

CODEX ALIMENTARIUS COMMISSION



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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

Comments of International Special Dietary Foods Industries (ISDI)

Mandate a)

ISDI thanks the European Union (Chair) and the Russian Federation (Co-Chair) for chairing the eWG and for their extensive work in preparing the agenda paper and recommendations for the development of a framework to consider technological justification of food additives, for consideration by the Committee.

ISDI supports the development of a systematic approach to enable CCNFSDU to consider the technological need for food additives prior to being proposed for evaluation by JECFA for their potential use as additives in commodity standards developed by CCNFSDU. We have provided comments regarding the 3 Recommendations in the final agenda paper CX/NFSDU 17/39/8, followed by specific comments on the series of questions comprising the Framework in Annex A.

Recommendation 1

ISDI agrees with the proposal to clarify the scope of the framework under development. Furthermore, this work should take into consideration the *process* for CCNFSDU to appraise the technological need using the criteria in the Framework, to document confirmation of the decision, and to send the request to CCFA as appropriate.

Recommendation 2

ISDI supports the development of a more simplified framework and criteria for considering technological justification. We consider that the current proposal (Annex A of the final agenda paper) is overly complex and will deliver ambiguous responses that cannot be objectively interpreted by the Committee. There are a number of examples of multiple questions within a sub-question, supported by explanatory notes that may unintentionally add to the complexity of the framework. In this document we have provided edits to the proposed framework for consideration by the Committee.

Recommendation 3

If the Committee makes sufficient progress on the scope and criteria for the Framework in this session, ISDI supports to address Mandate b), To consider and confirm the technological justification of gellan gum, and 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 (xanthan gum, pectin). The information to support the assessment for these 3 additives was provided to this Committee at its 38th session (2016) (NFSDU/38 CRD/11), to members of the CCNFSDU electronic Working Group on food additives (REP17/NFSDU, para 178), and is provided again to this Committee in a separate CRD for consideration.

CRD15

ISDI considers that CRD15 from CCFA49 is a valuable reference for the status of JECFA evaluations of additives used in foods for infants. While we support that CCNFSDU may take into account the information in CRD15 in their on-going work, it is not a mandatory input for *development of a framework* for considering if additives are technologically justified, and its further consideration should not delay progress on the framework.

**ISDI Comments on Annex A
CCNFSDU Framework for appraising the technological need for food additives intended for JECFA
evaluation**

ISDI Comments on Annex A - Proposal for Committee to Discuss

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?

ISDI

Q1: There are 3 questions asked in Q1. We recommend to simplify this by asking a single question. Compliance with the Codex definition for a food additive is repeated in Q1.1. The “food/food ingredients” for which CCNFSDU is responsible is confusing as CCNFSDU is not accountable for discrete food ingredients. Suggest to delete “food ingredients”.

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

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

ISDI

Q1.1 We support the question and the footnote to the Codex definition of food additive. However, for substances not meeting Codex definition of food additives, including food additives added to nutrient or to other food ingredients, these substances would be discarded from further assessment according to the Annex B flowchart. Therefore provisions are needed to address these substances if the intention is to include them.

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.

ISDI

Q1.2 We support the question.

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

ISDI

Q1.3 Carried over additives and secondary additives (additives used in preparations of additives or nutrients) have no intended use in the food, and therefore are not food additives according to the Codex definition. However, the predicament of the carried over additives and secondary additives not meeting the Codex food additives definition remains to be addressed. Additionally, since these substances do not have a technological effect in the commodities managed by this committee, we question whether CCNFSDU is the appropriate committee to be assessing their technological effect. Rather, would it be more appropriate for the assessment of technological effect of these substances be carried out by the commodity committee managing the ingredient in which the substances has a technological effect (e.g. CCFA for substances present in additives; CCFO for oils).

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:

ISDI

Q.2 We support this question provided that if Codex already considers the function or technological purpose in the food to be justified (such as those already listed in the Codex Infant Formula Standard 72-1981), a proposal for a new additive serving the same function or technological purpose would respond 'no' to this question.

"Food ingredient" should be deleted in Q2 since the additive in the food ingredient does not meet the Codex definition of food additive.

In modern manufacturing, the overwhelming majority of foods for infants and young children require the use of additives in order to achieve the highest standards of safety and quality. When an additive is needed, a manufacturer will first use already authorised additives if possible. Only if this is not possible will a manufacturer consider going for the process of a new additive, or extension of use. This is the least preferred option for a manufacturer as this requires significant investment with an uncertain timeline and uncertain final result.

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?

ISDI

Q2.1 We do not support this question as written as it is because it is speculative and partly redundant with Q2. Q2 already addresses if the food can be prepared without the use of a food additive or another additive with the same technological function. Whether the exact infant food is on the market elsewhere in the world without the use of the same additive substance in question is speculative, difficult to assess, and may give ambiguous information. We suggest to delete Q2.1 from the framework.

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.

ISDI

Q2.2. Two questions within the sub-question is confusing and will make interpretation of the response difficult. We support the spirit of the first question however, suggest that this is addressed adequately in Q1.2 where the relevant CCNFSDU standard and/or GSFA food categories are indicated.

The second question makes a false assumption that products without the proposed additive are marketed; suggest to delete the second question within the Q2.2 question.

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”.

ISDI

Q3. We question what objective criteria can be used by CCNFSDU to judge responses to this question? The notes suggest that aspects of safety assessment including ADI, and a safety risk classification of the additive are appropriate criteria however, JECFA is best suited to determine the appropriate criteria by which to assess safety aspects. As the assessment of technological effect occurs prior to addition to the JECFA priority list, food additives may not have an ADI established, thus eliminating the ability to use this as criteria to judge which additive is “more suitable”.

It is also unclear from the description why a xenobiotic substance would always be considered “less suitable” than a physical metabolite. This again appears to be a reference to a safety assessment (that JECFA is likely not to have conducted at this point).

We suggest to delete the references to aspects of safety evaluation in the framework that considers technological need.

When an additive is needed, a manufacturer will first use already authorised additives if possible. Only if this is not possible will a manufacturer consider going for the process of a new additive, or extension of use. This is the least preferred option for a manufacturer as this requires significant investment with an uncertain timeline and uncertain final result.

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.

ISDI

Q4. We suggest rewording of question to: “What is the proposed level of use needed to accomplish the desired technological effect?”

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:

ISDI

Q5. We support the principle of compliance with section 3.2 of the preamble to GSFA

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

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

ISDI

Q5.1 We support the principle of compliance with section 3.2 of the preamble to GSFA.

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.

ISDI

Q5.2 We support the principle of compliance with section 3.2 of the preamble to GSFA

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.

ISDI

Q5.3 We support the principle of compliance with section 3.2 of the preamble to GSFA

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.

ISDI

Q5.4 We support the principle of compliance with section 3.2 of the preamble to GSFA

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.

ISDI

Q5.5 We support the principle of compliance with section 3.2 of the preamble to GSFA

ISDI suggests the following framework for considering technological justification of food additive provisions in CCNFSDU commodity standards:

Q1: Does the proposed substance meet the Codex definition of a food additive?

Q2: Identify the functional class and technological purpose of the food additive based on CAC/GL 36-1989 (Class Names and the International Numbering System for Food Additives).


Q3: Identify the specific foods, the relevant CCNFSDU commodity standards, and/or the GSFA food categories (General Standard for Food Additives CX STAN 192-1995) for which the food additive is intended to be used.

Q4: What is the proposed level of use of the food additive needed to accomplish the desired technological effect?

Q5: Does the proposed food additive meet the criteria in Section 3.2 of the Preamble to the GSFA?

Q5.1: Explain the purpose for using the food additive and how such use satisfies one or more of the needs set out in Section 3.2 (a) through (d) of the Preamble to the GSFA.

For convenience, a side-by-side of the ISDI framework proposal, and the proposal in CX/NFSDU 17/39/8 is shown here:



Proposed Framework: Discussion Paper vs. ISDI proposal

Proposal from the CP	Proposal from ISDI
<p>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?</p> <p>Q1.1: Does the proposed use meet the Codex definition of a food additive?</p> <p>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?</p> <p>Q1.3: Is the intended use in the food through direct addition or carried-over from use in raw materials or ingredients?</p> <p>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?</p> <p>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?</p> <p>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?</p> <p>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?</p> <p>Q4: What are the lowest possible amounts necessary to accomplish the desired technological effect?</p> <p>Q5: Is the proposed food additive use in compliance with Section 3.2 of the Preamble to the GSFA?</p> <p>Q5.1: Does the use of an additive have an advantage?</p> <p>Q5.2: Does the use of an additive not mislead the consumer with regard to properties of the food?</p> <p>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.</p> <p>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?</p> <p>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?</p>	<p><u>Q1:</u> Does the proposed substance meet the Codex definition of a food additive?</p> <p><u>Q2:</u> Identify the functional class and technological purpose of the food additive based on CAC/GL 36-1989 (Class Names and the International Numbering system for Food Additives).</p> <p><u>Q3:</u> Identify the specific foods, the relevant CCNFSDU commodity standards, and/or the GSFA food categories (General Standard for Food Additives CX STAN 192-1995) for which the food additive is intended to be used.</p> <p><u>Q4:</u> What is the proposed level of use of the food additive needed to accomplish the desired technological effect?</p> <p><u>Q5:</u> Does the proposed food additive meet the criteria in Section 3.2 of the Preamble to the GSFA?</p> <p><u>Q5.1:</u> Explain the purpose for using the food additive and how such use satisfies one or more of the needs set out in Section 3.2 (a) through (d) of the Preamble to the GSFA.</p>

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Food additive technological function – Mandate b) and c)

As indicated in paragraph 26 of the Discussion Paper on the Mechanism/Framework for Considering Technological Justification and Other Matters (CX/NFSDU 17/39/8), some electronic Working Group (eWG) members were concerned that there could be unnecessary delays in the authorization of gellan gum, xanthan gum, and pectin if parts b) and c) of the mandate were not discussed during the 39th CCNFSDU plenary.

To enable discussion of these additives in the context of the framework being developed, and to provide real examples to evaluate the applicability of these frameworks, the following information has been provided which would allow the evaluation of parts b) and c) of the mandate. While this information has been previously provided at the 38th CCNFSDU (NFSDU/38 CRD/11) and submitted to the eWG, for each of the three additives (gellan gum, xanthan gum, and pectin), responses are provided to the questions in the simplified decision tree presented in Annex B of the discussion paper (CX/NFSDU 17/39/8) to aid in discussion at the 39th CCNFSDU plenary.

Part (b) of the Mandate of the eWG:

To consider and confirm the technological justification of gellan gum;

Gellan gum

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?

Yes

Gellan gum is not normally consumed as a food by itself, nor used as a typical ingredient of food. The intention of the addition of this substance to food (in this case infant formula) is for a technological purpose.

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

No

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. These technological functions (thickener/stabilizer) are indispensable and unavoidable for the products that are the subject of this petition.

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. Without an ingredient added for stabilization, infant formula would be more likely to produce insoluble sediments or creaming (separation of fat). This technical effect is particularly important to ensure infant formula is homogenous and delivers the appropriate level of all essential nutrients. Use of product that is not properly stabilized will result in suboptimal delivery of nutrients to an infant, and long-term use could result in nutrient deficiency. Infant formula products can uniquely benefit from these multifunctional properties of gellan gum.

Gellan gum is cold or hot water-soluble, which allows for advantageous flexibility of addition for manufacturing applications. It also has good thermal and acid stability. Full hydration of the gum occurs during thermal processing temperatures used in infant formula ensuring desired effectivity of the stabilizer. The elasticity of the gel obtained from gellan gum is adjustable based on presence of ions, pH, or temperature. Therefore, gellan gum can be adapted to improve the physical stability of a variety of nutritionally complete, low viscosity formulas. Another benefit of gellan gum is that it does not influence the efficacy of the other components, particularly the vitamins and minerals in the formulation. Thus, gellan gum is compatible with formulation processing, allowing the minimum undesirable impact on the ingredients and during subsequent storage.

A study demonstrating the technological effect of gellan gum has been provided in Appendix A. This study provides information to support the conclusion that other additives having the same/similar technological effect were not effective in this product matrix and under these manufacturing conditions to produce an acceptable product.

Q3: Is there other food additive performing the same/similar technological effect which is more suitable for use in foods for infants and young children?

No

Gellan gum is the most suitable additive for this technological effect in particular products.

The use of additives in infant products is essential for preserving the nutritional quality, enhancing the quality or stability and/or aiding in the manufacturing, processing, or storage of these products. Due to differences in manufacturing process (e.g. spray dried vs. dry blend), ingredients (e.g. intact vs. hydrolyzed protein), environmental conditions in the country of sale, and product format (e.g. powder vs. liquid), a variety of additives need to be available to manufacturers to allow for the most appropriate food additive use for each product. Limiting the number of permitted additives could result in increased concentrations of food additives in product formulations if manufacturers are forced to switch to additives that are less effective for particular products.

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

The amount of gellan gum required to produce the technical effect is 0.005 g/100 mL as consumed.

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

Yes

Gellan gum meets the following needs described in Section 3.2 of the Preamble of the GSFA:

- b) Provides 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 young infants, and the use of gellan gum in these products ensures that products remain homogeneous and that the products, as-fed, provide the level of nutrients defined in the Codex Standard (72-1981)

- c) Enhances 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

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.

Provides aid 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).

Part (b) of the Mandate of the eWG: Conclusions

The technological justifications for gellan gum (INS 418) should be confirmed by the Committee, with a reference to CCFA recommending the addition of gellan gum to the JECFA priority list for safety evaluation.

Pending confirmation of the safety of gellan gum by JECFA, this additive would ultimately be added to the Infant Formula Standard (CX STAN 72-1981), Section B, as a thickener up to a maximum proposed use level as shown in the following table:

INS	Additive	Maximum level in 100 mL of the product ready for consumption
4.1 Thickeners		
418	Gellan gum	0.005 g in hydrolyzed protein and/or amino acid based formula

Part (c) of the Mandate for the eWG:

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 (eg. Xanthan gum, pectin).

ISDI proposes that substances that have already been evaluated by JECFA for use in foods for young infants, but for which technological justification has not yet been confirmed according to the newly developed framework by CCNFSDU, namely xanthan gum and pectin, may be handled by confirming their technological justification according to the framework under discussion by the Committee at this 39th CCNFSDU. Once confirmed, the CCNFSDU committee adopts the substances for use in the relevant Codex Standard (CX STAN 72-1981, Infant Formula Standard), for specified uses, at specified maximum use levels.

Technological justification for 1) xanthan gum and 2) pectin are provided here, following the framework presented in Annex B of the discussion paper (NFSDU 17/39/8).

Xanthan gum (INS 415)

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?

Yes

Xanthan gum is not normally consumed as a food by itself, nor used as a typical ingredient of food. The intention of the addition of this substance to food (in this case infant formula) is for a technological purpose.

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

No

Xanthan gum is a food additive for use as a thickener/stabilizer in formulas made with partially or extensively hydrolyzed protein, or free amino acids. These technological functions (thickener/stabilizer) are indispensable and unavoidable for the products that are the subject of this petition.

Use of a thickening agent in these types of formulas increases viscosity once reconstituted. Protein hydrolysis often yields a reduction in viscosity, and in infant formulas made with hydrolyzed proteins, thickener and stabilizer ingredients are used to improve product quality. 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. Use of product that is not properly stabilized will result in suboptimal delivery of nutrients to an infant, and long-term use could result in nutrient deficiency.

Xanthan gum can be used at relatively low levels to achieve significant viscosity without gelling. 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, as per the already established specifications for xanthan gum, the hydrocolloid must meet stringent limits for potential microbial contaminants. A low microbial load is of particular importance for an ingredient intended for use in infant formulas. 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.

A study demonstrating the technological effect of xanthan gum has been provided in Appendix B. These experimental data show that xanthan gum is uniquely effective compared to alternative additives having the same technological function in achieving the required technological effect in the hydrolyzed protein and amino acid-based matrix.

Q3: Is there other food additive performing the same/similar technological effect which is more suitable for use in foods for infants and young children?

No

Xanthan gum is the most suitable additive for this technological effect, in this product matrix and under specific manufacturing conditions.

The use of additives in infant products is essential for preserving the nutritional quality, enhancing the quality or stability and/or aiding in the manufacturing, processing, or storage of these products. Due to differences in manufacturing process (e.g. spray dried vs. dry blend), ingredients (e.g. intact vs. hydrolyzed protein), environmental conditions in the country of sale, and product format (e.g. powder vs. liquid), a variety of additives need to be available to manufacturers to allow for the most appropriate food additive use for each product. Limiting the number of permitted additives could result in increased concentrations of food additives in product formulations if manufacturers are forced to switch to additives that are less effective for particular products.

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

The amount of xanthan gum required to produce the technical effect is 0.1 g/100 mL as consumed.

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

Yes

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

- b) Provides 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 young infants, and the use of xanthan gum in these products ensures that products remain homogeneous and that the products, as-fed, provide the nutrients defined in the Codex Standard (72-1981).

- c) Enhances 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) Provides aid 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).

Pectin (INS 440)

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?

Yes

The use of pectin in formulas for infants is exclusively for a technological purpose. Pectin is not consumed as a food by itself, nor used as a typical ingredient of formulas for infants. The intention of the use of this substance in food (in this case infant formula) is for a technological purpose.

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

No

Pectin is a food additive for use as a thickener and stabilizer in infant formulas. These technological functions (thickener/stabilizer) are indispensable and unavoidable for the products that are the subject of this petition.

Infant formula manufacturing may be influenced by factors such as heat treatment, acidity, product form (liquid or powder) and compositional factors (e.g. whey proteins and other constituents). Manufacturing conditions can affect protein denaturation, aggregation, and sedimentation. In typical processing operations, for example, heating will result in formation of sedimentable protein aggregates composed of both denatured and non-denatured proteins. Pectin addition minimizes protein agglomeration and sedimentation during thermal processing, and over the shelf life. Thermal processes can also substantially impact the stability of emulsions. With the addition of pectin, whey protein-pectin complexes are adsorbed to the emulsion interface, leading to the formation of stable emulsions (stabilizer) which help maintain product homogeneity during shelf life. Finally, pectin also provides increased viscosity (thickener) in the formula matrix, which also serves to minimize product separation and maintain homogeneity during shelf life. The level selected to use in product was the minimum required to achieve the desired physical properties throughout shelf life.

A study demonstrating the technological effect of pectin has been provided in Appendix C. These experimental data show that pectin is uniquely effective compared to alternative additives having the same technological function in achieving the required technological effect in the hydrolyzed protein matrix.

Q3: Is there other food additive performing the same/similar technological effect which is more suitable for use in foods for infants and young children?

No

Pectin is the most suitable additive for this technological effect in this product matrix and under specific manufacturing conditions.

The use of additives in infant products is essential for preserving the nutritional quality, enhancing the quality or stability and/or aiding in the manufacturing, processing, or storage of these products. Due to differences in manufacturing process (e.g. spray dried vs. dry blend), ingredients (e.g. intact vs. hydrolyzed protein), environmental conditions in the country of sale, and product format (e.g. powder vs. liquid), a variety of additives need to be available to manufacturers to allow for the most appropriate food additive use for each product. Limiting the number of permitted additives could result in increased concentrations of food additives in product formulations if manufacturers are forced to switch to additives that are less effective for particular products.

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

The maximum proposed use level of pectin needed to achieve the required technical effect is 0.2 g/100 mL as consumed.

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

Yes

Pectin meets the following needs described in Section 3.2 of the Preamble of the GSFA:

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

The products in GSFA Food Category 13.1 have a one-to-one correspondence with those of the Codex Infant Formula Standard (CX-STAN 72-1981), and are intended to provide the sole source of nutrition for young infants. The use of the food additive pectin in certain formulas with hydrolyzed proteins ensures that products remain homogeneous and that the products, as-fed, deliver as the nutrients defined by the essential composition in the Infant Formula Standard.

- c) Enhances 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

Pectin functions as a thickener (increases the viscosity of the food), and stabilizer (maintains a uniform dispersion of two or more components), in certain formulas for infants with hydrolyzed proteins. These technological functions are critical to the homogeneity of these products and thus the effective delivery of nutrient, as defined by the essential composition in the Infant Formula Standard.

- d) Provides aid 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.

Pectin is uniquely effective as a thickener and stabilizer in certain hydrolyzed protein matrices. Addition of pectin at up to 0.2% (0.2 g/100 mL) ready to consume in certain infant formula assures acceptable product quality including product uniformity throughout shelf life, thus delivering the appropriate level of essential nutrients to infants.

Part (c) of the Mandate for the eWG: Conclusions

The technological justifications for xanthan gum (INS 415) and pectin (INS 440) should be confirmed by the Committee with a recommendation that they be added to the Infant Formula Standard (CX STAN 72-1981), Section B, as thickeners up to a maximum proposed use level as shown in the following table:

INS	Additive	Maximum level in 100 mL of the product ready for consumption
4.1 Thickeners		
415	Xanthan gum	0.1 g in hydrolyzed protein and/or amino acid based formula
440	Pectin	0.2 g in formulas containing hydrolyzed protein

Finally, CCNFSDU should provide a reference to CCFA to add xanthan gum and pectin to the GSFA in Food Category 13.1, Infant Formula, follow-up formulae, and formulae for special medical purposes for infants.

COMMENTS SUBMITTED BY THE INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)

APPENDIX A – GELLAN GUM

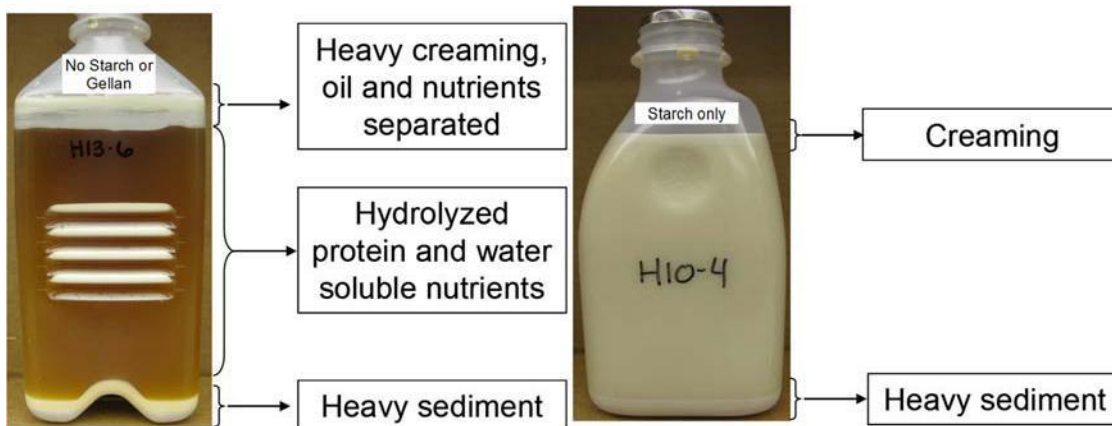
Compared to intact proteins, hydrolyzed proteins are not as effective in creating or maintaining a stable emulsion. Development of physically stable nutritional products based on hydrolyzed proteins is further challenged when high levels of insoluble ingredients, like mineral salts, are incorporated. 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.

In this experiment, gellan gum and OSA-modified starch alone and in combination were evaluated in a concentrated liquid product made with an extensively hydrolyzed protein. Experimental products were manufactured and then allowed to settle for 40 days prior to photographs being taken. These conditions simulate liquid product manufacturing and distribution, prior to consumption of the product.

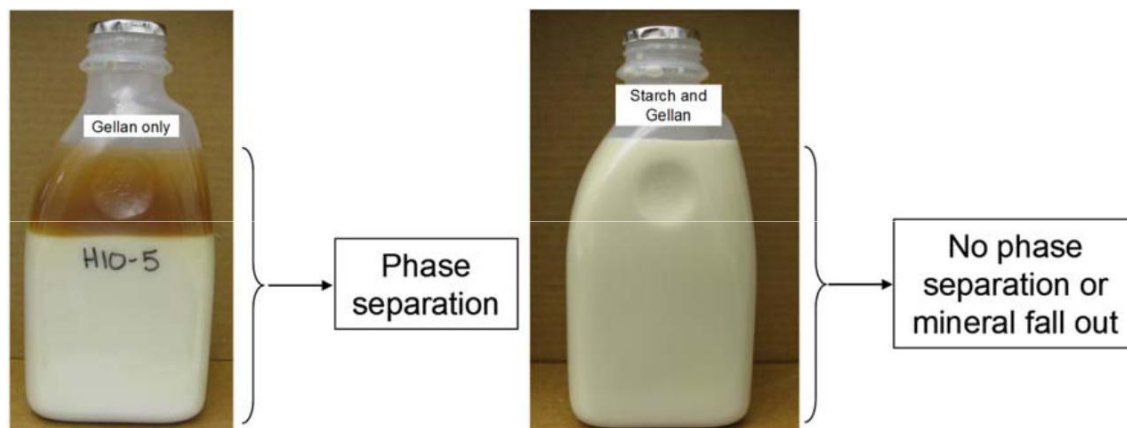
As annotated in the photos, heavy creaming, separation of oil and liquid phases, and sedimentation were observed in a control sample (top left) without either OSA-modified starch (INS 1450) or gellan gum (INS 418). When only OSA-modified starch was used (top right), the product had creaming and sedimentation. When only gellan gum was used (bottom left), the product had phase separation. However, when OSA starch and gellan gum were combined (bottom right), the product was stable with no phase separation, creaming, or sedimentation. It should be noted that the separation of this product was also evident within 24

hours of being allowed to settle. While the separation was less dramatic visually, the consequences of the separation, as described above, would still be relevant.

Top left: Control; Top right: OSA-modified starch only



Bottom left: Gellan gum only; Bottom right: Both OSA-modified starch and gellan gum



COMMENTS SUBMITTED BY THE INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)

APPENDIX B – XANTHAN GUM

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 such as phase separation and foaming). 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.

In this experiment, addition of the same amount of xanthan gum (INS 415), CITREM (INS 472c), or carrageenan (INS 407) in both an extensively hydrolyzed (Figure 1) and an amino acid-based (Figure 2) formula powders were compared. Experimental formulas were reconstituted and allowed to settle overnight (~20 hours) prior to photographs being taken. This method simulates what a caregiver might see if a bottle was prepared according to label instructions, stored in refrigerator, and used the following day.

The images in Figures 1 and 2 are annotated to highlight differences. After overnight refrigeration, formula with xanthan gum exhibited the lowest amount of creaming and showed no sedimentation. Additionally, as shown in Table 1, xanthan gum increased viscosity (which helps maintain homogeneity) more effectively than other additives in both product matrices.

Table 1: Viscosity with different additives and product matrices

Table 1. Viscosity with different additives			
Sample ID	Matrix	Additive	Viscosity (cps)
A1	Extensively Hydrolyzed	None	3.6
A2	Extensively Hydrolyzed	Xanthan Gum	34
A3	Extensively Hydrolyzed	CITREM	3.7
A4	Extensively Hydrolyzed	Carrageenan	5
B1	Amino Acid	None	3.5
B2	Amino Acid	Xanthan Gum	30.1
B3	Amino Acid	CITREM	3.4
B4	Amino Acid	Carrageenan	4.7

Figure 1: Extensively hydrolyzed protein formula samples

(A1: control, A2: xanthan gum, A3: CITREM, A4: carrageenan)



Figure 2: Amino acid-based formula samples

(B1: control, B2: xanthan gum, B3: CITREM, B4: carrageenan)

**COMMENTS SUBMITTED BY THE INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)****APPENDIX C – PECTIN**

For manufacturers of formulas for infants and young children, it is essential to have a variety of food additives available to produce safe and suitable formulations for these populations. It is well known that certain additives are uniquely effective in certain formula matrices, while other authorized additives in the same functional class cannot necessarily perform the required technical functions in the same formula matrix, resulting in product failures. The current experimental work demonstrates this concept, focusing on the food additive pectin (INS 440).

In this experiment, 5 batches of a concentrated liquid infant formula containing hydrolyzed protein, medium chain triglycerides, vegetable fats, long chain polyunsaturated fatty acids, and vitamins and minerals were produced, each batch using a different food additive variable.

The control formula includes pectin. The experimental additives were a variable with 20% less pectin, carob bean gum, carrageenan, and OSA modified starch. Selection of alternative additives for this trial was made on the basis that each has a emulsifier/thickener/stabilizer function, is an adopted CODEX provision for use in infant formula (except pectin), and level of use was less than the maximum use level specified in CX Stan 72-1981. All products were formulated to be at the same pH, protein, carbohydrate, fat and % solids.

The original protocol included evaluations of formula performance at time zero (immediate post sterilization), 2 weeks, 1 month, 3 months, and 6 months, at 25°C storage temperature. Outcomes measured included viscosity, pH, physical properties (sediment, gel, serum, grain etc), and visual inspection. Photos were taken throughout the experiment to visually document the outcomes.

The results are summarized in the photos below for the 25°C series, starting with outcomes at Time 0, followed by 2 weeks, and 1 month. The experiment was terminated after 1 month due to product failure in all but the pectin Control, as shown in the 3rd panel below.

The samples containing carob bean gum, carrageenan, OSA modified starch, and reduced level of pectin were not acceptable in overall quality after heat treatment. These products had excessive thickness, serum separation, grain, and large particle size. The larger the particle size, the lower the product quality, consistency and shelf life. They completely failed after 1 month and formed solid gels with entrapped air.

Time 0



Phase separation and sediment

1. Control – pectin in infant formula with hydrolyzed protein
2. Reduced pectin
3. Carob bean gum
4. Carrageenan
5. OSA modified starch

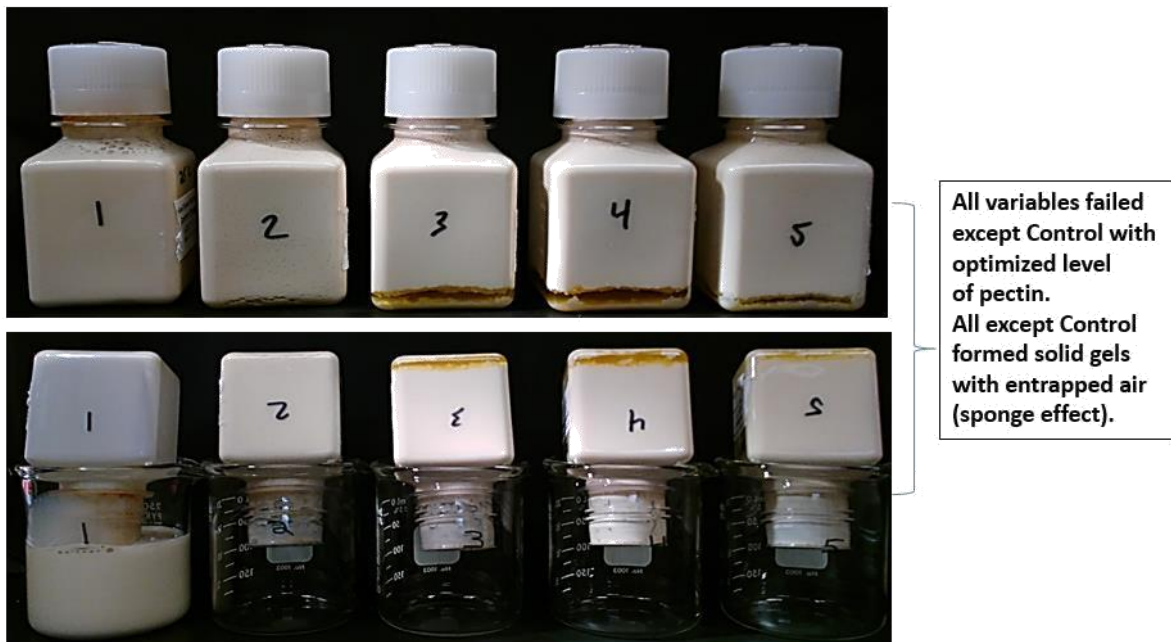
Time 2 weeks



Serum separation and grain are unacceptable in all except Control pectin. Gel formation becomes evident. Viscosity and particle size are out of Specification, except Control.



Time 1 month



This experiment demonstrates the highly specific effectiveness of additives to achieve a particular technical effect in specific matrices. Only pectin at specific concentration was effective to produce an acceptable product under the specified manufacturing conditions, whereas a lower level of pectin, the use of carob bean gum, carrageenan or OSA modified starch failed in this application. These experiments illustrate that technological need is dependent on the specific physical properties and processing methods of a formula, characteristics that are more multifaceted than food category descriptors.

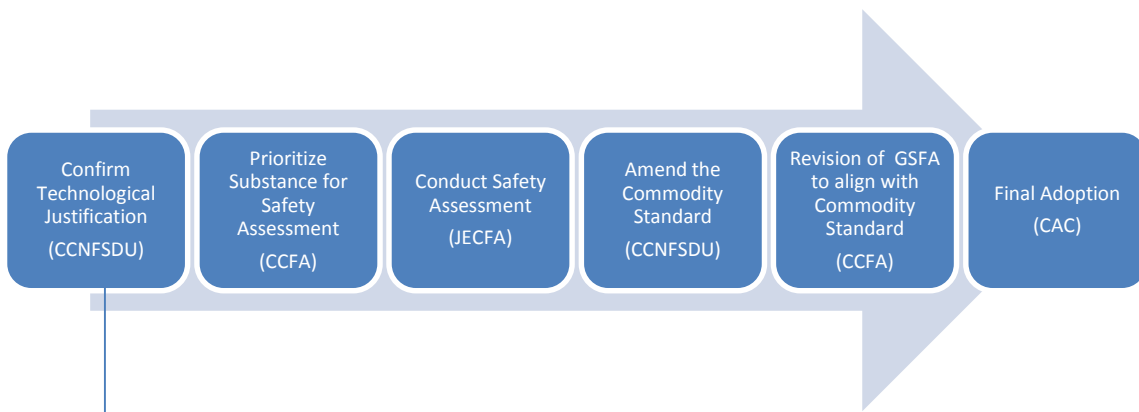
Understanding the CODEX Food Additives Process for CCFSDU Commodity Standards

At this 39th session of the CCFSDU, discussion will take place on a framework for considering the technological justification for substances intended for inclusion on the priority list of substances for JECFA evaluation (Agenda Item 9, CX/NFSDU 17/39/1).

In light of this discussion, and in view of the sometimes differing understandings among Committee members on food additives topics, it may be useful for the Committee to have a brief overview of the CODEX food additive process as it applies to commodity standards under the mandate of CCFSDU.

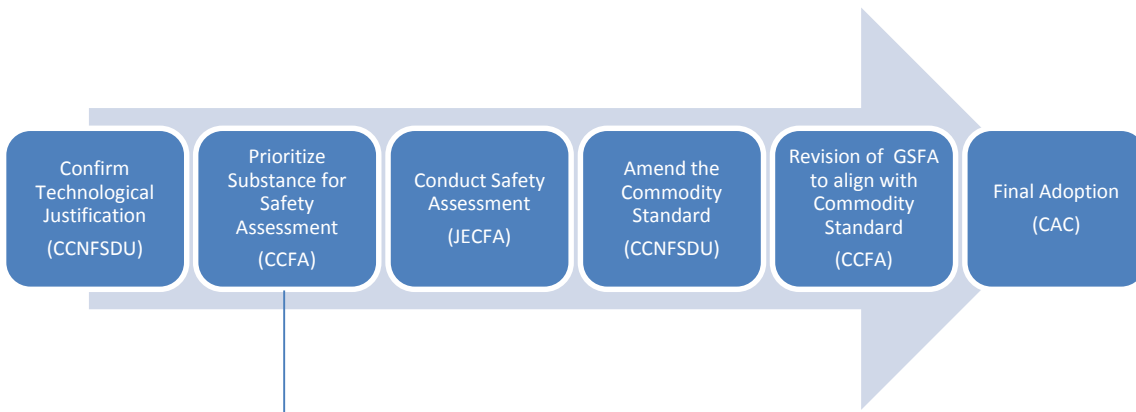
The aim of this information document is to provide interested Committee members with an outline of the main roles and outcomes of the different CODEX committees and the FAO/WHO Expert Committee involved in risk assessment and risk management of food additives.

Establishing a common understanding of the specialized expertise and accountabilities of these CODEX procedures and processes will help ensure that the framework for technological justification of food additives will be based on sound scientific principles.



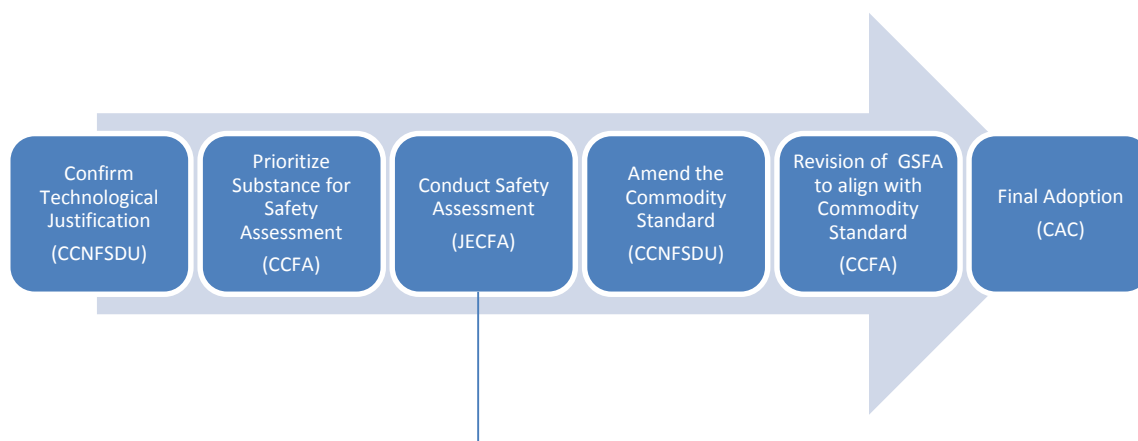
Step 1: Confirm Technological Justification

- **Accountable:** CCNFSDU
- **Initiated by:** Requests submitted by industry/sponsor with country support
- **Process/Criteria:** Framework for Technological Justification is being proposed by the electronic Working Group (eWG) established in the 2016 CCNFSDU meeting (REP17/NFSDU, para 178; 39th CCNFSDU Agenda Item 9)
- **Output(s):**
 - When technological justification is confirmed, CCNFSDU provides a reference to CCFA to request inclusion of the substance on the JECFA priority list



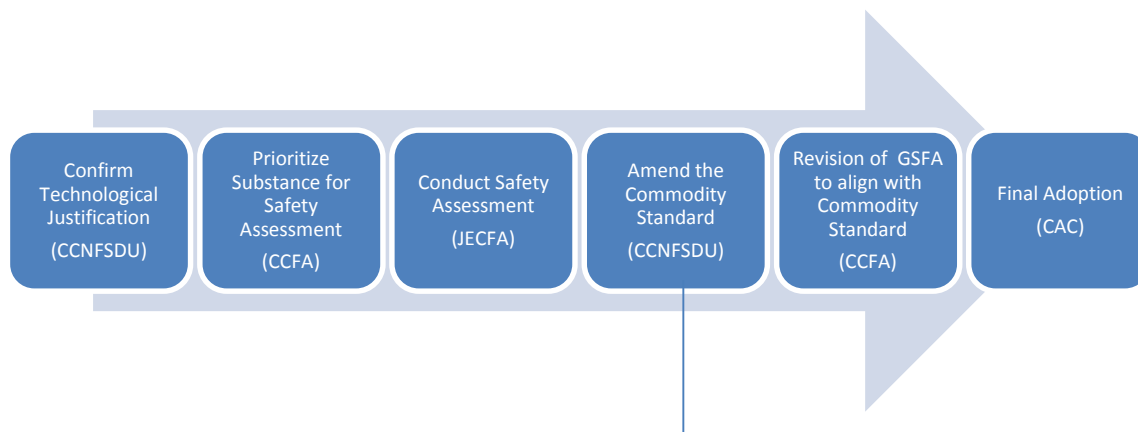
Step 2: Prioritize Substance for Safety Assessment

- **Accountable:** CCFA
- **Initiated by:** After CCNFSDU has confirmed technological justification for a substance, Codex members and observers request for the substance to be included on the priority list for JECFA evaluation by submission of a Circular Letter in response to the CCFA call for proposals
- **Process/Criteria:** Requests should follow the existing policies and procedures in the *Codex Procedural Manual*. CCFA manages the priority list.
- **Output(s):**
 - If the Committee agrees, CCFA updates the JECFA priority list to include the substance for evaluation.



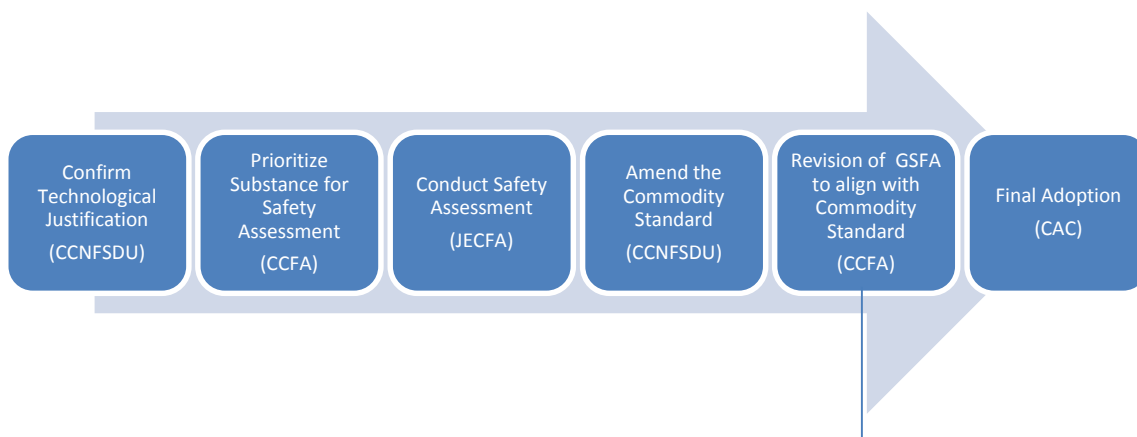
Step 3: Conduct Safety Assessment

- Accountable: JECFA (Joint FAO/WHO Expert Committee on Food Additives)
- Initiated by: CCFA prepares the priority list of substances on which JECFA performs the risk assessment.
- Process/Criteria: JECFA conducts the science-based risk assessment using established practices, taking into consideration any special circumstances associated with the use of the substance (for example consideration of whether infants below 12 weeks will be exposed)
- Output(s):
 - JECFA will provide recommendation concerning safety of the substance at proposed concentrations and specific conditions of use.



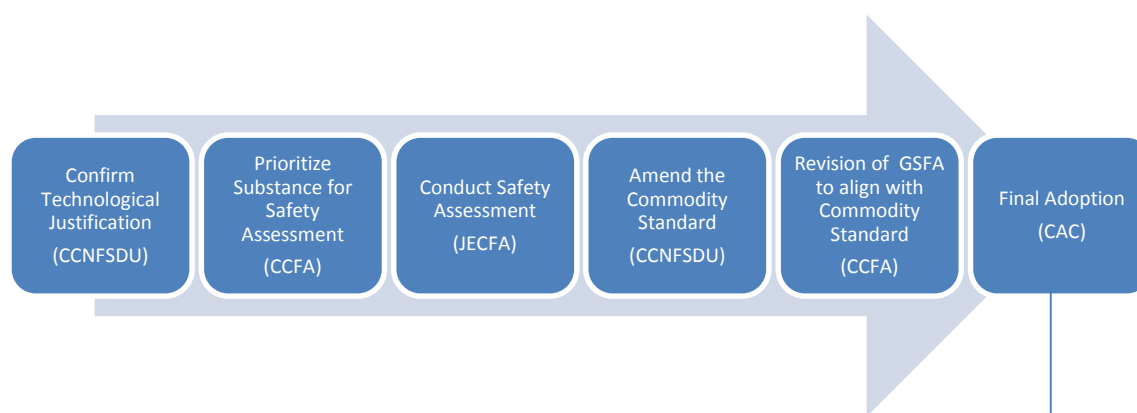
Step 4: Authorize Addition to the Commodity Standard

- Accountable: CCNFSDU
- Initiated by: JECFA recommendation concerning safety, and on Matters Referred communication among Codex Committees
- Process/Criteria: When JECFA's risk assessment concludes the substance is safe for use, CCNFSDU may then amend the appropriate commodity standard by adding the substance, given that the technological justification has already been confirmed (Step 1). Consideration of the maximum level and any other specific conditions is taken into account by CCNFSDU.
- Output(s):
 - CCNFSDU would forward a recommendation for amendment of the appropriate commodity standard to CAC, and
 - CCNFSDU would provide a reference to CCFA to request revision of the GSFA.



Step 5: Align GSFA with the Commodity Standard

- Accountable: CCFA
- Initiated by: Requests submitted to CCFA by Codex Committees, Codex members, or CAC, via submission of a Circular Letter in response to the CCFA call for proposals
- Process/Criteria: In order to maintain alignment between the GSFA and commodity standards, once the commodity standard has been authorized for amendment, CCFA may recommend revision of the GSFA in the appropriate Food Categories
- Output(s):
 - CCFA would forward a recommendation for amendment of the GSFA to CAC



Step 6: Final Adoption

- Accountable: CAC (Codex Alimentarius Commission)
- Initiated by: Referral by CCNFSDU (amendment to commodity standard) and CCFA (GSFA revision)
- Process/Criteria: CAC would adopt the proposed provisions based on the recommendations of the appropriate Codex Committees
- Output(s):
 - Finalization of provisions in the appropriate commodity standard and aligned provisions in the GSFA