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**Agenda Item 9** **CX/NFSDU 17/39/8**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES**

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# FOOD ADDITIVES – MECHANISM / FRAMEWORK FOR CONSIDERING TECHNOLOGICAL JUSTIFICATION AND OTHER MATTERS

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

## Background

1. At the 38th Session of the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU38) the Codex Secretariat 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 as additives in commodity standards developed by CCNFSDU. The Committee noted that the Codex Committee on Food Additives (CCFA) was developing guidelines on alignment and agreed to defer the alignment of food additives until the guidance document is finalised by CCFA (REP17/NFSDU, paras. 171 and 173).

2. The observer from ISDI informed the Committee that CCNFSDU36 had recommended the evaluation of Xanthan gum (INS 415) and Pectin (INS 440) by JECFA and based on the recent 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 noted that members had not had sufficient time to study the information on technological justification and proposed to refer the substances to the EWG for consideration and to discuss the outcome at the next session (REP17/NFSDU, paras. 174-175).

3. Regarding the use of Gellan gum (INS 418) in infant formula, formulas for special medical purposes intended for infants, and follow-up formula, the Committee noted that in the European Union, these products were being produced without the use of Gellan gum and that in the EU's view gellan gum was not necessary and not technologically justified for use in these foods. This view was supported by other delegations. Noting that confirmation of the technological need was required to support JECFA's evaluation of Gellan gum (INS 418), the Committee agreed to refer the matter to the EWG for consideration and agreed to inform CCFA that reply would be provided at a future date (REP17/NFSDU, paras. 176-177).

## Mandate of the EWG

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

Establish an EWG[1], chaired by the European Union, and co-chaired by the Russian Federation working in English with the following terms of reference:

a) Propose a mechanism or framework for considering the technological justification for substances intended for inclusion on the priority list of substances for JECFA evaluation;

b) To consider and confirm the technological justification of gellan gum; and

[1] The EWG was participated by Australia, Austria, Brazil, Canada, Chile, Egypt, Finland, India, Indonesia, Iran, Ireland, Japan, New Zealand, Russian Federation, South Africa, Sweden, Switzerland, Thailand, United States of America, European Union, Association for international promotion of Gums (AIPG), Comité Européen des Fabricants de Sucre (CEFS), European Cocoa Association (ECA), EU Specialty Food Ingredients (EUSFI), International Food Additives Council (IFAC), International Special Dietary Foods Industries (ISDI), FAO and WHO JECFA secretariat.

c) To propose how to handle new substances that have already been evaluated by JECFA, but for which technological justification has not yet been confirmed by CCNFSDU (i.e. xanthan gum, pectin).

**Use of food additives in the commodity standards of the Committee**

5. There are nine adopted commodity standards under the mandate of the Committee. All standards fall under the food category 13.0 'Foodstuffs intended for particular nutritional uses' and its subcategories of the *General Standard for Food Additives* (GSFA, CXS 192-1995). Six standards contain food additive provisions. Four standards[2] deal with foods for infants or young children for which specific considerations are taken into account as regards the food additive uses[3].

6. The restrictions in place reflect the approach proposed by JECFA (1971), implemented by the Codex Alimentarius Commission, endorsed by the CCFA43 (2011) and reaffirmed by CCNFSDU38 (2016, see REP17/NFSDU, para 172) 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*".

**JECFA assessments of food additives**

7. Any substance used as a food additive needs to be assessed and determined to be safe by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) prior its inclusion in the GSFA or in the commodity standards. This requirement is laid down in section 1.1 'Food Additives Included in this Standard' of the Preamble to the GSFA as well as in the Procedural Manual[4].

8. Whilst not explicitly mentioned in the Procedural Manual nor in the GSFA Preamble[5] there is a general agreement that the proposals for the inclusion of an additive in Codex standards for foods intended for infants below 12 weeks of age require a separate evaluation by JECFA since for additives used in foods for this population the toxicological investigations should be more extensive and include evidence of safety to young animals.

9. CCNFSDU36 adopted a structured approach (based on the Procedural Manual and the Preamble of the GSFA) to be used for inclusion of additives into CXS 72-1981 or the GSFA:

   - Step 1: Proposal to be checked for: status at JECFA, specifications, intended technological use, and safety when used at proposed levels in infant formula. Any deficiency needs to be addressed by interested parties with CCFA and JECFA before further discussions at CCNFSDU.

   - Step 2: Once all requirements are met, CCNFSDU will consider whether there is sufficient support based on technological needs that supports the use of the food additives in Sections A or B of the standard (REP15/NFSDU, para. 143).

10. JECFA assesses substances based on the requests included in a priority list of substances for JECFA evaluation. The priority list is managed by the CCFA and discussed and updated at each CCFA session. The CCFA takes into account the *Risk Analysis Principles* laid down in the Procedural Manual when preparing the priority list[6]. The data availability and the commitment of a sponsor to provide the data are considered as well.

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[2] CXS 72-1981 - *Standard for Infant Formula and Formulas for Special Medical Purposes Intended For Infants*, CXS 73-1981 - *Standard for Canned Baby Foods*, CXS 74-1981 - *Standard for Processed Cereal-Based Foods for Infants and Young Children* and CXS 156-1987 - *Standard for Follow-Up Formula.*

[3] Such as the restrictions to carry-over of food additives from ingredients and raw materials; restricted food additive uses – i.e. individual food additives are listed in the standards and the inclusion of the corresponding GSFA categories 13.1 and 13.2 in Annex to Table 3, i.e. among the food categories for which Table 3 additives cannot be used unless they are listed in Tables 1 and 2 of the GSFA.

[4] See the part 'Food Additives' in the chapter 'Relations between Commodity Committees and General Subject Committees' and the chapter 'Procedures for Consideration of the Entry and Review of Food Additive Provisions in the General Standard for Food Additives'.

[5] At CCFA47 the JECFA secretariat clarified that the requirement for an assessment of substances to be used in food for infants below twelve weeks of age were addressed under Section 3.1 of the GSFA where it is stated that '*'the inclusion of a food additive in this Standard shall have taken into account any ADI or equivalent safety assessment established for the additive by JECFA and its probable daily intake at the proposed use levels by special groups of consumers (e.g. those on special medical diet)*''. With regard to the safety assessment of food additives for use in infant formula, the JECFA Secretariat reminded that the ADI concept does not apply to infants up to age of 12 weeks and that in this case the margin of exposure (MOE) approach should be used (REP15/FA, para. 11).

[6] Para 17 of the Risk Analysis Principles Applied by the Codex Committee on Food Additives lays down the aspects which shall be considered when preparing the priority list of substances for JECFA review, 25th Procedural Manual, page 136.

11. At CCFA48 (2016), the JECFA Secretariat pointed out that there was a very long list of requests for scientific advice, whose consideration required at least three JECFA meetings. The JECFA Secretariat explained that at the moment, it was not clear when all the requests would be addressed. Therefore, there was a need for CCFA to better prioritize the requests and to evaluate their technological need. At the same meeting it was agreed that CCNFSDU needed to confirm the technological need of food additives intended for use in infant formula prior to the inclusion in the CCFA priority list and that it would be the sponsors' responsibility to obtain CCNFSDU confirmation of the technological need of food additives before submitting the request to CCFA (REP16/FA, paras. 113, 119 and 120).

12. In its paper prepared for CCNFSDU38 the Codex Secretariat highlighted that the two step process agreed by CCNFSDU36 was in conflict with the request from CCFA48 and suggested to establish an EWG to propose a mechanism or framework for considering the technological justification for substances intended for inclusion on the priority list of substance for JECFA evaluation (CX/NFSDU 16/38/11, paras. 6 and 8).

13. At CCFA49 the JECFA Secretariat provided as CRD 15 an overview on the status of evaluation by JECFA of all additives listed in CXS 72–1981 and of the provisions in the GSFA for food categories (FC) 13.1.1 and 13.1.3. It was recognized that there was no appropriate safety assessment for several adopted food additive provisions for foods intended for infants below 12 weeks of age. The JECFA Secretariat proposed as a way forward to provide the document to CCNFSDU for the consideration in their on-going work, after which requests for safety considerations might be made to CCFA for consideration. It was clarified that CCNFSDU could take into account the information in their on-going work on technological justification for certain food additives and also in terms of the future work on alignment of food additives in standards developed by CCNSFDU with provisions in the GSFA (REP17/FA, paras. 26-31).

**Restrictions to carry-over of food additives into certain foods**

14. According to Section 4.3 of the Preamble to the GSFA carry-over of a food additive from a raw material or ingredient is unacceptable for foods belonging to *a) 13.1 - Infant formulae, follow-up formulae, and formulae for special medical purposes for infants, b) 13.2 - Complementary foods for infants and young children*, unless a food additive provision in the specified category is listed in Tables 1 and 2 of the GSFA. Similar restrictions are laid down in CXS 72-1981 and the *Standard for Processed Cereal-Based Foods for Infants and Young Children* (CXS 74-1981).

15. *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CXG 10-1979) provide for an advisory list of food additives which may be used as nutrient carriers and which may be present as a result of carry-over in the foods falling within the scope of CXS 72-1981 and CXS 74-1981.

16. Therefore, the technological need has to be also appraised for food additives added to nutrients or to other food ingredients intended to be used in foods for infants and young children.

**Criteria for determination of technological need for food additives**

17. Section 1.2 of the Preamble of the GSFA clarifies that commodity committees have the responsibility and expertise to appraise and justify the technological need for the use of additives in foods subject to a commodity standard and that the information given by the commodity committees may also be taken into account when considering the additive provisions for similar non-standardised foods. Similarly, the Procedural Manual lays down that all provisions in respect of food additives contained in commodity standards will require endorsement by the Committee on Food Additives on the basis of technological justification submitted by the commodity committees[7].

18. The criteria for justification for the use and technological need of the food additive are laid down in Section 3.2 of the Preamble to the GSFA. According to the Procedural Manual adherence to these criteria is necessary for the inclusion of the food additive in the General Standard for Food Additives[8].

The criteria in Section 3.2 of the Preamble of the GSFA are as follows:

"*The use of food additives is justified only when such use has an advantage, does not present an appreciable health risk to consumers, does not mislead the consumer, and serves one or more of the technological functions set out by Codex and the needs set out from (a) through (d) below, and only where these objectives cannot be achieved by other means that are economically and technologically practicable:*

[7] Procedural Manual 25th edition, p. 51.

[8] Procedural Manual 25th edition, p. 65.

*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.*"

19. CCNFSDU28 discussed a possible development of specific principles/ criteria for use of additives in infant formula but it agreed that it would be preferable to defer consideration of this matter pending advice from JECFA on certain relevant issues[9]. At the same meeting, JECFA considerations that "*it is prudent that foods intended for infants under 12 weeks should contain no additives at all*" were noted. On the other hand, it was acknowledged that the *Principles for the Safety Assessment of Food Additives and Contaminants* (WHO EHC 70,1987) recognized "*that in practice there may be certain exceptions on technological grounds*"[10](ALINORM 07/30/26, paras. 57-59).

**Way forward to address the mandate of the EWG**

20. The chairs note that part a) of the mandate requires proposing a mechanism or framework for considering the technological justification whilst parts b) and c) require appraising and justifying the technological need for specific food additive uses. In order to apply a consistent approach a mechanism or framework needs to be developed first before addressing parts b) and c) of the mandate. Once the framework is developed it can be tested by the proposed food additive uses (i.e. gellan gum, xanthan gum and pectin).

Annex A to this paper contains a suggestion for a framework for considering the technological justification. The framework consists of series of questions which are based on:

(i) The verification that the substance under consideration meets the Codex definition of a food additive and it is intended for use in foods/ food ingredients within the Terms of Reference of the CCNFSDU

(ii) The 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*" which is applicable to foods intended for infants and young children

(iii) The criteria for the justification for the use of additives laid down in Section 3.2 of the Preamble to the GSFA

**Discussion by the EWG**

21. In the consultation the members of the EWG were requested to comment on the framework outlined in the circular paper and on whether the questions proposed reflected appropriately the criteria which should be used to appraise the technological need. The comments received are summarised below.

Summary of the comments received:

22. Numerous comments were received suggesting fine-tuning, amendments, reformulations or alternative proposals for the framework. Nevertheless, there was a consensus supporting the development of a systematic approach to appraise the technological need.

[9] I.e. pending the clarification on (i) the applicability of an ADI to young infants below 12 weeks; (ii) the scientific principles for the evaluation of additives intended for this population group and (iii) whether the establishment of an ADI in itself was sufficient or whether other issues had to be addressed.

[10] The Principles stipulate that "*the use of food additives for infants under 12 weeks may be justified, for example, to increase shelf life, to ensure adequate sterilization by promoting homogenization, or to maintain consistency and texture in order to ensure safe and acceptable use. However, appeal to the eye or organoleptic acceptability to the mother, as opposed to the infant, does not constitute justification*".

23. Questions and comments were received as regards the scope of the framework which could range from foods intended for infants and young children to all CCNFSDU standards plus similar non-standardised foods. One EWG member suggested consulting the Codex Secretariat as regards the intended scope.

24. Comments on the use of an appropriate and uniform terminology were raised. In the circular paper the term “baby foods” was used based on the wording formulated by JECFA (1971) and used in the relevant section of the CCNFSDU38 report (see REP17/NFSDU, para 172). However, several EWG members pointed out that the term “foods for infants and young children” was more appropriate since both terms (i.e. “infants” and “young children”) are defined in the Codex standards. In addition, it was noted that in the circular paper different terms with the similar meaning such as “technological effect, technological function and technological purpose” were used creating possible confusion. Therefore, for the sake of clarity and consistency the terms “infants", "young children” and “technological effect” are used in the proposed framework except for the quotations or references to other Codex texts containing other terms.

25. Several EWG members were of the view that the questions proposed for the framework in the circular paper reflected appropriately the criteria which should be used to appraise the technological need. Especially for foods intended for infants and young children they stressed the importance to follow the approach on the use of additives in baby foods proposed by JECFA and endorsed by the Committee as well as by the CAC. However, several other EWG members expressed misgivings on certain questions which in their view were not directly linked with the technological justification, were beyond the mandate of the EWG and thus should be omitted or replaced. Those EWG members considered that the use of additives is indispensable and unavoidable also for foods for infants and young children and that it is necessary to provide for a range of food additives for product innovation and selection of the most appropriate ones.

26. Whilst there was a general support on the way forward (as outlined in para 20) recognising the rationale for focusing on part a) of the mandate, some EWG members were concerned that if parts b) and c) were not discussed in parallel to part a) they may not be discussed at the CCNFSDU39 and may be delayed. Those EWG members suggested amendments to the framework and some of them outlined how according to the modified framework and based on the existing data the use of gellan gum, xanthan gum and pectin would be technologically justified in foods for which the use was requested.

27. One EWG member pointed out that the food additives referred to in parts b) and c) have a similar technological function and that the framework should be rigorously tested using additives representing a wide range of technological functions. The same EWG member was of the view that the progress through the series of the questions should not depend on an affirmative or negative response but that all questions should be replied to anyway.

28. Several EWG members referred to CRD 15 of the CCFA49 as valuable information for the Committee relevant for the current work and supporting the need for establishing the framework under part a) of the EWG mandate.

29. One EWG member proposed a whole process to appraise the technological need starting by issuing a Circular Letter with a call for requests for additives to be placed on the JECFA priority list when they are to be used in foods under the CCNFSDU responsibility. Such Circular Letter should contain a template based on the agreed framework by the CCNFSDU requesting the relevant information. The Committee then should assess the information against the agreed framework and record the outcome in the report of the meeting. In case of a positive outcome the next steps should follow the usual CCFA procedure.

30. Several EWG members suggested developing a decision tree based on the proposed framework. One EWG member sent the decision tree as part of its comments.

31. Different views were expressed on the applicability of the restrictions to the carry-over principle as regards additives used in preparations (e.g. preparations of additives or nutrients).

32. Two EWG members referred to the JECFA data requirements specified in the “*Form for the submission of substances to be evaluated by JECFA*”. One of them stressed the need to discuss the data requirements by the Committee. The other underlined the importance of considering the production method and the raw materials as a part of the JECFA assessment, especially when the additive is produced using GM microorganisms or with other food ingredients which could have negative impact on the nutritional quality of foods intended in particular for the specific population groups such as infants, children etc. These issues are however out of the scope of this EWG.

33. One EWG member also expressed the need for the intake assessment before the additive is considered by JECFA.

**Concluding remarks**

34. From the comments received there is an obvious interest and support for development of the framework. Firstly, however, the scope of such framework needs to be clarified. The status of the framework (e.g. the CCNFSDU working tool, informative document or guidance?) as well as further steps (e.g. translation of the framework into a template requesting the relevant information for appraising the technological need) could be considered as well.

35. The framework in Annex A to this paper attempts to reflect the several comments made by the EWG members. Nevertheless, it could be rather considered as a starting point for further discussion taking into account the numerous comments received and the divergent views of the EWG members as regards certain matters/ questions of the framework and alternative proposals made.

36. Based on the comments received this paper includes a decision tree (Annex B), however, only for illustrative purposes since it will have to be amended based on the outcomes of the discussion on the framework.

37. It is acknowledged that this paper does not address parts b) and c) of the EWG mandate due to the approach outlined in para 20. The Committee should consider the further work of finalising the framework and testing it with the specific food additive uses (e.g. parts b) and c) and possibly the additives listed in CRD 15 of the CCFA49).

**Recommendations**

**Recommendation 1**

38. The Committee is invited to clarify the scope of the framework under development.

The framework could be either (i) of a general nature covering all foods within the mandate of the CCNFSDU (with a specific set of questions for particular foods, e.g. for foods intended for infants and young children) or (ii) more specific. The Committee should clarify this aspect.

**Recommendation 2**

39. The Committee is invited to further discuss and consider the criteria which should be used to appraise the technological need for food additives intended for JECFA evaluation.

    Annex A could be used as a basis for such discussion.

**Recommendation 3**

40. The Committee is invited to continue the work on the framework including its testing with the food additives referred to in parts b) and c) of the EWG mandate and if possible also those listed in CRD 15 of the CCFA49.

**Annex A**

**CCNFSDU framework for appraising the technological need for food additives intended for JECFA evaluation**

**SCOPE**

[Chairs note: the text on the scope will be fine-tuned based on the clarification provided by the Committee as regards Recommendation 1]

A series of questions was developed to appraise the technological need for the use of additives in….

[Chairs note: the questions below attempted to reflect the comments received. However, due to divergent views on certain questions further discussion at the CCNFSDU39 is envisaged.]

**I ELIGIBILITY AND INTENDED USE**

***Q1: Does the proposed use fall within the scope of the Codex definition of a food additive and within the foods/ food ingredients for which the CCNFSDU is responsible for? Are the following requirements met?***

***Q1.1: Does the proposed use meet the Codex definition of a food additive[11]?***

*Note: the information submitted should provide sufficient clarity to decide on the status of the substance under consideration.*

***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 GSFA subcategory and/or Codex standard.*

***Q1.3: Is the intended use in the food through direct addition or carried-over from use in raw materials or ingredients?***

*Note: the reply should provide clarity as regards the technological effect either directly in the food or in some of its ingredients (e.g. in nutrients) taking into account the applicable restrictions to the carry-over principle for some foods.*

**In case of positive replies to all Q1 sub-questions proceed to Q2**

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

***Q2: Can the food/ food ingredient under consideration be prepared without the proposed food additive or without other additive having the same/similar technological effect?***

*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. Sub-questions which should provide further clarifications are as follows*:

***Q2.1: Is the food under consideration available on the market without using the proposed additive or without other additive use having the same/similar technological effect?***

***Q2.2: Is the additive use proposed needed only in certain specific products/ for specific medical purposes? Are there any considerations why the use is necessary despite the fact that products without the proposed food additive use are on the market?***

*Note: 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. In addition, 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. This sub-question should help in deciding whether a positive or a negative reply should be given to Q2.*

**In case of a negative reply to Q2 proceed to Q3**

[11] Food Additive means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result, (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include "contaminants" or substances added to food for maintaining or improving nutritional qualities. **Codex Alimentarius Commission Procedural Manual, 25th edition. Section 1. Basic texts and definitions.**

***Q3: Is there 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?***

*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 - 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 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 should be "yes".*

**In case of a negative reply to Q3 proceed to Q4**

***Q4: What are the lowest possible amounts necessary to accomplish the desired technological effect?***

*Note: this question reflects that great caution should be exercised as regards the level of use of a food additive in baby foods. The intention is to obtain the information on the amount of the substance that is necessary to accomplish the desired technological effect. 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.*

**The reply to Q4 should provide the Committee with the proposed use level that is to be considered in the JECFA's assessment**

**III COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA**

***Q5: Is the proposed food additive use in compliance with Section 3.2 of the Preamble to the GSFA?***

*Note: the compliance with Section 3.2 is a prerequisite for the inclusion of additive provisions in the GSFA and Commodity Standards. The following sub-questions need to be addressed:*

***Q5.1: Does the use of an additive have an advantage?***

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

***Q5.2: 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.*

***Q5.3: 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 (CXG 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.*

***Q5.4: 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 therein.*

***Q5.5: 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.*

In case of positive replies to Q5.1-5.5 the technological need is appraised by the Committee and the sponsor could submit the request for inclusion of the additive into the priority list of JECFA.

**Annex B**

## Decision tree on the CCNFSDU framework for appraising the technological need for food additives intended for JECFA evaluation

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