CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Items 2, 4.1, 5, 6.1, 6.2, 6.21, 7 **CRD22**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Forty-fourth Session

Dresden, Germany

(Comments by African Union)

AGENDA ITEM 2 MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND ITS SUBSIDIARY BODIES

Matters for action

Issue 1: CCNFSDU to consider CCFA53(2023) request whether CXS 73-1981(Standard for canned baby foods) permits the use of the food additives listed in CXG 10-1979 (Advisory lists of nutrient compounds for use in foods for special dietary uses Intended for infants and young children) Part D as nutrient carriers; noting that the CCFA EWG could not agree on whether CXS 73-1981 permits the use of the food additives listed in CXG 10-1979 Part D as nutrient carriers or not.

Background: CXG 10-1979, the food additives in part D on advisory list of food additives for special nutrient forms are recommended for use as nutrient carriers. The additives include Gum arabic (gum acacia), Silicon dioxide, Mannitol (for vitamin B12 dry rubbing, 0,1% only), Starch sodium octenyl succinate and Sodium L-ascorbate (in coating of nutrient preparations containing polyunsaturated fatty acids). CCFA53 during the alignment work between food additives for FC 13.2, noted the above listed food additives were excluded for products covered by CXS 73 and agreed to seek concurrence with CCNFSDU on whether the additives may be used.

Position: African Union agrees that the food additives listed in CXG 10-1979 part D maybe used as a carriers in baby foods in the standard for CXS 73-1981.

Rationale: Considering that they are technologically justified and approved for use in FC 13.2, complementary foods for infants and young children, canned baby foods are also considered as complementary foods and thus the additives are justified to be used.

Issue 2: CCNFSDU to appraise the technological need/justification of methacrylate copolymer, basic (BMC) in commodity standards under their purview in GSFA FCs 13.1, 13.2, and 13.3 as requested by CCFA54 (2024) and inclusion of General Principles for the Addition of Essential Nutrients to Foods (CXG 9-1979) on the list of Codex texts requiring technological justification.

Background: During CCFA51, JECFA submitted the risk assessment for BMC (INS 1205) with toxicological data results indicating low adsorption and did not indicate any adverse health effects even at the highest doses tested. The JECFA Secretariat also stressed that the safety evaluation only covered the proposed uses of BMC as a coating or glazing agent for solid food supplements; for foods for special medical purposes; micronutrient encapsulation for food fortification and at the intended use levels (REP19/FA Para 16). As a result, CCFA51 agreed to issue circular letters on use level to populate the GSFA. CCFA52 (2021) adopted the use of BMC in flours and salt. CCFA54 received a request to include BMC in FC 13.1, 13.2 and 13.3 but as required procedurally where there is an active committee, CCFA request for technological need/justification from that Committee. It is against this background that CCFA54 requests CCNFSDU44 to appraise the technological justification for the use of BMC in these food categories.

Position: African Union agrees that there is a technological justification for use of BMC as a carrier/glazing agent for nutrients in FC 13.1, 13.2 and 13.3 for products covered by CXS 72-1981, CXS 156-1987, CXS 73-1981, CXS 74-1981, and CXG 95-2022 and recommends to CCNFSDU44 to advise the CCFA of the technological use of BMC accordingly.

Rationale: JECFA conducted a risk assessment and concluded that BMC can be used at GMP levels. Therefore, there is no known risk of exposure associated with BMC usage. Additionally, in the fortification of oil with vitamin A, there is a high risk of vitamin A loss due to environmental conditions, which reduces availability in the carrier/food vehicle. Therefore, coating vitamin A with BMC will significantly increase the availability and retention of vitamin A in fortified foods such as oil intended for human consumption, thereby

achieving the objective of strengthening the immune system and reducing mortality risk in young children and other vulnerable populations.

Issue 3: Adoption of the Nitrogen to protein conversion factors Annex in CXS 234-1999 and revoking Nitrogen conversion factors in the standards

Background: CCMAS43 recommended the inclusion into CXS 234-1999 an annex in which information on Nx that has been determined by Codex committees could be accessible. These Nx values would be drawn from the specific commodity standards. As a result, CCMAS recommended that relevant committees should consider revoking Nx values in commodities standards to ensure that CXS 234-1999 becomes a single authoritative reference for Nx values. The recommendations by CCMAS43 to have the annex to CXS 234-1999 on nitrogen conversion factors will be submitted during CAC47 (November 2024) for adoption.

Position: African Union supports the inclusion of an annex into CXS 234-1999 for the nitrogen conversion factors and subsequent revocation of nitrogen conversion factors in commodity standards. However, there is need to provide a standard text as a guideline for the commodity standards users linking the proposed annex in CXS 234-1999 and commodity standards regarding Nx values.

Rationale: A single point of reference will ensure consistency in the Nx values of products and avoid different values for similar products. This is consistent with ongoing efforts on alignment of food additives with CXS 192-1995 and well as alignment between CXS 1-1995 (General Standard for the Labelling of Prepackaged Foods) and commodity standards.

AGENDA ITEM 4.1 GENERAL PRINCIPLES FOR THE ESTABLISHMENT OF NRVS-R FOR PERSONS AGED 6 –36 MONTHS (AT STEP 7)

Background: Nutrient reference values (NRVs) are a set of numerical values based on scientific data for the purposes of nutrition labelling and relevant claims. They indicate the daily amount of nutrients (energy, macronutrients, vitamins and minerals) required for good health, as well as an upper safe level of nutrient intake. The primary purpose of NRVs is to give meaningful (not-misleading) information to consumers. Nutrient reference values – requirements (NRVs-R), refer to NRVs that are based on levels of nutrients associated with nutrient requirements. NRVs-R are established for vitamins, minerals and protein.

The recognition of the need for NRVs for persons aged 6 – 36 months was highlighted as far back as 2007 in the finalized project document (CCNFSDU, 2007) for the work on developing general principles for establishment of NRVs for vitamins and minerals for the general population. The project document which outlined the proposed scope and stepwise approach to the work mentioned the need to establish relevant principles for NRVs for individuals of 6 months to 36 months of age, using as a basis the principles for NRVs for the general population and modifying them as appropriate and thereafter establish NRVs for this age group.

During the 43rd session of the CCNFSDU (REP23/NFSDU para 52 – 73) it was noted that significant progress had been made on all three tasks assigned to the 2022-23 EWG and PWG which were: consideration of the draft general principles; a stepwise process to apply the draft general principles for establishing NRVs-R, and piloting the draft general principles on the agreed-upon nutrients.

The CCNFSDU at the 43rd session agreed to forward the proposed draft General Principles for establishing Nutrient Reference Values (NRVs-R) for persons aged 6 to 36 months to CAC46 for adoption at Step 5. At its deliberation, CAC46 adopted the draft General Principles at Step 5 and advanced it to Step 6. The 43rd session of the CCNFSDU43 further agreed to re-establish the EWG (2023-24 EWG) to complete work on revision of the draft Stepwise Process taking into account the revisions to the draft General Principles and to develop an approach to propose NRVs-R for the combined age range of 6 to 36 months. The EWG were also to apply the revised draft Stepwise Process to propose NRVs-R for persons aged 6 – 12 months, 12-36 months and 6 – 36 months, for the following nutrients: Vitamins A, D, C, K and E, thiamine, riboflavin, niacin, vitamins B6 and B12, folate, pantothenic acid and biotin; calcium, magnesium, iron, zinc, iodine, copper, selenium, manganese, phosphorus and potassium.

Following the work of the EWG (2023-24 EWG), the CCNFSDU is invited to:

a. Consider the revised General Principles in Appendix 1 under para (a) taking into account the following recommendations of the EWG Chair and co-Chairs:

i. agree with the definition of Adequate Intake currently in square brackets [ ] (see Section 2 (DEFINITIONS AS USED IN THESE PRINCIPLES) presented in Appendix I).

ii. consider Option 3 whereby the combined NRV-R value for persons aged 6-36 months is determined by selecting the mean value of the proposed NRVs-R for older infants and young children.

iii. Note that clarification on how these combined NRVs-R for persons aged 6–36 months should be used will be outlined in relevant text that relates to where the three sets of NRVs-R are presented in CXG 2-1985.

Issue 1: Definition of Adequate Intake

Position: African Union agrees with the definition of Adequate Intake as provided by FAO/WHO and therefore support that the text be retained with the square brackets removed.

Rationale: The definition provided the level of intake that is considered adequate for healthy population of the age group that is expected to meet the amount of nutrients needed to maintain a nutritional state of the defined age group.

Issue 2: Consideration of Option 1, Option 2 and Option 3

Position: The African Union (AU) would like to thank the Electronic Working Group (EWG) for the significant progress made on the Nutrient Reference Values – Requirements (NRV-R) for persons aged 6-36 months. The African Union recognizes the extensive discussions that have taken place and appreciate the efforts of all members and observers involved in this work. The African Union acknowledges the diverse perspectives shared by member countries and the importance of ensuring that Nutrient Reference Values-Requirements (NRVs-R) are appropriately tailored to meet the nutritional needs of infants and young children. The African Union supports Option 3, whereby the combined NRV-R value for persons aged 6–36 months is determined by selecting the mean value of the proposed NRVs-R for older infants and young children. This approach provides flexibility and is in line with the methodology used for general population NRVs-R.

However, recognizing the need for a balanced approach, the African Union is open to considering Option 1 in cases where the combined value might exceed the upper limit for one of the age groups or for nutrients where a higher value is deemed necessary to meet the specific requirements of the age group. AU is of the opinion that CCNFSDU44 should adopt a flexible approach to ensure that NRVs-R are not only scientifically sound but also provide clear guidance to protect and promote the health of this vulnerable population. This approach will facilitate consensus on the issue whilst allowing for the application of the most appropriate option based on the scientific evidence and characteristics of each nutrient.

AGENDA ITEM 5 TECHNOLOGICAL JUSTIFICATION FOR SEVERAL FOOD ADDITIVES

Background: According to the preamble of the General Standard for Food Additives (GSFA), one of the key criteria for inclusion of a food additive into the GSFA is that adequate safety risk assessment by Joint FAO/WHO Expert Committee on Food Additives (JECFA) must be done. The 47th session of the CCFA requested JECFA secretariat to verify the status of its assessments of all food additives listed in foods category 13.1.1 infant formulae and 13.1.3 formulae for special medical purposes for infants of the GSFA, that were endorsed by CCFA at its 39th and subsequent sessions. A report of the JECFA Secretariat tabled during the CCFA49 (CCFA49/CRD 15Rev) indicated that several food additives had no adequate risk assessment for infants under the age of 12 weeks given that in the guidance on the principles and methods for the risk assessment of chemicals in food (EHC 70 and EHC 240, published in 1987 and in 2009) the ADI does not apply to infants below the age of 12 weeks. During theCCNFSDU43, the session identified first batch (batch 1 comprising of guargum, distarch phosphate, phosphate distarch phosphate, acetylated distarch phosphate and hydroxypropyl starch) and requested CCFA to include them in priority list for JECFA evaluation. CCNFSDU issued two circular letters requesting use levels for the purpose of submitting the data to JECFA for re-evaluation. The feedback received indicated the food additives listed are not used in any product.
Issue: The is no technological justification for use of guargum, distarch phosphate, phosphate distarch phosphate, acetylated distarch phosphate and hydroxypropyl starch in foods conforming to CXS 72- 1981 (Infant formula).
Position: African Union supports the recommendation of EWG to withdrawal the use of the additives in CXS 72-1981.
Rationale: JECFA will not be able to conduct risk assessment due to lack of supporting data. In addition, the additives are not currently in use based on the feedback received after the circular letter was issued.

AGENDA ITEM 6.1 GUIDELINE FOR THE PRELIMINARY ASSESSMENT TO IDENTIFY AND PRIORITIZE NEW WORK FOR CCNFSDU

Background: Following the request by CCEXEC75 (2018) that all committees develop a prioritization mechanism of its work, in CCNFSDU41 the Germany Secretariat proposed a draft prioritization mechanism to which CCNFSDU agreed to use it on a pilot basis to assess their usefulness. The session also agreed to set up a PWG to meet prior to CCNFSDU42 to review all new work proposals and to simplify the draft guideline. However, the meeting did not happen due to Covid 19 pandemic and hence was postponed prior to CCNFSDU43(2023). The resultant discussions recommended improvement on the mechanism in particular focusing on alignment of Codex procedural manual in regard to initiating new work item, agreed on the 17 stepwise points procedure of prioritization and agreed to improve the decision tree based on comment submitted in regard to the 17-point step wise process such as ensuring that new work proposed by an observer

is supported by a Codex member as required procedurally. The meeting tasked the co-chairs through an EWG to improve the guidelines based on the discussions (REP23/NFSDU Para 92-97).
Position: Africa Union supports the adoption by CCNFSDU of prioritization mechanisms of its work.
Rationale: The draft guideline for the preliminary assessment to identify and prioritize new work for CCNFSDU as presented has been improved taking into consideration the discussions and recommendation of CCNFSDU43. In particular, the draft has been fully aligned to the Codex procedural manual as evidenced by steps 5 to 6 as well as amendment of the questions in decision tree such as question 1 that requires support of a Codex Member for any work to be initiated.

AGENDA ITEM 6.2 PROPOSALS FOR NEW WORK/EMERGING ISSUES

(REPLIES TO CL 2024/52-NFSDU)

Background: During CCNFSDU43 session, an agreement was reached to establish an electronic working group (EWG) open to all Members and Observers, chaired by Canada and co-chaired by Germany. The terms of reference were to prepare a revised draft guideline for the preliminary assessment and identification of work priorities for CCNFSDU, including the prioritization criteria and the decision tree, taking into account the comments made in the PWG held prior and during CCNFSDU43.
Codex Secretariat issued a Circular letter (CL 2024/52-NFSDU) requesting for proposals for new work using the revised draft guideline, which would be implemented on a trial basis. A CL was sent out to all Members and Observers in May 2024. One proposed amendment and two new work proposals were received in response to the circular letter. Following the responses, a physical working group (PWG), chaired by Canada and co-chaired by Germany will be established and held prior to CCNFSDU44 to consider the revised draft guideline on a trial basis and assess any new work proposals received in response to the aforementioned CL.

AGENDA ITEM 6.21 DISCUSSION PAPER ON HARMONIZED PROBIOTIC GUIDELINES FOR USE IN FOODS AND FOOD SUPPLEMENTS

Background: At CCNFSDU41 in 2019, Argentina presented the working document on harmonized guidelines on probiotics for use in foods and dietary supplements (CX/NFSDU 19/41/11). The Committee agreed that the proposal could be subjected to newly established criteria for CNCFSDU's Priority Setting mechanism for better management of its work by the priority setting working group for the Committee. Argentina and Malaysia were requested to prepare a proposal and submit it to the CCNFSDU's priority setting working group.
During CCNFSDU43 (2023), the priority working group reviewed the proposal by Argentina and Malaysia and recommended to CCNFSDU that a new project could be undertaken. CCNFSDU agreed with the recommendation of the priority working group and agreed to establish an EWG chaired by Argentina and co-chaired by Malaysia and China to;
i. Further refine and clarify the proposal on harmonised guidelines on probiotics for use in foods and food supplements, in particular with regard to the scope, impact on food safety and need for scientific advice.
ii. Prepare a revised working document and project document taking into account the comments made at the CCNFSDU43
Position: African Union supports further work to establish Guidelines on Probiotics for Use in Foods and Dietary Supplements. There is a need to develop guidelines and a harmonized framework for probiotics, including general specifications and provisions, in order to ensure and sustain the quality of probiotic products globally.
Rationale: According to the WHO and FAO, probiotics are live microorganisms that, when administered in adequate amounts, produce a physiological benefit in the host.
They are resistant to stomach acid and pancreatic juices and have been shown to be effective in boosting immunity, preventing and treating certain types of diarrhea.
In view of the considerable growth in the global market for probiotics, there is a need to develop guidelines and a harmonized framework for probiotics, including general specifications and provisions, in order to ensure and sustain the quality of probiotic products worldwide. This objective is in line with Codex's core values of collaboration, inclusiveness, consensus-building and transparency, and follows the principles set out in the Codex Scientific Foundation, as listed in the Codex Alimentarius Commission's Strategic Plan 2020-2025. The proposed new work will contribute in particular to the following Goals 1, 2 and 3: Strategic Objective 1: "Respond to current, emerging and critical issues in a timely manner". Strategic Objective 2: "To establish standards based on science and Codex risk analysis principles". Strategic Objective 3: "Increasing impact through the recognition and application of Codex standards".

AGENDA ITEM 7 REVIEW OF TEXTS UNDER THE PURVIEW OF CCNFSDU

Background: The Codex Secretariat informed through document CX/NFSDU 24/44/7 the background to the revision, amendment and NWIPs handling of the Codex Committees including CCNFSDU. This was with reference to the Codex Procedural Manual and the developed draft Guideline for the preliminary assessment to identify and prioritize new work and revision/amendment of the texts for CCNSFSDU. Noted that the CCNFSDU had the earliest standards developed in 1970s and 80s with recent interventions on the Guidelines for ready-to-use therapeutic foods (RUTF) (CXG 95-2022) adopted in 2022 and revision of Standard for follow-up formula (CXS 156-1987) renamed as the Standard for follow-up formula for older infants and product for young children. Lately, the amendment to Canned baby foods (CXS 73 -1981) and regular updates to the Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children (CXG 10-1979). The only fully revised standard in recent years has been the recently completed and adopted revised Standard for follow-up formula (CXS 156-1987) which has been renamed as the Standard for follow-up formula for older infants and product for young children.

At CCNFSDU43, the Committee noted that the electronic working group (EWG) for draft Guideline for the preliminary assessment to identify and prioritize new work and revision/amendment of the texts for CCNSFSDU agreed that the Codex Secretariat would consider approaches to review all texts under the purview of CCNFSDU.

Considering that some of the standards developed by CCNFSDU were developed before the currently introduced version of the format for Codex commodity standards hence CCNFSDU does not necessarily need to follow the format for commodity standards as prescribed in the Procedural Manual. The Secretariat further noted that for certain standards, a section on contaminants needs to be included or where they exist, needs to be updated. In accordance, with section on Elaboration of Codex standards and related texts in Codex Procedural Manual that give reference to the Relations between commodity committees and general subject committees, and Format for Codex commodity standards and for the Codex Secretariat to submit to and approval by the Codex Alimentarius Commission (CAC) to undertake such updates.

Several limited screening exercises were done to identify gaps, any new nutrition science, or other scientific/technological developments that could be of relevance for the following standards: CXG 55-2005, CXS 180-1991, CXS 203-1995, CXS 118-1979, CXS 180-1991, CXS 73-1981, CXS 74-1981, CXG 8-1991, CXG 9-1987, CXS 181-1991, CXS 72-1981, CXS 53-1981.

From the screening exercises it was suggested that the standards were still relevant and that certain/some might require updating for amendment and fit with future relevance. Those identified for amendment included; CXS 118-1979, CXS 73-1981, CXS 74-1981, CXS 181-1991, CXG 55-2005, CXS 72-1981 and CXS 180-1991. The standards that required no need for immediate revision/amendment were noted; CXG 8-1991, CXG 9-1987, CXS 53-1981 and CXS 203-1995.

Issue: CCNFSDU is invited to consider the recommendations from the Codex Secretariat on the process of revision/ amendment of the standards under the Committee.

Position: African Union supports the recommendations below from the Codex Secretariat on the revision, amendment and update of Codex standards under CCNFSDU.

i) to use the existing procedures to review standards under the purview of CCNSFDU
ii) encourage Members (and Observers) to propose revisions / amendments to existing standards, where needed, in response to the regular circular letter requesting new work proposals with initial screening exercises could be taken into account to guide new work proposals
iii) request the Codex Secretariat to submit the consequential amendments identified for CXS 72-1981 and/or any other editorial amendments for consideration and approval by CAC47; and
iv) request the CCNFSDU host country Secretariat to include the existing standards developed by CCNFSDU in the inventory of proposals and potential areas of work as proposed in the “Process for compiling new work proposals” (CL 2024/52-NFSDU)

Rationale: Given that there are existing procedures and guidance in the Procedural Manual for proposals for new work (including revision / amendment of standards) and that CCNFSDU has embarked on a process of prioritization of new work / emerging issues including the revision / amendment of existing standards and the issuance of a regular circular letter calling for proposals for new work since 2020. With the limited number of existing CCNFSDU standards, a specific mechanism to review standards under the purview of CCNSFDU is not necessary. Maintaining an inventory list as introduced with the draft Guideline for the preliminary assessment to identify and prioritize new work for CCNFSDU could be sufficient to create transparency on the need for updates.