the GSFA[3] and the commodity standard is updated if not aligned with the GSFA.
- A reply is provided to CCFA in case of CCFA's inquiries concerning the technological justification for the use of additives in foods under the CCNFSDU's purview.

[1] This could be done e.g. by a Circular Letter (CL) issued by the Codex Secretariat (for food additive uses for which the JECFA assessment will be required) or via an EWG (e.g. in case of a new standard under development).
[2] If needed a specific EWG or an in-session WG could be established for this to prepare draft recommendations for the Committee.
[3] Procedural Manual 26th edition, p. 51.: "*when an active commodity committee exists, proposals for the use of additives in any commodity standard under consideration should be prepared by the committee concerned, and forwarded to the Committee on Food Additives for endorsement and inclusion in the General Standard for Food Additives*"

ANNEX 2

CCNFSDU framework for appraising the technological need

SCOPE

The framework applies for the use of additives in foods within the mandate of CCNFSDU

Q1 IDENTITY AND INTENDED USE

Q1.1: Provide name and INS No of the food additive as listed in CAC/GL 36-1989 (for substances not yet included in CAC/GL 36-1989, chemical name of the substance).

Q1.2: State the food for which the additive is intended to be used and indicate the relevant CCNFSDU standard and if known the GSFA food subcategory.

Q1.3: Indicate what is (are) the proposed use level(s) of the food additive needed to accomplish the desired technological effect. [Is information on the lowest possible amounts necessary to accomplish the desired technological effect for each type of food provided and justified?] [Is information provided on the technological effect of the additive?]

Note: there were diverging views on the need for the second sentence of Q1.3. During the discussion on Q2 complex it was indicated that the last sentence is being repeated and thus might be removed as being redundant.

Q2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA

Q2.1: Describe the technological function of the food additive relative to the CAC/GL 36-1989 (include the functional class) and the advantage conferred by its use.

Q2.2: Does the use of an additive serve one or more of the needs set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA? Indicate which one(s).

a) To preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified in the circumstances dealt with in sub-paragraph (b) and also in other circumstances where the food does not constitute a significant item in a normal diet;

b) To provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;

c) To enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer;

d) To provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities.

Q2.3: Cannot the objectives set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA be achieved by other means that are economically and technologically practicable?

Q2.4: Would the use of this food additive in the intended food(s) modify any characteristic of the food that might mislead the consumer? For example the nature, substance, quality or nutritional quality of the food, the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques by which the consumer might be misled.

[Q3 COMPLIANCE WITH THE APPROACH ON THE USE OF ADDITIVES IN FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN

OR

COMPLIANCE WITH THE APPROACH ON THE USE OF ADDITIVES IN FOODS INTENDED FOR YOUNG INFANTS (Codex STAN 72-1981)]

Note: there were diverging views on the scope of Q3 complex as indicated, i.e. either for the use of additives in foods for infants and young children OR for the use in foods for young infants.

[Q3.1: Does the proposed food additive perform the same/similar technological purpose as other additives that have already been authorized for use in the same product category? If not, what is the justification for the need for an additive with a new functional class and/or technological purpose? If yes, what advantage(s) does the proposed additive provide over currently permitted options?]

Note: the question was discussed at the end of the in-session group. A need for some further discussion was indicated.