



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**  
**CODEx COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES**  
**Forty-first Session**  
**Düsseldorf, Germany**  
**24 - 29 November 2019**

**REPORT OF THE PHYSICAL WORKING GROUP ON THE MECHANISM / FRAMEWORK FOR  
CONSIDERING TECHNOLOGICAL JUSTIFICATION OF FOOD ADDITIVES**

**23 November 2019**

*(Prepared by the European Union and the Russian Federation)*

At CCNFSDU40 the Committee agreed to establish a physical working group (pWG) to meet immediately prior to the CCNFSDU41, chaired by the European Union and co-chaired by the Russian Federation, working in English, French and Spanish.

The pWG was tasked with the following mandate:

To further consider:

- (i) the text in square brackets (Appendix VIII, Annex 2, REP19/NFSDU),
- (ii) the questions under question Q3 in document CX/NFSDU 18/40/11; and
- (iii) appraise the technological need for the proposed use of xanthan gum (INS 415), pectins (INS 440) and gellan gum (INS 418) taking into account the information submitted by the applicant (Annex D, CX/NFSDU 18/40/11).

**DISCUSSION IN THE IN-SESSION WG**

1. The chair presented the background to the matter and the work completed at CCNFSDU40. He explained that the intention was first to complete the work on the framework by discussing parts (i) and (ii) of the mandate and afterwards to appraise the technological need for the three candidate additives. He referred to CRD 8 prepared to facilitate the discussion at the pWG and CRD 18 containing comments made by the applicant.

**Completion of the work on the framework**

2. The chair presented all questions covered by the parts (i) and (ii) of the mandate and opened the discussion on the individual questions.

(i) The text in square brackets (Appendix VIII, Annex 2, REP19/NFSDU)

*“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?”*

3. The pWG generally supported the wording of the question. However, some pWG Members did not support the last sentence, i.e. *“If yes, what advantage(s) does the proposed additive provide over currently permitted options”*, as in their view that part is redundant as “advantage” is already covered by Section Q2. Some other pWG Members stressed that Section Q3 shall verify whether the proposed use complies with the approach on the use of food additives in baby foods as outlined in para 9 of CRD 8 and that the last sentence is important as in contrast to Section Q2 it focuses on the advantage of the candidate additive when compared with the permitted options.

(ii) The questions under question Q3 in document CX/NFSDU 18/40/11

*“Q3.1: Is the same food currently available without the additive? Are there any reasons why the use is necessary even if there are products without the proposed food additive on the market?”*

4. Some Codex Members, not supporting the question, outlined that the question is already covered by Q2.3 that intends to check whether the technological needs cannot be achieved by other economically and technologically practicable means. Some other Codex Members stressed that the applicant was able to reply to the question providing additional valuable information and as the question reflects the principle that baby foods should be prepared without food additives whenever possible it should be retained.

*“Q3.2: Is there another food additive performing the same/similar technological effect which is more suitable/has already been approved for use in foods for infants and young children?”*

5. Divergent views were expressed on this question. Those supporting the question referred a cautious approach needed in order to select the most suitable food additives for use in foods intended for infants and young children. Those opposing the question were of the view that the choice of food additives shall not be limited for those assessed as safe by JECFA as there are many variables in the product development.

*“Q3.2rev & Q3.1 and Q3.2rev”*

6. For the other two remaining questions in CX/NFSDU 18/40/11 it was pointed out that they are covered by the text in square brackets (Appendix VIII, Annex 2, REP19/NFSDU) and thus do not need to be discussed further.

#### Conclusions

7. After further reflection and as a compromise solution the pWG agreed with the full text of Q3.1 captured in Appendix VIII, Annex 2, REP19/NFSDU.

**Recommendation 1:** the Committee is invited to endorse Q3.1 question outlined below in order to complete the framework for the technological justification:

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?

8. The square brackets from the text in Appendix VIII, Annex 2, REP19/NFSDU shall be removed. For information purposes this paper also includes the updated form for appraising the technological need (Appendix I) and the updated decision tree (Appendix II).

#### **Appraisal of the technological need for the three candidate additives**

9. As a general remark some pWG members pointed out that the information relevant for Q3.1 question shall be written in that section of the form for appraising the technological need and not in Section Q2.

#### Xanthan gum (INS 415)

10. Some Codex Observers questioned whether the proposed use is necessary for the safety of the product and/or for nutritional purposes and called for a cautious approach. After providing further clarification the pWG agreed that the proposed use is intended to ensure product safety and to deliver the appropriate level of nutrients.
11. Based on the information provided the pWG concluded that the proposed use of xanthan gum in formulas for special medical purposes intended for infants (i.e. in section B of CXS 72-1981) at the ML of 0.1 g/100 mL limited to powdered hydrolysed protein and/or amino acid-based formula is technologically justified.

**Recommendation 2:** the Committee is invited to endorse the above conclusion of the pWG on xanthan gum.

#### Pectins (INS 440)

12. The pWG considered the information provided and concluded that the proposed use of pectins in formulas for special medical purposes intended for infants (i.e. in section B of CXS 72-1981) at the ML of 0.2 g/100 mL limited to liquid infant formula containing hydrolysed protein is technologically justified.

**Recommendation 3:** the Committee is invited to endorse the conclusion of the pWG on pectin.

#### Gellan gum (INS 418)

13. Within the discussion a number of questions were raised as regards the 87<sup>th</sup> JECFA meeting which assessed gellan gum for the use under consideration and confirmed safety only for low-acyl clarified form of gellan gum. The Codex Secretariat clarified that the discussion at CCNFSDU focuses on appraising the technological need and that the output of the JECFA evaluation would be considered by the Codex Committee on Food Additives. The representative of FAO, speaking on behalf of JECFA, further explained that the JECFA evaluation could neither be construed as to pre-empt CCNFSDU's decision regarding the justification of technological use of gellan gum in infant formula nor create facts that would be pre-empting any decisions by CCFA in its next meetings. It was further noted that the specifications for gellan gum was labelled as "tentative" only and further information to make the specification "full" would be needed.
14. The applicant further clarified that the proposed use and information provided in CRD 8 relates to low-acyl clarified gellan gum.
15. Further information on the technological justification was requested by some pWG members. In particular it was noted that gellan gum was tested in comparison with sodium octenyl succinate (INS 1450) but no information was provided on the functionality of other alternative additives. A question was raised whether the type of products for which gellan gum is requested is available in those countries that do not currently permit the use of gellan gum and how the described technological challenges are addressed without gellan gum.
16. The applicant clarified that the use of permitted additives would be the easiest option and that permitted additives were tested. He further clarified that the use of gellan gum together with sodium octenyl succinate (INS 1450) leads to low use levels of both additives which would be in line with the approach on the use of additives in baby foods. The applicant offered to prepare additional information prior to the Plenary for consideration by the Committee<sup>1</sup>. One Codex Member, supported by other two Codex Members, outlined that it needed more time to consider the replies provided by the applicant at the pWG meeting and indicated their possible reservation which would also depend on the additional information provided at the Plenary.
17. In light of the above considerations the pWG concluded that although there was some support for the proposed use of gellan gum, some pWG requested more information on the technological justification which would be provided by the applicant at the Plenary to decide whether or not the proposed use of low-acyl clarified gellan gum in formulas for special medical purposes intended for infants (i.e. in section B of CXS 72-1981) at the ML of 0.005 g/100 mL limited to liquid hydrolysed protein and/or amino acid-based formula is technologically justified.

**Recommendation 4:** the Committee is invited to decide on the technological justification of the proposed use of gellan gum taking into account the information provided by the applicant and the discussion at the pWG.

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<sup>1</sup> Additional information is contained in CRD44.

**Appendix I: Form for appraising the technological need for the use of additives in foods within the mandate of CCNFSDU (i.e. standardized or non-standardized foods following a request by CCFA)**

THE PROPOSAL IS SUBMITTED BY:		
<b>Q1 IDENTITY AND INTENDED USE</b>		
<b>Q1.1 Name and INS number of the additive as listed in CAC/GL 36-1989:</b> <i>For substances not yet included in CAC/GL 36-1989, chemical name of the substance.</i>		
<b>Q1.2 Describe the food and its form (e.g. liquid, powder) for which the additive is intended to be used and indicate the relevant CCNFSDU standard and if known the GSFA food subcategory</b>		
CCNFSDU standard		
Reference	Name of the standard	Comments (e.g. limitation of use to specific products)
GSFA food category		
Food category No	Name of the GSFA food category	
<b>Q1.3 Indicate and justify the range of the proposed use level of the food additive needed to accomplish the desired technological effect at the lowest possible use level</b>		
<b>Proposed (range of) lowest possible use level to accomplish the desired effect</b> <i>(expressed on the final product as consumed)</i>		<b>Justification of the level(s) proposed</b>
<b>Q2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA</b>		
<b>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</b>		
<i>Technological function relative to the CAC/GL 36-1989:</i>		
<i>Advantage from the use of the additive:</i>		
<b>Q2.2 Does the use of the 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)</b>		
<b>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?</b>		
<b>Q2.4 Would the use of this additive in the intended food(s) modify any characteristic of the food that might mislead the consumer?</b>		

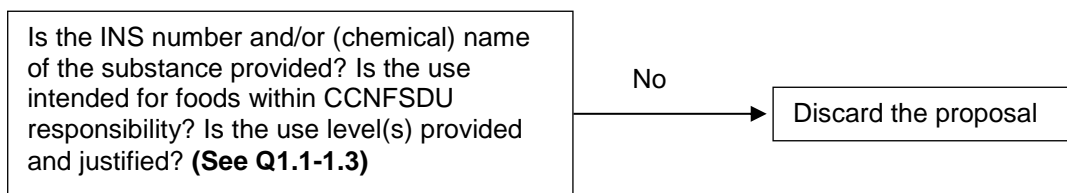
*For example the nature, substance, quality or nutritional quality of the food, the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques by which the consumer might be misled.*

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

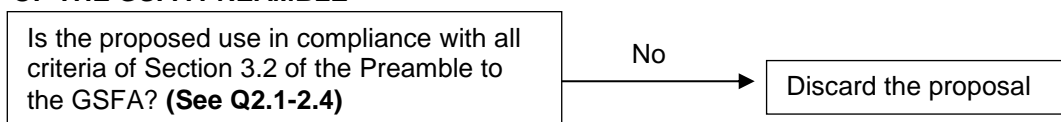
**Q3.1: Does the proposed food additive perform the same/similar technological purpose as other additives that have already been authorized for use in the same product category? If not, what is the justification for the need for an additive with a new functional class and/or technological purpose? If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

## Appendix II: Decision tree on the CCNFSDU framework for appraising the technological need

### Q1 IDENTITY AND INTENDED USE



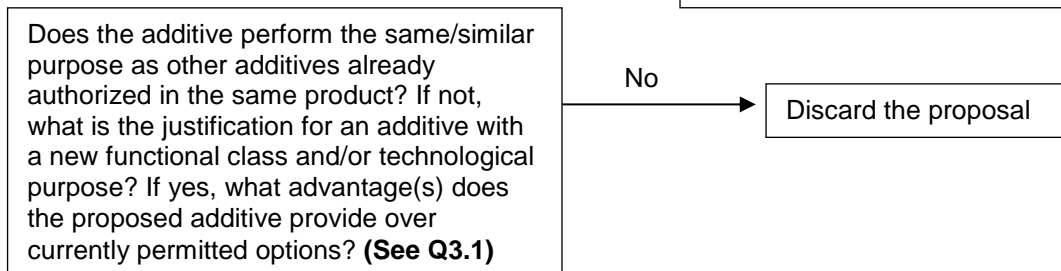
### Q2 COMPLIANCE WITH SECTION 3.2 OF THE GSFA PREAMBLE



The proposed use is for foods intended for infants and young children

The technological need is appraised by CCNFSDU for foods NOT intended for infants and young children and when relevant\* the sponsor could submit the request for inclusion of the additive into the JECFA priority list.

### Q3 COMPLIANCE WITH THE APPROACH FOR INFANTS AND YOUNG CHILDREN\*\*



The technological need is appraised by CCNFSDU for foods intended for infants and young children and when relevant\* the sponsor could submit the request for inclusion of the additive into the JECFA priority list.

\* The framework applies to three potential scenarios (see footnote 3 of CX/NFSDU 18/40/11):

- To appraise and justify the technological need prior to a possible inclusion of the additive in the JECFA priority list;
- To appraise the technological need for the use of additives within the CCNFSDU standards that does not warrant the JECFA assessment (e.g. in case of a development of new standards for additives already assessed by JECFA);
- To answer requests from CCFA concerning the technological justification for the use of additives in foods under the purview of the CCNFSDU.

\*\* The outcome of assessing Q3 (i.e. YES/NO) is whether the proposed use complies with the approach for the use of additives in baby foods (see REP17/NFSDU, para 172).