CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5e **CX/FA 16/48/11 Add.1**

March 2016

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-eighth Session

Xi'an, China, 14-18 March 2016

PROPOSALS FOR NEW AND/OR REVISION OF FOOD ADDITIVE PROVISIONS

Comments (replies to CL 2015/12-FA) of Senegal, Russian Federation, African Union and ISDI

SENEGAL

Problème:

-Proposition de nouvelles dispositions des additifs alimentaires suivants qui ont été présentés par les Etats membres et observateurs:

(I) Advantame - Un édulcorant et exhausteur de goût

(Ii) carraghénane - agent de charge, Carrier, Émulsifiant, gélifiant, agent d'enrobage, humectant, Stabilisateur, Épaississant

(Iii) citriques et esters d'acides gras et de glycérol - Émulsifiant, Antioxydant, Stabilisateur

(Iv) octényle succinate d'amidon sodique - émulsifiant, stabilisant, épaississant

(V) l'alcool de polyvinyle (PVA) -polyethylene glycol (PEG) greffé co-polymère - Binder, Carrier, Agent de glaçage, Stabilisateur

-Proposition de révision des additifs alimentaires suivants qui ont été présentés par les Etats membres et observateurs:

(I) nisine (SIN 234) - Un agent de conservation

(Ii) Stéarate de magnésium (SIN 470 (iii)) - antiagglomérant, émulsifiant, épaississant

Position: Nous soutenons la demande par les Etats membres et observateurs au JECFA de procéder à l'évaluation de la sécurité des additifs alimentaires ci-dessus.

Justification: De nouvelles données ont été générées et fournies par les Etats membres et observateurs.

RUSSIAN FEDERATION

We consider it is necessary to use sweeteners (Advantame INS 969) only in food products with low energy value or in products with no added sugar, according to CAC/GL 23-1997. Such a rule is also established in the Russian Federation and Customs Union.

AFRICAN UNION

Issue: Proposed new provisions of the following food additives that have been submitted by member states and observers:

(i) Advantame – A sweetner and flavor enhancer

(ii) Carrageenan - Bulking Agent, Carrier, Emulsifier, Gelling Agent, Glazing Agent, Humectant, Stabilizer, Thickener

(iii) Citric and fatty acid esters of glycerol - Emulsifier, Antioxidant, Stabilizer

(iv) Starch sodium octenyl succinate - Emulsifier, Stabilizer, Thickener

(v) Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft co-polymer – Binder, Carrier, Glazing agent, Stabilizer

Proposed revision of the following food additives that have been submitted by member states and observers:

(i) Nisin (INS 234)– A preservative

(ii) Magnesium stearate (INS 470 (iii))– anticaking agent, emulsifier, thickener

Position: AU supports the request by member states and observers to JECFA to conduct the safety evaluation of the above food additives.

Rationale: New data has been generated and provided by member states and observers.

International Special Dietary Foods Industries (ISDI)

In the final report (REP16/NFSDU) of the 37th session of the Codex Committee on Nutrition for Special Dietary Foods (CCNFSDU) it is indicated that the Codex Secretariat informed the Committee of the procedures for entry of new substances and/or revision of adopted food additives provisions in the GSFA. It was also confirmed in the report (see para 93 & 94) to respond to circular letter CL 2015/12-FA for new additives or changes to existing additives in CODEX STAN 72-1981 for alignment in the GSFA. The Committee encouraged members to reply to circular letters CL 2015/12-FA and agreed to consider alignment of the food additives provisions in the different standards under its jurisdiction within the GSFA at its next session.

As per these directions, ISDI responded to CL 2015/12-FA with proposals for food additive provisions in the GSFA. ISDI further notes that the guidelines for the inclusion of specific provisions in Codex standards and related texts as outlined in the procedural manual (24th edition, WHO/FAO, 2015) has been followed by including the data required in response to the CL 2015/12-FA. The additives already adopted in the Codex Standard 72-1981 were requested for adoption in the GSFA food category 13.1 in the step process as summarized below.

Name of the additive	**Carrageenan**	**Starch Sodium Octenyl Succinate**	**CITREM**
INS Number	407	1450	472c
Maximum use level and food category	300 mg/kg (13.1.1) 1000 mg/kg – (13.1.3)	20,000 mg/kg (13.1.3)	0.9 g/100 mL (ready for consumption) in all types of liquid infant formula; 0.75 g/100 mL (ready for consumption) in all types of powder infant formula (13.1)
Functional Class	Bulking agent, carrier, emulsifier, gelling agent, glazing agent, humectant, stabilizer, thickener	Emulsifier, stabilizer, thickener	Emulsifier, antioxidant, stabilizer

See below for complete details.

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Citric and fatty acid esters of glycerol (INS 472c)

THE PROPOSAL IS SUBMITTED BY:	International Special Dietary Foods Industries (ISDI)
IDENTITY OF THE FOOD ADDITIVE: Citric and fatty acid esters of glycerol, Citric acid esters of mono- and diglycerides of fatty acids, citroglycerides, mono- and diglycerides of fatty acids esterified with citric acid, CITREM, CAEM; trade name is GRINDSTED® CITREM. INS No. 472c; CAS# 97593-31-2.; E 472c	
Name of the Additive	Citric and fatty acid esters of glycerol

As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989			
INS Number		472c	
Functional Class *As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989*		Emulsifier, Antioxidant, Stabilizer	
PROPOSED USE(S) OF THE FOOD ADDITIVE ([1]): *The rows below may be copied as many times as needed.*		The proposal for ☑a new provision; or ☐revising an existing provision	
Food Category No. ([2])	**Food Category Name ([2])**	**Maximum Use Level ([3])**	**Comments ([4])**
13.1	Infant formulae, follow-on formulae, and formulae for special medical purposes for infants	0.9 g in all types of liquid infant formula 0.75 g in all types of powder infant formula	Maximum level in 100 ml of the product ready for consumption
EVALUATION BY JECFA:			
Evaluation by JECFA *Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).*		Citric and fatty acid esters of glycerol INS 472 (CITREM) was most recently assessed in 2014 proposed use is as an emulsifier in food category 13.1 infant formulae, follow-on formulae and formulae for special medical purposes for infants. The output of the assessment was included in 79th report of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Geneva, 17–26 June 2014. In 2015 the Standard for Infant Formula and Formulas for Special Medical Purposes intended for Infants, CODEX STAN 72 – 1981, was amended to include new provisions for INS 472c. The provisions for CITREM/INS 472c are now listed in Section 4 Table 1 of this standard. Prepared at the 79th JECFA (2014) and published in FAO JECFA. Monographs 16 (2014), superseding specifications prepared at the 35th. JECFA (1989), published in FNP 49 (1990) and in FNP 52 (1992). Metals and arsenic specifications revised at the 61st JECFA (2003). An ADI 'not limited' was established at the 17th JECFA (1973). The specification for lead is under consideration for CCFA 48, 2016. Data has been provided by industry to support this consideration.	
JUSTIFICATION:			
Justification for use and technological need *Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).*		Infant formula, follow on formula and Formulas for Special Medical Purposes intended for Infants manufactured with amino acids and hydrolyzed proteins. Formulations manufactured with amino acids and hydrolyzed proteins have different hydrophobic/hydrophilic characteristics and lower emulsifying capacity than products based on whole protein. CITREM/INS 472c improves the stability and organoleptic properties of products containing (partially) hydrolysed proteins, peptides or amino acids. Emulsifiers are therefore a technological requirement for these formulas to ensure both palatability and prevention of separation of the formula after reconstitution. The JECFA Committee concluded that there are no toxicological concerns about the use of CITREM/INS 472c in infant formula and formula for special medical purposes at concentrations up to 9 g/L. At the higher use levels, there is a possibility of diarrhoea from free citric acid released from formula containing CITREM/INS 472c. Given the paucity of clinical data and the fact that exposure assumptions for citric acid have been maximized, it is difficult to estimate the risk of diarrhoea, but it is considered to be low. Therefore the use of CITREM/INS 472c does not present an appreciable health risk to consumers.	

Safe use of additive: Dietary intake assessment (*as appropriate*)	Table 3 additive: ☐ Yes ☑ No (Please provide information on dietary intake assessment below)

Dietary Intake Determinations for CITREM:

In the context of infants fed with breast milk substitutes formula constitutes the sole source of nutrition up to 6 month of age. By way of consequence, formula is the unique source of exposure to CITREM. Consumption of CITREM from its use in infant formula was estimated according to the Joint FAO/WHO/UNU expert report on Human Energy Requirements (FAO, 2004) (see Table 1).

Table 1. Exposure estimations in 'typical' infant formula consumers matching with FAO Human Energy Requirements

[a] Weight and energy requirements reported according to the Joint FAO/WHO/UNU expert report on Human Energy Requirements (Food Agricultural Organization of the United Nations, 2004)

[b] Volume of ingested formula extrapolate at based on a standard energy density of 67 kcal/100 mL to meet infant's energy requirements in full

Max usage of CITREM usage (9.0 g/L of formula as consumed)					
Age	**Weight[a]**	**Energy requirements[a]**	**Volume of formula[b]**	**Intake of CITREM**	
months	kg	kcal/d	mL/d	g/d	mg/kg bw/d
0-1	4.58	518	773	6.96	1519.0
2-3	6.28	596	890	8.01	1275.5
5-6	7.93	639	954	8.59	1082.7

Based on a maximum use level of 9 g/L, the mean intake of CITREM/INS472c from its intended use in infant formula and formulae for special medical purposes for infants is estimated to range from 6.96 to 8.59 g per day in infants from birth to six months, as shown in Table 1.

Summary and Conclusion

CITREM/INS 472c is proposed for use in formulae for special medical purposes intended for infants at levels up to 9 g/L formula. The maximum proposed use-level results in estimated intakes of 1.08 to 1.52 g/kg bw per day in infants ages zero to six months.

Justification that the use does not mislead consumer	In accordance with the provisions of CODEX STAN 72 – 1981 CITREM/INS 472c may be used to produce stable formulations of Infant formula, follow on formula and Formulas for Special Medical Purposes intended for Infants manufactured with amino acids and hydrolyzed proteins. This use servers a technological function as an Emulsifier and ensures the suitability and safety of these formulas for their intended use. Where used, in accordance with CODEX STAN 1-1985 CITREM/INS 472c must be appropriately declared on the label of these products in the list of ingredients by indicating either: (i) the Functional Class together with the specific name or (ii) the Functional Class together with the recognized numerical identification such as the Codex International Numbering System (CAC/GL 36-1989). The placement of CITREM/INS 472c in the ingredients list in descending order must be in accordance with the proportion added to the formula.

([1]) For proposed revisions of adopted provisions, the current adopted provision should be provided, with deletions noted in ~~strikethrough~~ text, and changes or additions noted in bold font.

([2]) Food category number and name, as listed in Annex B of the GSFA.

([3]) For consistency, the maximum use level should be reported on the same basis as the ADI. A numerical use level should be provided for a food additive assigned a numerical ADI. GMP or a numerical use level may be provided for a food additive assigned a non-numerical ADI (e.g., "not-specified").

([4]) Comments on specific restrictions on the use of the food additive to be included as Notes (e.g., limitation of use to specific products in a food category).

Carrageenan (INS 407)

<table>
<tr><td colspan="2">THE PROPOSAL IS SUBMITTED BY:</td><td colspan="2">International Special Dietary Foods Industries (ISDI)</td></tr>
<tr><td colspan="4">IDENTITY OF THE FOOD ADDITIVE:</td></tr>
<tr><td colspan="2">Name of the Additive
As listed in Class Names and the International Numbering System (INS) – CAC/GL 36-1989</td><td colspan="2">Carrageenan</td></tr>
<tr><td colspan="2">INS Number</td><td colspan="2">407</td></tr>
<tr><td colspan="2">Functional Class
As listed in Class Names and the International Numbering System (INS) – CAC/GL 36-1989</td><td colspan="2">Bulking Agent, Carrier, Emulsifier, Gelling Agent, Glazing Agent, Humectant, Stabilizer, Thickener</td></tr>
<tr><td colspan="2">PROPOSED USE(S) OF THE FOOD ADDITIVE([1]): The rows below may be copied as many times as needed.</td><td colspan="2">The proposal for a
☒new provision; or
☐revising an existing provision.</td></tr>
<tr><td>Food Category No. ([2])</td><td>Food Category Name m([2])</td><td>Maximum Use Level ([3])</td><td>Comments ([4])</td></tr>
<tr><td>13.1.1</td><td>Infant formulae</td><td>300 mg/kg</td><td>0.03 g/100 mL in regular milk – and soy-based liquid infant formula (consistent with Codex Standard for Infant Formulas and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981)</td></tr>
<tr><td>13.1.3</td><td>Formulae for special medical purposes for infants</td><td>1000 mg/kg</td><td>0.1g/100mL in hydrolysed protein- and/or amino acid based liquid infant formula only (consistent with Codex Standard for Infant Formulas and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981)</td></tr>
<tr><td colspan="4">EVALUATION BY JECFA:</td></tr>
<tr><td colspan="2">Evaluation by JECFA
Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or “not specified”); specifications monograph).</td><td colspan="2">79th JECFA Session (2014)
“The Committee concluded 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.”</td></tr>
<tr><td colspan="4">JUSTIFICATION:</td></tr>
<tr><td colspan="2">Justification for use and technological need
Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</td><td colspan="2">The safety of carrageenan for use in infant formula products has been confirmed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 2014.
Carrageenan provides a technical effect in infant formula and formulas for special medical purposes which cannot be duplicated by other additives used as stabilizers.
• Builds viscosity – Helps to stabilize the sedimentation of dense components such as insoluble calcium and phosphate salts; Slows the upward migration of fat, which is less dense
• Deters separation – Without carrageenan for stabilization, formulas would be more likely to produce insoluble sediments or creaming (separation of fat); Assures uniformity of all nutrients throughout shelf life and prevents suboptimal delivery of nutrients
• Promotes emulsion – Creating an emulsion during manufacture of formulas made with hydrolyzed proteins would be difficult without carrageenan as oil would immediately separate
• Promotes proper mouthfeel – Through proper suspension of insoluble components of</td></tr>
</table>

	formulas, carrageenan creates a smooth, pourable liquid with suitable mouthfeel • Efficacy – Carrageenan does not influence the efficacy of other components in formulas, particularly vitamins and minerals • Lower use needed to achieve function – Carrageenan can be used at lower levels as compared to other stabilizers to achieve the necessary functionality
Safe use of additive: Dietary intake assessment (*as appropriate*)	Table 3 additive: ☐Yes ☒No (Please provide information on dietary intake assessment below)

Estimation of Carrageenan intake based on consumption data for infant formula

HUMAN ESTIMATES OF CARRAGEENAN INTAKE FROM INFANT FORMULA

JECFA (2008) has published estimates of carrageenan consumption in infants and 12-month old babies for current use levels: 0.03 g/100 ml (300 ppm) for regular milk and soy-based liquid formulas and 0.1 g/100 ml (1,000 ppm) for hydrolyzed protein- and/or amino acid-based liquid formulas. I nfants fed with 100% formula with the carrageenan at 300 ppm and 1,000 ppm show the highest consumption: 47 and 160 mg/kg bw/day, respectively. Estimates for 12-month old babies assume that a caloric intake from infant formula is 13.5% of the total caloric intake; thus, the carrageenan intakes are 6 and 22 mg/kg bw/day for the formula with 300 ppm and 1,000 ppm, respectively (JECFA,2008).

In a human epidemiology study infants were fed formula with 300 ppm carrageenan (Sherry et al., 1993; Sherry et al., 1999). A total carrageenan daily intake of 191 mg/day for the first six months of life was reported (the method of calculation was not published). The mg/kg bw/day intake estimate will depend on the average body weight of a six-month old infant. Using body weight and fluid consumption data from Koletzko et al (2000), it can be estimated that an infant consumes approximately 30.4 mg/kg bw/day carrageenan during the first six months of life from infant formula containing 300 ppm carrageenan. The average carrageenan consumption for the period of 1 to 6 months was estimated as the average of the values for each of the age groups in Table 1.

TABLE 1: Carrageenan Exposure to Infants from the Infant Formula Application

Carrageenan in formula: ppm	mg/kg bw/day	Method of Calculation	Reference
Regular Milk-Based and Soy-Based Liquid Infant Formula			
300	47	Assumes 100% formula fed infants (100% of caloric intake)	JECFA, 2008
300	6	Assumes 12-month old infants based on a survey in France showing that consumption of formula represents 13.7% of total caloric intake for this age	JECFA, 2008
300	30.4	Assumes 100% formula fed infants, one to six months old, using reported body weight data –averaged for 1-6 month olds	Sherry et al., 1993, 1999; Koletzko et al., 2000
300	39.50 28.24 23.46	One month old Four month old Six month old	Calculated based on Sherry et al., 1993, 1999; Koletzko et al., 2000
Hydrolyzed Protein and/or Amino Acid-based Liquid Infant Formula			
1,000	160	Assumes 100% formula fed infants (100% of caloric intake)	JECFA, 2008
1,000	101.2	Assumes 100% formula fed infants, one to six months old, using reported body weight data –averaged for 1-6 month olds and extrapolated	Sherry et al., 1993, 1999; Koletzko et al., 2000

		from 300 ppm to 1,000 ppm exposure	
1,000	22	Assumes 12-month old infants, based on a survey in France showing that consumption of formula represents 13.7% of total caloric intake for this age	JECFA, 2008

Calculations are on specific age infants: based on Sherry et al., 1993, 1999

In addition, the consumption of carrageenan on a body weight basis (Koletzko et al., 2000) can be calculated as follows.

One Month old: 191 mg/day ÷ 4.835 kg bw = 39.50 mg/kg bw/day Four Month old: 191 mg/day ÷ 6.763 kg bw = 28.24 mg/kg bw/day Six Month old: 191 mg/day ÷ 8.140 kg bw = 23.46 mg/kg bw/day

Thus, the average carrageenan exposures estimated over the time of one to six months is 30.4 mg/kg bw/day as an approximation.

References:

JECFA: Joint FAO/WHO Expert Committee on Food Additives. (2008). 68th Meeting of the Joint FAO/WHO Expert Committee on Food Additives; Safety Evaluation of Certain Food Additives and Contaminants, held on June 19-28, 2007 in Geneva, Switzerland. WHO Food Additives Series:59: 65-85.

Sherry, B., Flewelling, A., & Smith, A. L. (1993). Carrageenan: an asset or detriment in infant formula? *Am J Clin Nutr, 58*(5):715.

Sherry, B., Flewelling, A., & Smith, A. L. (1999). Carrageenan: an asset or detriment in infant formula? *Am J Clin Nutr* 58(5): 715, 1993. Erratum: *Am J Clin Nutr, 69*(6):1293.

Koletzko, B., Dokoupil, K., Reitmayr, S., Weinert-Harendza, B., & Keller, E. (2000). Dietary fat intakes in infants and primary school children in Germany. *American J. of Clinical Nutrition, 72* (suppl.):1392S-8S

Justification that the use does not mislead consumer	Carrageenan is currently used in infant formulas and formulas for special medical purposes around the world. As an ingredient in these products, it is identified on the ingredient list of the product label and does not mislead the consumer. Also, the amount used does not exceed the approved maximum limit and is used as per the technological need indicated above.

(1) For proposed revisions of adopted provisions, the current adopted provision should be provided, with deletions noted in ~~strikethrough~~ text, and changes or additions noted in **bold** font.

(2) Food category number and name, as listed in Annex B of the GSFA.

(3) For consistency, the maximum use level should be reported on the same basis as the ADI. A numerical use level should be provided for a food additive assigned a numerical ADI. GMP or a numerical use level may be provided for a food additive assigned a non-numerical ADI (e.g., "not-specified").

(4) Comments on specific restrictions on the use of the food additive to be included as Notes (e.g., limitation of use to specific products in a food category).

Starch sodium octenyl succinate (INS 1450)

THE PROPOSAL IS SUBMITTED BY:	International Special Dietary Foods Industries (ISDI)
IDENTITY OF THE FOOD ADDITIVE:	
Name of the Additive *As listed in Class Names and the International Numbering System (INS) – CAC/GL 36-1989*	Starch sodium octenyl succinate
INS Number	1450
Functional Class *As listed in Class Names and the International Numbering System (INS) – CAC/GL 36-1989*	Emulsifier, Stabilizer, Thickener
PROPOSED USE(S) OF THE FOOD ADDITIVE(1): *The rows below may be copied as many times as needed.*	The proposal for a ☒new provision; or ☐revising an existing provision.

Food Category No. ([2])	Food Category Name ([2])	Maximum Use Level ([3])	Comments ([4])
13.1.3	Formulae for special medical purposes for infants	20,000 mg/kg	2 g/100mL (of product ready for consumption} in hydrolysed protein- and/or amino acid based infant formula only (consistent with Codex Standard for Infant Formulas and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981)
EVALUATION BY JECFA:			
Evaluation by JECFA *Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).*		79th JECFA Session (2014) "The Committee concluded that the use of Starch sodium octenyl succinate in infant formula or formula for special medical purposes at concentrations up to 20g/L is not of concern."	
JUSTIFICATION:			
Justification for use and technological need *Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).*		The safety of starch sodium Octenyl Succinic Acid (OSA-modified starch) for use in infant formula products has been confirmed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 2014. OSA-modified starch provides a technical effect in formulas for special medical purposes as an emulsifier as detailed below. • Acts as an emulsifier during the processing of liquid infant formula. Stability of emulsions may need to be maintained for several days before drying. By using OSA-modified starch, the uniformity of the formula composition during drying is ensured. • Acts as an emulsifier after reconstitution of the formula. OSA-modified starch improves the overall dispersability of powder formula • Prevents free fat formation. The use of OSA-modified starch reduces free fat formation through its emulsifying properties. When formulae are not properly emulsified, free fat rises to the top of the formula over time. When a poor emulsion is dried, the free fat passes through the spray nozzle as larger drops of liquid separated from the remainder of the product (rather than being tightly associated with other macronutrients as in a good emulsion). The free fat then adheres to the surface of the dried particles as the particles descend to the bottom of the drier. Once on the surface of the particle, the fat is exposed to oxygen. Oxidation of free fat is undesirable from a nutritional standpoint, as well as from a sensory acceptability standpoint. Additionally, free fat on the particle surface tends to stick to the manufacturing equipment, causing build-up on the surface of the equipment. This results in the requirement for frequent cleaning of equipment and reduced yields.	
Safe use of additive: Dietary intake assessment (*as appropriate*)		Table 3 additive: ☐Yes ☒No (Please provide information on dietary intake assessment below)	
Dietary Intake Determinations for Starch sodium octenyl succinate ***International estimates of intake***			

Consumption of OSA-modified starch from its use in infant formula was estimated using the World Health Organization (WHO) recommended intakes of milk or infant formula (WHO, 2009) and weight-for-age standards (WHO, 2006) (see Table 1).

Table 1: Recommended average daily intake of milk or infant formula in infants

Age of Infant	Recommended amount of formula per day (mL/kg bw)[a]	Mean body weight (kg)[b]	Total milk or formula per day (mL)
Newborn	60	3.3	198
6 months	150	7.6	1,140

[a] WHO (2009)

[b] Average of mean body weights for boys and girls (WHO, 2006).

Based on a maximum use level of 20 g/L, the mean intake of OSA-modified starch from its intended use in infant formula and formulae for special medical purposes for infants is estimated to range from 3.96 to 22.8 g per day in infants from birth to six months, as shown in Table 2.

Table 2: Predicted intakes of OSA-modified starch from its use in infant formula based on WHO recommendations (WHO, 2006)

Age of Infant	Average intake (g per day)	Average intake (g/kg bw per day)
Newborn	3.96	1.2
6 months	22.8	3

WHO = World Health Organization

Summary and Conclusion

OSA-modified starch is proposed for use in formulae for special medical purposes intended for infants at levels up to 20 g/L formula. The maximum proposed use-level results in estimated intakes of 1.2 to 3 g/kg bw per day in infants ages zero to six months.

References

JECFA (1982). Starch sodium octenyl succinate. In: Toxicological evaluation of certain food additives. 26th Report of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), Apr. 19-28, 1982, Rome, Italy. Geneva, Switz., World Health Organization (WHO). (WHO Food Additives Series No. 17; http://www.inchem.org/documents/jecfa/jecmono/v17je21.htm)

WHO (2006). Weight-for-age standards [construction] (chapter 4). In: Child growth standards: length/height-for-age, weight-for-age, weight-for-length, weight-for-height and body mass index-for-age: Methods and development. Geneva, Switz., World Health Organization (WHO), WHO Multicentre Growth Reference Study Group, pp. 79–138. (http://www.who.int/childgrowth/standards/technical_report/en/index.html).

WHO (2009). Infant and young child feeding: model chapter for textbooks for medical students and allied health professionals. Geneva, Switz., World Health Organization (WHO). (http://www.waba.org.my/pdf/Infant-n-Young-Feeding.pdf).

Justification that the use does not mislead consumer	Starch sodium octenyl succinate is currently used in formulas for special medical purposes around the world. As an ingredient in these products, it is identified on the ingredient list of the product label and does not mislead the consumer. Also, the amount used does not exceed the approved maximum limit and is used as per the technological need indicated above.

(1) For proposed revisions of adopted provisions, the current adopted provision should be provided, with deletions noted in ~~strikethrough~~ text, and changes or additions noted in **bold** font.

(2) Food category number and name, as listed in Annex B of the GSFA.

(3) For consistency, the maximum use level should be reported on the same basis as the ADI. A numerical use level should be provided for a food additive assigned a numerical ADI. GMP or a numerical use level may be provided for a food additive assigned a non-numerical ADI (e.g., "not-specified").

(4) Comments on specific restrictions on the use of the food additive to be included as Notes (e.g., limitation of use to specific products in a food category).