CODEX ALIMENTARIUS COMMISSION E

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World Health Organization

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Agenda Item 9a **NFSDU/41 CRD 44**

Original language only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Forty-first Session

Düsseldorf, Germany

24 - 29 November 2019

MECHANISM / FRAMEWORK FOR CONSIDERING TECHNOLOGICAL JUSTIFICATION OF FOOD ADDITIVES

Comments by ISDI

ISDI thanks the Chairs and the participants of the Physical Working Group on the Framework for Technological Justification for the progress made in the session held November 23, 2019 on each of the mandates of the PWG.

(i) In particular, ISDI notes that consensus was reached on the first two items: the text in square brackets (Appendix VIII, Annex 2, REP19/NFSDU), and

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

ISDI encourages CCNFSDU to adopt the recommendations of the Physical Working Group and is providing in the below the additional information requested by some delegations on Gellan gum to facilitate the progresses on this agenda item.

Xanthan Gum (INS 415) and Pectins (INS 440)

ISDI also welcomes the conclusions of the physical working group confirming the technological function of both xanthan gum (INS 415) and pectins (INS 440), for the following uses under Codex Standard 72-1981:

INS	Additive	Maximum level in 100 mL of the product ready for consumption
4.1 Thickeners		
415	Xanthan gum	0.1 g/100 mL in powdered formula containing hydrolysed protein and/or amino acids
440	Pectins	0.2 g/100 mL in liquid formula containing hydrolysed protein

With the confirmation of the technological function of these additives by the Physical Working Group, together with the conclusions by JECFA in their 82nd meeting (2016, table below), ISDI encourages the committee at the Plenary to consider the following recommendations under Agenda Item 9a:

Xanthan gum (INS 415)

- 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 formula containing hydrolysed protein and/or amino acids
- Provide a reference to CCFA to amend the GSFA with the addition of xanthan gum to Food Category 13.1.3, Formula for Special Medical Purposes (FSMP) for infants

Pectin (INS 440)

- Recommend to CAC to include pectins (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 liquid formula containing hydrolysed protein
- Provide a reference to CCFA to amend the GSFA with the addition of pectins to Food Category 13.1.3,

Formula for Special Medical Purposes (FSMP) for infants

Additive	INS	JECFA Safety Assessment	JECFA Conclusion
Xanthan gum	415	82nd 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	82nd 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 (INS 418)

ISDI appreciates the opportunity for continued discussion on the technological function of gellan gum (INS 418). During the Physical Working Group Codex members raised the following additional questions for clarification regarding gellan gum:

1. Identity of the type of gellan gum under consideration
2. Explain how these technological challenges are addressed in countries where gellan gum has not been authorized for these products
3. Discuss whether other additives were considered as alternatives to gellan gum
4. Provide more details about the use of both gellan gum (INS 418) and OSA-modified starch (INS 1450) in the product example provided in NFSDU/41 CRD18
5. Clearly respond to the new language for Q3 adopted in the Physical Working Group

Identity of the type of gellan gum under consideration

ISDI would like to clarify that the type of gellan gum described in the information provided to the committee in NFSDU/41 CRD 18, and the gellan gum ingredient used in manufacturing, applies to **low acyl, clarified gellan gum** (INS 418). Thus, the technological function being considered at CCNFSDU applies to the same type of gellan gum that was the subject of the safety assessment in the 87th JECFA meeting (2019, table below).

Additive	INS	JECFA Safety Assessment	JECFA Conclusion
Gellan gum	418	87th 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"

Explain how these technological challenges are addressed in countries where gellan gum has not been authorized for these products

Formula for Special Medical Purposes (FSMP) for infants (Food Category 13.1.3) containing gellan gum have been marketed in countries where gellan gum has been authorized for these products.

Products containing gellan gum are not marketed in countries that have not authorized gellan gum, and instead, these countries rely on less innovative products for similar needs. As an example, gellan gum is used in a liquid fortifier that is designed to supplement milk or infant formula with additional nutrients (such as protein) in order to meet the unique nutritional needs of the target patient population.

A powdered form of this liquid fortifier is available in countries where gellan gum is not authorized. Due to differences in the manufacturing process (including spray drying of the powdered product) and the powder product format, the powder version of the product requires a different additive to ensure the proper product characteristics including homogeneity.

The liquid form of this product has some advantages over the powdered form, including that the liquid format is a commercially-sterile product and aids in homogenous reconstitution. Since the currently authorized additives were unable to produce a commercially acceptable version of a liquid version of this product, gellan gum was selected.

Discuss whether other additives were considered as alternatives to gellan gum

During the Physical Working Group, one Codex member observed that the data presented in NFSDU/41 CRD18 only included one comparison, and inquired whether the efficacy of gellan gum was also compared to other authorised additives.

During the development of the product presented in NFSDU/41 CRD18, a wide variety of food additives (including other thickeners already authorised by Codex) were evaluated for their effectiveness in this product. Due to the unique composition of this product, the manufacturing processes used, and the finished product format (liquid product that needs to maintain homogeneity over shelf life) gellan gum was shown to be the most effective additive, which had the added benefit of being able to produce this technological function with a comparatively low concentration.

The example provided in NFSDU/41 CRD18 (as well as previously in NFSDU39 CRD6) was in part selected because it effectively demonstrates, through photographs alone the differences in homogeneity that occur with the use of different additives.

Provide more details about the use of both gellan gum (INS 418) and OSA-modified starch (INS 1450) in the product example provided in NFSDU/41 CRD18

The currently authorized thickeners in Codex Standard 72-1981 are authorized with maximum use rates between 1 and 25 g/L, as-consumed, for products based on hydrolysed protein or amino acids. During the Physical Working Group, ISDI made the point that the use of an additive “system”, consisting of multiple additives, in many cases allows the use of lower concentrations of additives in the finished product. Based on its effectiveness in these products when used as part of an additive system, the requested authorization for gellan gum is a comparatively low maximum level of 0.05 g/L, as-consumed.

The product example provided in NFSDU/41 CRD18 contains both gellan gum (INS 418) and OSA-modified starch (INS 1450). During the Physical Working Group, a Codex member made the observation that the comparatively low maximum use level of gellan gum would be irrelevant if the product also contained concentrations of OSA-modified starch near maximum levels.

The applicant was able to confirm that the use of gellan gum in this product (NFSDU/41 CRD18), in combination with OSA-modified starch, created an additive system that allowed for a low overall additive concentration in the product. While OSA-modified starch has been authorized for use in this product category up to 20 g/L, as-consumed, the product described in NFSDU41/CRD 8, which contained a relatively low concentration of gellan gum (0.05 g/L), contained OSA-modified starch at a concentration approximately 10% of the maximum allowable concentration (~2 g/L).

These data demonstrate that use of gellan gum as part of an additive system allowed for the creation of a product that had a lower overall additive concentration.

Clearly respond to the new language for Q3 adopted in the Physical Working Group

Q3. 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).

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.

Conclusion

ISDI encourages the Committee to consider the addition information provided here to confirm the technological function of gellan gum (INS 418), for the following use under Codex Standard 72-1981:

INS	**Additive**	**Maximum level in 100 mL of the product ready for consumption**
4.1 Thickeners		
418	Gellan gum	0.005 g/100 mL in powdered formula containing hydrolysed protein and/or amino acids

As discussed at the 40th CCNFSDU (REP19/NFSDU, p. 129), CCNFSDU can consider the conclusions from the 87th meeting directly. Thus, ISDI encourages the committee at the Plenary, pending confirmation of technological function, to consider the following recommendations under Agenda Item 9a:

Gellan gum (INS 418)

- Recommend to CAC to include gellan gum (INS 418) in the infant formula standard (CX STAN 72-1981), Section B, as a thickener up to 0.005 g/100 mL (ready-to-consume) in powdered formula containing hydrolysed protein and/or amino acids
- Provide a reference to CCFA to amend the GSFA with the addition of xanthan gum to Food Category 13.1.3, Formula for Special Medical Purposes (FSMP) for infants