CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 10 **NFSDU/40 CRD 13**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Fortieth Session

Berlin, Germany
26 – 30 November 2018

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

Comments of ISDI

ISDI – International Special Dietary Foods Industries

ISDI thanks the eWG chaired by the European Union and co-chaired by the Russian Federation for this discussion paper on the 'Mechanism/Framework for Considering Technological Justification for Food Additives' (CX/NFSDU 18/40/11).

ISDI continues to support the development of a systematic approach to enable CCNFSDU to consider the technological justification for food additives prior to submitting a request for JECFA priority list.

Herein we provide General Comments to the agenda paper; Simplified Framework for Technological Justification (Annex I); Technological Justification for xanthan gum, pectin, gellan gum (Annex II).

General Comments

1. ISDI supports to confirm an in-session WG at CCNFSDU, open to all delegates. Given the 3 Recommendations in the agenda paper (NFSDU 18/40/11), related to 1) the Process, 2) the Criteria, and 3) checking technological need for the additives xanthan gum, pectin, and gellan gum, we consider it would be very helpful to discuss some aspects in an in-session WG and bring recommendations to the plenary, with the aim to finalize the work at this session.

2. Regarding the Framework or criteria for considering technological justification, ISDI appreciates that the agenda paper summarizes all inputs from the EWG. However, in presenting all possible options brought forward by EWG members, the Framework (Annex B) has become more complex now. ISDI is therefore concerned that it will be extremely challenging for the Committee to work through the abundant options toward a final and simplified set of criteria. We suggest that a starting point for the framework discussion must go one step further and present a compromise, simplified framework, taking into consideration the comments from the EWG. ISDI-suggested framework is provided in Annex to these Comments. We consider this framework to be simplified and clear while addressing the critical points related to technological justification.

3. ISDI strongly urges the Committee to confirm technological justification of the 3 additives (pectin, xanthan gum, gellan gum) at this session, in spite of not yet achieving consensus on the criteria and process, for the following reasons:

    - Complete technological rationale has been provided to the CCNFSDU EWG on 2 occasions (2017, 2018), as part of the JECFA safety assessments for xanthan gum and pectin (82nd JECFA, 2016), and to the CCNFSDU Committee on 3 occasions thus far:
        - CCNFSDU 2016, Hamburg, CRD 11 (xanthan gum, pectin)
        - CCNFSDU 2017, Berlin, CRD 6 (xanthan gum, pectin, gellan gum)
        - CCNFSDU 2018, Berlin, present CRD (xanthan gum, pectin, gellan gum)
    - Though the final framework has not been agreed, we anticipate there will not be more rigorous criteria than already addressed in the above versions provided to the Committee
    - These 3 additives are *currently used* in FSMP formulas in international markets, having regulatory acceptance by some national authorities; exclusion of the additives in Codex standards without sound scientific basis fosters international trade barriers.

- Further impact of delaying progress may be a direct effect on infants with special medical needs in countries that do not have access to certain FSMP formulas that are available in other countries around the world; this can lead to differences in levels of care in infant nutrition and health outcomes.

- 2 of the additives have had recent JECFA safety assessment for use in infant foods (xanthan gum, pectin; 82nd JECFA), with an outcome of no safety concern for the applicable conditions of use; 1 additive is on JECFA priority list for safety assessment for use in foods for young infants (gellan gum) with a call for data due 1 December 2018, supporting review by JECFA in 2019

- In the case of xanthan gum and pectin, the Committee had already endorsed technological justification for these according to the then-accepted way of confirming technological need (e.g.REP15/NFSDU Appendix VI , Bali, 2014), before requesting JECFA safety assessment. Thus, according to the prevailing Committee practices at the time, xanthan gum and pectin had satisfied the requirements and moved through the process for 1) technological rationale and 2) safety, and should not be subject to further delays by new work that started *after* the Committee had agreed for these additives to proceed.

In conclusion, ISDI considers that progress on the 3 additives should proceed at this session, and requests the following:

Xanthan gum (INS 415)

- Request CCNFSDU to confirm adequate technological justification based on the rationale provided to this Committee.
- Considering the JECFA safety assessment has been completed, recommend to CAC to include xanthan gum (INS 415) in the infant formula standard (CX STAN 72-1981), Section B, as a thickener up to 0.1 g/100 mL (ready-to-consume) in powdered hydrolyzed protein and/or amino acid based formula only
- Request CCNFSDU to 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.

Pectin (INS 440)

- Request CCNFSDU to confirm adequate technological justification based on the rationale provided to this Committee
- Considering the JECFA safety assessment has been completed, recommend to CAC to include pectin (INS 440) in the infant formula standard (CX STAN 72-1981), Section B, as a thickener up to 0.2 g/100 mL (ready-to-consume) in infant formula, liquid only.
- Request CCNFSDU to 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.

Gellan gum (INS 418)

- Request CCNFSDU to confirm adequate technological justification based on the rationale provided to this Committee

4. We note the proposed expanded usage for the technological justification framework in the agenda paper which identifies additional scenarios where the framework may be useful (footnote 3 on page 2 of the agenda paper). While ISDI supports expanding the use of the new criteria on technological justification where it makes sense, we are very concerned that the new concepts introduced at this stage of the work, may be expected to lead to additional time spent discussing the points, resulting in further delays to complete the work under the original terms of reference. Therefore, ISDI suggests to focus on the original mandate at this session before considering the expanded usage as suggested in the agenda paper.

Annex I

1 Simplified Framework for Considering Technological Justification of Food Additives (ISDI)

Q1 ELIGIBILITY, INTENDED USE, TECHNOLOGICAL EFFECT

Q1.1 Is Name of substance and INS number as listed in CAC/GL 36-1989 provided? For substances not listed in CAC/GL 36-1989, is the chemical name of the substance provided?

Q1.2 Is the food for which the additive is intended to be used covered by a relevant CCNFSDU standard?

Q1.3 What is the proposed use level(s) of the food additive needed to accomplish the desired technological effect? Is information provided on the technological effect of the additive?

Q2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA

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

Q3 COMPLIANCE WITH THE APPROACH ON THE USE OF ADDITIVES IN FOODS INTENDED FOR INFANTS (CODEX STAN 72-1981)

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?

ISDI has prepared Annex II for Xanthan gum, Pectin, and Gellan gum, according to the original EWG proposal. We note that comments from the EWG to modify certain questions, and simplify the entire Framework would help avoid repetition of information in this form, however, since the Committee has not reached consensus on the criteria, we have not reflected the suggested improvements at this time. Clarifications requested by EWG members regarding xanthan gum and pectin are shown at the start of each form for the respective additive.

Annex II

FORM FOR THE SUBMISSION OF PROPOSALS FOR FOOD ADDITIVES TO BE PLACED ON THE JECFA PRIORITY LIST FOR THEIR USE IN FOODS WITHIN CCNFSDU MANDATE

XANTHAN GUM

Clarification Requested by EWG members: Xanthan Gum (INS 415)

- Approval is only needed for powdered products, CL has been updated
- Authorization of up to 1000 mg/kg (0.1 g/100 mL ready-to-consume) has been requested. This accounts for the need for specific product conditions that necessitate higher concentrations, as well as consideration for manufacturing variability. The requested value of 0.1 g/100 mL ready-to-consume is similar to authorizations in many countries, such as in the European Union (where it is authorized up to 0.12 g/100 mL ready-to-consume) and the products marketed in those countries that require these concentrations for technological reasons. The JECFA evaluation of xanthan gum for infants under 12 weeks of age concluded that there were no safety concerns with use of xanthan gum up to 0.1 g/100 mL ready-to-consume in infant formula.
- Other comments from EWG members were related to the conclusions from the safety evaluation conducted by JECFA. These comments are not addressed below, as they are outside the scope of the technological evaluation.

THE PROPOSAL IS SUBMITTED BY:	*ISDI (International Special Dietary Foods Industries)*
1 ELIGIBILITY AND INTENDED USE	
Q1.1 Name and INS Number of the Additive: *(as listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989)* *For substances not yet included in CAC/GL 36-1989 name of the substance*	*Xanthan Gum (INS 415) (CAC/GL 36-1989)* *Meets Codex definition of food additive (STAN 192-1995)* *Specifications; JECFA 53rd meeting, 1999* *JECFA Specification for INS 415* *ADI: "not specified"*

and justification that the substance meets the Codex definition of a food additive. *Reference to the existing or proposed specifications.*	*JECFA concluded that the consumption of xanthan gum in infant formula or formula for special medical purposes intended for infants is of no safety concern at a use level of 1000 mg/L.*

XANTHAN GUM

Q1.2 Relevant CCNFSDU standard and GSFA food category

CCNFSDU standard

Reference	**Name of the standard**	**Comments (e.g. limitation of use to specific products)**
72-1981	*Standard for infant formula and formulas for special medical purposes intended for infants*	*Limited to powdered hydrolysed protein and/or amino acid-based formula*

GSFA food category

Food category No	**Name of the GSFA food category**
13.1.3	*Formulae for special medical purposes for infants*

Q1.3 Lowest level(s) necessary for accomplishing the desired technological effect

Lowest level(s) in mg/kg in the final product as consumed	**Justification of the level(s) proposed**
0.1 g/100 mL, ready-to-consume	*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.*

2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA

Q2.1 Justification of an advantage from the use of an additive

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

Q2.2 Justification that the use does not mislead consumer

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

XANTHAN GUM

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

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

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

Technological purpose: thickener

AND

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

Technological purpose: emulsion stabilizer

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

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

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

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

c) To enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer

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

d) To provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities.

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

XANTHAN GUM

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

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.

From an economic perspective, manufacturers often create proprietary protection around the use of specific additives. This proprietary protection prevents competition in certain product categories in some markets by preventing competitors from marketing products with currently authorized additives. In these situations, the only option that manufacturers have in terms of working around proprietary protection is by formulating products with novel additives in the same functional class that are not covered by proprietary protection. While proprietary protection can represent a challenge to manufacturers, this has the beneficial consequence of stimulating innovation in the use of additives which in turn can lead to the development of more effective additive systems.

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

Q3.1 Information whether the same food is currently available without the additive or other additive having the same/similar technological effect and why the use of the additive is necessary if it was the case.

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.
Q3.2 Information whether there is other food additive performing the same/similar technological effect which [is more suitable/ has already been approved] for use in foods for infants and young children.
While other additives with a similar technological function are authorized for use in this product category, due to differences in manufacturing process (e.g. spray dried vs. dry blend), ingredients (e.g. intact vs. hydrolyzed protein), and product format (e.g. powder vs. liquid), a variety of additives are needed to allow for the most appropriate food additive use for each product. 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. Additional information regarding the technological function of xanthan gum is provided in NFSDU/39 CRD6.

ISDI has prepared Annex II for Xanthan gum, Pectin, and Gellan gum, according to the original EWG proposal. We note that comments from the EWG to modify certain questions, and simplify the entire Framework would help avoid repetition of information in this form, however, since the Committee has not reached consensus on the criteria, we have not reflected the suggested improvements at this time. Clarifications requested by EWG members regarding xanthan gum and pectin are shown at the start of each form for the respective additive.

Annex II

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PECTIN

Clarification Requested by EWG members: Pectin (INS 440)

- Pectin is intended to be used in liquid formulations only
- Pectin acts in an acidified environment as a thickener and stabilizer for hydrolysed protein-based infant formula, whose technological function is 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.
- Other comments from EWG members were related to the conclusions from the safety evaluation conducted by JECFA. These comments are not addressed below, as they are outside the scope of the technological evaluation

THE PROPOSAL IS SUBMITTED BY:	*ISDI (International Special Dietary Foods Industries)*
1 ELIGIBILITY AND INTENDED USE	
Q1.1 Name and INS Number of the Additive: *(as listed in Class Names and the*	*PECTIN (INS 440) (CAC/GL 36-1989)* *Meets Codex definition of food additive (STAN 192-1995)*

International Numbering System (INS) - CAC/GL 36-1989) *For substances not yet included in CAC/GL 36-1989 name of the substance and justification that the substance meets the Codex definition of a food additive.* *Reference to the existing or proposed specifications.*	*Specifications; JECFA 82nd meeting, 2016* *http://www.fao.org/3/a-bq695e.pdf* *ADI: "not specified"* *JECFA concluded that the intake of pectin in infant formula and formula for special medical purposes intended for infants is of no safety concern at the maximum proposed use level of 0.2% (0.2 g/100mL) ready to consume in infant formula. (JECFA 82nd meeting, 2016)*

Q1.2 Relevant CCNFSDU standard and GSFA food category

CCNFSDU standard

Reference	**Name of the standard**	**Comments (e.g. limitation of use to specific products)**

PECTIN

STAN 72-1981	*Standard for infant formula and formulas for special medical purposes intended for infants*	*Liquid infant formula containing hydrolysed protein*

GSFA food category

Food category No	**Name of the GSFA food category**
FC 13.1.3	Formulae for special medical purposes for infants

Q1.3 Lowest level(s) necessary for accomplishing the desired technological effect

Lowest level(s) in mg/kg in the final product as consumed	**Justification of the level(s) proposed**
0.2 g per 100 mL, (ready-to-consume)	*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 have not been shown in experimental trials to provide the needed technical effect*

2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA

Q2.1 Justification of an advantage from the use of an additive

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

specialized formula based on hydrolyzed protein and manufactured under pH conditions less than neutral

Q2.2 Justification that the use does not mislead consumer

PECTIN

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

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

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

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

Technological purpose: thickener, and

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

Technological purpose: emulsion stabilizer

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

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

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

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

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

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 functions as a thickener (increases viscosity) and stabilizer (maintains uniform dispersion) in this hydrolysed protein formula for special medical purposes. These technological functions are critical to achieve and maintain homogeneity of the constituents of the formula and thus the consistent and effective delivery of the product and all nutrients contained therein.

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-consumed not meeting the nutrient requirements defined in the Codex Standard (72-1981) nor the nutrient needs of infant patients. Ingredients, manufacturing, processing, preparation, packaging, transport and post market monitoring of formulas for infants comply with rigorous safety and quality standards which are not compromised in any way due to the use of food additive ingredients.

Q2.5Justification that the objectives set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA cannot be achieved by other means that are economically and technologically practicable
The objectives set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA, as related to the use of pectin in the manufacture of hydrolysed protein formula for special medical purposes, cannot be achieved by other means that are economically and technologically practicable. Commercially acceptable infant formulas based on hydrolyzed proteins cannot be safely manufactured without the use of additives, and in the case of this product that is manufactured under pH conditions slightly less than neutral, pectin has been demonstrated to provide uniquely effective technical effects to achieve a stable, homogeneous formula with acceptable physical properties.
3 COMPLIANCE WITH THE APPROACH ON THE USE OF ADDITIVES IN FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN
Q3.1 Information whether the same food is currently available without the additive or other additive having the same/similar technological effect and why the use of the additive is necessary if it was the case.
Commercially acceptable infant formulas based on hydrolyzed proteins cannot be safety 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 Information whether there is other food additive performing the same/similar technological effect which [is more suitable/ has already been approved] for use in foods for infants and young children.
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.

ISDI has prepared Annex II for Xanthan gum, Pectin, and Gellan gum, according to the original EWG proposal. We note that comments from the EWG to modify certain questions, and simplify the entire Framework would help avoid repetition of information in this form, however, since the Committee has not reached consensus on the criteria, we have not reflected the suggested improvements at this time. Clarifications requested by EWG members regarding xanthan gum and pectin are shown at the start of each form for the respective additive.

Annex II

FORM FOR THE SUBMISSION OF PROPOSALS FOR FOOD ADDITIVES TO BE PLACED ON THE JECFA PRIORITY LIST FOR THEIR USE IN FOODS WITHIN CCNFSDU MANDATE

GELLAN GUM

Clarification Requested by EWG members: Gellan Gum (INS 418)

- Approval is only needed for liquid products, CL has been updated
- Other comments from EWG members were related to the safety evaluation that will be conducted by JECFA in 2019. These comments are not addressed below, as they are outside the scope of the technological evaluation.

THE PROPOSAL IS SUBMITTED BY:	*ISDI (International Special Dietary Foods Industries)*

1 ELIGIBILITY AND INTENDED USE	
Q1.1 Name and INS Number of the Additive: *(as listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989)* *For substances not yet included in CAC/GL 36-1989 name of the substance and justification that the substance meets the Codex definition of a food additive.* *Reference to the existing or proposed specifications.*	*Gellan Gum (INS 418) (CAC/GL 36-1989)* *Meets Codex definition of food additive (STAN 192-1995)* *Specifications; JECFA 79th meeting, 2014* *JECFA Specification for INS 418* *ADI: "not specified"* *JECFA has reviewed gellan gum for the general population and has issued a call for data so that it can be considered during the 2019 JECFA meeting specifically for infants under 12 weeks of age.*

Q1.2 Relevant CCNFSDU standard and GSFA food category

CCNFSDU standard

Reference	**Name of the standard**	**Comments (e.g. limitation of use to specific products)**
72-1981	*Standard for infant formula and formulas for special medical purposes intended for infants*	*Limited to liquid hydrolysed protein and/or amino acid-based formula*

GSFA food category

GELLAN GUM

Food category No	**Name of the GSFA food category**
13.1.3	*Formulae for special medical purposes for infants*

Q1.3 Lowest level(s) necessary for accomplishing the desired technological effect

Lowest level(s) in mg/kg in the final product as consumed	**Justification of the level(s) proposed**
0.005 g/100 mL, ready-to-consume	*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.*

2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA

Q2.1 Justification of an advantage from the use of an additive

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.

Q2.2 Justification that the use does not mislead consumer

Products containing gellan gum in the formulation would identify this additive in the list of ingredient, providing transparency to consumers. The technological purpose for the addition of this additive is to maintain homogeneity of the product, and does not conceal damage or inferiority, or make the product appear to be greater than actual value.

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

Codex sets out functional class and technological purpose for additives in CAC/GL 36-1989. In the case of 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

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

GELLAN GUM

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).

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

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.

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.

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

Q3.1 Information whether the same food is currently available without the additive or other additive having the same/similar technological effect and why the use of the additive is necessary if it was the case.

GELLAN GUM

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

Q3.2 Information whether there is other food additive performing the same/similar technological effect which [is more suitable/ has already been approved] for use in foods for infants and young children.

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

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

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