16/01/2023

European Union comments on

Codex Circular Letter CL 2022/80/OCS - NFSDU:

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

European Union Competence
European Union Vote

The European Union (EU) would like to provide the following comments:

General comments

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.

PART 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)

Specific comments on the additives included in CL 2022/80/OCS - NFSDU

Food additive	**Gellan gum (INS 418), low-acyl, clarified**
Comments, questions and assessment of the technological need	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.

Food additive	**Ascorbyl palmitate (INS 304)**
Comments, questions and assessment of the technological need	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*".

Food additive	**Tocopherol concentrate, mixed (INS 307b)**
Comments, questions and assessment of the technological need	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*".

Food additive	**Phosphates (INS 339(i), 339 (ii) and 339(iii) and INS 340(i), 340(ii), and 340(iii))**

Comments, questions and assessment of the technological need	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).

PART II - the plan/programme for the consideration of remaining food additives

Comments, suggestions on the plan to appraise the technological need for food additives listed in CRD15Rev (CCFA49)	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.