



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

Thirty-eighth Session

Hamburg, Germany, 5 – 9 December 2016

ALIGNMENT OF FOOD ADDITIVE PROVISIONS IN STANDARDS DEVELOPED BY CCNFSDU

Comments of Nigeria, Thailand, African Union, IFMA and ISDI

NIGERIA

Nigeria supports the recommendation to establish an Electronic Working Group to:

- Review the food additive provisions in the adopted standards, with the objective of aligning them with the GSFA and if necessary propose changes to the GSFA; and
- Propose a mechanism or framework for considering the technological justification for substances intended for inclusion on the priority list of substances for JECFA evaluation.

It is also important to establish the criteria for determination of technological need for food additives.

Rationale: It is important to ensure that commodity standards do not conflict with provisions in the General Standard for Food Additives (GSFA). It is also important to establish the criteria for determination of technological need for food additives.

THAILAND

Thailand would like to express our appreciations for efforts of the Codex Secretariat for preparing a document for work on the alignment of food additive provisions in standards developed by CCNFSDU (CX/NFSDU 16/38/11).

Our comments on this subject matter are as follows:

1. We agree that CCNFSDU should work on the alignment of food additives provisions in its standards (Appendix) with the General Standard for Food Additives; GSFA (CODEX STAN 192-1995). And, CCNFSDU should be responsible for considering technological justification and providing safety evaluation data of food additives prior to inclusion in the JECFA priority list for evaluation.
2. An Electronic Working Group should be established to review food additive provisions in the standards with the aim of aligning them with the GSFA and if necessary to propose changes to the GSFA. In addition, the EWG should propose a mechanism or framework for considering the technological justification for substances intended for inclusion in the priority list of substances for JECFA evaluation.
3. It is recommended that FAO and WHO should hold an Expert Consultation Meeting to consider the use of food additives in current situation and important issues on the use of food additives in products for special dietary uses.

AFRICAN UNION

Issue: CCNFSDU is recommended to establish an Electronic Working Group to

- Review the food additive provisions in the adopted standards, with the objective of aligning them with the GSFA and if necessary propose changes to the GSFA; and
- Propose a mechanism or framework for considering the technological justification for substances intended for inclusion on the priority list of substances for JECFA evaluation.

Comment: The AU supports the recommendations

Rationale: It is important to ensure that commodity standards do not conflict with provisions in the General Standard for Food Additives (GSFA). It is also important to establish the criteria for determination of technological need for food additives.

ISDI – International Special Dietary Foods Industries

Overview

While ISDI supports establishing an eWG to facilitate completion of the alignment of additives in commodity Standards with the General Standard for Food Additives (GSFA), we encourage CCNFSDU to avoid delaying work on additives currently under consideration for addition to the commodity standards and subsequent referral to CCFA to support amendment of the GSFA.

Specifically, xanthan gum (INS 415) and pectin (INS 440) have both satisfied the prerequisites for inclusion in the Infant Formula Standard (CX STAN 72-1981), including a 2016 JECFA evaluation with a review of safety for infants <12 weeks of age, and information on technological function and purpose. ISDI requests the 38th CCNFSDU to consider the addition of these two food additives to the Infant Formula Standard (CX STAN 72-1981), and referral to CCFA to support amendment of the GSFA.

- a) At its 82nd meeting in 2016, JECFA had no concerns regarding the safety of use of xanthan gum (INS 415) or pectin (INS 440) in formulas for infants. Technological purpose and justification are reviewed as part of the JECFA assessment.
- b) CCFA does not need to formally endorse the JECFA decision nor formally advise the CCNFSDU of the JECFA result in order for CCNFSDU to amend Standard CX STAN 72-1981 to include xanthan gum and pectin.
- c) In case needed, ISDI has provided a description of the technological justification for each of xanthan gum and pectin in the Annexes to this document.

Establish an Electronic Working Group (eWG)

ISDI supports the recommendation to establish an eWG to 1) align the food additive provisions of commodity standards under the mandate of CCNFSDU with the General Standard for Food Additives (GSFA) managed by CCFA, and 2) to propose a framework for considering the technological justification for substances intended for inclusion on the priority list of substances for JECFA evaluation. ISDI looks forward to participating in this eWG to provide data and assistance where needed.

Summary of Requests for the 38th CCNFSDU regarding food additives recently reviewed by JECFA for safety of use in formula for infants.

Xanthan gum

- Request CCNFSDU to consider addition of xanthan gum (INS 415) to the infant formula standard (CX STAN 72-1981), Section B, as a thickener up to 0.1 g/100 mL in 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

- Request CCNFSDU to consider addition of pectin (INS 440) to the infant formula standard (CX STAN 72-1981), Section B, as a thickener up to 0.2 g/100 mL in infant formulas.
- 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.

Annex I

Xanthan Gum – Technological Justification

Annex II

Pectin – Technological Justification

Annex I

Technological justification for the use of xanthan gum

XANTHAN GUM (INS 415)

Introduction

ISDI would like the 38th CCNFSDU to consider the addition of xanthan gum (INS 415) to the infant formula standard (CX STAN 72-1981), Section B, as a thickener up to 0.1 g/100 mL in hydrolyzed protein and/or amino acid based formula only; and provide a reference to CCFA to add xanthan gum to the GSFA (General Standard for Food Additives CX STAN 192-1995) for formula for special medical purposes (FSMP) for infants, food category 13.1.3.

At its 82nd meeting in June 2016, the JECFA assessment of xanthan gum, which included a review of safety for infants between 0-12 weeks of age, concluded that the intake 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 (0.1 g/100 mL) ready to consume formula. The JECFA review process included a comprehensive assessment of technological data for xanthan gum in the Chemical & Technical Assessment (CTA).

In this conference room document (CRD), ISDI provides the 38th CCNFSDU with a summary of the technological justification for the use of xanthan gum.

Technological justification

Xanthan gum is used as a thickener in formulas made with partially or extensively hydrolyzed protein, or free amino acids. Protein hydrolysis often yields a reduction in viscosity, and in infant formulas made with hydrolyzed proteins, 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. 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.

Unique Properties

Xanthan gum can be used at relatively low levels to achieve significant viscosity without gelling. 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, as per the already established specifications for xanthan gum, the hydrocolloid must meet stringent limits for potential microbial contaminants. A low microbial load is of particular importance for an ingredient intended for use in infant formulas. 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.

Annex II

Technological justification for the use of pectin

PECTIN (INS 440)

Introduction

ISDI would like the 38th CCNFSDU to consider the addition of pectin (INS 440) to the Infant Formula Standard (CX STAN 72-1981), Section B, as a thickener up to 0.2 g/100 mL in infant formulas, and refer to CCFA to support amendment of the GSFA (General Standard for Food Additives, CX STAN 192-1995) with addition of pectin to Food Category 13.1.3, Formula for special medical purposes for infants (FSMP).

At its 82nd meeting in June 2016, JECFA's assessment of pectin, which included a review of safety for infants between 0-12 weeks of age, concluded that the intake of pectin in infant formula or 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/100 mL) ready to consume in formula. The JECFA review process includes a comprehensive assessment of technological data for pectin in the section Chemical & Technical Assessment.

In this conference room document (CRD), ISDI provides the 38th CCNFSDU with a summary of the technological justification for the use of pectin in formula for infants.

Technological justification

Pectin is a food additive for use as a thickener in formulas for infants. Pectin provides increased viscosity in the reconstituted formula matrix, which serves to minimize product separation and maintain homogeneity during shelf life. Infant formula manufacturing may be influenced by factors such as heat treatment, acidity, product form (liquid or powder) and compositional factors (e.g. protein source and other constituents). Manufacturing conditions can affect protein denaturation, aggregation, and sedimentation. In typical processing operations, for example, heating will result in formation of sedimentable protein aggregates composed of both denatured and non-denatured proteins. Pectin addition minimizes protein agglomeration and sedimentation during thermal processing, and over the shelf life. Thermal processes can also

substantially impact the stability of emulsions. With the addition of pectin, whey protein-pectin complexes are adsorbed to the emulsion interface, leading to the formation of stable emulsions which help maintain product homogeneity during shelf life. The level of pectin selected to use in product is the minimum required to achieve the desired physical properties throughout shelf life.

Unique Properties

Its water soluble properties and good processing characteristics are well suited for infant formula manufacture, either in liquid or powdered forms. Pectin is uniquely effective as a thickener in certain hydrolyzed protein matrices. Addition of pectin at up to 0.2% (0.2 g/100 mL) ready to consume in infant formula improves product quality and ensures product uniformity throughout shelf life, thus delivering the appropriate level of essential nutrients to infants.