

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of
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World Health
Organization

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Agenda Item 10

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty-seventh Session
Bad Soden a.T. – Germany
23 – 27 November 2015

FOOD ADDITIVES IN THE STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (CODEX STAN 72-1981)

Comments of Colombia, Indonesia, Philippines and Thailand

COLOMBIA

Documento general de 2014, en el cual se evidencia que se incluyeron los aportes enviados por Colombia. No hay nuevo documento y este ya finalizo tramite.

INDONESIA

Food Additives	Use level	Conclusion of 36th CCNFSDU	Indonesia Comments
Xanthan gum (INS 415)	GMP	Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority in 2015: remove from list.	Indonesia agrees to maintain Xanthan gum (INS 415) in the list and wait for the JECFA evaluation
Sucrose esters of fatty acids* (INS 473)	12 mg in formula containing hydrolysed protein or amino acids ¹	Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority in 2015: remove from list	Indonesia proposes to remove the additive from the list Rationale : According to the 47th session of CCFA the additive does not include in JECFA's priority list. Since this additive also has an ADI, Indonesia is of the view that it is better to find out other additives from the additives provision in Codex Stan 72-1981 that have the same functional class.
Tartaric and fatty acid esters of glycerol (INS 472e)	GMP (China) 0.5 g	Maintain on the list and wait whether sponsor proposes JECFA evaluation to	Indonesia proposes to remove the additive from the list, since it is not included in JECFA's priority list (CCFA47)

		CCFA If not added to JECFA priority in 2015: remove from list.	
Acetic and fatty acid esters of glycerol (INS 472a)	GMP (USA)	Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority in 2015: remove from list.	Indonesia proposes to remove the additive from the list, since it is not included in JECFA's priority list (CCFA47)
Phosphoric acid (INS 338)	0.1 g expressed as P ₂ O ₅ singly or in combination and within the limits for sodium, potassium and phosphorus in Section 3.1.3 (e) in all types of infant formula	Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority in 2015: remove from list.	Indonesia proposes to remove the additive from the list, since it is not included in JECFA's priority list (CCFA47)
Section B (Infant Formula as Food for Special Medical Purposes):			
Sodiumalginate (INS 401)	100 mg	Maintain on the list and wait whether sponsor proposes JECFA evaluation to CCFA If not added to JECFA priority in 2015: remove from list.	Indonesia proposes to remove the additive from the list, since it is not included in JECFA's priority list (CCFA47)
Carob bean gum (Locustbean gum) (INS 410)	0.5 g	Listed at 0.1 g/100 ml in Section A. Maintained on the list and wait whether a sponsor proposes JECFA evaluation of higher level to CCFA If not added to JECFA priority in 2015: remove from list.	Indonesia agrees to maintain Carob bean gum (Locustbean gum) (INS 410) in the list and wait for the JECFA evaluation

Guar gum (INS 412)	1 g	Listed at 0.1 g/100 ml in Section A. Maintained on the list and wait whether a sponsor proposes JECFA evaluation of higher level to CCFA. If not added to JECFA priority in 2015: remove from list.	Indonesia proposes to remove the additive from the list, since it is not included in JECFA's priority list (CCFA47)
Xanthan gum (INS 415)	0.12 g	Maintain on the list and wait whether a sponsor proposes JECFA evaluation to CCFA. If not added to JECFA priority in 2015: remove from list.	Indonesia agrees to maintain Xanthan gum (INS 415) in the list and wait for the JECFA evaluation
Sucrose esters of fatty acids (INS 473)	12 mg in formula containing hydrolysed protein, peptides or amino acids	Maintain on the list and wait whether a sponsor proposes JECFA evaluation of higher level to CCFA. If not added to JECFA priority in 2015: remove from list.	Indonesia proposes to remove the additive from the list, since it is not included in JECFA's priority list (CCFA47)

PHILIPPINES

POSITION

The Philippines supports the retention of carrageenan as food additive in the Codex Standard for Infant Formula and Formula for Special Medical Purposes Intended for Infants. This food additive has undergone complete risk assessment based on current JECFA assessment.

We are of the opinion that there is sufficient technological need for carrageenan to be retained as a food additive in the Codex Standard for Infant Formula and Formula for Special Medical Purposes Intended for Infants.

RATIONALE

The Philippines supports inclusion of Carrageenan (INS 407) for use in infant formula and formula for special medical purposes intended for infants based on current JECFA assessment. This food additive has undergone complete risk assessment based on current scientific principles.

There are several uses of carrageenan as a food additive in infant formula and formula for special medical purposes intended for infants. Carrageenans are used to gel, thicken, or suspend; therefore they are used in

emulsion stabilization, for syneresis control, and for bodying, binding and dispersion. Carrageenan also have a high reactivity with a range of materials including, most importantly, milk proteins, being widely used at low concentrations in dairy products to prevent fractionation of milk constituents (Stanley). One of the most important properties that makes carrageenan different from other hydrocolloids is its ability to interact with milk proteins. The high reactivity of carrageenan with milk is due to the strong electrostatic interaction between the negatively charged ester sulfate groups in the carrageenan molecule, with strong positive charges of the milk casein micella. Another form of interaction is through links established among ester sulfate groups of carrageenan with carboxylic residues of amino acids that make up the protein. The ability of carrageenan to complex with milk proteins combined with its water gelling properties makes it an efficient ingredient for stabilizing and gelling milk products (Porto, 2003). The advantageous synergy that exists between carrageenan and milk proteins makes carrageenan an important and cost effective additive for a wide range of dairy applications. Apart from controlling the texture and stability, the carrageenan will also improve the overall organoleptical quality and extend the shelf-life of the finish dairy product (Lausten, 2011).

In response to the request of 36thCCNFSDU if food additives in CODEX STAN 72-1981 and sections 13.1.1 and 13.1.3 of the GSFA could be prioritized for alignment, CCFA47 reminds active commodity committees (e.g. CCNFSDU) of their responsibility to consider alignment of provisions. Thus PCFMI notes that CODEX STAN 72-1981 was amended in 2015 and section 4 now includes the addition of INS 472c, INS 1450, INS 339 i,ii,iii and INS 340 i,ii,iii, and removes the footnote linked to INS 407. Therefore, the following additives can be requested for addition at Step 8 to the GSFA in the appropriate food categories:

	INS number	Additive name	Food Categories	Safety Evaluation
1	472c	Citric and fatty acid esters of glycerol (CITREM)	13.1.1, 13.1.3	Endorsed by 79th JECFA, 2014
2	1450	Starch sodium octenyl succinate (OSA modified starch)	13.1.3	Endorsed by 79th JECFA, 2014
3	407	Carrageenan	13.1.1, 13.1.3	Endorsed by 79th JECFA, 2014
4	339 i, ii, iii 340 I, ii, iii	Phosphates	13.1.1, 13.1.3	Endorsed by 44th CCFA, 2012

We recommend that carrageenan(INS 407): be removed from the “wish list” at this time. Upon endorsement by 79th JECFA, 2014, the footnote has been removed and reflected in the amended Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981). As discussed under Agenda Item 2 (Matters Referred by CCFA47), carrageenan now needs to be proposed by CCNFSDU for adoption at Step 8 in the GSFA for food categories 13.1.1 and 13.1.3.

We support the provisions for xanthan gum(INS 415) as outlined in Appendix VI of the report of CAC38. Xanthan gum was added to the JECFA priority list during the 47th CCFA (2015 meeting), after which a call for data was issued from JECFA confirming JECFA’s intention to review safety data for xanthan gum. As this data will be submitted to JECFA in December 2015 and considered during JECFA’s 2016 meeting we recommend that this substance be kept on the list and noted as “in progress.” Xanthan gum is used to increase thickness of infant formula that use partially or extensively hydrolysed protein.

We support the provisions for sucrose esters of fatty acids (INS 473)as outlined in Appendix VI of the report of CAC 38. We request that JECFA review this substance but all necessary data was not available to respond to a 2015 call for data. If enough data is not gathered, it is understood that without a commitment to submit a request for a JECFA priority review in 2016 this substance will be removed from the list.

We note that Carob bean gum (INS 410) is already permitted in the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981). We recommend that this substance be kept on the list as it is currently on the JECFA priority list and will be reviewed by JECFA in

2016 based on data which will be submitted by December 2015 requesting a higher maximum use level for certain conditions in formulas for special medical purposes.

The Philippines recommends that pectin be maintained on the list until JECFA's review is completed. Pectin (INS 440) was reviewed by JECFA in 2014 and JECFA requested additional data to continue its safety review. Additional pectin data will be submitted to JECFA by December 2015 for review at JECFA's 2016 meeting. The OSA starch (INS 1450) and CITREM (citric and fatty acid esters of glycerol; INS 472c): These substances have been approved for use in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981). These substances now need to be proposed by CCNFSDU for adoption at Step 8 in the GSFA for food categories 13.1.1 and 13.1.3.

Technological Justification for Carrageenan

STABILIZES EMULSIONS

Carrageenan stabilizes the sedimentation of dense components such as insoluble calcium and phosphorus salts as well as slowing the upward migration of fat, which is less dense. It also keeps protein in solution. Carrageenan stabilizes the emulsion of protein, fat and water created in process, maintaining this single phase during storage, display and feeding. Without an ingredient added for stabilization, infant formulas would be more likely to produce insoluble sediments or creaming (separation of fat). This technical effect is particularly important to ensure infant formula is uniform and delivers the appropriate level of all essential nutrients. Use of product that is not properly stabilized will result in suboptimal delivery of nutrients to an infant, and long-term use could result in nutrient deficiency. These multifunctional properties are unique to carrageenan as a hydrocolloid.

HYDROLYZED PROTEINS

Carrageenan produces a unique technical effect to ensure that products containing hydrolyzed protein are stabilized. Hydrolyzed proteins are often beneficial for infants who do not tolerate or have allergies to cow milk or soy protein—this can be critical for infants with certain gastrointestinal problems or other conditions. Without carrageenan, it would be extremely difficult to manufacture the hydrolyzed protein product.

TEXTURE

Carrageenan also helps to produce a smooth pourable liquid that is not too thick or thin during processing, storage or feeding. Carrageenan ensures that the formula will be palatable to infants by providing proper texture and mouth feel,

OTHER FORMULA INGREDIENTS

Another unique advantage with the use of carrageenan is that it does not influence the efficacy of the other components, particularly the vitamins and minerals. It is also compatible with formulation processing, allowing the minimum negative impact on the ingredients during processing and subsequent storage.

OTHER ALTERNATIVES

No other hydrocolloid provides the same level of structural stability as carrageenan. Other hydrocolloids with negatively charged sites that react with protein, like pectin and alginate, form weaker interactions, and, even at increased concentrations do not provide the same stability as carrageenan. In addition, they may interact with some essential minerals contained in infant formula.

In addition, low levels of carrageenan are sufficient to prevent whey separation from a range of dairy products during manufacture and storage. Carrageenan is the only hydrocolloid that meets all the technological and economical requirements.

References

International Special Dietary Foods Industries (ISDI) Position Paper 2015

Lausten, K. (2011). Dairy Products and Carrageenan: a Perfect Pairing. *Food Marketing & Technology*; 10:7-11.

Porto, S. (2003). Carrageenan Structure. *Agar Brasileiro*

Stanley N. Production, Properties and Uses of Carrageenan. FAO DocumentRepository, Production and utilization of products from commercial seaweeds, Fisheries and Aquaculture Department.

Weiner, LM. Food additive carrageenan: Part II: A critical review of carrageenan in vivo safety studies. *Crit Rev Toxicol*. 2014 Mar;44(3):244-69. doi: 10.3109/10408444.2013.861798. Epub 2014 Jan 28.

THAILAND

General comments

In principle, foods for a baby or young children should be prepared with a minimum level of food additives, as necessary. It is proposed that JECFA should periodically evaluate food additives used for infant formula and formulas for special medical purposes intended for infants. And, the evaluated food additives should be re-evaluated when new evidence is available. Subsequently, the food additives should be proposed to CCFA for endorsement.

Specific comments

Carrageenan (INS 407)

We agree with the maximum level of carrageenan (INS 407) of 1000 mg/L in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (Codex Stan 72-1981) which was evaluated by 79th JECFA (2014) and endorsed by 47th CCFA (March 2015).

Pectin (INS 440)

It is agreed that additional data should be requested to support the safety evaluation of pectin (INS 440) in infant formula, since 79th JECFA concluded that the use of pectin in infant formulas at the maximum proposed use level (0.5%) is of concern.