CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

E

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda item 6 **CX/NFSDU 23/43/6**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Forty-third Session, Düsseldorf, Germany

7 – 10 March with report adoption by virtual mode on 15 March 2023

TECHNOLOGICAL JUSTIFICATION FOR SEVERAL FOOD ADDITIVES

Comments in reply to CL 2022/80/OCS-NFSDU

Comments of Brazil, Canada, Chile, Colombia, Cuba, European Union, Iran, Iraq, Japan, New Zealand, Paraguay, Peru, Philippines, Republic of Korea, Saudi Arabia, South Africa, Syrian Arab Republic, United States of America and European Network of Childbirth Associations (ENCA), International Food Additives Council (IFAC), International Baby Food Action Network (IBFAN), International Special Dietary Food Industries (ISDI)

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2022/80/OCS-NFSDU issued in November 2022. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the Annex

2. The comments submitted through the OCS are hereby attached as **Annex I** and presented in table format.

Annex I

GENERAL COMMENTS	MEMBER / OBSERVER
Chile appreciates the opportunity to comment on the information requested. In this regard, we agree that the information provided in the form is sufficient to accept the technological justification for the additives mentioned in the circular letter.	**Chile**
Cuba appreciates the opportunity to provide its views on CL 2022/80/OCS - NFSDU and supports the use of these additives in products as long as the use of these additives is technologically justified.	**Cuba**
The EU appreciates the use of the framework for considering the technological justification developed by the Committee. It allows to fulfil the duty of the Committee, to appraise and justify the technological need for the use of additives in foods falling under its remit, in a systemic way. This is of a particular importance especially for the standards destined for infants and young children where the extra precaution must be given to the principle that food additives could be added only if they are necessary and if so, at the lowest possible levels. The EU also supports that JECFA assesses the safety of food additives included in CXS 72-1981, for which no appropriate safety assessment for infants (below 12 weeks of age) has been undertaken and for which the Committee concludes that their use is technologically justified. The food additive provisions for which the JECFA safety assessment is not requested in due time following the positive appraisal of the technological need by the Committee or for which the Committee does not conclude that their use is technologically justified shall be removed from CXS 72-1981	**European Union**
No comments.	**Iraq**
The Philippines supports the technological justification of low acyl clarified gellan gum (INS 418), ascorbyl palmitate (INS 304), mixed tocopherol concentrates (INS 307b) and phosphates (INS 339(i), 339(ii) and 339(iii) and INS 340(i), 340(ii) and 340(iii)) in Infant Formula and Formula for Special Medical Purposes Intended for Infants as presented in Annex 1 of CL 2022-80-OCS-NSFDU. These food additives comply with Section 3.2 of the Preamble to the General Standard for Food Additives (GSFA) and perform technological function(s) relative to CXG 36-1989 (Class Names and the International Numbering System for Food Additives). Based on the 1971 Joint FAO/WHO Expert Committee on Food Additives (JECFA) Report on Additives in Baby Foods, the use of food additives with functions of maintaining consistency and texture is justified in infant formula and formula for special medical purposes (FSMP) intended for infants to ensure their safety and acceptability.	**Philippines**
The United States would like to provide the following General Comments below in response to CL 2022/80/OCS-CCNFSDU on: (i) the technological justification for the use of certain food additives in foods complying with the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981); and (ii) the plan/programme for the consideration of remaining food additives • With regard to (i), the United States has the view that low acyl clarified gellan gum, ascorbyl palmitate, mixed tocopherol concentrates, and phosphates are technically justified for use as additives in infant formula based on the information provided. • With regard to (ii), the United States questions the need for the proposed plan/programme for the consideration of remaining food additives. The United States does not believe there is a need to spend resources to reaffirm the technical justification of additives already permitted as part of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981). These additives were included in the Standard and Codex already has agreed there was a basis/justification for their use. The United States suggests that the list be reviewed to determine if all the additives are still being used and the typical levels of use in commercial infant formula products to be sure that use levels are consistent with those already listed in CXS 72-1981. Those in use would be considered technically justified and remain listed in CXS 72-1981 and would be submitted for safety assessment. Those not in use would be removed from CXS 72-1981 and not be submitted for safety clearance. The United States believes this work could be completed in one	**USA**

Electronic Working Group (EWG) period and as a pragmatic way to progress this work. Finally, the United States believes that detailed technical justification should be reserved for new additives not currently listed as part of CXS 72-1981.	
(i) the technological justification for the use of certain food additives in foods complying with The Standard for Infant Formula and Formulas for Special Medical Purposes (CXS 72-1981); and 1. the technological justification for the use of the following food additives for use in foods complying with CXS 72-1981: i. low acyl clarified gellan gum (INS 418) ii. ascorbyl palmitate (INS 304) iii. mixed tocopherol concentrates (INS 307b) iv. phosphates (INS 339(i), 339(ii) and 339(iii) and INS 340(i), 340(ii) and 340(iii)) The use of food additives for infant formula (IF) and formula for special medical purposes (FSMP) is to suspend a matrix of chemical micronutrients and macro nutrients derived from food substances to give it the appearance and consistency of a milk product. Although the technical justification used by the food industry is to deliver nutrients in an acceptable manner, the use of these additives to expand product marketing and the critical lack of consideration of the health impact of the more than 25 permissible additives (CXS 72-1981) in these products is not addressed. 1. It should be noted that IF and SMP products are approved for feeding infants exclusively from birth, low-birth-weight, premature and those with special medical needs. This means feed after feed exclusively for the first six months of life and promoted for consumption for up to 24 months or more. It is the lack of independent scientific evidence of the safety of the exclusive consumption of these additives during vulnerable ages of growth and development that is of primary concern. 2. The negative impacts of formula feeding are well documented on both short- and long-term health and development such as growth, immune system, microbiome, brain/neurological development, metabolic priming and premature death. Increasingly studies on the health impact of food additives are demonstrating negative effects on renal, cardiovascular and gut health. 3. The justification of “history of apparent safe use” and other vague and meaningless terms currently used to validate other vague inclusions such as “guidance upper levels” when scientific data on the safety of ingredients and additives is lacking must be prohibited in Codex Standards. The justification of “history of apparent safe use” in the Standard for IF and FSMP (CODEX STAN 72 – 1981, Para 3.1.3 Footnote 1 in Annex II, and the Review of the Standard for Follow-up Formula, Sections A (Footnote 1 to Para 3.1. and B Footnote 2 to para 3.1.3) needs to be reviewed and replaced with adequate independent scientific review. 4. Additives and manipulation of ingredients such as hydrolyzation of whey proteins are also used as marketing devices. For example, hydrolyzation requires certain additives to emulsify and stabilize the peptides and the addition of amino acids. The use of additives to create products has expanded into addressing normal infant and young child behaviours. Products with trademarked names exploit these behaviours with names such as “total comfort”, “sensitive”, “pure bliss”. 5. The WHO1 How the marketing of formula milk influences our decisions on infant feeding reports that the formula industry promoted products to address normal infant and young child behaviours: “Specialized Milks and Comfort Milks include formula products that can be promoted for specific medical conditions,e.g. lactose intolerance or allergy. Additionally, there are products marketed as comfort milks to address specific infant behaviours such as fussiness, poor sleep or hungry, where the formulation of the milks has been modified, for example the balance of whey or casein protein. There has been a rise in marketing for specialized and comfort milks that make bold claims to solve common infant ailments and behaviours such as colic, reflux and crying, despite insufficient evidence that they	**IBFAN**

are effective"…[and]…"raise awareness of a problem, or convince potential customers that they have a problem which can be solved by purchasing a product". (2-8)

6. The lack of research on the safety for infants of the proposed food additives necessitates close scrutiny of the research that is available – in this case on the impact on adult populations. Research9 on the health impacts of phosphate additives available from adult epidemiological studies shows that phosphate levels in the general population has risen linked to increased consumption of processed foods with phosphate additives. Elevated serum phosphate levels are correlated with mortality of those with chronic renal failure and with cardiovascular morbidity in the general population.

7. Research10 on the impact of additives on the gut microbiome demonstrates negative impact. The gut microbiome as an immunological organ protects against inflammation of the mucous gut membrane and protects its permeability. For infants, the gut microbiome is critical for their immune system development. Evidence now suggests that food additives can disturb gut homeostasis, and contribute to tissue-damaging inflammatory responses.

8. The use of food additives to extend shelf life for IF and SMP is not a technical justification but an economic one. Increasing the health risks for infants and those with special medical needs based on shelf life is unacceptable and contrary to the mandate of Codex to protect consumer health.

9. IBFAN does not accept the expanded use of additives for IF and SMP products. It is unethical to research the health impact of the proposed additives on infant and young child populations. The health risks and documented impact in animal and adult studies demonstrates that there are health risks and one must conclude that these would be even greater in this vulnerable population.

References:

1. How the marketing of formula milk influences our decisions on infant feeding. Geneva: World Health Organization and the United Nations Children's Fund (UNICEF), 2022. Licence: CC BY-NC-SA 3.0 IGO.

2. Munblit D, Crawley H, Hyde R, Boyle RJ. Health and nutrition claims for infant formula are poorly substantiated and potentially harmful. BMJ. (Clinical researched) 2020;369:m875.

3. Verfuerden ML, Dib S, Jerrim J, Fewtrell M, Gilbert RE. Effect of long-chain polyunsaturated fatty acids in infant formula on long-term cognitive function in childhood. A systematic review and meta-analysis of randomised controlled trials. PLoS One. 2020;15(11):e0241800.

4. Hughes H, Landa M, Sharfstein J. Marketing claims for infant formula: The Need for Evidence. JAMA Pediatrics. 2017;171(2):1056.

5. Shewan D. Pain Points: A guide to finding and solving your customers' problems. WordStream [Online]; 2021 (https://www.wordstream.com/blog/ws/2018/02/28/pain-points.

6. Crawley H. Infant milks: a simple guide to infant formula, follow-on formula and other infant milks. London: First Steps Nutrition Trust [online]; 2019 (https://static1.squarespace.com/static/59f75004f09ca48694070f3b/t/5c59379e6e9a7f0c422fc06f/1549350816390/Infant_milks_a_simple_ guide_Feb_2019_final.pdf.

7. First Steps Nutrition Trust. Claims made for infant formula, ingredients and formulations. London: First Steps Nutrition Trust [online]; 2019 (https://www.firststepsnutrition.org/reviews-of-claims.

8. Matson M. Make them cry (and buy) with inspiring emotional marketing. ReferralCandy [online]; 2020 (https://www.referralcandy.com/blog/emotional-marketing-examples, accessed 10 February 2022).

9. Eberhard R, Kai H, Markus K, Martin K, Johannes M. Phosphate Additives in Food – a Health Risk. Dtsch Arztebi Int, 2012 109(4): 49-55.

10. Federica L, Carmine S, Giovanni M. Impact of Food Additives on Gut Homeostasis. Nutrients 2019, 11(10):2334.

IFAC continues to support the use and technological need for gellan gum and phosphates in products that comply with the Codex Infant Formula Standard. IFAC can support the suggestion to group and prioritize the remaining food additives for technological justification, but suggests the Committee first determine whether there are any concerns regarding the remaining additives and then evaluate this work .in the context of other CCNFSDU priorities	**IFAC**
SPECIFIC COMMENTS	
Gellan gum (INS 418), low-acyl, clarified	
Brazil has no comments at the moment and will follow the discussion.	**Brazil**
Canada believes the information provided by the applicant is sufficient to technologically justify the need for this food additive in liquid hydrolysed protein formulas and/or amino acid based formulas.	**Canada**
Agreed. The information provided in this Annex demonstrates the technological need for these additives, following the criteria set out in the CCNFSDU Framework for appraising the technological need for food additives (REP20/NFSDU, paragraph 166 and Appendix VIII).	**Colombia**
The applicant notes that the use of additives is the most effective way at maintaining the homogeneity and that here are no commercially feasible, superior technology alternatives to manufacture FSMP formulas without the use of selective additives. The EU wonders whether the applicant is aware of any other alternatives to manufacture the productions under consideration without food additives? If yes, what alternatives were considered and why the use of additives was considered superior to those alternatives?The EU further notes that according to the applicant (see NFSDU/41 CRD 44) 'a wide variety of food additives (including other thickeners already authorised by Codex) were evaluated for their effectiveness in this product'. However, the details were provided only for the experiment with OSA-modified starch (INS 1450), xanthan gum (INS 415) and gellan gum (INS 418). The EU acknowledges the outcomes of the experiment and the comparison of the use of INS 418, INS 1450 and INS 415 and the combination thereof (namely the advantage of the use of gellan gum together with OSA). Nevertheless, the EU would also acknowledge the information on the effectiveness of other thickeners tested by the applicant. This information is missing.Despite the above comments, overall, the EU considers that the use of gellan gum (INS 418), low-acyl, clarified at 5 mg/100 mL limited to liquid hydrolysed protein and/or amino acid-based formula is technologically justified.To be noted: the above assessment is applicable only to low-acyl clarified form of gellan gum that was subject to the JECFA assessment for its use in products complying with CXS 72-1981. This form has to be clearly distinguished and specified to ensure that only this form could be used in products complying with CXS 72-1981.	**European Union**
INS418 has not been used in Japan. We have no objection to the technological justification for the food additive by ISDI, even if its use is permitted in Codex in the future. (Question) It is mentioned in the reply to Q.3.1 on page 6 as follows. "Under specific conditions and product compositions, gellan gum has advantages over currently permitted additives in the functional class of "thickener." These advantages by gellan gum (INS 418) and xanthan gum (INS 415) have been demonstrated experimentally, as shown on pages 6-7. We would like to obtain the information whether or not other thickeners other than both thickeners have been demonstrated experimentally.	**Japan**
We have reviewed the reports submitted by ISDI, as well as existing reports of the use of the additive Gome gellan (INS 418).In this regard, during the 41st session the CCNFDU discussed the technological need for the use of this additive (REP20 paragraphs 156-161), where it could not be determined its technological use in formulas for infants and young children (CXS 72-1981)The applicant presented justification for the use of gellan gum (INS 418) with the function of thickener stabilizer, and made comparisons of the use of gellan gum versus xanthan gum (INS 415), alone and combined with OSA-modified starch (INS 1450) in a concentrated liquid, a product made with a widely hydrolyzed protein.In this regard, the thickener xanthan gum (INS 415), according to the GSFA (CXS 192-1995), is allowed for use in category 13.1.1. and in accordance with note 479 which states "only in powdered protein hydrolyzed or amino acid based infant formula", which is also written in CXS 72-1981, hence its use in liquid formula as proposed by the applicant in your comparison would not correspond.Regarding the use of OSA-modified starch (INS 1450) allowed as a thickener up to 20 g/L, (CXS 192-1995 and CXS 72-1981), the applicant has shown that using 2.4 g/L the function is obtained. Therefore, we do not find a technological justification to further reduce a low value with	**Paraguay**

which the technological function is already obtained.Due to all of the above, we found no technological need for the use of low acyl gellan gum (INS 418) in liquid products covered by the CXS72-1981 standard.	
As noted at the 43rd Session of the CCNFSDU, gellan gum has advantages over currently permitted additives by enabling a lower overall use level of additives in formulas for special medical purposes for infants. We therefore agree with the proposal; however, we suggest that it be incorporated into the safety assessment plan.	**Peru**
Low acyl gellan gum has very high gel strength, high gel transparency, adjustable gel elasticity and hardness, superior flavor release, good compatibility, excellent thermal stability, acid resistance, enzymatic resistance, etc. at very low dosage (Valli and Clark, 2009). Gellan gum is stable during heating, has a high melting point, high clarity, biocompatibility, and stronger gelling ability (Dave and Gor, 2018). These properties make low acyl gellan gum an effective thickener and stabilizer. Use of this food additive ensures stability and homogeneity of hydrolyzed protein and/or amino acid based infant formula and formula for medical purposes intended for infants making sure that such products provide intended complete nutritional profile. Without the use of low acyl gellan gum, it may not be possible to produce safe and stable infant formula products. As of now, there is no feasible and better technological alternative to produce foods for special medical purposes (FSMP) formula other than low acyl gellan gum that is uniquely applicable to account for formula and processing variables of such product as there was an advantage by enabling a lower use level of the additives in formulas for special medical purposes for infants. It fulfills a technological necessity ensuring that infant formula products are homogenous to specifically and consistently deliver essential nutrients for this vulnerable group. We are of the opinion that the technological justification for low acyl clarified gellan gum is sufficient as there was an advantage on its use at a lower level specific for hydrolyzed protein and/or amino acid-based formulas for special medical purposes for infants in liquid form. It is worth noting that based on its 2019 safety evaluation, JECFA concluded that the proposed uses (gelling agent, stabilizer, and thickener) of gellan gum do not pose any safety concern in formulas for special medical purposes for infants based on available scientific evidence (JECFA, 2019).	**Philippines**
Republic of Korea does not object to the use If a clear use level is established to ensure the safety of the Gellan gum in accordance with provision 3.1 of the preamble to the GSFA.	**Republic of Korea**
The suggested concentration • Is considered safe due to the scientific toxicity studies did not indicate any harmful effects observed after feeding experimental animals with the additive (gellan gum), which indicates that the toxicity of this substance is considered low. • The nutritional exposure was evaluated on the basis of the proposed concentration of the substance which is (0.005 g / 100 ml) and at infant milk consumption rates of up to (260 ml / kg body weight per day). The results showed that the expected dietary exposure to this substance falls within the permissible limits.	**Saudi Arabia**
South Africa supports the rationale on the technological justifications for Gellan gum (INS 418), low-acyl, clarified, which has been included in the CL as Annex 1.	**South Africa**
IFAC continues to support the use of this additive. Information on the technological use and need for INS 418 was previously provided by the International Special Dietary Foods Industries (ISDI).	**IFAC**
The information provided demonstrates the technological need for this additive, following the criteria established in the CCNFSDU Framework for Appraising the Technological Need for Food Additives (REP20/NFSDU, p. 166).	**ISDI**
Ascorbyl palmitate (INS 304)	
We would like to point out that the GMP limit proposed for ascorbyl palmitate as an antioxidant additive, within the levels of vitamin C established in the Codex Stan 72-1981 standard, is related to the nutritional purpose of the compound and not to its technological function. The level proposed for the use of a food additive must be consistent with the intended technological purpose, that is, with the antioxidant function.	**Brazil**

Furthermore, this additive has an established ADI. Therefore, setting a limit as GMP contradicts item 1.4 of GSFA. Thus, we are of the opinion that the rationale for using ascorbyl palmitate with GMP limit linked to vitamin C limits is not consistent with its use as a food additive.	
Canada believes the information provided by the applicant is sufficient to technologically justify the need for this food additive.	**Canada**
Change the limit to GMP. While the current maximum use level is 1 mg/100 ml (as consumed) in all types of infant formula, we consider that the required and appropriate use level should be restricted by good manufacturing practices (GMP). As the existing ADI for ascorbyl palmitate (0 - 1.25 mg/kg bw) is based on the 17th JECFA in 1973 and safety information has been updated since then, we request JECFA to evaluate the safety of using ascorbyl palmitate as an additive in infant food (Priority List of Substances Proposed for Evaluation by JECFA).	**Colombia**
The EU considers that the use of ascorbyl palmitate (INS 304) at 1 mg/100 mL is technologically justified in products complying with CXS 72-1981. The EU takes note of the technological need for this antioxidant to prevent oxidation of infant formula constituents and of the fact that ascorbyl palmitate is also listed as an acceptable source of vitamin C in the Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (CXG 10-1979). In the EU's view the use of acrobyl palmitate is in line with the principle 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".	**European Union**
The recommended amount is 170 PPM per 100 ml ready-to-use product.	**Iran**
We have no objection to the technological justification for the food additive by ISDI. In Japan, it is also used for the purpose of improving nutritional qualities as nutritional enhancer.	**Japan**
Taking into account the mandate emanating from the 41st session of the CCNFDU, which asks members for the technological justification of certain additives, we have not found technological justification for the modification of the use level of ascorbyl palmitate (INS 304) to pass it to GMP.Therefore, we do not find it necessary to modify the current permitted level of use to GMP.	**Paraguay**
Regarding ascorbyl palmitate, we agree with the proposal to modify the limits to GMP, because of its antioxidant action explained in the Background section, and also because it is currently accepted by CAC/GL10 as a permitted source of Vitamin C.	**Peru**
Ascorbyl palmitate has been listed as an antioxidant in the Codex Standard for Infant Formula and Formula for Special Medical Purposes Intended for Infants (CXS 72-1981) with a maximum level of 1 mg per 100 ml of the finished product singly or in combination. Since ascorbyl palmitate is a potent antioxidant in protecting lipids from peroxidation, it specifically prolongs the shelf life of infant formula products. These products contain lipids such as polyunsaturated fatty acids and important vitamins that are prone to oxidation. Without this antioxidant, lipid oxidation may result to nutrient degradation and deterioration of flavors of infant formula and formula for special medical purposes intended for infants. Thus, ascorbyl palmitate will extend the shelf life of such products by maintaining the organoleptic and nutritional composition through its antioxidant properties by inactivation of free radicals and scavenging of oxygen. We support to maintain the maximum permitted level of 1 mg/100 mL of the finished product. The proposal to use GMP level, as recommended by International Special Dietary Foods Industries (ISDI), within the limits for Vitamin C for infant formula and FSMP for infants (CXS 72-1981), should be further reviewed by the Committee.	**Philippines**
This may be acceptable within GMP limits as a nutrient enhancer. For other purposes of use (e.g. antioxidants), further discussion seems necessary to establish clear standards for safe use.	**Republic of Korea**

The proposed amendment in the circular letter is to change the maximum allowable limit for adding (Ascorbyl palmitate (INS 304)) to infant formula products from (1 mg / 100 ml) as stipulated in the specification (CXS 72-1981), to be (GMP) at It should not exceed the total limits stipulated in the current specification (1 mg / 100 ml). This proposed change allows this substance to be added as a dietary ingredient (Vitamin C) or as an antioxidant additive.	**Saudi Arabia**
South Africa is not opposed to the use of Ascorbyl palmitate (INS 304) as a food additive. However, given the existing numerical ADI for ascorbyl palmitate (0 – 1.25 mg/kg bw) based on the 17th JECFA meeting in 1973, South Africa cannot support the proposed GMP maximum usage levels.	**South Africa**
Referring to the technological justification proposed for Ascorbyl palmitate (INS 304) Syria supports its progress through the process	**Syrian Arab Republic**
The information provided demonstrates the technological need for this additive, following the criteria established in the CCNFSDU Framework for Appraising the Technological Need for Food Additives (REP20/NFSDU, p. 166). ISDI has requested consideration for a change in the maximum use level for ascorbyl palmitate when used in foods for infants. While the current maximum use level is 1 mg/100 mL (as consumed) in all types of infant formula], ISDI considers the required and appropriate use level should be restricted by good manufacturing practices (GMP). Given the existing ADI for ascorbyl palmitate (0 – 1.25 mg/kg bw) is based on the 17th JECFA meeting in 1973, and updated safety information has been available in the meantime, we would like to request for JECFA to evaluate the safety of use of ascorbyl palmitate in foods for infants (Priority List of Substances Proposed for JECFA Evaluation). We consider that this risk assessment would be very helpful to inform whether our request for GMP use level may be supported by CCNFSDU.	**ISDI**
Tocopherol concentrate, mixed (INS 307b)	
Brazil is of the opinion that the justification presented lacks robust data or experiments that demonstrate the need for the combination of antioxidants at higher levels or in conditions of use other than permitted. In addition, the way of expressing the limits is different for the compounds, which prevents the establishment of a single limit for the INS 304 and 307b additives.	**Brazil**
Canada believes the information provided by the applicant is sufficient to technologically justify the need for this food additive.	**Canada**
Agreed. The information provided in this Annex demonstrates the technological need for these additives, following the criteria set out in the CCNFSDU Framework for appraising the technological need for food additives (REP20/NFSDU, paragraph 166 and Appendix VIII).	**Colombia**
The EU considers that the use of tocopherol concentrate, mixed (INS 307b) at 1 mg/100 mL is technologically justified in products complying with CXS 72-1981. The EU takes note of the technological need for this antioxidant to prevent oxidation of infant formula constituents and of the information provided by the applicant on the need for both ascorbyl palmitate and tocopherol concentrate, mixed to achieve the sufficient antioxidant effect.Similarly to acrobyl palmitate, in the EU's view the use of tocopherol concentrate, mixed is also in line with the principle 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".	**European Union**
In the case of mixed tocopherol concentrate, a limit of 1 mg/100 cc is acceptable.	**Iran**
We have no objection to the technological justification for the food additive by ISDI. In Japan, it is also used for the purpose of improving nutritional qualities as nutritional enhancer. In Japan, INS307 b is used as Antioxidant and also as Nutritional enhancer. As a result of both use, the total amount used is larger than the current Maximum level (1 mg / 100 ml) listed in Codex CXS 72-1981.	**Japan**
We have no comments regarding its technological necessity and the limits already established in the CXS 72-1981 standard.	**Paraguay**

We agree with the proposal to keep tocopherol concentrates within the limit currently set in CXS 72.	**Peru**
Mixed Tocopherol Concentrates Mixed tocopherols as antioxidants are due to their free radical scavenging properties. Since infant formula products contain vegetable and marine oils, such products are prone to oxidation. The lipid oxidation could degrade nutrients and produce unwanted flavors. Thus, mixed tocopherols as antioxidants in infant formula products are needed to extend shelf life and maintain organoleptic properties. It works synergistically with ascorbyl palmitate.	**Philippines**
The suggested upper limit for the additive (Tocopherol concentrate, mixed (INS 307b)) (1 mg / 100 ml) proposes no concern in terms of the safety and security of adding this substance to infant formula products as stipulated in the standard (CXS 72-1981).	**Saudi Arabia**
South Africa supports the rationale on the technological justifications for Tocopherol concentrate, (INS 307b) which has been included in the CL as Annex 1. However, we would support the recommendation for the substance to be evaluated by JECFA for its safety in infant foods.	**South Africa**
The information provided demonstrates the technological need for this additive, following the criteria established in the CCNFSDU Framework for Appraising the Technological Need for Food Additives (REP20/NFSDU, p. 166).	**ISDI**
Phosphates (INS 339(i), 339 (ii) and 339(iii) and INS 340(i), 340(ii), and 340(iii))	
Brazil has no comments at the moment and will follow the discussion.	**Brazil**
Canada believes the information provided by the applicant is sufficient to technologically justify the need for this food additive. Furthermore, as phosphorous sodium and potassium are already approved as nutrient sources, Canada does not object to the applicant's technological justification for also using them as food additives for the purpose of acidity regulators.	**Canada**
Agreed The information provided in this Annex demonstrates the technological need for these additives, following the criteria set out in the CCNFSDU Framework for the technological evaluation of food additives (REP20/NFSDU, paragraph 166 and Appendix VIII).	**Colombia**
Based on the information provided, the EU considers that the use of INS 339(i), 339 (ii), 339(iii), INS 340(i), 340(ii) and 340(iii) as acidity regulators at 45 mg expressed as phosphorus singly and in combination is technologically justified.The EU notes that the mentioned substances are also listed in the Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (CXG 10-1979).	**European Union**
It can be added to the list of allowed minerals used in infant formula for better access to raw materials	**Iran**
We have no objection to the technological justification for the food additive by ISDI. In Japan, it is also used for the purpose of improving nutritional qualities as nutritional enhancer.	**Japan**
We have no comments regarding its technological necessity and the limits already established in the CXS 72-1981 standard.	**Paraguay**
We agree with aligning the limits for phosphates already established in CXS 72, to be replicated in GSFA food categories 13.1.1 and 13.1.3.	**Peru**
Sodium phosphates (sodium dihydrogen phosphate (INS 339 i), disodium hydrogen phosphate (INS 339 ii), and trisodium phosphate (INS 339 iii)) and potassium phosphates (potassium dihydrogen phosphate (INS 340 i), dipotassium hydrogen phosphate (INS 340 ii), and tripotassium phosphate (INS 340 iii)) regulate the acidity of infant formula products. Their important roles in acidity regulation and buffering action are critical in stabilizing pH sensitive components and the formula matrix of infant formula and formula for FSMP intended for infants. We are of the opinion that technological justifications of the food additives under consideration, namely, low acyl clarified gellan gum, ascorbyl palmitate, mixed tocopherol concentrates and phosphates, as presented by the International Special Dietary Foods Industries and/or International Food Additives	**Philippines**

Council, are sufficiently supported based on the criteria established in the CCNFSDU Framework for Appraising the Technological Need for Food Additives (REP20/NFSDU, p. 166).	
The proposed upper limit for phosphates (INS 339(i), 339(ii) and 339(iii) and INS 340(i), 340(ii), and 340(iii))) which is (45mg/100ml) proposes no concern in terms of the safety and security of adding these substances to infant formula products as stipulated in the standard (CXS 72-1981).	**Saudi Arabia**
South Africa supports the rationale on the technological justifications for Phosphates (INS 339(i), 339 (ii) and 339(iii) and INS 340(i), 340(ii), and 340(iii)) which has been included in the CL as Annex 1. However, we would support the recommendation for these substances to be evaluated by JECFA for its safety in infant foods.	**South Africa**
IFAC continues to support the use of this additive. IFAC contributed to the information supporting the technological use and need of phosphates previously submitted by ISDI.	**IFAC**
The information provided demonstrates the technological need for this additive, following the criteria established in the CCNFSDU Framework for Appraising the Technological Need for Food Additives (REP20/NFSDU, p. 166).	**ISDI**
Plan / programme for the consideration of the food additives in CRD15Rev from CCFA49	
Brazil has no comments at the moment and will follow the discussion.	**Brazil**
Canada would like to know what factors were used to group the food additives into specific batches and how and why these batches were prioritized. Further discussion is needed at the CCNFSDU43 session.	**Canada**
We recommend that, before designing the workplan, the outcome of the first batch of additives, and in particular the prioritisation of this work by JECFA and CCNFSDU and whether any concerns have been identified regarding the use of these additives, should first be known and evaluated, taking into account the different issues currently being addressed by these organisations. We stress the progress made in CCNFSDU41 on a review of the technological justifications for additives in CRD15rev of CCFA49 using the new framework, starting with food additives with ADI values. However, we recommend that, before designing the workplan, the outcome of the first batch of additives and in particular the prioritisation of this work by JECFA and CCNFSDU and whether any concerns have been identified with the use of these additives should first be known and evaluated, taking into account the different issues currently being addressed by these organisations. On the basis of the above and if the Committee considers that this Plan remains a priority, we support the proposed Plan.	**Colombia**
Cuba has no comments in principle on the plan for appraising the technological need for the food additives listed in CRD15rev (49th Session of the CCFA).	**Cuba**
EU supports working according to a plan based on CRD15Rev for food additives that do not have an appropriate safety assessment for their use in infant formula consumed by infants below 12 weeks of age. The EU also agrees with the grouping food additives into the 5 batches as proposed in CL 2022/80/OCS - NFSDU.	**European Union**
Iran agrees with the addition of new additives in the formula after complete technological studies	**Iran**
We agree with the proposed plan/programme.	**Japan**
New Zealand has the following general comments on CL 2022/80/OCS – NFSDU. Our comments relate to point (b): the plan/programme for the consideration of the remaining food additives as presented in Annex 2 of the CL. New Zealand welcomes a discussion on the proposed plan/programme for appraising the technological need of the food additives in CRD15Rev from CCFA49 for those food additives that do not have an appropriate safety assessment for their use in infant formula consumed by infants below 12 weeks of	**New Zealand**

age. We note that Batch 1 contains the food additives covered by point (a) of this CL and includes the food additives already covered by the TOR for the EWG (i.e. the current work). Noting that the additives presented in Annex 2 of the CL are already permitted in infant formula as per CXS 72-1981 and have a history of safe use, we encourage consideration be given to current Codex and JECFA workload and priorities before finalising a plan for the evaluation of the technological justification for the remaining additives. New Zealand considers Batch 5: packaging gases to be low risk, and notes additives contained within Batches 3 & 4 include those that dissociate into nutrients, and have already been evaluated as safe at higher nutrient levels for infant formula in the 2007 revision of the Infant Formula Standard. Discussion should therefore initially focus on whether there is a need, for the other additives to go on the JECFA priority list so that a valid specification and ADI can be generated.	
We agree with the proposal to do them in 5 batches, as recommended by the EWG.	**Paraguay**
We agree with drawing up the plan for appraising the technological need for the food additives listed in CRD15rev. In addition, the results should be made available to the working committees in the member countries.	**Peru**
Plan/programme for consideration of remaining food additives Completion of the framework to evaluate the technological need of food additives is a welcome development made by the Codex Committee on Foods for Special Dietary Uses in its 41st Session. The Philippines believes that the Committee should consider reviewing first the result of the evaluation of the first set of food additives with the addition of low acyl clarified gellan gum, before proceeding to the work plan relative to the assessment of technological justifications for the rest of the food additives since there are no pressing concern on their uses.	**Philippines**
South Africa is in support of the work of the Committee on the technological evaluation of food additives used in foods for infants, to review the technological justifications of additives in CRD15 rev of CCFA49 by using the new framework, starting with the food additives with numerical ADIs.	**South Africa**
Additives and 'optional ingredients' should never be permitted purely for cosmetic, technological, economic or manufacturing purposes. Additives should only ever be permitted if they make an essential contribution to the safety or nutritional requirements of young children, with the primary purpose of offsetting the risks associated with artificial feeding. Such a need can only be established on the basis of predominantly independently funded, ethically conducted, relevant and convincing evidence or the comparable level of evidence under the GRADE classification. If additives are permitted, in the interests of transparency, there should be a mandatory requirement that all ingredients are listed clearly on the label with the commonly used names of substances present. Parents and care givers have a right to know if ingredients or chemical additives might have negative health consequences. It should go without saying that the presence of any additive should never be used to idealise the product in any way. Food additives should never be justified by terms such as 'history of apparent safe use' 'science –based' and 'scientifically demonstrated'. Such ill-defined and meaningless terms allow the possibility of undue influence from commercially biased claims, opinion and evidence that has not been subject to adequate independent review or scrutiny. Parents and health workers have a right to expect that any product placed on the market has been independently scrutinised and that ingredients are not added merely on the basis of a manufacturers claim. the many instances of the term 'History of apparent safe use' should be removed from all Codex standards and texts.(CXS 72 – 1981, Para 3.1.3 Footnote 1, Annex 11, REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA, Sections A (Footnote 1 to Para 3.1.3) and B (Footnote 2 to para 3.1.3) All additives should be considered together so that efficacy and safety can be properly established.	**ENCA**
IBFAN is of the opinion that any plan to consider the remaining additives should prioritize the reduction of the number of additives in these products and to prioritize the health impact of additives as a primary consideration to protect consumer health as mandated. The synergistic impact of additives on the health of infants must be considered, including the carry-over chemicals such as heavy metals that may contaminate additives such as gellan gum.	**IBFAN**
IFAC can support the suggestion by a member of the Electronic Working Group to group the remaining food additives into batches, prioritize each batch and address one batch at a tiHowever, prior to creating and implementing this work plan, we suggest the Committee first determine whether there are any	**IFAC**

concerns regarding the remaining additives and then evaluate this work in the context of other CCNFSDU priorities. If there are no concerns regarding the additional additives, the Committee may wish to prioritize other activities.	
ISDI is pleased to contribute to this important work of the Committee on the technological evaluation of food additives used in foods for infants. In particular, we welcomed the progress made at CCNFSDU41 where the framework to evaluate technological need was completed, and work was immediately initiated on a review of technological justifications of additives in CRD15rev of CCFA49 by using the new framework, starting with the food additives with numerical ADIs (i.e. ascorbyl palmitate, mixed tocopherol concentrates, sodium & potassium phosphates). However, given current Codex and JECFA workload and priorities, before creating a work plan for evaluation of the technological justification for the remaining additives ISDI recommends reflecting on the outcome of the evaluation of the first set of additives to determine where this work would remain in the overall prioritization of work by JECFA and CCNFSDU. In the absence of any identified concern related to the use of these food additives, ISDI encourages the committee to consider whether this would still have priority over other work.If the committee determines that this work is still of priority, ISDI could support the proposed categorization.	**ISDI**