



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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DISCUSSION PAPER ON MECHANISM / FRAMEWORK FOR CONSIDERING TECHNOLOGICAL JUSTIFICATION OF FOOD ADDITIVES

(Prepared by the electronic Working Group led by the European Union and the Russian Federation)

Background

1. At the 38th session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU38) it was noted that the document [CX/NFSDU 16/38/11](#) proposed to establish an Electronic Working Group (EWG) to explore the alignment of food additive provisions and develop a framework on how to address the question on technological justification of substances prior to being proposed for evaluation by JECFA for their potential use in commodity standards developed by CCNFSDU. The observer from ISDI informed that CCNFSDU36 had recommended the evaluation of xanthan gum (INS 415) and pectin (INS 440) by JECFA and based on the evaluation by JECFA 82 (June 2016) requested CCNFSDU to consider including these two additives in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981). The Chairperson proposed to refer the substances to the EWG for consideration and to discuss the outcome at the next session ([REP17/NFSDU](#), paras. 171, 174-175).
2. The outcome of the EWG work ([CX/NFSDU 17/39/8](#)) was presented at CCNFSDU39. The Committee considered all three recommendations contained in CX/NFSDU 17/39/8 and agreed that (1) all foods within the mandate of CCNFSDU should be covered by the framework, (2) to use Annex A to CX/NFSDU 17/39/8, comments received at CCNFSDU39 (i.e. REP18/NFSDU, paras. 135-143) and comments reflected in the CRDs¹ as a basis for further consideration and (3) to continue the work on the framework ([REP18/NFSDU](#), paras. 133-141).

Mandate of the EWG

3. In the light of the above discussion the Committee agreed to:

Establish an EWG², chaired by the European Union, and co-chaired by the Russian Federation working in English with the following terms of reference:

 - (i) continue working on a mechanism or framework for considering the technological justification on the basis of CX/NFSDU 17/39/8 and taking into account the comments in the CRDs and the discussion at CCNFSDU39; and
 - (ii) test the agreed framework with the proposed use of xanthan gum (INS 415), pectin (INS 440) and gellan gum (INS 418).

¹CRD 6, CRD 12 and CRD 17

² The EWG was participated by Australia, Austria, Brazil, Canada, China, Colombia, Egypt, European Union, Finland, France, Indonesia, Ireland, Japan, Republic of Korea, Russian Federation, Singapore, New Zealand, Nigeria, South Africa, Sri Lanka, Sweden, Thailand, United Kingdom, United States of America, International Association for the Development of Natural Gums (AIDGUM), International Council of Grocery Manufacturers Associations (ICGMA), International Dairy Federation (IDF/FIL), International Fruit and Vegetable Juice Association (IFU), Institute of Food Technologists (IFT), EU Specialty Food Ingredients (EUSFI), International Food Additives Council (IFAC), International Special Dietary Foods Industries (ISDI), FAO and WHO JECFA secretariat.

Discussion by the EWG

4. The circular paper distributed to the EWG presented (A) a process (mechanism) to appraise the technological need, (B) an updated framework and (C) asked to test xanthan gum (INS 415), pectin (INS 440) and gellan gum (INS 418) with the framework under considerations. The EWG members were requested to comment on those three parts of the circular paper.

A) Process to appraise the technological need

5. The EWG was mandated to use Annex A to CX/NFSDU 17/39/8, comments received at CCNFSDU39 and comments reflected in the CRDs as a basis for further consideration. As one Codex Member and one Observer suggested clarifying the whole process from receiving a request to a possible amendment of a standard (see [CRD 12](#), p. 6 and [CRD 6](#), p. 16-19) this input was used in the circular paper where a process to appraise the technological need was outlined for a further consideration.
6. Some comments received expressed concerns that the circular paper established a new process which might be overlapping with the CCFA procedures that use a Circular Letter (CL) for requesting information and comments on the JECFA priority list. The rationale behind those comments was the understanding that the purpose of the framework is limited to answer requests from CCFA concerning the technological justification for the use of additives in foods under the purview of the CCNFSDU.
7. It should be noted that the current work was triggered by the CCFA48 that endorsed the recommendations that CCNFSDU needed to confirm the technological need of food additives intended for use in infant formula prior to the inclusion in the JECFA priority list and that for future requests it would be the sponsors' responsibility to obtain CCNFSDU confirmation before submitting the request to CCFA ([REP16/FA](#), paras. 119 and 120).
8. It follows from the previous paragraph that the purpose of the framework is not limited to answer requests from CCFA (for which it could be used as well) but rather to establish a mechanism/ framework which once put into practice should save time and resources since there will not be a need for CCFA to request clarification on technological justification in order to proceed with including a food additive on the priority list or the risk that JECFA would have undertaken a risk assessment for a food additive which would not be deemed to be technologically justified.

In other words there are more scenarios³ for which the use of framework should be considered.
9. For the sake of clarity the wording used in the suggested process (Annex A to this paper) was amended to avoid misunderstandings that it includes another CL just to collect the requests for placing substances on the JECFA priority list and thus duplicating the CL issued within the CCFA. Indeed, the intention of the first step described in the process is to find means how to collect the requests and information to appraise the technological need by CCNFSDU.
10. Although one EWG member pointed out that the discussion on the process exceeds the mandate of the EWG (it is up to the Committee to consider whether the discussion on the process is appropriate) there was a general wish of the EWG members to clarify the process by which CCNFSDU will appraise the technological need in order to avoid the overlaps between CCFA and CCNFSDU and to clarify the roles and responsibilities in each of the steps. Several EWG members mentioned that without having clarity on the process the work on the framework and testing the proposed use of xanthan gum (INS 415), pectin (INS 440) and gellan gum (INS 418) cannot be completed. One EWG member suggested that once the process is clarified it should be captured in a guidance document for a future reference.
11. Some EWG members referred to the CCFA CL on the JECFA priority list asking for clarity on the relation between the new CCNFSDU framework and the existing CCFA CL. In particular a reference was made to section 6 "*Justification for use*" which according to them could be used/ adjusted for information related to the justification of the CCNFSDU food additive uses. They reminded the EWG of the need for a Codex Member support prior the substance is included in the JECFA priority list and that such support might be needed as well before CCNFSDU evaluates the requests in the framework for appraising the technological need.

³i.e. (1) to appraise and justify the technological need prior to a possible inclusion of the additive in the JECFA priority list; (2) 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); or (3) to answer requests from CCFA concerning the technological justification for the use of additives in foods under the purview of the CCNFSDU.

12. One EWG member was of the view that the technological justification of food additives used in foods for special dietary use including those intended for infants and young children cannot be considered without reviewing safety of the finished product and thus without taking into account the impact on the nutritional value and contaminants of the finished product. In the view of this EWG member the discussion on the technological justification should involve all Codex and advisory bodies that work on different aspects of additives' safety.

B) Updated framework on the technological justification

13. The comments received indicated a general support to set up a framework for appraising the technological need. However, questions and divergent views were expressed on the roles and responsibilities of CCNFSDU versus CCFA and thus on the scope and the formulation of the questions which should be considered within the framework.
14. Several EWG members supported the criteria/ questions as formulated in the circular paper including specific questions reflecting the principle for the use of additives in "baby foods". Nevertheless, several other EWG members expressed misgivings on certain questions and suggested to reformulate or delete them.
15. Some MS expressed the view that sub-questions of Q1 and Q2 could interfere with the CCFA responsibilities and questioned the relevance of these sub-questions to appraise the technological need by CCNFSDU. As regards Q3 one EWG member suggested that it shall not be related to infants and young children (i.e. to "baby foods") but only to young infants (<12 weeks) for which a separate evaluation by JECFA is needed. Other EWG members suggested rewording and/or merging questions in complex Q3. One EWG was against any specific criteria for infants and young children at all.
16. One EWG member supported the questions in the framework being asked of petitioners, however, considered that the replies should be judged in their totality rather than to follow a "yes/no" approach for the individual questions. The need for an opportunity to ask additional questions was stressed by this EWG member as well. Another EWG pointed out that there are no criteria on how to assess the information received.
17. To address ambiguities described above a common understanding of the provisions outlined in the Procedural Manual is needed. In addition, the scope of the framework (i.e. as agreed for all foods within the mandate of CCNFSDU) and its purpose for use in different situations (see footnote 3 on p. 2) should be taken into account.
18. The relevant sections of the Procedural Manual lay down, inter alia, the following:
 - The section on the relations between commodity committees and general subject committees says that "*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....When no active commodity committee exists, proposals for new additive provisions or amendment of existing provisions for inclusion in the General Standard for Food Additives should be forwarded directly by Codex members to the Committee on Food Additives.*" (Procedural Manual 26th edition, p. 51).
 - The revision and review of the GSFA is outlined on pages 62-70. It describes the data and information that should be submitted to CCFA by Codex Committees, Codex members, or the Codex Alimentarius Commission to support amendment of the GSFA. For the revision it lists seven criteria that are now captured in the CCFA circular letters for new entry and or revision of food additive provisions in the GSFA.
 - If the food additive is used in standardized food "*The Committee on Food Additives, asks the relevant Codex commodity committee to consider the functional classes of additives, additives and their technological justification for the commodity and to refer back this information by the next available session. In light of this information, the Committee on Food Additives recommends appropriate conditions of use based on proposals of the commodity committee. In certain cases, however, it may be appropriate for the Codex commodity committee to develop a list of food additives with associated functional classes and acceptable maximum use levels that would be forwarded to the Committee on Food Additives for endorsement and, ultimately, incorporation into the General Standard for Food Additives. The development of such food additive lists should be consistent with the principles used in the development of the General Standard for Food Additives....*" (Procedural Manual 26th edition, p. 65-66).

- The same part of the Procedural Manual clarifies that “*Section 3.2 of the Preamble of the General Standard for Food Additives establishes the criteria for justifying the use of a food additive. Adherence to these criteria is necessary for the inclusion of the food additive in the General Standard for Food Additives. If the use of the additive does not meet these criteria, it is not considered further and the work is discontinued...*” (Procedural Manual 26th edition, p. 65).
 - The diagram summarising the procedure for consideration of the entry and review of food additives in the GSFA (Procedural Manual 26th edition, p. 70) outlines that firstly it is the CCFA that checks whether the additive use meets criteria in Section 3.2 of the GSFA Preamble and in case the additive is used in standardized food the appropriate commodity committee is consulted for opinion on technological need which is assessed by criteria in section 3.2.
19. Annex B to this paper presents the updated framework as outlined in the circular paper. It captures the amendments suggested by the EWG members and the notes describing the relevant comments made.
20. Annex C to this paper presents the decision tree on the framework. It is presented for information only. The decision tree can be finalised when a consensus is reached on the framework.

C) Testing xanthan gum (INS 415), pectin (INS 440) and gellan gum (INS 418)

21. The majority of the EWG members were of the view that it is not possible to test the framework before the discussion on the process and the framework is concluded. Thus the majority of the EWG members did not provide any comments/ views on whether or not the proposed use of xanthan gum (INS 415), pectin (INS 440) and gellan gum (INS 418) is technologically justified.
22. Two EWG members followed the order of the questions in the proposed framework and assessed the information available from the petitioner to appraise the technological need. One of them did it only for xanthan gum, the other for all three additives. The former came to a conclusion that xanthan gum is technologically justified for the proposed use ensuring stability and homogeneity of the products and the effective delivery of nutritional components, the latter reached the opposite conclusion for all 3 additive uses expressing several misgivings on them (e.g. on the methods of production, on some aspects not covered by the JECFA assessments, on the impact on the nutritional value of food, lacking evidence that the product cannot be prepared without those additives).
23. Three other EWG members considered the information made available by the petitioner as sufficient to acknowledge the technological need for the proposed uses. However, two of them requested some further clarification related to (i) the form(s) of the products in which the additives is(are) to be used (powdered and/or ready-to-eat liquid) as the technological need may be very different for different forms; (ii) a maximum level of use and (iii) how the use of pectin improves formula stability under either acidic condition, or after heat-treatment or both.
24. The replies of the petitioner to the questions included in the framework in the circular paper are captured for information in Annex D to this paper.

Concluding remarks

25. There was a consensus of the EWG members that it is important to clarify the process by which CCNFSDU will appraise the technological need (taking into account the scope and purpose of the current work) including its role and responsibilities.
26. Several comments were received on the draft framework. Further discussion is needed to finalise the framework also in the light of the discussion on the procedural matters as indicated in the previous paragraph.
27. No definitive conclusion on the technological need for xanthan gum (INS 415), pectin (INS 440) and gellan gum (INS 418) can be made at this stage. It follows from the comments provided that the testing of the proposed use can be completed only once there is clarity on the process and the framework.
28. Two EWG members requested to establish an in-session working group for this agenda item at CCNFSDU40 noting that the issues under discussion by the EWG are complex and may require extensive discussion to reach consensus. The Committee is invited to consider whether it would be appropriate to organise an in-session working group at CCNFSDU40 to discuss some or all the pending questions identified under paras. 25 to 27.

Recommendations

Recommendation 1

29. The Committee is invited to consider the appropriateness of the process as outlined in Annex A.

Recommendation 2

30. In the light of the outcome for Recommendation 1 the Committee is invited to further discuss and endorse the criteria/questions to appraise and justify the technological need for the use of additives in foods within the mandate of CCNFSDU.

Annex B to this paper should be the basis for such discussion.

Recommendation 3

31. Provided a consensus is reached on Recommendations 1 and 2 the Committee 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) and the discussion in the EWG.

Annex A

Process to appraise and justify the technological need for the use of additives in foods subject to CCNFSDU standards

- CCNFSDU collects requests and information in order to appraise the technological need by using the agreed framework⁴.
- CCNFSDU checks the adequacy of the information provided and evaluates it against the criteria/questions listed in the framework⁵.
- 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 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 GSFA⁶ or
- 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.

⁴This 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).

⁵If needed a specific EWG or an in-session WG could be established for this to prepare draft recommendations for the Committee.

⁶Procedural 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 B

CCNFSDU framework for appraising the technological need

The text below includes the questions of the framework as outlined in the circular paper plus the alternative proposals submitted by the EWG members. The alternative proposals are indicated as “rev”. If the intention was to replace more questions, the range of the questions to be replaced is indicated, e.g. “Q2.1 and Q2.3rev”. The brackets [] indicate the parts of the text as outlined in the circular paper for which a deletion was suggested by some EWG members.

Notes and comments “*in italics*” are included below the questions to provide additional clarifications. It should be noted that several EWG members supported the questions as formulated in the circular paper and thus the “rev” questions, brackets and information in the “comments” relate to the views of those EWG members that suggested certain amendments or expressed misgivings on the original questions.

SCOPE

The framework applies to all foods [and food ingredients] under the mandate of CCNFSDU.

Comments: one EWG member asked for a clarification on the inclusion of the term “food ingredients”. Another EWG member suggested deleting this term noting that the term could be deleted to align the sentence with the agreed language at CCNFSDU39.

Note: the term was used due to CAC/GL 10-1979 (Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children) and due to the fact that the food additive sections laid down in CXS 72-1981 and CXS 74-1981 and Section 4.3 of the Preamble to the GSFA do not allow carry-over of a food additive from a raw material or ingredient and thus any additive used in a raw material or ingredient needs to be captured in the mentioned standards or in the GSFA respectively.

Q1 ELIGIBILITY AND INTENDED USE

Q1.1: Does the proposed substance meet the Codex definition of a food additive [(including data about existing or proposed specifications which characterise the substance and methods of analysis in foods, justified use level(s))]?

Note: the information submitted should provide sufficient clarity to decide on the status of the substance under consideration. Name of a substance shall be given and its INS Number in case it is listed in CAC/GL 36-1989. For substances not yet included in CAC/GL 36-1989 name of the substance and justification that the substance meets the Codex definition of a food additive needs to be provided. Reference to the existing or proposed specifications shall be given.

Q1.1rev: Is 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) provided?

Comments: some EWG members suggested reformulating the question. The suggestions referred to the name and INS number and in one case to the chemical name if the substance was not included in CAC/GL 36-1989. One EWG member suggested deleting the part “justified use level(s)” from Q1.1 since it is a part of Q1.3. Another suggested deleting the whole text in the brackets in Q1.1.

Q1.2: Is the food for which the additive is intended to be used covered by a relevant CCNFSDU standard [and/or GSFA food subcategory]?

Note: the reply should provide clarity as regards the relevant CCNFSDU standard and GSFA food category. In the part “comments” information on the need for the food additive in specific sub-group of products, if relevant, should be provided.

Q1.2rev: Is the food for which the additive is intended to be used covered by a relevant CCNFSDU standard? If so, please describe the food in which the additive is to be used and provide the relevant CCNFSDU standard.

Comments: not too many comments were submitted on Q1.2. Some comments indicated that the information on the GSFA food subcategory is not necessary and should be deleted. One suggestion requested more information on the food in which the additive is to be used.

Q1.3: Is information on the lowest possible amounts necessary to accomplish the desired technological effect provided and justified?

Note: according to Section 3.3 of the Preamble to the GSFA food additives shall be used under conditions of good manufacturing practice which include, inter alia, that the quantity of the additive added to food shall be limited to the lowest possible level necessary to accomplish its desired effect.

In case of foods intended for infants and young children this question reflects that “great caution should be exercised as regards the level of use of a food additive in baby foods”.

In case of different levels proposed the lowest level should be always the default proposal for a discussion. Justification for any higher level would be needed. In case of no consensus the lowest level should be selected.

Q1.3rev: 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?

Comments: suggestions to amend the wording were made to reflect that there may be variability in minimum technologically effective levels (due to e.g. differences in climate, transportation and storage conditions, and cost effectiveness) and that the question does not prejudice the maximum level of use from being increased should an elevated maximum level be sufficiently justified. One EWG member was of the view that the question should not be included in the framework at all as the exact use level for an additive is discussed through the step process once a JECFA risk assessment is available. Other two EWG members suggested included the request for the information on the technological effect in the question. However, it is noted that the info on the technological effect is also required by Q2.3 (...“Clarify the technological effect for the use of the proposed food additive.”).

Q2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA

Note: the compliance with Section 3.2 ‘Justification for the Use of Additives’ is a prerequisite for the inclusion of additive provisions in the GSFA and Commodity Standards.

Q2.1: Does the use of an additive have an advantage?

Note: describe what the advantage from the proposed use of the additive is.

Comments: two EWG members pointed at the lack of clarity of what is expected from this question. One EWG member suggested deleting this question.

Q2.2: Does the use of an additive not mislead the consumer with regard to properties of the food?

Note: clarify whether there is any impact or not from the use of an additive (e.g. as regards the nature, freshness, quality of ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product) by which the consumer might be misled.

Q2.2rev: 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.

Comments: one EWG member was uncertain about the applicability of concerns regarding misleading the consumer for foods which will generally be subject to strict regulatory controls and asked for examples of such cases or situations and if not available to delete the question. Another EWG suggested an amendment to the wording as outlined in Q2.2rev above.

Q2.3: Does the use of an additive serve one or more of the technological functions set out by Codex? Clarify the technological effect for the use of the proposed food additive.

Note: check the functional class list used in Class Names and the International Numbering System (CAC/GL 36-1989) whether and what is/are the appropriate functional class(es) for the technological effect under consideration. Provide the description of the technological effect of the food additive. Describe how the additive is to be used and point in food manufacture where the additive is to be used.

Q2.1 and Q2.3rev: Describe the technological purpose of the food additive relative to the CAC/GL 36-1989 (include the functional class) and the advantage conferred by its use.

Comments: one EWG member suggested combining Q2.1 and Q2.3 into one question as outlined above (Q2.1 and Q2.3rev).

Q2.4: 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?

Note: check the mentioned parts (a) through (d) of Section 3.2 and describe how the proposed use relates to the needs described.

Q2.4rev1: Describe how the proposed use relates to one or more of the needs listed in section 3.2 of the GSFA (Codex STAN 192-1995).

Q2.5: 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?

Note: are there any other means by which the mentioned objectives can be achieved? If yes, describe those including technological and economic implications.

Comments: one EWG pointed out that this question would benefit from practical guidance on what may meet such conditions. Another EWG member was of the view that whilst information on the technical practicability can be assessed in an objective way it is not the case for the economic practicability for which only qualitative information could be provided explaining, for example, why an additive is used as opposed to applying an additional processing step.

Q2.1-2.5rev: Is the proposed food additive use in FSDU in compliance with Section 3.2 (Justification for the Use of Additives) of the Preamble to the General Standard for Food Additives?

Comments: one EWG member, while supporting the compliance with Section 3.2 of the Preamble to the GSFA, suggested considering a sentence referring to Section 3.2 rather than replicating the whole section in multiple questions.

Q2.1-3.2rev: In the standardized food under discussion, does the additive perform one of the technological functions which CCNFSDU has determined are necessary in the standardized food? If yes, please provide a discussion on the technological function of the additive in the standardized food and reference any supporting information.

Comments: one EWG member suggested revising complex Q2 into one question as outlined above. According to this EWG member such a question should be sufficient since in his view not all criteria of Section 3.2 of the GSFA Preamble apply to technological need. This EWG member was strongly against any specific criteria for infants and young children and suggested that complex Q3 is deleted.

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

Note: the questions in this part reflect the agreed principle that “baby foods should be prepared without food additives whenever possible. Where the use of a food additive becomes necessary in baby foods, great caution should be exercised regarding both the choice of additive and its level of use”.

Q3rev COMPLIANCE WITH THE APPROACH ON THE USE OF ADDITIVES IN FOODS INTENDED FOR YOUNG INFANTS (Codex STAN 72-1981)

Comments: whilst the wording of Q3 covers all foods for infants and young children, the revised text suggested by one EWG member (Q3rev) means that this section would apply only to foods for infants below 12 weeks of age (i.e. in practice to Codex STAN 72-1981). According to this EWG member the principle on baby foods formulated by JECFA applies only to young infants and not to young children.

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?

Note: this question reflects the principle that baby foods should be prepared without food additives whenever possible. If the information collected from the Codex Members and Observers indicate that the food under consideration can be prepared without the proposed food additive use (or without other additive use having the same/similar technological effect) the technological need is put in question.

In addition, this question allows those advocating the use of the additive to provide specific reasons why the use of additive is necessary (e.g. special character of a certain product, special medical condition) for consideration of the Committee. It could help to adjust the applicability of the food additive provision under consideration to the specific foods or medical conditions for which the use is necessary.

Comments: one EWG member indicated difficulties in comparing products in different parts of the world due to multiple factors (different manufacturing processes, ingredients, shelf-life considerations etc.) and that the use of a new additive may improve the quality of a product. In addition, he pointed out that multiple additives may be equally effective in achieving a technical purpose and the choice could depend on different factors such as, for example, supply chain considerations, intellectual property protection and freedom to operate.

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?

Note: this question reflects the principle that where the use of an additive becomes necessary great caution should be exercised as regards the choice of additive.

[The term “more suitable for use in baby foods” should be based on scientific considerations (taking into account FAO JECFA Monographs, official reports, edited scientific monographs and journals)- such as on the grouping of additives in accordance with their needs for different levels of assessment as advised by the CCFA. The CCFA proposed the following groups: (i) physiological body constituents, (ii) physiological metabolites and (iii) xenobiotics (see REP 12/NFSDU, para. 5). In addition, the fact whether the additive has been assigned (for a general population) an “ADI not specified” or a “numerical ADI” should be taken into account.

For example, if the food additive under consideration is a xenobiotic and there is an alternative additive being a physical metabolite or a physiological body constituent the reply to Q3.2 is “yes”. Similarly, the same reply should be given for an additive having a numerical ADI if there is an alternative additive having an ADI not specified.

In case of more additives falling into the “same suitability group”] the Committee should consider whether there are technological or other aspects why a certain additive is more suitable for use in baby foods than other. Indeed, in case of more suitable alternatives the reply to Q3.2 should be “yes”.

The submitted answers should be, supplemented by an appropriate evidence which can include JECFA Monographs, scientific assessments/reports/studies and regulatory documents.

Comments: some EWG members considered that Q3.2 should be reformulated or deleted since it relates to safety and it might be discriminatory for the use of certain additives.

Q3.2rev: Are there other food additives performing the same/similar technological effect in the type of product under consideration? If yes, what advantage(s) does the proposed additive provide over currently permitted options?

Comments: one EWG suggested replacing Q3.2 by the question as outlined above to give an opportunity to provide a justification for the specific food additive under consideration.

Q3.1 and Q3.2rev: 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?

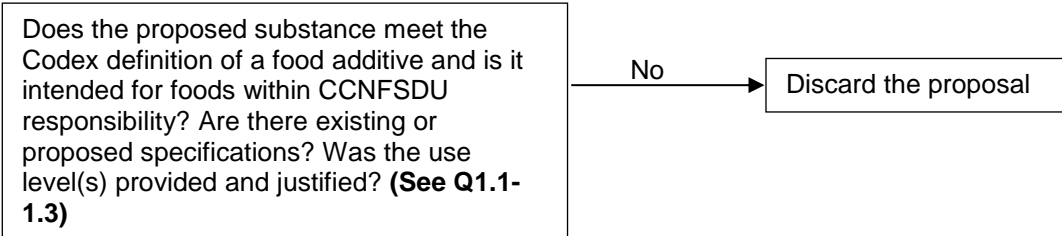
Comments: two EWG members suggested replacing Q3.1 and Q3.2 by the question above. The rationale behind Q3.1 and Q3.2rev is that if the food additive under consideration belongs to one of the functional classes for which there is at least one authorized additive in the same product category the default assumption is that all additives belonging to the same functional class are justified provided their functionality in the standardized foods is demonstrated (by Q2). Consequently, the justification would need to be provided only for new functional classes and/or technological purpose not currently included in the standards.

Annex C

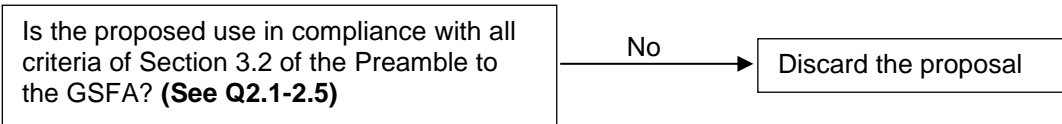
Decision tree on the CCNFSDU framework for appraising the technological need

Note: the decision tree is **outlined for information only** and shall be amended based on the outcomes of the discussion on the framework.

1 ELIGIBILITY AND INTENDED USE



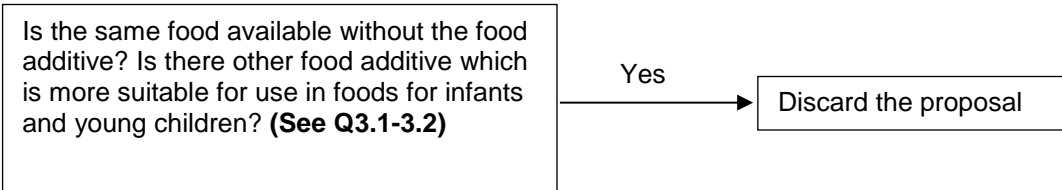
2 COMPLIANCE WITH SECTION 3.2 OF THE GSFA PREAMBLE



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 the sponsor could submit the request for inclusion of the additive into the JECFA priority list.

3 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 the sponsor could submit the request for inclusion of the additive into the JECFA priority list.

Annex D**Form for appraising the technological need presented in the EWG circular paper as filled in by the petitioner (ISDI)**

Note: similarly to Annex C it is **outlined for information only**. The information below was provided by the petitioner and thus it does not reflect the views of other EWG members neither it constitutes any outcome of the assessment of the additives under consideration by the EWG.

INS 415 Xanthan gum

THE PROPOSAL IS SUBMITTED BY:		<i>ISDI (International Special Dietary Foods Industries)</i>
1 ELIGIBILITY AND INTENDED USE		
Q1.1 Name and INS Number of the Additive: <i>(as listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989)</i> <i>For substances not yet included in CAC/GL 36-1989 name of the substance and justification that the substance meets the Codex definition of a food additive.</i> <i>Reference to the existing or proposed specifications.</i>		<i>Xanthan Gum (INS 415) (CAC/GL 36-1989)</i> <i>Meets Codex definition of food additive (STAN 192-1995)</i> <i>Specifications; JECFA 53rd meeting, 1999</i> <i>JECFA Specification for INS 415</i> <i>ADI: "not specified"</i> <i>JECFA concluded that the consumption of xanthan gum in infant formula or formula for special medical purposes intended for infants is of no safety concern at a use level of 1000 mg/L.</i>
Q1.2 Relevant CCNFSDU standard and GSFA food category		
CCNFSDU standard		
Reference	Name of the standard	Comments (e.g. limitation of use to specific products)
<i>72-1981</i>	<i>Standard for infant formula and formulas for special medical purposes intended for infants</i>	<i>Limited to hydrolysed protein and/or amino acid-based formula</i>
GSFA food category		
Food category No	Name of the GSFA food category	
<i>13.1.3</i>	<i>Formulae for special medical purposes for infants</i>	
Q1.3 Lowest level(s) necessary for accomplishing the desired technological effect		
Lowest level(s) in mg/kg in the final product as consumed		Justification of the level(s) proposed
<i>0.1 g/100 mL</i>		<i>The amount indicated has been demonstrated to be the amount necessary to produce the thickener/stabilizer function in these products, which in turn ensures the infant formula is homogenous and delivers the appropriate level of all essential nutrients. Lower levels have not been shown to provide the needed technical effect.</i>
2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA		
Q2.1 Justification of an advantage from the use of an additive		

Hydrolyzed proteins are used in different kinds of FSMP formulas which are formulated specifically for the unique nutritional requirements and dietary management of infant patients with various medical conditions such as gastrointestinal disorders, prematurity, failure to thrive, severe food allergy etc. Compared to intact proteins, hydrolyzed proteins are not as effective in creating or maintaining a stable emulsion. Development of physically stable nutritional products based on hydrolyzed proteins is further challenged when high levels of insoluble ingredients, like mineral salts, are incorporated. These characteristics can result in mineral fallout (resulting in sedimentation) and defects in emulsion stability (which results phase separation). These issues in turn can result in significant challenges to both manufacturing of these products and the optimal delivery of nutrition for infants consuming these products. Thickeners, such as xanthan gum, are required to ensure infant formula is homogenous and delivers the appropriate level of all essential nutrients.

Q2.2 Justification that the use does not mislead consumer

Hydrolyzed protein-based formula using xanthan gum would identify this food additive in the ingredient list, consistent with the requirements of STAN 1-1985 (General Standard for the labelling of pre-packaged foods), other applicable Codex labelling texts, and national requirements. This information is transparent and available to consumers, and would not mislead consumers as to the nature or intended use of the product.

Q2.3 Justification that the use serve one or more of the technological function set out by Codex

Codex sets out functional class and technological purpose for additives in CAC/GL 36-1989. In the case of xanthan gum in this product application, the following text from the Codex Guidance apply:

Functional class: thickener (“a food additive which increases the viscosity of a food”)

Technological purpose: thickener

AND

Functional class: stabilizer (“a food additive which makes it possible to maintain a uniform dispersion of two or more components”)

Technological purpose: emulsion stabilizer

Q2.4 Justification that the use serve one or more of the needs set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA

Xanthan gum meets several of the needs described in Section 3.2 of the Preamble of the GSFA:

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

The products in Category 13.1.3 are intended to be sole-source nutrition for infants, and the use of xanthan gum in these products ensures that products remain homogeneous and that the products, as-fed, provide the complete nutrient profiles defined in the Codex Standard (72-1981)

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

Xanthan gum, as a stabilizer, has a primary function of ensuring the stability of these products. This function is critical to the homogeneity of these products and thus the effective delivery of the complete nutritional components of these products.

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.

In addition to ensuring homogeneity during feeding, it is critical to ensure homogeneity of these products during manufacturing/processing/packaging. Loss of homogeneity of these products during manufacturing/processing/packaging of these products could lead to inconsistency in the nutrient levels throughout the batch, which could again lead to nutrient levels in the products, as-fed, not meeting the nutrient requirements defined in the Codex Standard (72-1981).

Q2.5 Justification that the objectives set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA cannot be achieved by other means that are economically and technologically practicable

<p><i>There are both technological and economic challenges to achieving the objectives described above in these products, especially considering the challenges when formulating products based on hydrolysed proteins or amino acids.</i></p> <p><i>Infant formula products based on hydrolysed proteins or amino acid face significant challenges in terms of maintaining homogeneity. Product research has demonstrated that the use of additives is the most effective way at maintaining the homogeneity of these products during manufacturing of these products, during shelf-life, through administration of the products to the consumers.</i></p> <p><i>From an economic perspective, manufacturers often create proprietary protection around the use of specific additives. This proprietary protection prevents competition in certain product categories in some markets by preventing competitors from marketing products with currently authorized additives. In these situations, the only option that manufacturers have in terms of working around proprietary protection is by formulating products with novel additives in the same functional class that are not covered by proprietary protection. While proprietary protection can represent a challenge to manufacturers, this has the beneficial consequence of stimulating innovation in the use of additives which in turn can lead to the development of more effective additive systems.</i></p>
<p>3 COMPLIANCE WITH THE APPROACH ON THE USE OF ADDITIVES IN FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN</p>
<p>Q3.1 Information whether the same food is currently available without the additive or other additive having the same/similar technological effect and why the use of the additive is necessary if it was the case.</p>
<p><i>Compared to intact proteins, hydrolyzed proteins are not as effective in creating or maintaining a stable emulsion. Development of physically stable nutritional products based on hydrolyzed proteins is further challenged when high levels of insoluble ingredients, like mineral salts, are incorporated. These characteristics can result in mineral fallout (resulting in sedimentation) and defects in emulsion stability (which results phase separation). These issues in turn can result in significant challenges to both manufacturing of these products and the optimal delivery of nutrition for infants consuming these products. Thickeners, such as xanthan gum, are required to ensure infant formula is homogenous and delivers the appropriate level of all essential nutrients.</i></p>
<p>Q3.2 Information whether there is other 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.</p>
<p><i>While other additives with a similar technological function are authorized for use in this product category, due to differences in manufacturing process (e.g. spray dried vs. dry blend), ingredients (e.g. intact vs. hydrolyzed protein), and product format (e.g. powder vs. liquid), a variety of additives are needed to allow for the most appropriate food additive use for each product.</i></p> <p><i>Xanthan gum has advantages over other additives in this class of additives under certain conditions which make it possible to use lower concentrations of xanthan gum (in comparison with other additive) or in formulations when other additives are not able to produce the same technological effect. Xanthan gum builds viscosity in the reconstituted formula matrix and helps to stabilize the emulsion of hydrolyzed protein or free amino acids, fat and water. Minimizing phase separation is particularly important to ensure infant formula is uniform and delivers the appropriate level of all essential nutrients. Xanthan gum is easily hydrated with relatively low temperature water, which makes it ideal for use in infant formula powders that are typically reconstituted with room temperature water. Xanthan gum also is suitable for use in dry-blended infant formulations. Furthermore, since xanthan gum is carbohydrate-based and is derived from a source that is typically not associated with allergenicity, inclusion of xanthan gum in hypoallergenic formulae as a thickening agent presents minimal risk of allergenicity or sensitization potential.</i></p> <p><i>Additional information regarding the technological function of xanthan gum is provided in NFSDU/39 CRD6.</i></p>

INS 440 Pectin

<p>THE PROPOSAL IS SUBMITTED BY:</p>	<p><i>ISDI (International Special Dietary Foods Industries)</i></p>
<p>1 ELIGIBILITY AND INTENDED USE</p>	

Q1.1 Name and INS Number of the Additive: <i>(as listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989)</i> <i>For substances not yet included in CAC/GL 36-1989 name of the substance and justification that the substance meets the Codex definition of a food additive.</i> <i>Reference to the existing or proposed specifications.</i>		PECTIN (INS 440) (CAC/GL 36-1989) <i>Meets Codex definition of food additive (STAN 192-1995)</i> <i>Specifications; JECFA 82nd meeting, 2016</i> http://www.fao.org/3/a-ba695e.pdf <i>ADI: "not specified"</i> <i>JECFA concluded that the intake of pectin in infant formula and formula for special medical purposes intended for infants is of no safety concern at the maximum proposed use level of 0.2% (0.2 g/100mL) ready to consume in formula. (JECFA 82nd meeting, 2016)</i>
Q1.2 Relevant CCNFSDU standard and GSFA food category		
CCNFSDU standard		
Reference	Name of the standard	Comments (e.g. limitation of use to specific products)
72-1981	<i>Standard for infant formula and formulas for special medical purposes intended for infants</i>	<i>Formulas containing hydrolysed protein</i>
GSFA food category		
Food category No	Name of the GSFA food category	
13.1.3	<i>Formulae for special medical purposes for infants</i>	
Q1.3 Lowest level(s) necessary for accomplishing the desired technological effect		
Lowest level(s) in mg/kg in the final product as consumed		Justification of the level(s) proposed
0.2 g per 100 mL		<i>The amount indicated has been demonstrated to be the amount necessary in this formula matrix of hydrolysed protein to produce the required thickener/stabilizer technical function in this specialized FSMP product, which ensures the formula is homogenous and consistently delivers the appropriate level of nutrients to infants throughout the shelf life of the product. The level selected was the minimum required to achieve the desired properties of small grain size, moderate viscosity build and maintenance or ready restoration of product homogeneity throughout shelf life.</i> <i>Lower levels have not been shown in experimental trials to provide the needed technical effect</i>
2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA		
Q2.1 Justification of an advantage from the use of an additive		

In this hydrolysed protein formula matrix, manufactured under pH conditions slightly less than neutral, the use of pectin is uniquely effective, and essential to ensure the formula is homogenous and consistently delivers the appropriate level of nutrients to the intended infant population. Hydrolyzed proteins are used in different kinds of FSMP formulas which are formulated specifically for the unique nutritional requirements and dietary management of infant patients with various medical conditions such as gastrointestinal disorders, prematurity, failure to thrive, severe food allergy etc. Compared to intact proteins (such as cow milk proteins found in formula for normal, healthy infants), hydrolyzed proteins are not as effective in creating or maintaining a stable emulsion of the water-soluble and fat-soluble components of formulas. This is because hydrolysed proteins have very poor emulsifying properties. One must add alternative non-protein surface active components to achieve acceptable physical properties. Development of physically stable nutritional products based on hydrolysed proteins is further challenged when high levels of insoluble ingredients, like some mineral salts, are incorporated. These characteristics can result in mineral fallout (resulting in sedimentation) and defects in emulsion stability (resulting in aqueous/lipid phase separation). Pectin has unique properties in relation to the hydrolysed protein in pH conditions less than neutral. Product manufacturing would fail without the use of pectin for this product. As demonstrated experimentally and shown in the document NFSDU/39 CRD 6, page 14-16, the use of other additives authorized as thickeners for use in FC 13.1.3, as well as a lower level of pectin, could not achieve the needed technical effect in this specialized formula based on hydrolyzed protein and manufactured under pH conditions less than neutral.

Q2.2 Justification that the use does not mislead consumer

Hydrolyzed protein-based formula using pectin would identify this food additive in the ingredient list, consistent with the requirements of STAN 1-1985 (General Standard for the labelling of pre-packaged foods), other applicable Codex labelling texts, and national requirements. This information is transparent and available to consumers, and would not mislead consumers as to the nature or intended use of the product. Additionally, this specialized formula using pectin is an FSMP product and thus, used under medical supervision and generally not available for consumer self-selection at retail outlets.

Q2.3 Justification that the use serve one or more of the technological function set out by Codex

Codex sets out functional class and technological purpose for additives in CAC/GL 36-1989. In the case of pectin in this product application, the following text from the Codex Guidance apply:

Functional class: thickener (“a food additive which increases the viscosity of a food”)

Technological purpose: thickener

AND

Functional class: stabilizer (“a food additive which makes it possible to maintain a uniform dispersion of two or more components”)

Technological purpose: emulsion stabilizer

Point where added in manufacturing: Pectin and hydrolysed protein solutions are prepared at less than boiling T, allowing time for adequate hydration. The solutions are combined and reaction occurs between the protein and pectin forming a stable complex (electrostatic). After additional ingredients, e.g., fat, minerals, carbohydrate, are added the product is homogenized to emulsify the fat and further promote pectin-protein interaction. Product is then pasteurized and sterilized.

Q2.4 Justification that the use serve one or more of the needs set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA

The use of pectin in this product application meets several of the needs described in Section 3.2 of the Preamble to the GSFA:

b) To provide necessary ingredients or constituents of foods manufactured for groups of consumers

having special dietary needs

The products in Food Category 13.1.3 (Formulae for special medical purposes for infants) are specially formulated for infant patients under medical supervision, and alone, are intended to provide the sole source of nutrition for infants not receiving human milk. The use of pectin in this product for infant patients ensures that the formula constituents remain homogeneous and that the products as consumed, provide the nutrients defined in Essential Composition in Codex STAN (72-1981)

<p>c) <i>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</i></p> <p><i>Pectin functions as a thickener (increases viscosity) and stabilizer (maintains uniform dispersion) in this hydrolysed protein formula for special medical purposes. These technological functions are critical to achieve and maintain homogeneity of the constituents of the formula and thus the consistent and effective delivery of the product and all nutrients contained therein.</i></p> <p>d) <i>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.</i></p> <p><i>In addition to ensuring homogeneity during feeding, it is critical to ensure homogeneity of these products during manufacturing/processing/packaging. Loss of homogeneity of these products during manufacturing/processing/packaging of these products could lead to inconsistency in the nutrient levels throughout the batch, which could again lead to nutrient levels in the products as-consumed not meeting the nutrient requirements defined in the Codex Standard (72-1981) nor the nutrient needs of infant patients. Ingredients, manufacturing, processing, preparation, packaging, transport and post market monitoring of formulas for infants comply with rigorous safety and quality standards which are not compromised in any way due to the use of food additive ingredients.</i></p>
<p>Q2.5 Justification that the objectives set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA cannot be achieved by other means that are economically and technologically practicable</p>
<p><i>The objectives set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA, as related to the use of pectin in the manufacture of hydrolysed protein formula for special medical purposes, cannot be achieved by other means that are economically and technologically practicable. Commercially acceptable infant formulas based on hydrolyzed proteins cannot be safely manufactured without the use of additives, and in the case of this product that is manufactured under pH conditions slightly less than neutral, pectin has been demonstrated to provide uniquely effective technical effects to achieve a stable, homogeneous formula with acceptable physical properties.</i></p>
<p>3 COMPLIANCE WITH THE APPROACH ON THE USE OF ADDITIVES IN FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN</p>
<p>Q3.1 Information whether the same food is currently available without the additive or other additive having the same/similar technological effect and why the use of the additive is necessary if it was the case.</p>
<p><i>Commercially acceptable infant formulas based on hydrolyzed proteins cannot be safely manufactured without the use of additives. This formula for special medical purposes for infants that uses the additive pectin cannot be produced without the additive (manufacturing fails), and therefore is not available without the additive. As demonstrated experimentally and shown in the document NFSDU/39 CRD 6, page 14-16, the use of other additives authorized as thickeners for use in FC 13.1.3, as well as a lower level of pectin, could not achieve the needed technical effect in this specialized formula based on hydrolyzed protein and manufactured under pH conditions less than neutral.</i></p>
<p>Q3.2 Information whether there is other 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.</p>
<p><i>Please refer to the response to Q3.1 regarding the experimental demonstration of the technological effect of pectin in the subject formula matrix, compared to other additives authorized for use in the commodity standard 72-1981 and in the corresponding GSFA food category, 13.1.3. Other additives failed; the formula had excessive thickness, serum separation, grain, large particle size, and air trapped to give a sponge effect resulting in non-flowing "liquid". Technological need is dependent on the specific physical properties, and processing methods, as well as the ingredients themselves, particularly the source and type of protein.</i></p> <p><i>Additional information regarding the technological function of pectin is provided in NFSDU/39 CRD6.</i></p>

INS 418 Gellan gum

<p>THE PROPOSAL IS SUBMITTED BY:</p>	<p><i>ISDI (International Special Dietary Foods Industries)</i></p>
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1 ELIGIBILITY AND INTENDED USE		
<p>Q1.1 Name and INS Number of the Additive:</p> <p><i>(as listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989)</i></p> <p><i>For substances not yet included in CAC/GL 36-1989 name of the substance and justification that the substance meets the Codex definition of a food additive.</i></p> <p><i>Reference to the existing or proposed specifications.</i></p>	<p><i>GellanGum (INS 418) (CAC/GL 36-1989)</i></p> <p><i>Meets Codex definition of food additive (STAN 192-1995)</i></p> <p><i>Specifications; JECFA 79th meeting, 2014</i></p> <p><i>JECFA Specification for INS 418</i></p> <p><i>ADI: "not specified"</i></p> <p><i>JECFA has not yet reviewed gellan gum specifically for infants under 12 weeks of age, but has issued a call for data so that it can be considered during the 2019 JECFA meeting.</i></p>	
Q1.2 Relevant CCNFSDU standard and GSFA food category		
CCNFSDU standard		
Reference	Name of the standard	Comments (e.g. limitation of use to specific products)
72-1981	<i>Standard for infant formula and formulas for special medical purposes intended for infants</i>	<i>Limited to hydrolysed protein and/or amino acid-based formula</i>
GSFA food category		
Food category No	Name of the GSFA food category	
13.1.3	<i>Formulae for special medical purposes for infants</i>	
Q1.3 Lowest level(s) necessary for accomplishing the desired technological effect		
Lowest level(s) in mg/kg in the final product as consumed	Justification of the level(s) proposed	
<i>0.005 g/100 mL</i>	<i>The amount indicated has been demonstrated to be the amount necessary to produce the thickener/stabilizer function in these products, which in turn ensures the infant formula is homogenous and delivers the appropriate level of all essential nutrients. Lower levels have not been shown to provide the needed technical effect.</i>	
2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA		
Q2.1 Justification of an advantage from the use of an additive		
<i>Compared to intact proteins, hydrolyzed proteins are not as effective in creating or maintaining a stable emulsion. Development of physically stable nutritional products based on hydrolyzed proteins is further challenged when high levels of insoluble ingredients, like mineral salts, are incorporated. These characteristics can result in mineral fallout (resulting in sedimentation) and defects in emulsion stability (which results phase separation). These issues in turn can result in significant challenges to both manufacturing of these products and the optimal delivery of nutrition for infants consuming these products. Thickeners, such as gellan gum, are required to ensure infant formula is homogenous and delivers the appropriate level of all essential nutrients.</i>		
Q2.2 Justification that the use does not mislead consumer		
<i>Products containing gellan gum in the formulation would identify this additive in the list of ingredient, providing transparency to consumers. The technological purpose for the addition of this additive is to maintain homogeneity of the product, and does not conceal damage or inferiority, or make the product appear to be greater than actual value.</i>		
Q2.3 Justification that the use serve one or more of the technological function set out by Codex		
<i>Codex sets out functional class and technological purpose for additives in CAC/GL 36-1989. In the case of gellan gum in this product application, the following text from the Codex Guidance apply:</i>		

<p><i>Functional class: thickener (“a food additive which increases the viscosity of a food”)</i></p> <p><i>Technological purpose: thickener</i></p> <p>AND</p> <p><i>Functional class: stabilizer (“a food additive which makes it possible to maintain a uniform dispersion of two or more components”)</i></p> <p><i>Technological purpose: emulsion stabilizer</i></p>
<p>Q2.4 Justification that the use serve one or more of the needs set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA</p>
<p><i>Gellan gum meets several of the needs described in Section 3.2 of the Preamble of the GSFA:</i></p> <p>b) <i>To provide necessary ingredients or constituents of foods manufactured for groups of consumers having special dietary needs</i></p> <p><i>The products in Category 13.1.3 are intended to be sole-source nutrition for infants not receiving human milk, and the use of gellan gum in these products ensures that products remain homogeneous and that the products, as-fed, provide the complete nutrient profiles defined in the Codex Standard (72-1981)</i></p> <p>c) <i>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</i></p> <p><i>Gellan gum, as a stabilizer, has a primary function of ensuring the stability of these products. This function is critical to the homogeneity of these products and thus the effective delivery of the complete nutritional components of these products.</i></p> <p>d) <i>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.</i></p> <p><i>In addition to ensuring homogeneity during feeding, it is critical to ensure homogeneity of these products during manufacturing/processing/packaging. Loss of homogeneity of these products during manufacturing/processing/packaging of these products could lead to inconsistency in the nutrient levels throughout the batch, which could again lead to nutrient levels in the products, as-fed, not meeting the nutrient requirements defined in the Codex Standard (72-1981).</i></p>
<p>Q2.5 Justification that the objectives set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA cannot be achieved by other means that are economically and technologically practicable</p>
<p><i>There are both technological and economic challenges to achieving the objectives described above in these products, especially considering the challenges when formulating products based on hydrolysed proteins or amino acids.</i></p> <p><i>Infant formula products based on hydrolysed proteins or amino acid face significant challenges in terms of maintaining homogeneity. Product research has demonstrated that the use of additives is the most effective way at maintaining the homogeneity of these products during manufacturing of these products, during shelf-life, through administration of the products to the consumers.</i></p> <p><i>From an economic perspective, manufacturers may create proprietary protection around the use of specific additives. This proprietary protection prevents competition in certain product categories in some markets by preventing competitors from marketing products with currently authorized additives. In these situations, the only option that manufacturers have in terms of working around proprietary protection is by formulating products with novel additives in the same functional class that are not covered by proprietary protection. While proprietary protection can represent a challenge to manufacturers, this has the beneficial consequence of stimulating innovation in the use of additives which in turn can lead to the development of more effective additive system.</i></p>
<p>3 COMPLIANCE WITH THE APPROACH ON THE USE OF ADDITIVES IN FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN</p>
<p>Q3.1 Information whether the same food is currently available without the additive or other additive having the same/similar technological effect and why the use of the additive is necessary if it was the case.</p>

Commercially acceptable Infant formulas based on extensively hydrolyzed proteins or amino acids cannot be safely manufactured without the use of additives. Compared to intact proteins, hydrolyzed proteins are not as effective in creating or maintaining a stable emulsion. Development of physically stable nutritional products based on hydrolyzed proteins is further challenged when high levels of insoluble ingredients, like mineral salts, are incorporated. These characteristics can result in mineral fallout (resulting in sedimentation) and defects in emulsion stability (which results phase separation). These issues in turn can result in significant challenges to both manufacturing of these products and the optimal delivery of nutrition for infants consuming these products.

Thickeners, such as gellan gum, are required to ensure infant formula is homogenous and delivers the appropriate level of all essential nutrients.

Q3.2 Information whether there is other 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.

While other additives with a similar technological function are authorized for use in this product category, due to differences in manufacturing process (e.g. spray dried vs. dry blend), ingredients (e.g. intact vs. hydrolyzed protein), and product format (e.g. powder vs. liquid), a variety of additives are needed to allow for the most appropriate food additive use for each product.

Gellan gum has advantages over other additives in this class of additives under certain conditions which make it possible to use lower concentrations of gellan gum (in comparison with other additive) or in formulations when other additives are not able to produce the same technological effect. Gellan gum acts as a thickener/stabilizer in ready-to-feed infant formula, or concentrated liquid products to improve physical stability through mechanisms such as maintaining homogeneity or minimizing ingredient sedimentation. Gellan gum acts as a thickening or gelling agent through formation of a fluid gel. The fluid gel can aid with the sedimentation of dense components such as insoluble calcium and phosphorus salts. The gelation also provides a secondary benefit of thickening the solution viscosity, slowing the upward migration of fat, which is less dense. Gellan gum stabilizes the emulsion of protein, fat and water created in the infant formula manufacturing process, minimizing phase separation during storage, display and feeding.

Additional information regarding the technological function of gellan gum is provided in NFSDU/39 CRD6.