CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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

Agenda Item 5 **CX/NFSDU 24/44/5**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Forty-fourth Session

Dresden, Germany

2 - 6 October 2024

TECHNOLOGICAL JUSTIFICATION FOR SEVERAL FOOD ADDITIVES

(Prepared by the electronic Working Group led by the European Union)

Background

1. The 41st Session of the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU41) completed the work on the "CCNFSDU framework for appraising the technological need for food additives". The framework was published on the Codex website as an information document [1] (REP20/NFSDU, para. 166).

2. CCFA49/CRD15Rev provided an overview of food additives permitted for use in infant formula or formulas for special medical purposes intended for infants noting that several food additives had no adequate risk assessment by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for infants under the age of 12 weeks.

3. CCNFSDU43 took decisions regarding the technological justifications for four additives in CCFA49/CRD15Rev (batch 1) and requested that CCFA include them in the priority list of substances proposed for evaluation by JECFA for use in foods intended for infants below 12 weeks of age. CCNFSDU43 also considered the Plan/programme for the consideration of the remaining food additives in CCFA49/CRD15Rev and agreed to continue the work related to batch 2 as listed in CL 2022/80/OCS-NFSDU Annex 2 (REP23/NFSDU, paras. 76-85).

Mandate of the EWG

4. In the light of the above CCNFSDU43 agreed to establish an EWG[2] open to all Members and Observers, chaired by the EU, working in English with the following terms of reference:

   a. to collect information from the applicants on the use and use levels and confirmation to provide data on the safety assessment for infants below 12 weeks of age on the following additives: guar gum (INS 412), distarch phosphate (INS 1412), phosphated distarch phosphate (INS 1413), acetylated distarch phosphate (INS 1414), hydroxypropyl starch (INS 1440);

   b. to collect information from the applicants with the framework for considering technological justification for use in the *Standard for infant formula and formulas for special medical purposes intended for infants* (CXS 72-1981) on food additives for which the use, use levels and commitment to provide the data is confirmed; and

   c. to review the information provided and provide recommendations to CCNFSDU44 on the technological justification of each additive.

Plan of the work

5. A stepwise approach was envisaged with the first EWG consultation to address part (a) of the terms of reference and the second consultation for part (b). The third consultation intended collecting views of the EWG members on the information received in order to appraise the technological need. The fourth consultation was planned to discuss further comments received with a view to obtain the final feedback

[1] https://www.fao.org/fao-who-codexalimentarius/resources/inf-doc/en/

[2] The EWG was participated by Australia, Austria, Belgium, Brazil, Canada, Chad, Chile, Finland, Guatemala, India, Indonesia, Italy, Japan, Malaysia, Morocco, New Zealand, Nigeria, Panama, Paraguay, Saudi Arabia, Senegal, South Africa, Sweden, Switzerland, Thailand, Uganda, United States of America, EU Specialty Food Ingredients, International Baby Food Action Network (IBFAN), International Council of Grocery Manufacturers Associations (ICGMA), International Food Additives Council (IFAC) and International Special Dietary Foods Industries (ISDI).

on the justification for the use of the additives under consideration and to prepare recommendations for the final EWG report.

Discussion by the EWG

The first EWG consultation

6. The first circular targeted primarily the applicants in order to collect the information on the use and use levels and the commitment to provide data for the safety assessment for infants below 12 weeks of age.

7. Feedback was received from seven EWG members (six Codex Members and one Codex Observer). Four EWG members replied positively as regards the use of the food additives under consideration and provided information on the use levels. In addition, two out of those four EWG members committed to provide the data necessary for the safety assessment for infants below 12 weeks of age. On the contrary, three EWG members reported no use in infant formulas. One of them, the Codex Observer commonly acting as a data provider for the JECFA assessments of food additives used in infant formulas, commented that its members do not use any of these additives as nowadays more technologically advanced alternatives exist noting however that those additives may have remained authorised per national or regional authorities.

The second EWG consultation

8. Inconsistent feedback was received in reply to the first circular. It was not clear whether the information from the EWG Members confirming the use and use levels was based on the respective regulatory provisions permitting the use of the additives in question or on real uses, i.e. based on examples of the products currently available on the market. Therefore, the second circular requested the EWG members, particularly those who reported the use of food additives under consideration, to confirm (i) that the reported use is based on the existing products available on the market and (ii) the commitment to generate and provide the data necessary for the safety assessment of the food additives when used in foods for infants below 12 weeks of age in products conforming to CXS 72-1981. The second circular also pointed out that the information necessary for appraising the technological need should be submitted only if the EWG members confirm the use and commit to provide the data. It was noted that the feedback received on the second circular would either confirm or deny the use of food additives in question in infant formulas and the commitment to provide the data for the adequate safety assessment. Finally, the second circular clarified that if the use or commitment to provide the data is not confirmed, no further work of the current EWG would be conducted and the outcome of the EWG consultation would imply (i) no technological need for the food additives under consideration in infant formulas and as a consequence (ii) the revocation of the respective food additive provisions.

9. Feedback was received from six EWG members. No use in products currently available on the market was reported and no commitment to generate the data necessary for the safety assessment was made.

Conclusions

10. There is no technological need for the use of

guar gum (INS 412),

distarch phosphate (INS 1412),

phosphated distarch phosphate (INS 1413),

acetylated distarch phosphate (INS 1414) and

hydroxypropyl starch (INS 1440) in foods conforming to CXS 72-1981.

Recommendations

11. The Committee is invited to endorse the above conclusions and inform CCFA accordingly.