CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 6 **NFSDU/43 CRD40**

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

REPORT OF THE IN-SESSION WORKING GROUP ON THE TECHNOLOGICAL JUSTIFICATION FOR SEVERAL FOOD ADDITIVES

Prepared by the European Union

The Committee agreed to establish an in-session Working Group, chaired by the European Union, to help advance work on the technological justification of several food additives.

The in-session WG was tasked with the following mandate:

To further consider:

1) the technological justification of the following additives for use in 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)

2) the plan/programme for the consideration of the remaining food additives in Annex 2 to CL 2022/80/OCS-NFSDU

DISCUSSION IN THE IN-SESSION WG

Appraisal of the technological need for the food additives under consideration

1. The chair presented the background to the matter referring to the work completed in the past that included the endorsement of the *Framework for appraising the technological need for food additives* and appraisal of the technological need for xanthan gum (INS 415) and pectin (INS 440) at CCNFSDU41, whilst for low acyl clarified gellan gum (INS 418) the appraisal of the technological need had not been completed.

2. As regards additives under consideration other than gellan gum, he referred to CRD15rev of CCFA49, which provides overview on JECFA assessments on food additives used in infant formulas outlining that for several adopted food additive provisions there has not been any appropriate safety assessment for infants below 12 weeks of age. Such safety assessment would be the next step for food additives for which the Committee concludes that their use is technologically justified.

3. He pointed out that the task of the in-session WG is to appraise the technological need in line with the agreed framework and that considerations on safety are not within the scope of this discussion.

4. The chair suggested addressing one food additive at a time following the order in the mandate. He referred to CL 2022/80/OCS-NFSDU, CX/NFSDU 23/43/6, CRD13, CRD19-21, CRD23-25 and CRD27 as the documents relevant for the discussion.

Low acyl clarified gellan gum (INS 418)

5. Questions were raised concerning alternatives to the use of additives, testing of effectiveness of other thickeners, whether the justification concerns only 'low acyl' form of gellan gum, the use is intended only for liquid formulas and it does not lead to the expansion of products. The applicant confirmed that (i) there is no alternative to the use of food additives, (ii) a wide variety of food additives (thickeners) had been screened as regards their suitability for the type of product under consideration, (iii) the justification is limited and applicable only to 'low acyl' form and liquid products, (iv) the products are intended only for special medical needs and the use of gellan gum does not expand the scope of products.

6. Based on the information provided the in-session WG concluded that the proposed use of low acyl clarified gellan gum (INS 418) at 5 mg/100 mL limited to hydrolysed protein and/or amino acid-based liquid formula is technologically justified.

Recommendation 1: the Committee is invited to endorse the above conclusion of the in-session WG on low acyl clarified gellan gum (INS 418).

Ascorbyl palmitate (INS 304)

7. The chair noted that a proposal was made for the use of ascorbyl palmitate (INS 304) at GMP (i.e. without the numerical maximum use level). The chair outlined that ascorbyl palmitate has a numerical ADI and therefore, the proposed change is not appropriate, it is not supported by several Codex Members pointing that GMP is related to the nutritional purpose and not to the use as a food additive and it would not be in line with the principle for the use of additives in foods intended for infants and young children, i.e. *"…great caution should be exercised regarded both the choice of additive and its level of use*". The chair suggested that the discussion focuses on the current provision for the use of ascorbyl palmitate in infant formulas.

8. Based on the information provided, the in-session WG recognised the technological need for the use of ascorbyl palmitate (INS 304) as an antioxidant at 1 mg/100 mL in all types of infant formula singly or in combination (with INS 307b) and considered that such use is technologically justified.

Recommendation 2: the Committee is invited to endorse the conclusion of the in-session WG on ascorbyl palmitate (INS 304).

Tocopherol concentrate, mixed (INS 307b)

9. The use of tocopherol concentrate, mixed (INS 307b) as an antioxidant complements the provisions for ascorbyl palmitate (INS 304).

10. The in-session WG considered the information provided and concluded that the use of tocopherol concentrate, mixed (INS 307b) at 1 mg/100 mL in all types of infant formula singly or in combination (with INS 304) is technologically justified.

Recommendation 3: the Committee is invited to endorse the conclusion of the in-session WG on tocopherol concentrate, mixed (INS 307b).

Phosphates (INS 339(i), 339(ii) and 339(iii) and INS 340(i), 340(ii) and 340(iii)

11. The in-session WG considered the information provided and concluded that the use of phosphates (INS 339(i), 339(ii) and 339(iii) and INS 340(i), 340(ii) and 340(iii) at 45 mg/100 mL as phosphorus singly or in combination and within the limits for sodium, potassium and phosphorus in section 3.1.3 (e) of CXS 72-1981 in all types of infant formula is technologically justified.

Recommendation 4: the Committee is invited to endorse the conclusion of the in-session WG on phosphates (INS 339(i), 339(ii) and 339(iii) and INS 340(i), 340(ii) and 340(iii).

Plan/programme for the consideration of the remaining food additives in CRDrev of CCFA49

12. The chair clarified that a plan/ programme to complete the review of food additives listed in CRD15rev of CCFA49 was proposed to avoid having ad hoc decision-making in CCNFSDU. He explained the rational for grouping the additives into batches 1-5 and reminded that the food additives in batch 1 are subject to the current discussion.

13. Some in-session WG members expressed the view that the work on CRD15rev should be considered within the context of the workload and resources both the Committee and JECFA. They pointed out that the review relates to the adopted provisions that have been in place for many years and whilst the framework should be used for new food additive provisions for the additives listed in CRD15rev they suggested a lighter procedure to check only the actual use and use levels.

14. Other in-session WG members supported a consistent approach for addressing the remaining work using the framework as it was done for batch 1, i.e. collecting up-to-date comprehensive information to check the compliance with the criteria laid down in the framework.

15. The in-session WG discussed further the use of the framework or alternative approaches and the scope of the follow-up work to be completed by CCNFSDU44.

16. In the spirit of compromise, the in-session WG agreed to recommend establishing an EWG which will continue the work on batch 2. In the first step, the EWG will collect the information on the use and use levels and the commitment of the applicants to provide the data on the safety assessment for infants below 12 weeks of age. This will allow, as appropriate, to exclude food additives for which no interest is expressed from further consideration. For food additives, for which the interest is expressed, the EWG will collect the data on the technological justification using the CCNFSDU framework for appraising the technological need. This information will be reviewed by the EWG to provide recommendation to the Committee on the technological justification on each additive.

Recommendation 5: the Committee is invited to establish an EWG to continue working on the technological justification for food additives in batch 2 following the approach agreed by the in-session WG.

Annex – Plan/ programme for the consideration of the remaining food additives in CRD15rev of CCFA49

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)