

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 9a

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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MECHANISM / FRAMEWORK FOR CONSIDERING TECHNOLOGICAL JUSTIFICATION OF FOOD ADDITIVES

Prepared by the European Union to facilitate the discussion at the Physical Working Group (PWG) held on Saturday, 23 November 2019

Background

1. At 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 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 JECFA82 (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, (3) to continue the work on the framework and to test the agreed framework with the proposed use of xanthan gum (INS 415), pectin (INS 440) and gellan gum (INS 418). The Committee agreed to evaluate the relevant food additives in CRD15 of CCFA49 as a next step. Finally, the Committee re-established the EWG to continue the work on points (2) and (3) ([REP18/NFSDU](#), paras. 133-144).
3. At CCNFSDU40 the outcomes of the EWG ([CX/NFSDU 18/40/11](#)) were presented. It was noted that there were a number of issues that needed further discussion before the framework could be finalised and applied. Therefore, the Committee established an in-session Working Group to review Annex A and Annex B of CX/NFSDU 18/40/11 and appraise the technological need for the use of the three candidate additives ([REP19/NFSDU](#), paras. 123-126).
4. The outcomes of the in-session Working Group ([CRD 34](#)) were further considered by the Committee. The Committee noted that the framework would be used on all foods within the CCNFSDU mandate and it could apply to three potential scenarios as presented in footnote 3 of CX/NFSDU 18/40/11. The Committee agreed with the proposed process to appraise and justify the need for the use of additives in foods within the mandate of CCNFSDU (Appendix VIII, Annex 1, REP19/NFSDU). The Committee also discussed the framework for appraising the technological need and reached a consensus on its scope and on sections Q1 and Q2 (Appendix VIII, Annex 2, REP19/NFSDU). The Committee agreed, that the framework should cover food intended for infants and young children, and agreed to Q3. Due to time constraints, the Committee could not consider other aspects of Q3 (i.e. sub-questions under Q3) and the application of the framework to appraise the technological justification of the three candidate additives ([REP19/NFSDU](#), paras. 127-138).

¹NFSDU/39/CRD 6, CRD 12 and CRD 17

Mandate of the PWG

5. In the light of the above discussion, CCNFSDU40 agreed to:

Establish a PWG to meet immediately prior to the next session, chaired by the European Union and co-chaired by the Russian Federation, working in English, French and Spanish, to further consider:

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

Discussion at the PWG

6. The aim of this paper is to provide short background information for the matter under consideration and to extract the relevant information from Appendix VIII, Annex 2, REP19/NFSDU and CX/NFSDU 18/40/11 to address the PWG mandate. Apart from that, the paper also contains Appendices with the information from the applicant to appraise the technological need for the candidate additives (Appendix 1), information on the experimental trials with the candidate additives (Appendix 2), the empty template "Form for appraising the technological need" (Appendix 3) and the "Decision tree on the framework" (Appendix 4). Appendices 3 and 4 would need to be adjusted once the section Q3 of the framework is completed.

7. At the PWG, points (i) and (ii) of the mandate should be addressed together in order to complete the work on the framework prior to appraising the technological need for the three candidate additives.

8. The appraisal of the technological need should follow the agreed framework which implies that the applicant should be ready to address the question(s) of Q3 section once it is agreed.

I. Completion of the framework for appraising the technological need by finalizing Q3 section

9. Q3 section is intended to verify the compliance with the agreed approach that the use of food additives in food intended for babies should be kept to a minimum in line with the basic principle on the use of additives in baby foods as set out by JECFA, adopted by CAC and reaffirmed by the Committee (see [REP17/NFSDU](#), para 172), i.e. "*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*".

10. It should be noted that whilst the Committee agreed on including Q3 in the framework, the question Q3.1 was not further discussed and it remained in the square brackets for further consideration. The questions under question Q3 in document CX/NFSDU 18/40/11 were also included in the PWG mandate. The report from the in-session Working Group indicated a need for a further discussion of Q3 questions and that certain elements from the question Q3.1 were missing ([CRD 34](#), para 11).

11. For ease of reference, the relevant parts of the text to be discussed under points (i) and (ii) of the mandate are outlined below. For more comprehensive information on the framework and the Q3 questions please consult Appendix VIII, Annex 2, REP19/NFSDU and CX/NFSDU 18/40/11, pages 9-10.

To be discussed at the PWG:

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

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

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

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

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

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?"

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?

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?"

Comment:

The aim of the PWG is to reach a consensus on the appropriate wording of the question(s) under Q3 section taking into account the question Q3.1 in the square brackets in Appendix VIII, Annex 2, REP19/NFSDU and the questions Q3.1, Q3.2, Q3.2rev, and Q3.1 and Q3.2rev from CX/NFSDU 18/40/11.

II. Appraising the technological need for the three candidate additives

12. The technological need shall be appraised taking into account the information submitted by the applicant captured in Annex D to CX/NFSDU 18/40/11. The structure of the information in Annex D, however, does not correspond to the agreed framework in Appendix VIII, Annex 2, REP19/NFSDU as amendments to the framework were made at CCNFSDU40. Thus the applicant submitted to the chairs the updated information respecting the structure of the framework in Annex D. It also includes the information pertaining to Q3.1 in the square brackets. This updated information is in Appendix 1 to this paper. As the work on section Q3 has not been completed also the information provided by the applicant on Q3 questions in Annex D was added by chairs to Appendix 1.

Comment:

The aim of the PWG is by using the framework to appraise the technological need for the proposed use of xanthan gum (INS 415), pectin (INS 440) and gellan gum (INS 418) based on the information provided by the applicant. The participants in the PWG are encouraged to study the information provided by the applicant to judge whether it is satisfactory to address the questions in the framework and whether, and under what conditions, the use is technologically justified.

In case any further clarification from the applicant is needed the participants to the PWG are encouraged to send their questions in writing prior to the PWG.

Appendix 1: Information from the applicant for appraising the technological need based on the questions of the framework

INS 415 Xanthan gum

THE PROPOSAL IS SUBMITTED BY:		<i>ISDI (International Special Dietary Foods Industries)</i>
Q1 IDENTITY AND INTENDED USE		
Q1.1 Name and INS number of the additive as listed in CAC/GL 36-1989: For substances not yet included in CAC/GL 36-1989, chemical name of the substance.		<i>Xanthan Gum (INS 415)</i>
Q1.2 Describe the food and its form (e.g. liquid, powder) for which the additive is intended to be used and indicate the relevant CCNFSDU standard and if known the GSFA food subcategory		
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 powdered 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 Indicate and justify the range of the proposed use level of the food additive needed to accomplish the desired technological effect at the lowest possible use level		
Proposed (range of) lowest possible use level to accomplish the desired effect (expressed on 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. Results from experimental trials are provided in Annex to this Form.</i>
Q2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA		
Q2.1 Describe the technological function of the food additive relative to the CAC/GL 36-1989 (include the functional class) and the advantage conferred by its use		
<u>Technological function relative to the CAC/GL 36-1989:</u> <i>The use of food additives in infant formula is justified in order to maintain consistency and texture in order to ensure safe and acceptable use.</i> <i>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:</i> <i>Functional class: thickener (“a food additive which increases the viscosity of a food”)</i> <i>Technological purpose: thickener</i> AND <i>Functional class: stabilizer (“a food additive which makes it possible to maintain a uniform dispersion of two or more components”)</i>		

Technological purpose: emulsion stabilizer

Advantage from the use of the additive:

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

Due to differences in manufacturing process (e.g. spray dried vs. dry blend), thermal processing method (e.g. retort vs. ultra-high temperature pasteurization), ingredients (e.g. intact vs. hydrolyzed protein, type and level of lipids), and product format (e.g. powder vs. liquid), a variety of additives are needed to allow for the most optimized food additive application for different products from different manufacturers.

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 formulas as a thickening agent presents minimal risk of allergenicity or sensitization potential. These advantages have also been demonstrated experimentally, as shown in the document in Annex to this Form.

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

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). Food safety and integrity are the highest priority for manufacturers of infant foods, including rigorous standards for quality including hygiene through the supply chain and life cycle of the products.

<p>Q2.3 Cannot the objectives set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA be achieved by other means that are economically and technologically practicable?</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. At this time, there are no commercially feasible, superior technology alternatives to manufacture FSMP formulas without the use of selective additives that are uniquely suitable for specific formula and processing variables.</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>Q2.4 Would the use of this additive in the intended food(s) modify any characteristic of the food that might mislead the consumer?</p>
<p>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.</p> <p><i>Products containing xanthan gum in the formulation would identify this additive in the list of ingredients according to the requirements in the General Standard for the Labelling of Pre-packaged Foods (STAN 1-1985), which specifies that the functional class shall be used together with the specific additive name or INS number in the ingredient panel (or per national legislation), providing transparency to consumers. The technological purpose for the addition of this additive is to maintain consistency and texture in order to ensure safe and acceptable use, and does not conceal damage or inferiority, or make the product appear to be greater than actual value. The purpose is to fulfil a technological necessity, without which the product would be inferior and not fit for use (e.g. it would not be able to ensure consistent delivery of essential nutrients in the product).</i></p>
<p>Q3 COMPLIANCE WITH THE APPROACH ON THE USE OF ADDITIVES IN FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN</p>
<p>Note: To be completed based on the discussion on parts (i) and (ii) of the PWG mandate</p>
<p>[Q3.1 Does the proposed food additive perform the same/similar purpose as other additives that have already been authorized for use in the same product category? If not, what is the justification for the need for an additive with a new functional class and/or technological purpose? If yes, what advantage(s) does the proposed additive provide over currently permitted options?]</p>
<p><i>Other additives with a similar technological function (thickener) are authorized for use by Codex STAN 72-1981 and corresponding GSFA food subcategory 13.1.3. These other permitted thickeners include carob bean gum (INS 410), carrageenan (INS 407), OSA-modified starch (INS 1450), guar gum (INS 412), and starch phosphates (INS 1412, 1413, and 1414).</i></p> <p><i>For advantages of the proposed additive over currently permitted options, refer to Q2.1 and the Annex to this Form.</i></p>
<p>[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?]</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</i></p>

<i>products. Thickeners, such as xanthan gum, are required to ensure infant formula is homogenous and delivers the appropriate level of all essential nutrients.</i>
[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?]
<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>
<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>
<i>Additional information regarding the technological function of xanthan gum is provided in NFSDU/39 CRD6.</i>
[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?]
[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?]

INS 440 Pectin

THE PROPOSAL IS SUBMITTED BY:	<i>ISDI (International Special Dietary Foods Industries)</i>	
Q1 IDENTITY AND INTENDED USE		
Q1.1 Name and INS number of the additive as listed in CAC/GL 36-1989: For substances not yet included in CAC/GL 36-1989, chemical name of the substance.	<i>Pectin (INS 440)</i>	
Q1.2 Describe the food and its form (e.g. liquid, powder) for which the additive is intended to be used and indicate the relevant CCNFSDU standard and if known the GSFA food subcategory		
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 liquid infant formula 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 Indicate and justify the range of the proposed use level of the food additive needed to accomplish the desired technological effect at the lowest possible use level	
Proposed (range of) lowest possible use level to accomplish the desired effect (expressed on the final product as consumed)	Justification of the level(s) proposed
Up to 0.2 g/100 mL	<p><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. Lower levels or higher levels have not been shown in experimental trials to provide the needed technical effect under these manufacturing and formulation conditions. Results from experimental trials are provided in Annex to this Form.</i></p>
Q2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA	
Q2.1 Describe the technological function of the food additive relative to the CAC/GL 36-1989 (include the functional class) and the advantage conferred by its use	
<p><u>Technological function relative to the CAC/GL 36-1989:</u></p> <p><i>The use of food additives in infant formula is justified in order to maintain consistency and texture in order to ensure safe and acceptable use.</i></p> <p><i>Codex sets out functional class and technological purpose for additives in CAC/GL 36-1989. In the case of Pectin (INS 440) in this product application, the following text from the Codex Guidance apply:</i></p> <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><i>AND secondarily, pectin also has the following technological function in this product application:</i></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><u>Advantage from the use of the additive:</u></p> <ul style="list-style-type: none"> • <i>In this hydrolysed protein formula matrix, manufactured under specific pH conditions, the use of pectin as a thickener is uniquely effective, and essential to ensure the formula is homogenous and consistently delivers the appropriate level of nutrients to the intended infant population. The use of pectin prevents separation of the emulsion, and avoids sedimentation of added nutrients/ingredients particularly insoluble minerals.</i> • <i>Compared to intact proteins, 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 often have 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 and sedimentation, and defects in emulsion stability (resulting in aqueous/lipid phase separation). By improving the suspension of ingredients or emulsions, pectin increases the stability of the product over the shelf life.</i> 	

- *The technological effects of pectin are required in both the initial parts of manufacturing (combining of protein and pectin solutions to form a stable complex), and during thermal processing to achieve sterile liquid product.*
- *Due to differences in manufacturing processes (e.g. spray dried vs. dry blend), thermal processing method (e.g. retort v. ultra-high temperature pasteurization), ingredients (e.g. protein source and type: intact vs. hydrolyzed protein, type and level of lipids), and product format (e.g. powder vs. liquid), a variety of additives of the same functional class are needed to allow for the most optimized food additive application for different products from different manufacturers.*
- *The use of other additives authorized as thickeners in FC 13.1.3, as well as a lower and higher level of pectin, cannot achieve the needed technical effect in this specialized liquid formula containing hydrolyzed protein. Trials of other additives have 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". Only pectin at the proposed use level in this request was suitable to deliver a high quality product. These advantages of pectin in this formula matrix have been demonstrated experimentally, as shown in the document in Annex to this Form.*

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

Pectin (INS 440) meets several of the needs described in Section 3.2 of the Preamble of the GSFA for this product application:

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 not receiving human milk exclusively, and the use of pectin in the FSMP formula ensures that products remain homogeneous and that the products, as-fed, provide the complete nutrient profiles defined in the Codex Standard (72-1981) and/or as adjusted to meet the special dietary needs of infant patients.

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

Pectin provides its primary technological effect as a thickener in this application, ensuring appropriate viscosity of the formula containing hydrolyzed protein and manufactured under specific pH conditions. This technological function is critical to the homogeneity and stability of these products and thus the effective delivery of the complete nutritional components to the patient population.

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 essential nutrient composition as set out in the Codex Standard (72-1981). Food safety and integrity are the highest priority for manufacturers of infant foods, including rigorous standards for quality including hygiene through the supply chain and life cycle of the products.

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

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.

Infant formula products based on hydrolysed proteins or amino acids face significant challenges in terms of maintaining homogeneity. Product research has demonstrated that the use of additives is the only commercially effective way of producing and maintaining the homogeneity of these products through manufacturing, throughout shelf-life, and through administration of the products to the consumers. At this time, there are no commercially feasible, superior technology alternatives to manufacture FSMP formulas without the use of selective additives that are uniquely suitable for specific formula matrices and processing variables.

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 systems.

Q2.4 Would the use of this 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.

Infant products containing pectin as an ingredient in the formulation would identify this additive in the list of ingredients according to the requirements in the General Standard for the Labelling of Pre-packaged Foods (STAN 1-1985), which specifies that the functional class shall be used together with the specific additive name or INS number in the ingredient panel (or per national legislation), providing full transparency to consumers on the presence of a food additive in the product. 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. The purpose is to fulfil a technological necessity, without which the product would be inferior and not fit for use (e.g. it would not be able to ensure consistent delivery of essential nutrients in the product).

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

Note: To be completed based on the discussion on parts (i) and (ii) of the PWG mandate

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

Other additives with the same technological function (thickener) are authorized for use by Codex STAN 72-1981 and corresponding GSFA food subcategory 13.1.3. These other permitted thickeners include carob bean gum (INS 410), carrageenan (INS 407), OSA-modified starch (INS 1450), guar gum (INS 412) and starch phosphates (INS 1412, 1413, and 1414).

For advantages of the proposed additive over currently permitted options, refer to Q2.1 and the Annex to this Form.

[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?]

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.

[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?]

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.

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

[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?]

[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?]

INS 418 Gellan Gum

THE PROPOSAL IS SUBMITTED BY:		<i>ISDI (International Special Dietary Foods Industries)</i>
Q1 IDENTITY AND INTENDED USE		
Q1.1 Name and INS number of the additive as listed in CAC/GL 36-1989: For substances not yet included in CAC/GL 36-1989, chemical name of the substance.		<i>Gellan Gum (INS 418)</i>
Q1.2 Describe the food and its form (e.g. liquid, powder) for which the additive is intended to be used and indicate the relevant CCFSDU standard and if known the GSFA food subcategory		
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 liquid 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 Indicate and justify the range of the proposed use level of the food additive needed to accomplish the desired technological effect at the lowest possible use level		
Proposed (range of) lowest possible use level to accomplish the desired effect (expressed on 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. Results from experimental trials are provided in Annex to this Form.</i>

Q2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA

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

Technological function relative to the CAC/GL 36-1989:

The use of food additives in infant formula is justified in order to maintain consistency and texture in order to ensure safe and acceptable use.

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:

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

Advantage from the use of the additive:

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.

Due to differences in manufacturing process (e.g. spray dried vs. dry blend), thermal processing method (e.g. retort vs. ultra-high temperature pasteurization), ingredients (e.g. intact vs. hydrolysed protein, type and level of lipids), and product format (e.g. powder vs. liquid), a variety of additives are needed to allow for the most optimized food additive application for different products from different manufacturers.

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. These advantages have also been demonstrated experimentally, as shown in the document in Annex to this Form.

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

Gellan 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 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)

<p><u>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</u></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><u>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.</u></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). Food safety and integrity are the highest priority for manufacturers of infant foods, including rigorous standards for quality including hygiene through the supply chain and life cycle of the products.</i></p>
<p>Q2.3 Cannot the objectives set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA be achieved by other means that are economically and technologically practicable?</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. At this time, there are no commercially feasible, superior technology alternatives to manufacture FSMP formulas without the use of selective additives that are uniquely suitable for specific formula and processing variables.</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>Q2.4 Would the use of this additive in the intended food(s) modify any characteristic of the food that might mislead the consumer?</p> <p>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.</p> <p><i>Products containing gellan gum in the formulation would identify this additive in the list of ingredients according to the requirements in the General Standard for the Labelling of Pre-packaged Foods (STAN 1-1985), which specifies that the functional class shall be sued together with the specific additive name or INS number in the ingredient panel (or per national legislation), providing transparency to consumers. The technological purpose for the addition of this additive is to maintain consistency and texture in order to ensure safe and acceptable use, and does not conceal damage or inferiority, or make the product appear to be greater than actual value. The purpose is to fulfil a technological necessity, without which the product would be inferior and not fit for use (e.g. it would not be able to ensure consistent delivery of essential nutrients in the product).</i></p>
<p>Q3 COMPLIANCE WITH THE APPROACH ON THE USE OF ADDITIVES IN FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN</p>
<p>Note: To be completed based on the discussion on parts (i) and (ii) of the PWG mandate</p>

<p>[Q3.1 Does the proposed food additive perform the same/similar purpose as other additives that have already been authorized for use in the same product category? If not, what is the justification for the need for an additive with a new functional class and/or technological purpose? If yes, what advantage(s) does the proposed additive provide over currently permitted options?]</p>
<p><i>Other additives with a similar technological function (thickener) are authorized for use by Codex STAN 72-1981 and corresponding GSFA food subcategory 13.1.3. These other permitted thickeners include carob bean gum (INS 410), carrageenan (INS 407), OSA-modified starch (INS 1450), guar gum (INS 412), and starch phosphates (INS 1412, 1413, and 1414).</i></p> <p><i>For advantages of the proposed additive over currently permitted options, refer to Q2.1 and the Annex to this Form.</i></p>
<p>[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?]</p>
<p><i>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.</i></p> <p><i>Thickeners, such as gellan gum, are required to ensure infant formula is homogenous and delivers the appropriate level of all essential nutrients.</i></p>
<p>[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?]</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>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.</i></p> <p><i>Additional information regarding the technological function of gellan gum is provided in NFSDU/39 CRD6.</i></p>
<p>[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?]</p>
<p> </p>
<p>[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?]</p>
<p> </p>

Appendix 2: Information from the applicant on the experimental trials with the candidate additives

INS 415 Xanthan gum

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. These data demonstrate that the use of xanthan gum in this product was critical for maintaining the consistency and texture in order to ensure safe and acceptable use.

Table: 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

Reconstituted powder infant formula after 20 hours

Figure: Extensively hydrolyzed protein formula samples (A1: control, A2: xanthan gum, A3: CITREM, A4: carrageenan)



Figure: Amino acid-based formula samples (B1: control, B2: xanthan gum, B3: CITREM, B4: carrageenan)



INS 440 Pectin

In this experiment, 5 batches of a concentrated liquid infant formula containing hydrolysed 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 the food additive pectin. The experimental additives were a variable with 20% less pectin, carob bean gum, carrageenan, or OSA-modified starch. Selection of alternative additives for this trial was made on the basis that each is an authorized Thickener by Codex Infant Formula Standard (72-1981), except pectin. The level of use for each was less than the maximum use specified in CXS 72-1981. All products were formulated to have the same pH, protein, carbohydrate, fat, and % solids.

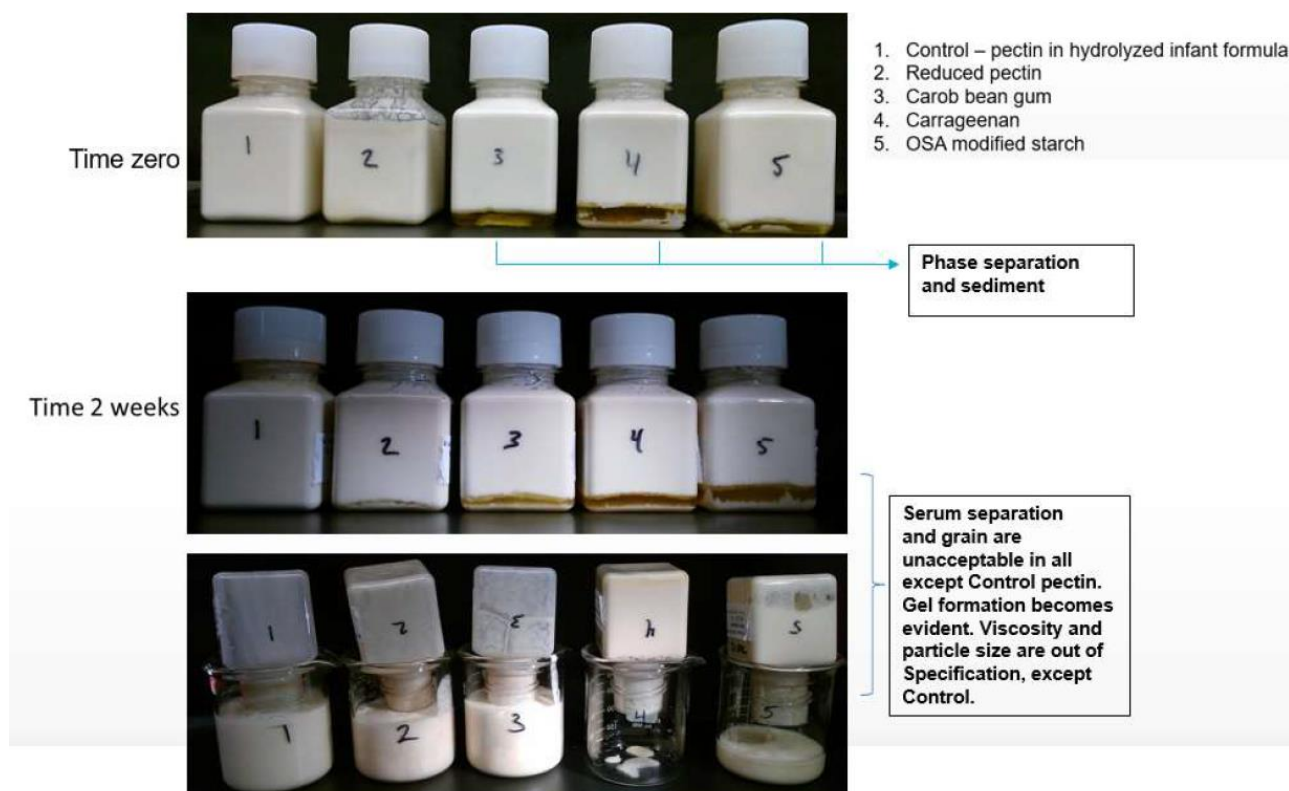
The original protocol included evaluations of formula performance at time zero (immediate poststerilization), 2 weeks, 1 month, 3 months and 6 months, at 250 C storage temperature. Outcomes measured included viscosity, pH, physical properties (sediment, gel, serum, grain etc.), and visual documentation of the outcomes.

Results are summarized in the photos (next page) for the 250 C series, starting with outcomes at time zero, followed by 2 weeks (2nd and 3rd panels of photos). The experiment was terminated after 1 month (not shown) due to product failure in all but the pectin control.

The samples containing carob bean gum, carrageenan, OSA-modified starch, and reduced level of pectin were not acceptable in overall quality after heat treatment by two weeks post-production. The latter experimental 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. After 1 month, all but the pectin control formed solid gels with entrapped air. These products were no longer fluid, and not acceptable for further use.

The experiment demonstrates 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 a given formula matrix.

Figure: Use of pectin as a thickener in FSMP formula



INS 418 Gellan Gum

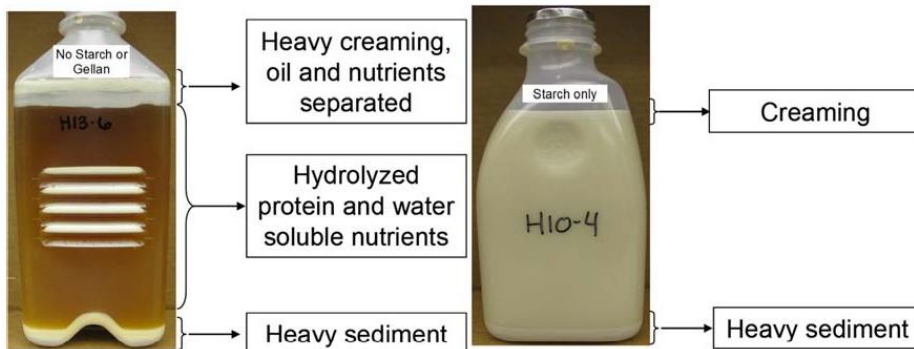
In this experiment, gellan gum and OSA-modified starch alone and in combination were evaluated in a concentrated liquid product made with an extensively hydrolyzed protein.

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.

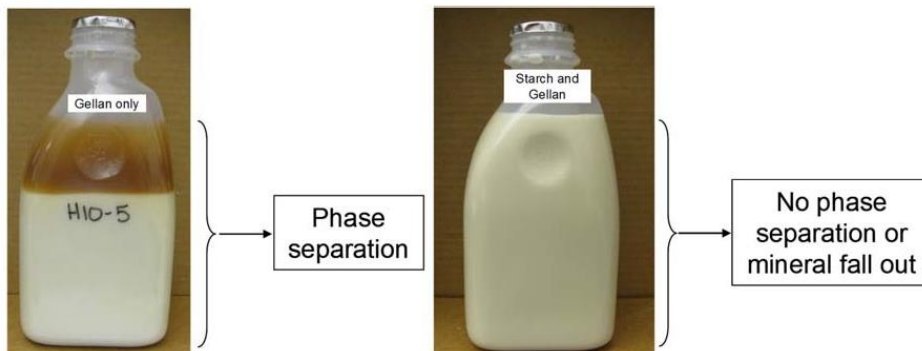
As annotated in the photos, heavy creaming, separation of oil and liquid phases, and sedimentation were observed in a control sample (top left) without either OSA-modified starch (INS 1450) or gellan gum (INS 418). When only OSA-modified starch was used (top right), the product had creaming and sedimentation. 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 after 24 hours, the consequences of the separation are still critical factors in maintaining the consistency and texture of these products in order to ensure safe and acceptable use.

Figure: Liquid infant formula with an extensively-hydrolyzed protein after 40 days

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



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



Appendix 3: Form for appraising the technological need for the use of additives in foods within the mandate of CCNFSDU (i.e. standardized or non-standardized foods following a request by CCFA)

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

Q3 COMPLIANCE WITH THE APPROACH ON THE USE OF ADDITIVES IN FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN
[...]
Note: To be completed based on the discussion on parts (i) and (ii) of the PWG mandate

Appendix 4: 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.

Q1 IDENTITY AND INTENDED USE

Is the INS number and/or (chemical) name of the substance provided? Is the use intended for foods within CCNFSDU responsibility? Is the use level(s) provided and justified? **(See Q1.1-1.3)**

No → Discard the proposal

Yes

Q2 COMPLIANCE WITH SECTION 3.2 OF THE GSFA PREAMBLE

Is the proposed use in compliance with all criteria of Section 3.2 of the Preamble to the GSFA? **(See Q2.1-2.4)**

No → Discard the proposal

Yes

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.

Q3 COMPLIANCE WITH THE APPROACH FOR INFANTS AND YOUNG CHILDREN

[to be completed with the consensual text on the question(s) within Q3 section, i.e. based on the discussion on parts (i) and (ii) of the PWG mandate]

Yes → Discard the proposal

No

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.