CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 2 **CRD 3**
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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

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER SUBSIDIARY BODIES

Comments of Ecuador, European Union, Kenya, Mali, African Union and ISDI

ECUADOR

English:

General Comments

Ecuador does not agree to make reference to General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995) (GSCTFF) to revoke the current ML of 0.02 mg/kg for lead from the section on contaminants in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981)

Rationale:

Ecuador considers that in oreder to prevent and to ensure the safety and quality of all relevant products, all the information must be complete and directly included in the relevant standard and not by reference to other standards as proposed by the numeral 15 .

Español:

Comentarios Generales:

Ecuador no está de acuerdo en hacer referencia a la Norma General para los Contaminantes y las Toxinas Presentes en los Alimentos y los Piensos (CODEX STAN 193-1995) para suprimir el NM de 0.02 mg/Kg de plomo de la sección de contaminantes de la Norma para preparados de lactantes y preparados para usos medicinales especiales destinados a lactantes (CODEX STAN 72-1981).

Justificación:

Ecuador considera que por prevención y para asegurar la inocuidad y calidad de los productos toda la información relevante a los mismos debe ir incluida completa y directamente en su norma correspondiente, y no haciendo referencia a otras normas como propone el numeral 15.

EUROPEAN UNION

Part B. MATTERS ARISING FROM OTHER CODEX SUBSIDIARY BODIES

Executive Committee of the Codex Alimentarius Commission (70th Session)
Monitoring of Standards Development

Member States competence
Member States vote

The Member States of the European Union (MSEU) do not see a need to develop an approach for the management of the work of CCNFSDU similar to that used by CCFH. However, the MSEU remain open to consider any suggestion that may be proposed for setting criteria for the prioritisation of the work of the Committee.

Committee on Contaminants in Foods (CCCF8)
ML for lead in infant formula

European Union Competence
European Union Vote

The European Union agrees with the removal of this ML from the section on contaminants in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants and instead to make reference to the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF).

Committee on Methods of Analysis and Sampling (CCMAS36)

Mixed competence
Member States vote

Lowest level of trans fatty acids
In light of the answer from CCMAS, the European Union and its Member States (EUMS) would like to ask the Committee to resume the discussion on the basis of the proposals made by Canada (CX/NFSDU 14/36/10), for the setting of the conditions of use of the claims 'trans-fat free': 0.1g per 100g/100ml/serving. Once these are agreed, CCMAS could be consulted on the basis of these conditions, if questions about their enforceability are raised.

Committee on Food Additives (CCFA47)
Use of gum Arabic (INS 414) and carrageenan (INS 407)

European Union Competence
European Union Vote

Before commenting on the use of specific food additives, the EU would like to reiterate the approach discussed and proposed by JECFA in 1971, implemented by the Codex Alimentarius Commission and endorsed by the 43rd Session of the Codex Committee on Food Additives (2011) that "*baby foods should be prepared without food additives whenever possible. Where the use of a food additive becomes necessary in baby foods, great caution should be exercised regarding both the choice of additive and its level of use*".

As regards the use of INS 414 Gum arabic in food category 13.1 "Infant formula, follow-up formula, and formula for special medical purpose for infants" and in products conforming to the corresponding commodity standards, the EU is of the view that products falling under the mentioned food category and under the corresponding commodity standards could be prepared without the use of INS 414, in the same way that products available on the EU market are. Taking into account the principle referred to in the previous paragraph (i.e. baby foods should be prepared without food additives whenever possible) the EU does not support the use of INS 414 in food category 13.1.

A similar cautious approach should be taken as regards the use of INS 407 Carrageenan in food category 13.2 Complementary foods for infants and young children and in products conforming to the corresponding commodity standards. For example, the EU is not aware of the necessity to use INS 407 for processed cereal-based foods and baby foods for infants and young children. Without the information as to why the use of INS 407 is necessary, at what level and for which products, the EU cannot support the use of INS 407 in food category 13.2 and the corresponding commodity standards.

KENYA

2.1 Paragraph 15: ML for lead in infant formula

Issue: CCCF8 agreed to revoke the current ML of 0.02 mg/kg for lead in infant formula in the General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995) (GSCTFF) and to request CCNFSDU to remove this ML from the section on contaminants in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981) and instead to make reference to the GSCTFF.

Position: We support the revocation of current ML of 0.02 mg/kg for lead in current infant formula and instead make reference to GSCTFF level of 0.01 mg/kg.

Rationale: This will ensure consistency in Codex texts and specification in various standards in accordance to the procedural manual. In addition the level of lead in GSCTFF is recently updated than the current level in infant formula.

2.2 Paragraph 21: Use of gum Arabic (INS 414) and carrageenan (INS 407)

Issue: CCFA47 agreed to ask CCNFSDU to clarify the use of: gum Arabic (Acacia gum) (INS 414) in food category 13.1 “Infant formula, follow-up formula, and formula for special medical purpose for infants”; and products conforming to the corresponding commodity standard; and the use of carrageenan (INS 407) in food category 13.2 “Complementary foods for infants and young children” and products conforming to the corresponding commodity standards.

Position: Currently Gum Arabic (INS 414) is not used in food category 13.1 but it is used in food category 13.2. However, we would propose that its evaluation for use in food category 13.1 be done.

Rationale: Gum Arabica need to be evaluated for use in infant formula given that its use is already in food category 13.2 which ideally covers similar age (older infants).

MALI

Observations d’ordre général:

Paragraphe 15: LM pour le plomb dans les préparations pour nourrissons
Le Mali est favorable à la révocation de l’actuelle LM de 0,02 mg/kg pour le plomb dans les préparations pour nourrissons et de faire référence à NGCTAHA.

Justification :
Cela permettra d’assurer la cohérence avec les textes du Codex et la spécification dans diverses normes ainsi que de veiller à ce que le comité compétent soit entièrement responsable de leur champ d’application tel que prévu dans le manuel des procédures. Nous prenons note de ce que le niveau de plomb dans la NGCTAHA est inférieur au niveau actuel dans les préparations destinées aux nourrissons.

AFRICAN UNION

2.1 Paragraph 15: ML for lead in infant formula

Issue: CCCF8 agreed to revoke the current ML of 0.02 mg/kg for lead in infant formula in the General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995) (GSCTFF) and to request CCNFSDU to remove this ML from the section on contaminants in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981) and instead to make reference to the GSCTFF.

Position: AU supports the revocation of current ML of 0.02 mg/kg for lead in current infant formula and instead make reference to GSCTFF.

Rationale: This will ensure consistency in Codex texts and specification in various standards and ensure that the competent committee is fully in charge of their scope as envisaged in the procedural manual. AU takes note that the level of lead in GSCTFF is lower than the current level in infant formula.

2.2 Paragraph 21: Use of gum Arabic (INS 414) and carrageenan (INS 407)

Issue: CCFA47 agreed to ask CCNFSDU to clarify the use of: gum Arabic (Acacia gum) (INS 414) in food category 13.1 "Infant formula, follow-up formula, and formula for special medical purpose for infants"; and products conforming to the corresponding commodity standard; and the use of carrageenan (INS 407) in food category 13.2 "Complementary foods for infants and young children" and products conforming to the corresponding commodity standards.

Position: Currently Gum Arabic (INS 414) is not used in food category 13.1 but it is used in food category 13.2. However, AU would propose that its evaluation for use in food category 13.1 be done.

Rationale: Complementary foods for infants and young children (Food category 13.2) include persons of below the age of 12 months where gum Arabic (INS 414) is used. It is important that either the results of JECFA evaluation that led to the decision to use Gum Arabic in 13.2 be applied to allow use in 13.1(Infant formula, follow-up formula, and formula for special medical purpose for infants).

ISDI - International Special Dietary Foods Industries

Technological Justification for the use of Carrageenan

INTRODUCTION

The International Special Dietary Foods Industries (ISDI) agrees and supports the Joint FAO/WHO Expert Committee on Food Additives (JECFA) conclusion at its 79th meeting that, "The use of carrageenan in infant formula or formula for special medical purposes at concentrations up to 1000 mg/L is not of concern." The safety of carrageenan for use in infant formula has been confirmed time and again, most recently by JECFA.[1] Further, following the confirmation by JECFA to the safety of carrageenan for use in infant formula and an endorsement by CCFA for a provision for carrageenan, the Infant Formula Standard (CODEX STAN 72-1981) was amended wherein the footnote for carrageenan which read, "Not endorsed by the 39th session of the CCFA. JECFA evaluation is pending; national authorities may restrict its use until JECFA evaluation has been completed."[2] were removed.

ISDI, through this conference room document (CRD), provides scientific rationale and technological justification pertaining to the use of carrageenan in infant formula and formula for special medical purposes.

TECHNOLOGICAL AND NUTRITIONAL CONSIDERATIONS RELATING TO THE MANUFACTURE AND USE OF CARRAGEENAN

Carrageenan (INS 407) is approved for use in several commodity standards listed in the GSFA. It is approved as a bulking agent, carrier, emulsifier, gelling agent, glazing agent, humectant, stabilizer and thickener. It is also listed in Table 3 of the GSFA as an additive for numerous food categories for use at levels consistent with good manufacturing practices (GMP).
Carrageenan is added to infant formula for the important technological effects listed below.

- To build viscosity which both helps stabilize the sedimentation of dense components such as insoluble calcium and phosphorus salts, as well as slow the upward migration of fat which is less dense.
- Without carrageenan added for stabilization, infant formula would be more likely to produce insoluble sediments or creaming (separation of fat)
- As carrageenan allows for optimal physical properties when forming an emulsion, to manufacture infant formula that contains hydrolyzed protein as without carrageenan oil would separate almost immediately.

Carrageenan is added to infant formula for its stability, palatability, and compatibility functions. Carrageenan is the ***only*** stabilizer that performs all of the above functions, on its own without the addition of any other hydrocolloids, and at the lowest use levels. Therefore, the use of carrageenan for infant formulas is justified over the use of other food additives that cannot perform all necessary functions. Carrageenan produces a

technical effect that cannot be readily duplicated by other stabilizers, as compared and detailed under “Other Alternatives” section below.

Its use is technologically justified for the purpose of building viscosity, stabilization and emulsion formation. Other ingredients with similar effects do not have the same total functionality of carrageenan and are therefore not as suitable for infant formulas. Furthermore, the use of carrageenan in infant formula and formulas for special medical purposes (FSMP) is in agreement with the principle of the CAC when adopting standards for baby foods which states that, “Where the use of food additive becomes necessary in baby foods, great caution should be exercised regarding the choice of the additive and its level of use” (Annex 3 of TRS 488).[3]

TECHNOLOGICAL JUSTIFICATION

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

The need for stabilization is particularly important in infant formulas that contain hydrolyzed proteins. 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. To manufacture the hydrolyzed protein product without carrageenan would make it extremely challenging. Carrageenan produces a unique technical effect to ensure these products are stabilized.

TEXTURE

Failure to suspend the insoluble components of formula correctly could lead to a non-homogeneous formulation, which would result in grittiness in the mouth. Carrageenan also helps to produce a smooth pourable liquid that is not too thick or thin during processing, storage or feeding. By providing proper texture and mouth feel, carrageenan ensures that the formula will be palatable to infants.

OTHER FORMULA INGREDIENTS

Another benefit to 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

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 level of structural stability as carrageenan. Additionally, they may interact with some essential minerals contained in infant formula.

Several hydrocolloids such as the starches namely, distarch phosphate (INS 1412), acetylated distarch phosphate (INS 1414), phosphated distarch phosphate (INS 1413), hydroxypropyl starch (INS 1440) starch sodium octenyl succinate (INS 1450), Carob bean gum (INS 410), guar gum (INS 412), provide only thickening or at best a minimal level of protein interaction and related stabilities. Concentrations would need to be significantly increased to realize an effective level of protein reactivity, for example, 0.5-3.0%. Also, several emulsifiers such as lecithin (INS 322), mono- and diglycerides (INS 471) and citric and fatty acid esters of glycerol (INS 472c) do not address the mineral suspension through gelling that is a characteristic of carrageenan. In addition, low levels of carrageenan are sufficient to prevent whey separation from a range of dairy products during manufacture and storage.

Thus, other hydrocolloids may provide some of the required functionalities for infant formulas, but carrageenan is the only hydrocolloid that meets all the technological and economical requirements.

GLOBAL MARKET DATA ON USE OF CARRAGEENAN IN INFANT FORMULAS

Carrageenan is used in hundreds of food products around the world, including infant formulas. It is currently used in some cow milk- and soy-based formulas, including both powders and liquids. The typical level of carrageenan used in powder and liquid cow milk- and soy-based formulas is 90-1,000 parts per million, with the higher levels being used in formulas containing hydrolyzed proteins. These products are sold on the global market and are available in dozens of countries worldwide.

Following is a list of countries/regions that market infant formula products for 0-6 months of age which contain carrageenan (Table 1). This list includes products marketed by major global manufacturers of infant formula as well as those extracted from the Mintel database[4], an online database which includes marketed consumer goods. The products included in this list are marketed for infants aged 0-6 months, but note that in some countries, these products are labeled for use by older infants as well. The levels of carrageenan in all products marketed are at levels within the maximum allowable limits in the country where marketed and at the Codex Infant Formula Standard limits.

Table 1: List of Countries/Regions that Market Infant Formula Products Containing Carrageenan

Country/Region	Age Group	Technological Justification
Argentina**	0-6 months	Stabilizer - Helps with sedimentation of dense components of formula - Delivers uniform formula with appropriate levels of essential nutrients - Aids stabilization of hydrolyzed proteins - Enhances palatability Does not influence efficacy of other components in formula (e.g. vitamins and minerals)
Bahrain	0-6 months	
Cambodia	0-6 months	
Canada**	0-6 months	
Caribbean**	0-6 months	
Central America**	0-6 months	
Chile	0-6 months	
Colombia**	0-6 months	
Costa Rica	0-6 months	
Dominican Republic	0-6 months	
Ecuador**	0-6 months	
Egypt	0-6 months	
El Salvador	0-6 months	
Guatemala	0-6 months	
Hong Kong	0-6 months	
Indonesia	0-6 months	
Iraq	0-6 months	
Jordan	0-6 months	
Kuwait	0-6 months	
Lebanon	0-6 months	
Malaysia**	0-6 months	
Mexico**	0-6 months	
Oman	0-6 months	
Panama	0-6 months	
Peru**	0-6 months	
Philippines	0-6 months	
Qatar	0-6 months	
Saudi Arabia	0-6 months	
Singapore**	0-6 months	
South Africa	0-6 months	
Taiwan	0-6 months	
United Arab Emirates	0-6 months	
United States**	0-6 months	
Venezuela	0-6 months	
Vietnam	0-6 months	

**Indicates availability of premature infant formula products for 0-3 months of age containing carrageenan

PROPOSED USE-LEVELS

Carrageenan will be used in regular milk-and soy-based infant formula or in hydrolyzed protein- and/or amino acid based liquid infant formula at levels up to 0.03 g/100 mL and up to 0.1 g/100mL respectively.

References

1. Joint FAO/WHO Expert Committee on Food Additives. 2014. Evaluation of certain food additives: seventy-ninth report of the Joint FAO/WHO Expert Committee on Food Additives. WHO technical report series; no.990.
2. Codex Alimentarius. Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants – CODEX STAN 72-1981. Amended July 2015.
3. Joint FAO/WHO Expert Committee on Food Additives. 1971. Evaluation of food additives – Some enzymes, modified starches, and certain other substances: toxicological evaluations and specifications and a review of the technological efficacy of some antioxidants. WHO technical report series; no. 488.
4. Mintel. Infant Formula – February 2015. 2015. Retrieved from Mintel Global New Products Database.