



**Food and Agriculture  
Organization of the  
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**World Health  
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**Agenda Item 9a**

**NFSDU/41 CRD 18**

**Original language only**

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

**Forty-first Session**

**Düsseldorf, Germany**

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### MECHANISM / FRAMEWORK FOR CONSIDERING TECHNOLOGICAL JUSTIFICATION OF FOOD ADDITIVES

*Comments by ISDI*

ISDI supports the ongoing efforts of the CCFNSDU committee to develop a framework for assessing the technological justification of food additives and thanks the WG chaired by the European Union and co-chaired by the Russian Federation for their work in preparing the Physical WG.

#### Mandate for Physical WG

Further Consider:

- i) the text in square brackets in the draft Framework (Appendix VIII of REP 19/NFSDU);
- ii) the questions under question Q3 in document CX/NFSDU 18/40/11
- 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 (See CX/NFSDU 18/40/11 Annex D).

ISDI Comments for parts (i) and (ii) of the Mandate for Physical WG are provided in the following section and the completed appraisal forms for part (iii) of the mandate, together with results of experimental trials for each of the 3 additives, are included in the latter part of this document.

#### **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 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?]

#### **ISDI Comment**

ISDI considers that Q3.1 as currently proposed is acceptable but general in nature and applicable to any food category where a new functional class were being proposed, and would not provide information unique for infants and young children. Information on the last question, "If yes, what advantage(s)...", is provided under Q2 in the framework and therefore is redundant in this Q3 question.

[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?]

#### **ISDI Comment**

It is not feasible or practical to compare products on the market in different parts of the world from different manufacturers due to multiple factors such as differences in sourcing of ingredients, manufacturing processes, trade secrets, shelf life considerations, recipes, product formats etc. This question may not be helpful as it will be difficult to objectively assess information provided. In addition, we consider that the answers to questions about technological necessity are provided in Q2.1 of the framework ("describe the technological function and the advantage conferred by its use").

[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?]
<b>ISDI Comment</b> “Suitability” may not be an appropriate criteria and could be wrongly interpreted as an assessment of safety which is the mandate of JECFA in its risk assessment role. Questions related to the technologically most suitable additive fall within the expertise of special dietary foods manufacturers and depend on ingredients, formulation, processing, packaging, product format, shelf life. This information would be provided in Q2.1 of the framework (“describe the technological function and the advantage conferred by its use”).
[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?]
<b>ISDI Comment</b> We note that Q3.2rev and (Q3.1&Q3.2rev) when combined together are essentially the same as Q3.1 in square brackets in Appendix VIII, Annex 2, REP19/NFSDU. Therefore this question Q3.2rev can be removed.
[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?]
<b>ISDI Comment</b> We note that Q3.2rev and (Q3.1&Q3.2rev) when combined together are essentially the same as Q3.1 in square brackets in Appendix VIII, Annex 2, REP19/NFSDU. Therefore this question Q3.1 and Q3.1 & Q2.3rev can be removed.

If the PWG participants agree that further specificity is desirable to distinguish the case for the use of additives in foods intended for young infants, ISDI considers that a question may be included to focus on the limited technological functions that are justified for use in foods for young infants.

The restrictions in place for young infants reflect the approach proposed by JECFA (1971), implemented by the Codex Alimentarius Commission, endorsed by the CCFA43 (2011) and reaffirmed by CCFNSDU38 (2016, see REP17/NFSDU, para 172) that “*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*”, based on physiological differences that make infants below 12 weeks of age different from the general population.

In the same report (JECFA, 1971), JECFA concludes that certain technological purposes are justified and accepted in foods for young infants (below 12 weeks of age) “to increase shelf life, ensure adequate sterilization by promoting homogenization, or maintain consistency and texture to ensure safe and acceptable use” (page 30) of the finished product through a technological function including: **emulsifier, stabilizer, thickener, antioxidant, acidity regulator, and packaging gases** (page 32-33).

Therefore, based on these principles of abundant caution, Q3 may be useful to confirm the technological purpose of additives used in foods for young infants.

ISDI suggests to consider the following question under Q3:

Q3.2 If used in foods for young infants,<sup>1</sup> does the proposed food additive increase shelf life, ensure adequate sterilization by promoting homogenization, or maintain consistency and texture to ensure safe and acceptable use of the finished infant formula product through a technological function limited to: emulsifier, stabilizer, thickener, antioxidant, acidity regulator and packaging gases? If not, does the justification for the need for an additive with a new functional class and/or technological purpose benefit the infant?

### ISDI Final Proposal Q3

#### **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 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?

<sup>1</sup> In line with the recommendations from FAO/WHO Meeting on Additives in Baby Foods, Rome, 14-16 June, 1971

**Q3.2** If used in foods for young infants does the proposed food additive increase shelf life, ensure adequate sterilization by promoting homogenization, or maintain consistency and texture to ensure safe and acceptable use of the finished infant formula product through a technological function limited to: emulsifier, stabilizer, thickener, antioxidant, acidity regulator and packaging gases? If not, does the justification for the need for an additive with a new functional class and/or technological purpose benefit the young infant?

### ISDI Comments on Decision Tree (Appendix 4 in CRD 8):

Finally, ISDI considers that the decision tree can be finalized subsequent to consensus on the framework.

### APPRAISAL FORMS FOR 3 ADDITIVES

In order for participants of the PWG to appraise the technological need for the proposed use of xanthan gum (INS 415), pectin (INS 440) and gellan gum (INS 418) ISDI provides in this CRD the completed appraisal forms for each of the 3 additives.

The appraisals for each additive have been updated slightly from CX/NFSDU 18/40/11 Annex D, taking into account feedback from EWG members prior to CCNFSDU 40, and using the updated Framework criteria agreed by the Committee at CCNFSDU40, per Appendix VIII of the final report.

### JECFA Safety Assessments

As the PWG considers the technological justifications for the three additives, it is necessary to separate the evaluation of technological function from the considerations of the safety evaluations of those additives.

For reference if needed, the following table provides information on the finalized JECFA safety assessments for the 3 additives that are currently subject to assessment of technological justification. JECFA considered the use of each additive using cautionary criteria applicable to additives used in foods for young infants (<12 weeks) with the specified conditions of use as noted in the table.

Additive	INS	JECFA Safety Assessment	JECFA Conclusion
Xanthan gum	415	82 <sup>nd</sup> JECFA Meeting, 2016	“the consumption of xanthan gum in infant formula or formula for special medical purposes intended for infants is of no safety concern at the maximum proposed use level of 1000 mg/L”
Pectin	440	82 <sup>nd</sup> JECFA Meeting, 2016	“the use of pectin at 0.2% in infant formula indicate low risk for the health of infants and are not of concern”
Gellan gum	418	87 <sup>th</sup> JECFA Meeting, 2019	“the use of gellan gum in formulas for special medical purposes for infants and liquid fortification products for addition to human milk or infant formula at a maximum level of 50 mg/L in the fed product indicates low risk for the health of infants, including preterm infants, and that its proposed use is therefore of no safety concern”

When technological justification for xanthan gum, pectin, and gellan gum are confirmed the following proposals can be brought to the Committee:

#### Xanthan gum (INS 415)

- Recommend the Committee to confirm adequate technological justification based on the rationale provided according to the agreed Framework;
- Recommend the Committee provide a reference to CCFA to amend the GSFA with addition of xanthan gum to Food Category 13.1.3, Formula for special medical purposes (FSMP) for infants, for use as a thickener up to 0.1 g/100 mL (ready-to-consume) in powdered hydrolyzed protein- and/or amino acid-based formula

#### Pectin (INS 440)

- Recommend the Committee to confirm adequate technological justification based on the rationale provided according to the agreed Framework;
- Recommend the Committee provide a reference to CCFA to amend the GSFA with addition of pectin

to the GSFA for Food Category 13.1.3, Formula for special medical purposes (FSMP) for infants, for use as a thickener up to 0.2 g/100 mL (ready-to-consume) in liquid hydrolyzed protein infant formula.

Gellan gum (INS 418)

- Recommend the Committee to confirm adequate technological justification based on the rationale provided according to the agreed Framework;
- Recommend the Committee provide a reference to CCFA to amend the GSFA with addition of gellan gum to Food Category 13.1.3, Formula for special medical purposes (FSMP) for infants, for use as a thickener up to 0.005 g/100 mL (ready-to-consume) in liquid hydrolyzed protein- and/or amino acid-based formula

ISDI has prepared Annex II for each of Pectin, Xanthan gum, and Gellan gum, according to REP19/NFSDU Appendix VIII, the final outcomes from CNFSDU40. These update the information submitted by the applicant in CX/NFSDU 18/40/11 Annex D (Form for appraising technological need).

## XANTHAN GUM (INS 415)

### Annex II

#### FORM FOR APPRAISING THE TECHNOLOGICAL NEED FOR THE USE OF ADDITIVES IN FOODS WITHIN THE MANDATE OF CCNFSDU<sup>2</sup>

<b>THE PROPOSAL IS SUBMITTED BY:</b>		ISDI ( <i>International Special Dietary Foods Industries</i> )
<b>1 IDENTITY AND INTENDED USE</b>		
<b>Q1.1 Name and INS Number of the Additive as listed in CAC/GL 36-1989:</b> <i>For substances not yet included in CAC/GL 36-1989, chemical name of the substance.</i>		Xanthan Gum (INS 415)
<b>Q1.2 Describe the food form (e.g. liquid, powder) for which the additive is intended to be used and indicate the relevant CCNFSDU standard and if known the GSFA food subcategory</b>		
<b>CCNFSDU standard</b>		
<b>Reference</b>	<b>Name of the standard</b>	<b>Comments (e.g. limitation of use to specific food forms)</b>
72-1981	Standard for infant formula and formulas for special medical purposes intended for infants	Limited to powdered hydrolysed protein and/or amino acid-based formula
<b>GSFA food category</b>		
<b>Food category No</b>	<b>Name of the GSFA food category</b>	
13.1.3	Formulae for special medical purposes for infants	
<b>Q1.3 Indicate and justify the range of the proposed use level of the food additive needed to accomplish the desired technological effect at the lowest possible use level</b>		
<b>Proposed use level (per 100 mL in final product as consumed)</b>	<b>Justification of the level(s) proposed</b>	
0.1 g/100 mL	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.	
<b>2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA</b>		
<b>Q2.1 Describe the technological function of the food additive relative to the CAC/GL 36-1989 (include the functional class) and the advantage conferred by its use</b>		
<p><i>Technological function</i></p> <p>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.</p> <p>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:</p> <p>Functional class: thickener (“a food additive which increases the viscosity of a food”)</p>		

<sup>2</sup> Standardized foods or non-standardized foods following a request by CCFA (REP 19/NFSDU)

<p>Technological purpose: thickener</p> <p>AND</p> <p>Functional class: stabilizer (“a food additive which makes it possible to maintain a uniform dispersion of two or more components”)</p> <p>Technological purpose: emulsion stabilizer</p> <p><i>Advantage from its use</i></p> <p>Commercially acceptable Infant formulas based on extensively hydrolyzed proteins or amino acids cannot be safely manufactured without the use of additives. Compared to intact proteins, hydrolyzed proteins are not as effective in creating or maintaining a stable emulsion. Development of physically stable nutritional products based on hydrolyzed proteins is further challenged when high levels of insoluble ingredients, like mineral salts, are incorporated. These characteristics can result in mineral fallout (resulting in sedimentation) and defects in emulsion stability (which results phase separation). These issues in turn can result in significant challenges to both manufacturing of these products and the optimal delivery of nutrition for infants consuming these products. Thickeners, such as xanthan gum, are required to ensure infant formula is homogenous and delivers the appropriate level of all essential nutrients.</p> <p>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.</p> <p>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.</p>
<p><b>Q2.2 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? Indicate which one(s)</b></p>
<p>Xanthan gum meets several of the needs described in Section 3.2 of the Preamble of the GSFA:</p> <p><i>b) To provide necessary ingredients or constituents of foods manufactured for groups of consumers having special dietary needs</i></p> <p>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)</p> <p><i>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</i></p> <p>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.</p> <p><i>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.</i></p> <p>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</p>

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.

**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 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.

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.

**Q2.4 Would the use of this food additive in the intended food(s) modify any characteristic of the food that might mislead the consumer?**

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).

**3 COMPLIANCE WITH THE APPROACH ON THE USE OF ADDITIVES IN FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN<sup>3</sup>**

**[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 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).

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

<sup>3</sup> From REP 19/NFSDU Q3.1 remains in square brackets, for further discussion and finalization in the November 2019 pWG. Therefore the response provided by the applicant in this document is based on the Q3.1 in square brackets and shall be modified as needed to address the final text as recommended by the pWG and confirmed by the Committee.

**ANNEX – XANTHAN GUM EXPERIMENTAL TRIAL**

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 1: Viscosity with different additives and product matrices

<b>Table 1. Viscosity with different additives</b>			
<b>Sample ID</b>	<b>Matrix</b>	<b>Additive</b>	<b>Viscosity (cps)</b>
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 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)



**PECTIN (INS 440)****Annex II****FORM FOR APPRAISING THE TECHNOLOGICAL NEED FOR THE USE OF ADDITIVES IN FOODS WITHIN THE MANDATE OF CCNFSDU<sup>4</sup>**

<b>THE PROPOSAL IS SUBMITTED BY:</b>		<i>ISDI (International Special Dietary Foods Industries)</i>
<b>1 IDENTITY AND INTENDED USE</b>		
<b>Q1.1 Name and INS Number of the Additive as listed in CAC/GL 36-1989:</b> <i>For substances not yet included in CAC/GL 36-1989, chemical name of the substance.</i>		<i>Pectin (INS 440)</i>
<b>Q1.2 Describe the food form (e.g. liquid, powder) for which the additive is intended to be used and indicate the relevant CCNFSDU standard and if known the GSFA food subcategory</b>		
<b>CCNFSDU standard</b>		
<b>Reference</b>	<b>Name of the standard</b>	<b>Comments (e.g. limitation of use to specific food forms)</b>
<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>
<b>GSFA food category</b>		
<b>Food category No</b>	<b>Name of the GSFA food category</b>	
<i>13.1.3</i>	<i>Formulae for special medical purposes for infants</i>	
<b>Q1.3 Indicate and justify the range of the proposed use level of the food additive needed to accomplish the desired technological effect at the lowest possible use level</b>		
<b>Proposed use level (per 100 mL in final product as consumed)</b>		<b>Justification of the level(s) proposed</b>
<i>Up to 0.2 g/100 mL</i>		<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>
<b>2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA</b>		
<b>Q2.1 Describe the technological function of the food additive relative to the CAC/GL 36-1989 (include the functional class) and the advantage conferred by its use</b>		
<i>Technological function</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.		
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:		
<u>Functional class:</u> thickener (“a food additive which increases the viscosity of a food”)		

<sup>4</sup> Standardized foods or non-standardized foods following a request by CCFA (REP 19/NFSDU)

Technological purpose: thickener

AND secondarily, pectin also has the following technological function in this product application:

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 its use*

- 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 builds viscosity in the liquid product, prevents separation of the emulsion, and avoids sedimentation of added nutrients/ingredients particularly insoluble minerals.
- 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.
- 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 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? 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 food additive in the intended food(s) modify any characteristic of the food that might mislead the consumer?**

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 build viscosity and 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).

**3 COMPLIANCE WITH THE APPROACH ON THE USE OF ADDITIVES IN FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN<sup>5</sup>**

**[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?]**

<sup>5</sup> From REP 19/NFSDU Q3.1 remains in square brackets, for further discussion and finalization in the November 2019 pWG. Therefore the response provided by the applicant in this document is based on the Q3.1 in square brackets and shall be modified as needed to address the final text as recommended by the pWG and confirmed by the Committee.

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.

**ANNEX – PECTIN EXPERIMENTAL TRIAL**

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 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 documentation of the outcomes.

Results are summarized in the photos (next page) for the 25° C series, starting with outcomes at time zero, followed by 2 weeks (2<sup>nd</sup> and 3<sup>rd</sup> 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.



**ANNEX – PECTIN (INS 440) EXPERIMENTAL TRIAL**

Experiment using Pectin, a thickener in FSMP formula

Time zero



Time 2 weeks





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

Phase separation and sediment

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.

**GELLAN GUM (INS 418)****Annex II****FORM FOR APPRAISING THE TECHNOLOGICAL NEED FOR THE USE OF ADDITIVES IN FOODS WITHIN THE MANDATE OF CCNFSDU<sup>6</sup>**

<b>THE PROPOSAL IS SUBMITTED BY:</b>		<i>ISDI (International Special Dietary Foods Industries)</i>
<b>1 IDENTITY AND INTENDED USE</b>		
<b>Q1.1 Name and INS Number of the Additive as listed in CAC/GL 36-1989:</b> <i>For substances not yet included in CAC/GL 36-1989, chemical name of the substance.</i>		<i>Gellan Gum (INS 418)</i>
<b>Q1.2 Describe the food form (e.g. liquid, powder) for which the additive is intended to be used and indicate the relevant CCNFSDU standard and if known the GSFA food subcategory</b>		
<b>CCNFSDU standard</b>		
<b>Reference</b>	<b>Name of the standard</b>	<b>Comments (e.g. limitation of use to specific food forms)</b>
<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>
<b>GSFA food category</b>		
<b>Food category No</b>	<b>Name of the GSFA food category</b>	
<i>13.1.3</i>	<i>Formulae for special medical purposes for infants</i>	
<b>Q1.3 Indicate and justify the range of the proposed use level of the food additive needed to accomplish the desired technological effect at the lowest possible use level</b>		
<b>Proposed use level (per 100 mL in final product as consumed)</b>	<b>Justification of the level(s) proposed</b>	
<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>	
<b>2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA</b>		
<b>Q2.1 Describe the technological function of the food additive relative to the CAC/GL 36-1989 (include the functional class) and the advantage conferred by its use</b>		
<p><i>Technological function</i></p> <p>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.</p> <p>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:</p> <p>Functional class: thickener (“a food additive which increases the viscosity of a food”)</p> <p>Technological purpose: thickener</p> <p>AND</p> <p>Functional class: stabilizer (“a food additive which makes it possible to maintain a uniform dispersion of two or more components”)</p> <p>Technological purpose: emulsion stabilizer</p> <p><i>Advantage from its use</i></p>		

<sup>6</sup> Standardized foods or non-standardized foods following a request by CCFA (REP 19/NFSDU)

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. 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.

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 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? 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)

- 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

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.

- 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.

**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 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.

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.

**Q2.4 Would the use of this food additive in the intended food(s) modify any characteristic of the food that might mislead the consumer?**

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 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).

**3 COMPLIANCE WITH THE APPROACH ON THE USE OF ADDITIVES IN FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN<sup>7</sup>**

**[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 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).

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

**ANNEX – GELLAN GUM EXPERIMENTAL TRIAL**

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.

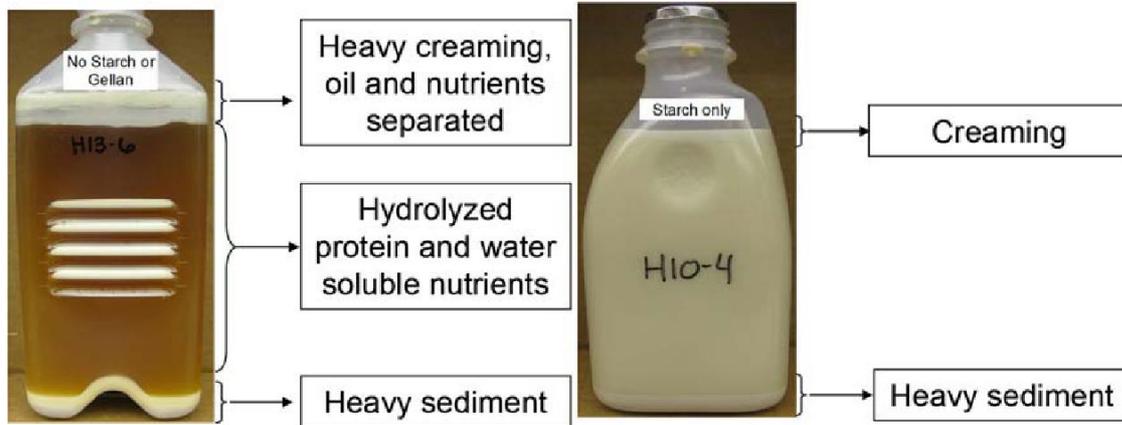
As annotated in the photos, heavy creaming, separation of oil and liquid phases, and sedimentation were observed in a control sample (top left) without either OSA-modified starch (INS 1450) or gellan gum (INS 418). When only OSA-modified starch was used (top right), the product had creaming and sedimentation. When only gellan gum was used (bottom left), the product had phase separation. However, when OSA

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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.

**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

