CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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**CL 2022/80/OCS - NFSDU**
**November 2022**

**TO:** Codex Contact Points

Contact Points of international organizations having observer status with Codex

**FROM:** Secretariat, Codex Alimentarius Commission,
Joint FAO/WHO Food Standards Programme

**SUBJECT: Request for comments 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**

**DEADLINE: 16 January 2023**

## BACKGROUND

1. For information, please refer to the report attached as Appendix I to this CL.

## REQUEST FOR COMMENTS

2. Codex members and observers are invited to submit comments on:
    a. 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)
    b. the plan/programme for the consideration of the remaining food additives as presented in Annex 2).
3. When providing comments and a rationale on the technological justification for the abovementioned food additives, members and observers should review the information and comments received by the EWG and presented in Annex 1.
4. All the above-mentioned are uploaded to the Codex Online Commenting System (OCS): https://ocs.codexalimentarius.org/, as per the guidance below.

## GUIDANCE ON THE PROVISION OF COMMENTS

5. Comments should be submitted through the Codex Contact Points of Codex members and observers using the OCS.
6. Contact Points of Codex members and observers may login to the OCS and access the document open for comments by selecting “Enter” in the “My reviews” page, available after login to the system.
7. Contact Points of Codex members and observer organizations are requested to provide general comments at the document level. Additional guidance on the OCS comment categories and types can be found in the OCS Frequently Asked Questions (FAQs).
8. Other OCS resources, including the user manual and short guide, can be found at the following link: http://www.fao.org/fao-who-codexalimentarius/resources/ocs/en/.
9. For questions on the OCS, please contact Codex-OCS@fao.org.

**APPENDIX I**

**Update of work of the EWG on food additives**
**(prepared by the EU, chair of the EWG)**

## BACKGROUND

1. The 41st Session of the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU41) agreed to establish an EWG, chaired by the European Union and co-chaired by the Russian Federation, working in English with the following terms of reference:

- to collect information from the applicants on the following additives: 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)) with the framework for considering technological justification[1] for use in CXS 72-1981; and
- to review the information provided by the applicants and provide recommendation to the Committee on the technological justification of each additive (REP20NFSDU, para. 168).

2. An invitation to join the EWG was issued in January 2020 and 25 members and 9 observers joined the EWG[2].

3. The EWG issued a circular paper to address the first part of the terms of reference. The information on the technological justification was provided, together with some comments made by the EWG members. In addition, some EWG members suggested that a plan/ programme should be developed to avoid having ad hoc decision-making in CCNFSDU on how to proceed with the rest of the food additives in CRD15Rev (CCFA49). This would also be in line with the request from CCEXEC for CCNFSDU to better plan and prioritize its work. In this regard, one EWG member submitted to the chair of the EWG a proposal for further consideration by the EWG.

4. The EWG chairs were not able to issue a second circular paper to review the information and comments provided. Thus, the EWG did not complete its work.

5. In consultation with the Codex Secretariat and the chair and co-chair of the Committee, it was agreed that in order to allow work to proceed, a Circular Letter would be issued to further consider the technological justification for food additives under consideration and on the proposed plan/ programme for future work on food additives. It is envisaged that the replies to the CL will be considered by CCNFSDU43 with the possibility to establish an in-session working group to help advance work.

6. The information and comments on the technological justification of the food additives under consideration submitted to the EWG are in Annex 1, the proposal for a plan/ programme for the future work in Annex 2 and the background on the work on the appraisal of the technological need of the food additives in CRD15Rev of CCFA49 in Annex 3 to this CL.

[1] The framework was agreed by CCNFSDU41 and is published as an information document available here

[2] Australia, Belgium, Brazil, Canada, Chile, Colombia, European Union, Finland, France, Ghana, Guatemala, Indonesia, Malaysia, New Zealand, Netherlands, Nigeria, Paraguay, Peru, Poland, Russian Federation, Thailand, United Kingdom, United States of America, Uganda, Zimbabwe, Association internationale pour le développement des gommes naturelles (AIDGUM), Conseil européen de l'industrie chimique (CEFIC), EU Specialty Food Ingredients (EUSFI), Institute of Food Technologists (IFT), International Food Additives Council (IFAC), International Fruit and Vegetable Juice Association (IFU), International Special Dietary Foods Industries (ISDI), Natural Products Association (NPA) and Specialised Nutrition Europe (SNE).

**Annex 1**

**INFORMATION AND COMMENTS ON THE TECHNOLOGICAL JUSTIFICATION OF THE FOOD ADDITIVES UNDER CONSIDERATION**

**PART A: Information provided by the applicants**

The information below was submitted by the applicants (ISDI and IFAC) in reply to the first circular paper. This information reflects the first part of the terms of reference of the EWG, i.e. the information that should be reviewed in order to provide the recommendations concerning the technological need of each additive.

**Gellan gum (INS 418), low-acyl, clarified**

*To be noted: a discussion on the technological need for low-acyl clarified gellan gum took place at CCNFSDU41 (see REP20/NFSDU, paras 156-161) where the Committee agreed to request the applicant to provide more information on the substance, in particular its advantages over currently permitted food additives (i.e. Q3 of the framework).*

<table>
<tr><td colspan="2">THE PROPOSAL IS SUBMITTED BY:</td><td colspan="2">ISDI (International Special Dietary Foods Industries)</td></tr>
<tr><td colspan="4">1 IDENTITY AND INTENDED USE</td></tr>
<tr><td colspan="2">Q1.1 Name and INS Number of the Additive as listed in CXG 36-1989:<br>For substances not yet included in CXG 36-1989, chemical name of the substance.</td><td colspan="2">Gellan Gum (INS 418), Low-acyl, Clarified</td></tr>
<tr><td colspan="4">Q1.2 Describe the food form (e.g. liquid, powder) for which the additive is intended to be used and indicate the relevant CCNFSDU standard and if known the GSFA food subcategory</td></tr>
<tr><td colspan="4">CCNFSDU standard</td></tr>
<tr><td>Reference</td><td colspan="2">Name of the standard</td><td>Comments (e.g. limitation of use to specific food forms)</td></tr>
<tr><td>72-1981</td><td colspan="2">Standard for infant formula and formulas for special medical purposes intended for infants</td><td>Limited to liquid hydrolysed protein and/or amino acid-based formula</td></tr>
<tr><td colspan="4">GSFA food category</td></tr>
<tr><td>Food category No</td><td colspan="3">Name of the GSFA food category</td></tr>
<tr><td>13.1.3</td><td colspan="3">Formulae for special medical purposes for infants</td></tr>
<tr><td colspan="4">Q1.3 Indicate and justify the range of the proposed use level of the food additive needed to accomplish the desired technological effect at the lowest possible use level</td></tr>
<tr><td colspan="2">Proposed use level (per 100 mL in final product as consumed)</td><td colspan="2">Justification of the level(s) proposed</td></tr>
<tr><td colspan="2">0.005 g/100 mL</td><td colspan="2">The amount indicated has been demonstrated to be the amount necessary to produce the thickener/stabilizer function in these products, which in turn ensures the infant formula is homogenous and delivers the appropriate level of all essential nutrients. Lower levels have not been shown to provide the needed technical effect. Results from experimental trials are provided in Annex to this Form.</td></tr>
<tr><td colspan="4">2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA</td></tr>
<tr><td colspan="4">Q2.1 Describe the technological function of the food additive relative to the CXG 36-1989 (include the functional class) and the advantage conferred by its use</td></tr>
<tr><td colspan="4">Technological function relative to the CXG 36-1989</td></tr>
</table>

The use of food additives in infant formula is justified in order to maintain consistency and texture in order to ensure safe and acceptable use.

Codex sets out functional class and technological purpose for additives in CXG 36-1989. In the case of gellan gum in this product application, the following text from the Codex Guidance apply:

Functional class: thickener ("a food additive which increases the viscosity of a food")

Technological purpose: thickener

AND

Functional class: stabilizer ("a food additive which makes it possible to maintain a uniform dispersion of two or more components")

Technological purpose: emulsion stabilizer

Advantage from the use of the additive

Per the 1971 JECFA Report on Additives in Baby Foods, the use of food additives in infant formula is justified in order to maintain consistency and texture in order to ensure safe and acceptable use. The 1971 JECFA report also notes that stabilizers and thickeners are technological functions that are justified for infant formula products.

Commercially acceptable Infant formulas based on extensively hydrolyzed proteins or amino acids cannot be safely manufactured without the use of additives. Compared to intact proteins, hydrolyzed proteins are not as effective in creating or maintaining a stable emulsion. Development of physically stable nutritional products based on hydrolyzed proteins is further challenged when high levels of insoluble ingredients, like mineral salts, are incorporated. These characteristics can result in mineral fallout (resulting in sedimentation) and defects in emulsion stability (which results in phase separation). These issues in turn can result in significant challenges to both manufacturing of these products and the optimal delivery of nutrition for infants consuming these products. Thickeners, such as gellan gum, are required to ensure infant formula is homogenous and delivers the appropriate level of all essential nutrients.

Due to differences in manufacturing process (e.g. spray dried vs. dry blend), thermal processing method (e.g. retort vs. ultra-high temperature pasteurization), ingredients (e.g. intact vs. hydrolyzed protein, type and level of lipids), and product format (e.g. powder vs. liquid), a variety of additives are needed to allow for the most optimized food additive application for different products from different manufacturers.

**Q2.2 Does the use of an additive serve one or more of the needs set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA? Indicate which one(s)**

Gellan gum meets several of the needs described in Section 3.2 of the Preamble of the GSFA:

b) To provide necessary ingredients or constituents of foods manufactured for groups of consumers having special dietary needs

The products in Category 13.1.3 are intended to be sole-source nutrition for infants not receiving human milk, and the use of gellan gum in these products ensures that products remain homogeneous and that the products, as-fed, provide the complete nutrient profiles defined in the Codex Standard (72-1981)

c) To enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer

Gellan gum, as a stabilizer, has a primary function of ensuring the stability of these products. This function is critical to the homogeneity of these products and thus the effective delivery of the complete nutritional components of these products.

d) To provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities.

In addition to ensuring homogeneity during feeding, it is critical to ensure homogeneity of these products during manufacturing/processing/packaging. Loss of homogeneity of these products during manufacturing/processing/packaging of these products could lead to inconsistency in the nutrient levels throughout the batch, which could again lead to nutrient levels in the products, as-fed, not meeting the nutrient requirements defined in the Codex Standard (CXS 72-1981). Food safety and integrity are the highest priority for manufacturers of infant foods, including rigorous standards for quality including hygiene through the supply chain and life cycle of the products.

**Q2.3 Cannot the objectives set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA be achieved by other means that are economically and technologically practicable?**

There are both technological and economic challenges to achieving the objectives described above in these products, especially considering the challenges when formulating products based on hydrolysed proteins or amino acids.

Infant formula products based on hydrolysed proteins or amino acid face significant challenges in terms of maintaining homogeneity. Product research has demonstrated that the use of additives is the most effective way at maintaining the homogeneity of these products during manufacturing of these products, during shelf-life, through administration of the products to the consumers. At this time, there are no commercially feasible, superior technology alternatives to manufacture FSMP formulas without the use of selective additives that are uniquely suitable for specific formula and processing variables.

**Q2.4 Would the use of this food additive in the intended food(s) modify any characteristic of the food that might mislead the consumer?**

Products containing gellan gum in the formulation would identify this additive in the list of ingredients according to the requirements in the General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985), which specifies that the functional class shall be used together with the specific additive name or INS number in the ingredient panel (or per national legislation), providing transparency to consumers. The technological purpose for the addition of this additive is to maintain consistency and texture in order to ensure safe and acceptable use, and does not conceal damage or inferiority, or make the product appear to be greater than actual value. The purpose is to fulfil a technological necessity, without which the product would be inferior and not fit for use (e.g. it would not be able to ensure consistent delivery of essential nutrients in the product).

**3 COMPLIANCE WITH THE APPROACH ON THE USE OF ADDITIVES IN FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN**

**Q3.1 Does the proposed food additive perform the same/similar purpose as other additives that have already been authorized for use in the same product category? If not, what is the justification for the need for an additive with a new functional class and/or technological purpose? If yes, what advantage(s) does the proposed additive provide over currently permitted options?**

Yes, gellan gum performs a similar purpose as other additives for use in the same product category. Of the 106 additives listed in the General Standard for Food Additives with the functional class of “thickener”, 10 other additives are currently permitted for use in infant formula (FC 13.1.1) and/or formula for special medical purposes for infants: Guar gum (INS 412), Carob bean gum (INS 410), Distarch phosphate (INS 1412), Acetylated distarch phosphate (INS 1414), Phosphated distarch phosphate (INS 1413), Hydroxypropyl starch (INS 1440), Carrageenan (INS 407), Starch sodium octenyl succinate (INS 1450), Xanthan gum (INS 415), and Pectins (INS 440).

Under specific conditions and product compositions, gellan gum has advantages over currently permitted additives in the functional class of "thickener". Gellan gum acts as a thickener/stabilizer in ready-to-feed infant formula, or concentrated liquid products to improve physical stability through mechanisms such as maintaining homogeneity or minimizing ingredient sedimentation. Gellan gum acts as a thickening or gelling agent through formation of a fluid gel. The fluid gel can aid with the sedimentation of dense components such as insoluble calcium and phosphorus salts. The gelation also provides a secondary benefit of thickening the solution viscosity, slowing the upward migration of fat, which is less dense. Gellan gum stabilizes the emulsion of protein, fat and water created in the infant formula manufacturing process, minimizing phase separation during storage, display and feeding.

Additionally, as noted at the 43rd Session of CCNFSDU, gellan gum has advantages over the currently permitted additives by enabling a lower overall use level of additives in formulas for special medical purposes for infants (REP20/NFSDU, p 159).

These advantages have also been demonstrated experimentally, as shown below.

*Experimental trials with gellan gum*

In this experiment, gellan gum (INS 418) and xanthan gum (INS 415), both of which are in the functional class of "thickener", were evaluated alone and in combination with OSA-modified starch (INS 1450) in a concentrated liquid product made with an extensively hydrolyzed protein. Experimental products were manufactured and then allowed to settle for 40 days prior to photographs being taken. These conditions simulate liquid product manufacturing and distribution, prior to consumption of the product.

Heavy creaming, separation of oil and liquid phases, and sedimentation were observed in a control sample (far left) without either OSA-modified starch (INS 1450) or gellan gum (INS 418). OSA-modified starch added at 0.4 g/L as-fed (second from the left), the product had creaming and sedimentation, which was resolved when the concentration of OSA-modified starch was increased by 6-fold (far right). When gellan gum or xanthan gum alone were added at 0.05 g/L (center), the product had phase separation and creaming, respectively. However, when gellan gum (at 0.05 g/L) was added with 0.4 g/L of OSA-modified starch (top photo, second from the right), the product was stable with no phase separation, creaming, or sedimentation. This increased product homogeneity was not seen when xanthan gum (at 0.05 g/L) was added in combination with 0.4 g/L of OSA-modified starch (bottom photo, second from the right).

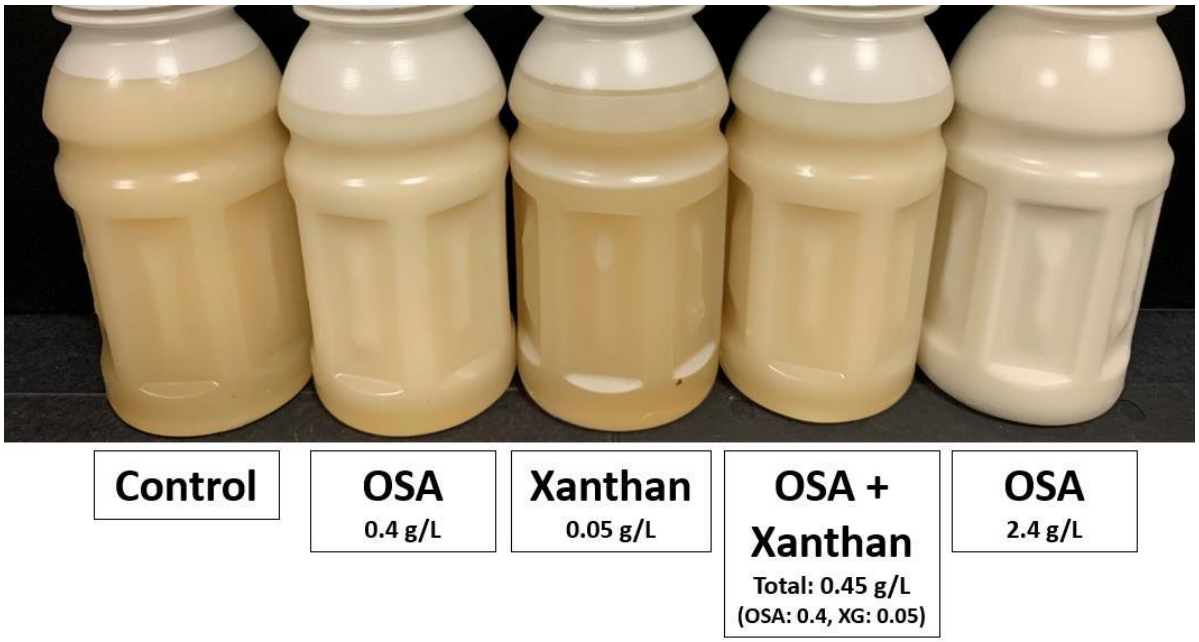
This experiment demonstrates that:

1. The additive system of gellan gum and OSA-modified starch was able to maintain homogeneity of the product by using a total thickener concentration more than 5-fold lower than if OSA-modified starch was added alone, and
2. Gellan gum was effective while xanthan gum was not effective at producing this technological effect.

| **Comparison of additive technological effectiveness** | | | |
|---|---|---|---|
| Experimental group | Additive Concentrations As-Fed (g/L) | Observations | Homogeneity Maintained? |
| Control | No stabilizer/thickener | Complete separation | **No** |
| OSA Low Conc | Total: **0.4 g/L** | Creaming and sedimentation | **No** |
| Gellan Gum | Total: **0.05 g/L** | Phase separation | **No** |
| Xanthan Gum | Total: **0.05 g/L** | Creaming and sedimentation | **No** |
| Gellan Gum + OSA Low Conc | Total: **0.45 g/L** OSA: 0.4 g/L, GG: 0.05 g/L | Homogeneity maintained | **Yes** |
| Xanthan Gum + OSA Low Conc | Total: **0.45 g/L** OSA: 0.4 g/L, XG: 0.05 g/L | Creaming and sedimentation | **No** |
| OSA High Conc | Total: **2.4 g/L** | Homogeneity maintained | **Yes** |

*Gellan Gum (INS 418)*


*Xanthan Gum (INS 415)*



**I. Ascorbyl palmitate (INS 304)**

| | |
|---|---|
| **THE PROPOSAL IS SUBMITTED BY:** | *ISDI (International Special Dietary Foods Industries)* |

**1 IDENTITY AND INTENDED USE**

| | |
|---|---|
| **Q1.1 Name and INS Number of the Additive as listed in CXG 36-1989:**<br>*For substances not yet included in CXG 36-1989, chemical name of the substance.* | Ascorbyl palmitate (INS 304) |

**Q1.2 Describe the food form (e.g. liquid, powder) for which the additive is intended to be used and indicate the relevant CCNFSDU standard and if known the GSFA food subcategory**

**CCNFSDU standard**

| **Reference** | **Name of the standard** | **Comments (e.g. limitation of use to specific food forms)** |
|---|---|---|
| *72-1981* | *Standard for infant formula and formulas for special medical purposes intended for infants* | *None* |

**GSFA food category**

| **Food category No** | **Name of the GSFA food category** |
|---|---|
| *13.1.1* | *Infant formulae* |
| *13.1.3* | *Formulae for special medical purposes for infants* |

**Q1.3 Indicate and justify the range of the proposed use level of the food additive needed to accomplish the desired technological effect at the lowest possible use level**

| **Proposed use level (per 100 mL in final product as consumed)** | **Justification of the level(s) proposed** |
|---|---|
| *GMP**<br>** Within the limits for Vitamin C in the Standard for Infant Formula and Formula for Special Dietary Purposes Intended for Infants (CXS 72-1981)* | *Ascorbyl palmitate is used as a food additive and it 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), and as such may be added to infant formula for this nutritive purpose in order to provide this essential nutrient in addition to its technological purpose as an additive.*<br>*Setting a limit as GMP with a reference to the nutrient limits in the standard forces consistency in how this substance can be added to food, regardless of whether it is for nutritive or additive purposes.*<br>*The level of ascorbyl palmitate proposed supports the sensory (maintains organoleptic properties by preventing oxidation) and nutritional quality of the infant formula during shelf life.* |

**2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA**

**Q2.1 Describe the technological function of the food additive relative to the CXG 36-1989 (include the functional class) and the advantage conferred by its use**

Technological function relative to the CXG 36-1989

Functional class: Antioxidant, Technological Purpose: Antioxidant

- A food additive, which prolongs the shelf-life of foods by protecting against deterioration caused by oxidation

Advantage from the use of the additive

Per the 1971 JECFA Report on Additives in Baby Foods, the use of food additives in infant formula is justified in order to increase shelf life, with antioxidants specifically mentioned as a justified class of additive. The 1971 JECFA report further asserts that naturally occurring tocopherols and ascorbic acid, or their appropriate esters (such as ascorbyl palmitate), are justified in maintaining an acceptable shelf life.

In food products such as infant formula that rely on lipids (such as those from vegetable oils or marine oil sources), vitamins, and minerals to provide essential nutrition, lipid oxidation is a major concern. This oxidation can lead to degradation of nutrients, which in turn could lead to nutrient deficiencies. Lipid oxidation can also lead to the development of undesirable off flavours that in turn could reduce compliance (and again lead to nutrient deficiencies). This is especially important for infant formulas that contain elevated amounts of polyunsaturated fatty acids that are especially prone to oxidation.

The antioxidant capacity of ascorbyl palmitate is based on the activity of its ascorbic acid moiety, whereas the palmitic acid moiety is present to make the overall compound hydrophobic. The antioxidant action of ascorbyl palmitate is via inactivation of free radicals, regeneration of primary antioxidants via hydrogen donation, metal chelating, and scavenging oxygen by reduction.

While effective by itself, combination of ascorbyl palmitate with other antioxidants with different molecular mechanisms, such as tocopherols, can produce synergistic antioxidant effects.

**Q2.2 Does the use of an additive serve one or more of the needs set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA? Indicate which one(s)**

Ascorbyl palmitate meets several of the needs described in Section 3.2 of the Preamble to the GSFA:

*a) To preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified in the circumstances dealt with in sub-paragraph (b) and also in other circumstances where the food does not constitute a significant item in a normal diet*

Ascorbyl palmitate preserves the nutritional quality of infant formula by preventing the degradation of nutrients.

*c) To enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer*

Ascorbyl palmitate maintains the quality of infant formula by preventing the degradation of nutrients, and also maintains the organoleptic properties of the formula by preventing lipid oxidation that can lead to the development of undesirable flavours.

**Q2.3 Cannot the objectives set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA be achieved by other means that are economically and technologically practicable?**

The benefits of the use of ascorbyl palmitate as an antioxidant cannot be met by other means.

The required composition of infant formulas includes a number of components that are oxidizable including lipids and a number of essential vitamins. In the absence of antioxidant systems that include ascorbyl palmitate, these oxidizable substances would degrade very quickly, resulting in products that do not maintain this important nutritional composition over the shelf life of the product.

**Q2.4 Would the use of this food additive in the intended food(s) modify any characteristic of the food that might mislead the consumer?**

The use of this additive would not modify any characteristic that would mislead the consumer. The addition of ascorbyl palmitate is for the purpose of maintaining the overall quality, nutritional composition, and organoleptic properties of the infant formula over the course of shelf life. The use of ascorbyl palmitate would clearly identify ascorbyl palmitate in the list of ingredients according to the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985), which specifies that the functional class shall be used together with the specific additive name or INS number (or per national legislation).

| **3 COMPLIANCE WITH THE APPROACH ON THE USE OF ADDITIVES IN FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN** |
|---|
| **Q3.1 Does the proposed food additive perform the same/similar purpose as other additives that have already been authorized for use in the same product category? If not, what is the justification for the need for an additive with a new functional class and/or technological purpose? If yes, what advantage(s) does the proposed additive provide over currently permitted options?** |
| Yes, ascorbyl palmitate performs a similar purpose as one other additive (mixed tocopherols concentrate, INS 307b) for use in the same product categories.<br><br>Ascorbyl palmitate is currently permitted for use in both infant formula (FC 13.1.1) and formula for special medical purposes for infants (FC 13.1.3) by both the *Codex Standard for Infant Formula and Formula for Special Medical Purposes Intended for Infants* (CXS 72-1981) and the *General Standard for Food Additives* (CXS 192-1995).<br><br>Of the 39 additives listed in the General Standard for Food Additives with the functional class of "antioxidant", only two are currently permitted for use in infant formula (FC 13.1.1) and formula for special medical purposes for infants (FC 13.1.3). The only other currently permitted antioxidant in these two food categories is Mixed Tocopherols Concentrate (INS 307b), and neither antioxidant is alone sufficient to provide the antioxidant function needed to maintain a normally acceptable shelf-life. Both antioxidants are required to produce the necessary technological effect, therefore, a choice of one or the other is not applicable in this case. |

**II. Tocopherol concentrate, mixed (INS 307b)**

| **THE PROPOSAL IS SUBMITTED BY:** | *ISDI (International Special Dietary Foods Industries)* |
|---|---|
| **1 IDENTITY AND INTENDED USE** | |
| **Q1.1 Name and INS Number of the Additive as listed in CAC/GL 36-1989:**<br>*For substances not yet included in CXG 36-1989, chemical name of the substance.* | Tocopherol concentrate, mixed (INS 307b) |

**Q1.2 Describe the food form (e.g. liquid, powder) for which the additive is intended to be used and indicate the relevant CCNFSDU standard and if known the GSFA food subcategory**

**CCNFSDU standard**

| **Reference** | **Name of the standard** | **Comments (e.g. limitation of use to specific food forms)** |
|---|---|---|
| *Codex CXS 72-1981* | *Standard for infant formula and formulas for special medical purposes intended for infants* | *None* |

**GSFA food category**

| **Food category No** | **Name of the GSFA food category** |
|---|---|
| *13.1.1*<br>*13.1.3* | *Infant formulae*<br>*Formulae for special medical purposes for infants* |

**Q1.3 Indicate and justify the range of the proposed use level of the food additive needed to accomplish the desired technological effect at the lowest possible use level**

| **Proposed use level (per 100 mL in final product as consumed)** | **Justification of the level(s) proposed** |
|---|---|
| *Maximum 1mg/100mL in finished product as consumed* | *The level of mixed tocopherol concentrate proposed is in line with the current accepted maximum level in the CXS 72-1981, Standard for Infant Formula and Formulae for Special Medical Purposes intended for Infants. This has been considered to support the sensory (maintains organoleptic properties by preventing oxidation) and nutritional quality of the infant formulae during shelf life.* |

**2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA**

**Q2.1 Describe the technological function of the food additive relative to the CXG 36-1989 (include the functional class) and the advantage conferred by its use**

Technological function relative to the CXG 36-1989

Functional class: Antioxidant, Technological Purpose: Antioxidant

- A food additive, which prolongs the shelf-life of foods by protecting against deterioration caused by oxidation

Advantage from the use of the additive

Per the 1971 JECFA Report on Additives in Baby Foods, the use of food additives in infant formula is justified in order to increase shelf life, ensure adequate sterilization by promoting homogenization, or to maintain consistency and texture in order to ensure safe and acceptable use.

The functional class of antioxidant is intended to increase the shelf life of products, such as infant formula, by protecting against deterioration caused by oxidation. As per the 1971 JECFA report, some antioxidants have been considered as needed for a variety of baby foods as experience shows that under favourable climatic conditions, a normally acceptable shelf-life can be maintained for some foods solely by the use of such naturally occurring antioxidants as tocopherols and ascorbic acid, or their appropriate esters.

In food products such as infant formula that rely on lipids (such as those from vegetable oils or marine oil sources), vitamins, and minerals to provide essential and sole source of nutrition, lipid oxidation is a major concern. This oxidation can lead to degradation of nutrients, which in turn could lead to nutrient deficiencies. Lipid oxidation can also lead to the development of undesirable off flavors that in turn could reduce compliance (and again lead to nutrient deficiencies). This is especially important for infant formulas that contain substances such as docosahexaenoic acid (DHA) that are especially prone to oxidation.

The antioxidant capacity of mixed tocopherol concentrate is based on the free radical scavenging activity of the mixed tocopherol concentrate. δ-Tocopherol shows the highest scavenging activity followed by γ-, β-, and α-tocopherol.

While effective by itself, combination of mixed tocopherol concentrate with other antioxidants with different molecular mechanisms, such as ascorbyl palmitate, produces more favourable synergistic antioxidant effects.

**Q2.2 Does the use of an additive serve one or more of the needs set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA? Indicate which one(s)**

Mixed tocopherol concentrate meets several of the needs described in Section 3.2 of the Preamble to the GSFA:

*a) To preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified in the circumstances dealt with in sub-paragraph (b) and also in other circumstances where the food does not constitute a significant item in a normal diet*

*b) To provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;*

Mixed tocopherol concentrate preserves the nutritional quality of infant formula by preventing the degradation of nutrients, including fats. This is critical to ensure infant formulas meet the nutritional requirements set in the infant formula and infant FSMP standard.

*c) To enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer*

*d) To provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities.*

Mixed tocopherol concentrate maintains the quality of infant formula by preventing the degradation of nutrients and fats, and also maintains the organoleptic properties of the formula by preventing lipid oxidation that can lead to the development of undesirable flavors, thus providing aids to store the food and ensure consistency in the nutrient levels throughout the batch and shelf life of the product.

**Q2.3 Cannot the objectives set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA be achieved by other means that are economically and technologically practicable?**

Because of the restricted list of positively approved food additives in infant formulas, the benefits of the use of mixed tocopherol concentrate alone or combined with ascorbyl palmitate as an antioxidant system cannot be met by other means.

The required composition of infant formulas includes a number of components that are oxidizable including lipids and a number of essential vitamins. In the absence of antioxidant systems that include mixed tocopherol concentrate, these oxidizable substances would degrade very quickly, resulting in products that do not maintain this important nutritional composition over the shelf life of the product.

| |
|---|
| **Q2.4 Would the use of this food additive in the intended food(s) modify any characteristic of the food that might mislead the consumer?** |
| The use of this additive would not modify any characteristic that would mislead the consumer. The addition of mixed tocopherol concentrate is for the purpose of maintaining the overall quality, nutritional composition, and organoleptic properties of the infant formula over the course of shelf life. The use of mixed tocopherol concentrate would clearly identify mixed tocopherol concentrate in the list of ingredients according to the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985), which specifies that the functional class shall be used together with the specific additive name or INS number (or per national legislation). |
| **3 COMPLIANCE WITH THE APPROACH ON THE USE OF ADDITIVES IN FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN** |
| **Q3.1 Does the proposed food additive perform the same/similar purpose as other additives that have already been authorized for use in the same product category? If not, what is the justification for the need for an additive with a new functional class and/or technological purpose? If yes, what advantage(s) does the proposed additive provide over currently permitted options?** |
| Yes, mixed tocopherol concentrate performs the same/similar purpose as one other additive permitted for use in the same product category.<br><br>Mixed tocopherol concentrate is currently a permitted option that is positively listed in the GSFA (CXS 192-1995) for use in both infant formula (FC 13.1.1) and formula for special medical purposes for infants (FC 13.1.3), as well as in CXS 72-1981.<br><br>The only other currently permitted antioxidant in these food categories is Ascorbyl Palmitate (INS 304), and neither antioxidant is alone sufficient to provide the antioxidant function needed to maintain a normally acceptable shelf-life. Both antioxidants are required and therefore, a choice of one or the other is not applicable in this case. |

### III. Phosphates (INS 339(i), 339(ii) and 339(iii) and INS 340(i), 340(ii), and 340(iii))

| | |
|---|---|
| **THE PROPOSAL IS SUBMITTED BY:** | *ISDI (International Special Dietary Foods Industries)*<br>*IFAC (International Food Additives Council)* |
| **1 IDENTITY AND INTENDED USE** | |
| **Q1.1 Name and INS Number of the Additive as listed in CXG 36-1989:**<br>*For substances not yet included in CXG 36-1989, chemical name of the substance.* | <u>Sodium Phosphates</u><br>Sodium dihydrogen phosphate (INS 339 i)<br>Disodium hydrogen phosphate (INS 339 ii)<br>Trisodium phosphate (INS 339 iii)<br><u>Potassium Phosphates</u><br>Potassium dihydrogen phosphate (INS 340 i)<br>Dipotassium hydrogen phosphate (INS 340 ii)<br>Tripotassium phosphate (INS 340 iii)<br>For brevity, these food additives will be referred to as sodium and potassium phosphates in this assessment unless otherwise noted. |

**Q1.2 Describe the food form (e.g. liquid, powder) for which the additive is intended to be used and indicate the relevant CCNFSDU standard and if known the GSFA food subcategory**

**CCNFSDU standard**

| **Reference** | **Name of the standard** | **Comments (e.g. limitation of use to specific food forms)** |
|---|---|---|
| *CXS 72-1981* | *Standard for infant formula and formulas for special medical purposes intended for infants* | All types of infant formula and formulas for special medical purposes for infants |

**GSFA food category**

| **Food category No** | **Name of the GSFA food category** |
|---|---|
| *13.1.1*<br>*13.1.3* | *Infant formulae*<br>*Formulae for special medical purposes for infants*<br><u>*Note:*</u> Sodium and Potassium Phosphates are not currently listed in GSFA FC 13.1.1 and 13.1.3 however are identified to be included as part of CCFA Alignment work (See the following text from CX/NFSDU 19/41/9 page 3 which references amendment of GSFA to include sodium and potassium phosphate acidity regulators in FC 13.1.1 and 13.1.3): |

| | |
|---|---|
| | The following changes of the GSFA seem to be necessary for the full alignment:<br>Food categories 13.1.1.and 13.1.3:<br>Adding a provision as follows:<br>**Phosphates** **339(i)-(iii); 340(i)-(iii)** **450 mg/kg** **33, 230 & New note (a): Sodium dihydrogen phosphate (INS 339 (i)), Disodium hydrogen phosphate (INS 339 (ii)), Trisodium phosphate (INS 339 (iii)), Potassium dihydrogen phosphate (INS 340 (i), Dipotassium hydrogen phosphate (INS 340 (ii)) and Tripotassium phosphate (INS 340 (iii)) only, singly or in combination & New note (b): Within the limits for sodium, potassium and phosphorus specified in the Standard for Infant Formula and Formula for Special Dietary Purposes Intended for Infants (CXS 72-1981)** . |

**Q1.3 Indicate and justify the range of the proposed use level of the food additive needed to accomplish the desired technological effect at the lowest possible use level**

| **Proposed use level (per 100 mL in final product as consumed)** | **Justification of the level(s) proposed** |
|---|---|
| ** 45 mg per 100 mL (final product as consumed) expressed as phosphorus singly or in combination and within the limits for sodium, potassium and phosphorus in CXS 72-1981.* | *The technological function for sodium and potassium phosphates is the regulation of pH. Infant formula and FSMP for infants encompass a wide variety of different products in powdered, liquid, or concentrated liquid forms, each with a specific formulation and hence each with its own technological requirements regarding acidity regulation. This group of sodium and potassium phosphates represents a wide range of pH values and can each provide buffering capacity and pH modification for stabilization of the formula matrix where necessary.*<br>*The level proposed is adequate to achieve the technological purpose of the phosphates as food additives.*<br>*In addition, phosphorus, potassium and sodium are essential nutrients and unavoidable constituents of many foods including milk proteins used in infant formula. These phosphates are also permitted nutrient sources of potassium, phosphorus and sodium as per CXG 10-1979. CXS 72-1981 defines minimum and maximum levels for phosphorus as well as for the cations of the phosphate salts (i.e. sodium and potassium) in the final infant formula. The phosphates that are permitted as food additives (up to 45 mg/100 mL as consumed, expressed as phosphorus) contribute to the total permitted levels for each.* |

**2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA**

**Q2.1 Describe the technological function of the food additive relative to the CAC/GL 36-1989 (include the functional class) and the advantage conferred by its use**

Technological function relative to the CXG 36-1989

Functional class: Acidity Regulator

Definition: A food additive, which controls the acidity or alkalinity of a food

Technological Purpose: acidity regulator, acid, acidifier, alkali, base, buffer, buffering agent, pH adjusting agent

Advantage from the use of the additive

Acidity regulators are used to change or maintain pH of the formula during production. Such phosphates represent a wide range of pH values and can each provide excellent buffering capacity as well as pH modification for stabilization of the formula matrix where necessary.

In milk based formula, the buffering action of phosphates stabilizes the pH thus keeping the calcium micelle intact and preventing curdling/precipitation, in particular during heat treatment. The pH-regulating property and buffering impact of phosphate salts supports ion exchange and the loosening of the protein structure.

**Q2.2 Does the use of an additive serve one or more of the needs set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA? Indicate which one(s)**

Sodium and Potassium Phosphates meet several of the needs described in Section 3.2 of the Preamble to the GSFA:

*a) To preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified in the circumstances dealt with in sub-paragraph (b) and also in other circumstances where the food does not constitute a significant item in a normal diet*

Sodium and Potassium Phosphates, through stabilization of the pH of the product, preserve the nutritional quality of infant formula by preventing the degradation of nutrients during processing as well as throughout product shelf life. Infant formulas are specially formulated to deliver specific nutrients that require stable storage conditions to maintain their efficacy. Sodium and potassium phosphates stabilize and buffer the pH of the formula so that nutritional degradation will be minimized.

*c) To enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer*

Sodium and Potassium Phosphates maintain the quality of infant formula by stabilizing the formulation through pH control. Sodium and potassium phosphates protect proteins used in infant formula from denaturation that can occur during heat processing. Sodium and potassium phosphates also prevent age gelation, sedimentation and other undesirable effects that can occur during shelf life. Sodium and potassium phosphates maintain the sensory and organoleptic properties required in formulas for infants.

**Q2.3 Cannot the objectives set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA be achieved by other means that are economically and technologically practicable?**

Because of the restricted list of positively approved food additives in infant formulas, the benefits of the use of sodium and potassium phosphate alone or their combination as acidity regulator cannot be met by other means.

The required composition of infant formulas includes a number of components that are pH sensitive including protein, a number of essential vitamins and minerals, and emulsion system which maintains lipid stability. In the absence of a stable and proper pH range, product property and nutrients would deteriorate and degrade, respectively, resulting in products becoming inedible and losing this important nutritional composition over the shelf life of the product. There is not another technologically feasible means to achieve the functional outcomes provided by these acidity regulators.

**Q2.4 Would the use of this food additive in the intended food(s) modify any characteristic of the food that might mislead the consumer?**

The use of these acidity regulator additives would not modify any characteristic that would mislead the consumer. The addition of sodium or potassium phosphates is for the purpose of maintaining the overall quality, nutritional composition, and organoleptic properties of the infant formula over the course of shelf life. The use of these acidity regulators would be clearly identified in the list of ingredients according to the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985), which specifies that the functional class shall be used together with the specific additive name or INS number (or per national legislation).

**3 COMPLIANCE WITH THE APPROACH ON THE USE OF ADDITIVES IN FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN**

**Q3.1 Does the proposed food additive perform the same/similar purpose as other additives that have already been authorized for use in the same product category? If not, what is the justification for the need for an additive with a new functional class and/or technological purpose? If yes, what advantage(s) does the proposed additive provide over currently permitted options?**

Yes, sodium and potassium phosphates perform the same/similar purpose (acidity regulator) as other additives that have already been authorized for use in these product categories.

Other acidity regulators that are permitted for use by CXS 72-1981 include:

| INS number | Acidity Regulatory | Max level per 100 mL ready to consume |
|---|---|---|
| 524 | Sodium hydroxide | 0.2 g singly or in combination and within the limits for sodium, potassium and calcium in section 3.1.3 (e) in all types of infant formula |
| 525 | Potassium hydroxide | |
| 526 | Calcium hydroxide | |
| 500i | Sodium carbonate | |
| 500ii | Sodium hydrogen carbonate | |
| 501i | Potassium carbonate | |
| 501ii | Potassium hydrogen carbonate | |
| 330 | Citric acid | GMP |
| 331i | Sodium dihydrogen citrate | GMP |
| 331ii | Trisodium citrate | GMP |
| 332 | Potassium citrate | GMP |

Advantage of phosphates as acidity regulators compared to the others available: Phosphates have different optimal functionality under different formulation considerations compared to citrates or carbonates or hydroxide acidity regulators. Due to their buffering capacity and wide range of pH selection with one and/or their combinations, sodium and potassium phosphates could be used to stabilize proteins against their coagulation from extreme heat during thermal process, promote and support emulsification and reduce lipid oxidation, improve finished product texture, and help reduction in the rate of vitamin degradation. Sodium, potassium and phosphorous are essential minerals. Use of sodium/potassium phosphates for their technical purpose as additives can reduce usage of other food additives as their sources simultaneously contribute to control targeted levels of sodium, potassium and phosphorous in desired finished FSMP and infant formula products. With these considerations, other acidity regulators listed in the table cannot provide such functionalities and benefits.

**PART B:** Comments provided by the EWG Members

Although not requested in the first circular paper, some EWG members provided some information and comments on the technological justification of the food additives under consideration. Those comments are summarised below for the sake of completeness and transparency.

One EWG member pointed out that the GMP limit proposed for ascorbyl palmitate as an antioxidant additive, within the levels of vitamin C established in the CXS 72-1981 standard, is related to the nutritional purpose of the compound and not to its technological function. In the view of this EWG member the rationale for using ascorbyl palmitate with GMP limit linked to vitamin C limits is not consistent with its use as a food additive and therefore the current limit (1 mg/ 100 mL) should be the reference for further consideration.

Another EWG member sent brief information, using the form for appraising the technological need for the use of additives in foods within the mandate of CCNFSDU, on ascorbyl palmitate (INS 304) and tocopherol concentrate, mixed (INS 307b). The information provided by this EWG member is already covered by more comprehensive information submitted by ISDI as presented in Annex 1, PART A.

Another EWG member provided information and comments in the form for appraising the technological need. According to this EWG member, the use of low acyl clarified gellan gum (INS 418) and phosphates ((INS 339(i), 339 (ii), 339(iii), INS 340(i), 340(ii), and 340(iii)) is not technologically justified as their use does not meet the requirements of Section 3.2 of the Preamble to the GSFA. For ascorbyl palmitate (INS 304), the EWG member recognises the technological justification for the use in complementary foods for infants and young children at the maximum level of 100 mg/kg. For tocopherol concentrate, mixed (INS 307b) at 10 mg/kg in infant formula and follow-up formula and at 100 mg/kg for complementary foods for infants and young children. It should be noted that the appraisal of the technological need was planned for the second circular paper of the EWG that has not been issued. Moreover, the terms of reference clarify that the technological justification shall be appraised for the use of the additives under consideration in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981) only.

**Annex 2**

**PLAN / PROGRAMME FOR THE CONSIDERATION OF THE FOOD ADDITIVES IN CRD15REV FROM CCFA49**

Some EWG members suggested that the EWG discusses a plan or programme to appraise 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 age.

One EWG member submitted to the chair a suggestion to group the food additives into 5 batches as outlined below. The priority goes from batch 1 to 5 and the intention is to address one batch at a time, i.e. in total, five consecutive EWG should address 5 batches listed below. The first batch contains the food additives already covered by the terms of reference of the EWG on additives established at CCNFSDU41 (i.e. the current work).

**Batch 1: Additives with Numerical ADI**

- Ascorbyl palmitate (INS 304)
- Mixed tocopherol concentrate (INS 307b)
- Sodium Phosphates (INS 339 i,ii,iii)
- Potassium phosphates (INS 340 i,ii,iii)

**Batch 2: Additives that are not permitted nutrient sources**

- Guar gum (INS 412)
- Distarch phosphate (INS 1412)
- Phosphated distarch phosphate (INS 1413)
- Acetylated distarch phosphate (INS 1414)
- Hydroxypropyl starch (INS 1440)

**Batch 3: Additives that dissociate into nutrients normally present in dietary sources and/or permitted nutrient sources (GL 10-1979)**

- L(+) lactic acid
- Lecithins (INS 322i)
- Citric acid and citrates (INS 330, 331, 331iii, 332,332ii)
- Mono- and diglycerides (INS 471)

**Batch 4: Additives that dissociate into nutrients normally present in dietary sources and/or permitted nutrient sources (GL 10-1979)**

- Hydroxides (INS 524, 525, 526)
- Carbonates (INS 500, 501)

**Batch 5: Packaging gases**

- Carbon dioxide (INS 290)
- Nitrogen (INS 941)

**Annex 3**

## BACKGROUND ON THE WORK ON ADDITIVES LISTED IN CRD15Rev

1. At CCNFSDU38 the Committee agreed to establish an EWG hosted by the European Union, and co-hosted by the Russian Federation to (a) propose a mechanism or framework for considering the technological justification for substances intended for inclusion on the priority list of substances for JECFA evaluation, (b) to consider and confirm the technological justification of gellan gum; and (c) to propose how to handle new substances that have already been evaluated by JECFA, but for which technological justification has not yet been confirmed by CCNFSDU (i.e. xanthan gum, pectin) (REP17/NFSDU, para. 178).

2. The outcome of the EWG work (CX/NFSDU 17/39/8) was presented at CCNFSDU39. As regards the proposed list of food additives for testing the framework, the Committee noted the explanation and views that:

    - there had been concerns that several adopted food additive provisions for foods intended for infants below 12 weeks of age had no appropriate safety assessment (see CRD15rev of CCFA49), and that the Committee was requested to consider this matter in its ongoing work on technological justification; depending on the outcome of technological justification, these food additives could be either deleted from the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981) or included in the JECFA priority list;

    - testing of the framework should be focused first on xanthum gum (INS 415), pectin (INS 440) and gellan gum (INS 418); and that the food additives in CRD15 of CCFA49 should only be considered after the framework had been tested on the aforementioned three food additives; and

    - the framework should be applicable to new food additive requests and not delay decision on pectin and xanthan gum for which JECFA has already undertaken safety assessments, and for which sufficient technological justification had already been provided.

3. In the spirit of compromise, the Committee agreed to evaluate the relevant food additives in CRD15 of CCFA49 as a next step and agreed to continue working on a mechanism or framework for considering the technological justification on the basis of CX/NFSDU 17/39/8 and taking into account the comments in the CRDs and the discussion at CCNFSDU39 and test the agreed framework with the proposed use of xanthan gum (INS 415), pectin (INS 440) and gellan gum (INS 418) (REP18/NFSDU, paras. 133-144).

4. A significant progress on the framework was made at CCNFSDU40. The Committee agreed with the proposed process to appraise and justify the need for the use of additives in foods within the mandate of CCNFSDU (see REP19/NFSDU, Appendix VIII, Annex 1), reaffirmed that the framework would apply to all foods within the mandate of CCNFSDU, including non-standardised foods when requested by CCFA, and agreed on the Q13 and Q24 question complexes. The Committee further reached an agreement that the framework should cover food intended for infants and young children and agreed on the Q3 complex title 'Compliance with the Approach on the Use of Additives in Foods Intended for Infants and Young Children'. Due to time constraints, the Committee could not consider other aspects of Q3 and the application of the framework to appraise the technological justification of the three candidate additives and therefore decided to address those points at a Physical Working Group to meet immediately prior to CCNFSDU41 (REP19/NFSDU, paras. 123-139).

5. At CCNFSDU41 the Committee finalised the work on the framework and agreed to publish the document titled "CCNFSDU framework for appraising the technological need for food additives" as an information document on the Codex website (see REP20/NFSDU, Appendix VIII Part A). The Committee also endorsed the recommendations on the technological justification of xanthan gum (INS 415) and pectins (INS 440) used as thickeners in formulas for special medical purposes intended for infants. As regards gellan gum (INS 418) delegations expressed divergent views on whether sufficient information had been provided on the technological justification for use in CXS 72-1981 and the Committee agreed to request the applicant to provide more information on the substance, in particular its advantages over currently permitted food additives (i.e. Q3 of the framework).

6. One Member Organization proposed to initiate a review of technological justifications of food additives in CRD15rev of CCFA49 by using the new framework, and to start with the food additives with

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numerical ADIs. The Member Organization further proposed the process to implement this exercise, i.e. to set a deadline to collect information, to review the information and to provide recommendations for consideration by the Committee. An Observer supported the proposal and expressed the need to receive sufficient time in order to allow them to consult with their members and generate the required information (REP20NFSDU, paras. 152-166).

7. In the light of the above considerations CCNFSDU41 agreed to:

8. Establish an EWG, chaired by the European Union and co-chaired by the Russian Federation, working in English with the following terms of reference:

- to collect information from the applicants on the following additives: low acyl clarified gellan gum, ascorbyl palmitate (INS 304), mixed tocopherol concentrates (INS307b) and phosphates (INS 339(i), 339(ii) and 339(iii) and INS 340(i), 340(ii), and 340(iii)) with the framework for considering technological justifications for use in CXS 72-1981; and
- to review the information provided by the applicants and provide recommendation to the Committee on the technological justification of each additive (REP20NFSDU, para. 168).