



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

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REVIEW OF STANDARDS UNDER THE PURVIEW OF CCNFSDU

(Prepared by the Codex Secretariat)

Background

1. The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) has developed guidelines, standards and other texts which have been adopted and published in the Codex Alimentarius. These standards¹ are available [here](#). Many of these standards were first developed in the late 70s and 80s with updates over the years. The most recently developed new text is the *Guidelines for ready-to-use therapeutic foods (RUTF)* (CXG 95-2022) adopted in 2022 and the complete revision of the *Standard for follow-up formula* (CXS 156-1987) renamed as the *Standard for follow-up formula for older infants and product for young children*.²

2. Part of the responsibilities of the Codex Alimentarius Commission (CAC) and its subsidiary bodies is the revision, as necessary, of Codex standards to ensure that they are consistent with and reflect current scientific knowledge and other relevant information³. Thus, committees should keep their standards and related texts under review to ensure that they are up to date and relevant. The need to update existing standards (revision / amendments) or removal of standards are normally brought to the attention of a committee by Members or Observers in accordance with procedures for the elaboration of Codex standards and related texts⁴, following also whichever specific procedures have been identified by a particular committee. In some instances, committees might even have systematic approaches to review their existing standards.

3. At CCNFSDU43, the Committee noted that the electronic working group (EWG) which had developed the draft Guideline for the preliminary assessment to identify and prioritize new work for CCNSFSDU had recommended that CCNFSDU regularly review its standards and other texts to ensure that they remain relevant, up to date and consistent with other Codex texts. At that session, it was agreed that the Codex Secretariat would consider approaches to review all texts under the purview of CCNFSDU to assess if they were still fit for purpose.⁵

4. This paper sets out to explore approaches to review texts under the purview of CCNFSDU, provides background to the review of standards in CCNFSDU since their adoption, mechanisms for review, and possible updates that could be undertaken as part of the amendments (editorial / alignment) or revision falling under the responsibilities of committees and/or the Codex Secretariat. In preparation for this paper, the Codex Secretariat together with the chairs of CCNFSDU and the host Secretariat with the assistance of Australia, Canada, Finland, Germany Ghana, WHO and FAO undertook screening exercises of certain standards as examples to facilitate further discussion on the need to review existing standards. The standards chosen did not include those most recently updated or developed, such as CXS 156 or CXG 95, neither the *Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children* (CXG 10-1979) as this Guideline is regularly updated as the need arises.

¹ Standard in this document implies all texts developed by CCNFSDU, including guidelines.

² Other equivalent names for this product are “drink for young children with added nutrients”, or “product for young children with added nutrients”, or “drink for young children”.

³ General Principles of the Codex Alimentarius: Revision of Codex standards, Procedural Manual.

⁴ Procedures for the elaboration of Codex standards and related texts, Proposals to undertake new work or to revise a standard: Codex Procedural Manual (latest edition)

⁵ REP23/NFSDU, paras 116 – 118.

Discussion

History of amendments / revisions to bring standards up to date with new developments in science and technology or in line with general decisions applicable to all Codex standards

5. The majority of the standards developed by CCNFDU have been updated, barring the *Statement on infant feeding* (CXA 2-1976), the *Standard for labelling of and claims for foods for special medical purposes* (CXS 180-1991) and the *Guidelines for vitamin and mineral food supplements* (CXG 55-2005). The most recent updates were in 2023 to address decisions of the Committee on Food Additives (CCFA) on the alignment of food additives with the *General Standard for Food Additives* (CXS 192-1995). In addition some editorial amendments have been introduced or changes made following proposals from Members where they had identified a particular need for updates due to technological/scientific developments, need to take into account WHO guidelines or decisions, to clarify the scope or provisions or to correct an error (e.g. most recently the amendment to the *Standard for 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*.⁶

6. A summary explaining the history of revisions or amendments to standards over the years is available [here](#).

Revision of standards to bring them up to date

7. Other than updating standards because new information (scientific or other) has become available, following the general procedures of Codex, updating can also be of a more editorial nature or to align with the *Format for codex commodity standards* as per Section 2 of the Procedural Manual for which no new work proposal is required (i.e. no need to submit a project document). Examples include the recent alignment work on food additives (as mentioned in para. 5) or inclusion of general statements about hygiene or methods of analysis and sampling.

8. Considering that some of the standards developed by CCNFDU were developed before the current version of the format for Codex commodity standards was introduced and thus do not necessarily follow the format for commodity standards as prescribed in the Procedural Manual, the Secretariat has noted that for certain standards, by way of example, a section on contaminants needs to be included or where they exist, needs to be updated in accordance with Section 2: *Elaboration of Codex Standards and Related Texts: Relations between commodity committees and general subject committees*, and *Format for Codex commodity standards*.

9. This is particularly important as in recent years, several maximum levels (MLs) for contaminants, viz. for lead and for total aflatoxins in cereal-based foods for infants and young children have been adopted and included in the *General Standard for contaminants and toxins in food and feed* (GSCTFF) (CXS 193-1995). These MLs are relevant for commodities covered by the *Standard for processed cereal-based food for infants and young children* (CXS 74-1981) and yet there is no reference to the GSCTFF in CXS 74. Inclusion of a reference would assist the user of the standard to be aware of the requirements for certain contaminants in the products covered by the standard to ensure safety of the consumer.

10. Such updates can be undertaken by the Codex Secretariat for submission to and approval by the Codex Alimentarius Commission (CAC). Submission can be made directly to CAC or through the Committee. The Committee should, however, consider if such editorial amendments should be made in a piece-meal fashion or whether it would be more useful to do a full review of a standard to determine if other more substantive amendments / revisions are also required.

Approaches to review/revise Codex standards for nutrition and special dietary uses

11. Part of the mandate of a committee is to review its existing standards to ensure that they are kept up to date and relevant. Most committees, CCNFDU included, are reliant on Members (or Observers) to bring forward proposals to revise or amend an existing standard through the normal processes for new work proposals (i.e. no specific systematic approach to review standards). While in other cases, there are more systemic approaches to identify possible review of an existing standard.

⁶ Other equivalent names for this product are “drink for young children with added nutrients”, or “product for young children with added nutrients”, or “drink for young children”.

The current process in CCFNSDU relies on the procedures outlined in the Procedural Manual and more recently CCFNSDU has introduced a process by which proposals can be submitted and prioritized by the Committee (see [CL 2024/52-NFSDU](#)).

Review approaches / procedures in other committees

12. While there is no given need to prescribe additional approaches/procedures to review existing standards in Codex other than what is already prescribed by the Procedural Manual, some committees given the nature of their work have developed internal procedures to either identify existing standards that require review or have prescribed formal procedures for periodic reviews.

13. For example, the Committee on Contaminants in Foods (CCCF) has recently developed a procedure and criteria to identify existing standards within their purview for review. This does not mean that the committee necessarily undertakes new work but identifies standards (either MLs or codes of practice) which should be reviewed in order to determine if there is a need for an update. Decision on whether to undertake new work still relies on a member developing a discussion paper setting out the rationale for new work and submission of a project document. The process by which CCCF works is an internal process for their use.

14. The Committee on Pesticide Residues (CCPR) on the other hand has a set procedure in the Risk analysis principles applied by CCPR (Procedural Manual) for periodic review of maximum residue levels (MRLs) for pesticides. However, it must be borne in mind that the latter is a specific case due to the nature of pesticide use. Such procedures might be useful for a particular committee but there is no obligation for committees to develop such procedures. In the case of CCFNSDU, there are limited texts and the nature of nutrition science and developments in this field might be very different from setting MLs for contaminants or MRLs for pesticides, therefore need for additional procedures might not be warranted.

15. It should be noted that all these additional procedures are complementary to the general procedures for the development and revision of Codex standards prescribed in the Procedural Manual and applying across subsidiary bodies of the Commission. So, they are not a replacement for the general procedures and are set on a case-by-case basis depending on the nature, the need, and workload of Codex committees and may apply consistently or as needed by the concerned committees.

16. CCFNSDU therefore needs to carefully consider whether there is merit in developing additional procedures when it has already embarked on a prioritization mechanism for new work overall (including revision or amendments of existing standards). The proposed procedure for prioritization of work currently under discussion in CCFNSDU is a procedure to guide the committee in identifying and prioritizing new work proposals, including proposals to revise / amend existing standards. These guidelines set out a process for submission of new work proposals, for compiling new work proposals, including an inventory list and for prioritizing new work proposals.

17. There are similar processes in the Committee on Food Hygiene (CCFH) and the Committee on Food Labelling (CCFL), for example, where they keep an inventory of identified areas of possible new work including the need to review existing texts and Members/Observers are encouraged to submit proposals in response to calls for new work proposals through circular letters.

Outcomes of the review of standards

18. As mentioned in para. 4 above, 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:

- *Guidelines for vitamin and mineral food supplements* (CXG 55-2005)
- *Standard for labelling and claims for foods for special medical purposes* (CXS 180-1991)
- *Standard for formula foods for use in very low energy diets for weight reduction* (CXS 203-1995)
- *Standard for foods for special dietary uses for persons intolerant to gluten* (CXS 118-1979)
- *Standard for labelling of and claims for foods for special medical purposes* (CXS 180-1991)
- *Standard for canned baby foods* (CXS 73-1981)
- *Standard for processed cereal-based food for infants and young children* (CXS 74-1981)
- *Guidelines on formulated complementary foods for older infants and young children* (CXG 8-1991)
- *General principles for the additional of essential nutrients to foods* (CXG 9-1987)

- *Standard for formula foods for use in weight control diets* (CXS 181-1991)
- *Standard for infant formula and formulas for special medical purposes intended for infants* (CXS 72-1981)
- *Standard for special dietary foods with low-sodium content (including salt substitutes)* (CXS 53-1981)

19. The aim of requesting these screening exercises was to set the ball rolling for discussions on (i) possible new work to revise/amend existing standards, or (ii) further in-depth reviews to determine whether there is a need to update certain standards. A summary of the screening exercises is compiled in Appendix I. Proposed updates will still require a proposal for new work by a Member following the procedures outlined in the Procedural Manual and the draft Guideline for the preliminary assessment to identify and prioritize new work for CCNFSDU.

20. From the screening exercises it is suggested that the standards considered are still relevant and that certain might require updating (there is already sufficient information to undertake a revision/amendment); require further review to identify possible revision/amendment in the future or are fit for purpose and require no further action at this time. Those identified for amendment/revision, further review or no action at this time are the following:

Possible revision/amendment

- *Standard for foods for special dietary use for persons intolerant to gluten* (CXS 118-1979)
- *Standard for canned baby foods* (CXS 73-1981)
- *Standard for processed cereal-based foods for infants and young children* (CXS 74-1981)
- *Standard for formula foods for use in weight control diets* (CXS 181-1991)
- *Guidelines for vitamin and mineral food supplements* (CXG 55-2005)

Further review / possible revision/amendment in future

- *Standard for infant formula and formulas for special medical purposes intended for infants* (CXS 72-1981)
- *Standard for labelling of and claims for foods for special medical purposes* (CXS 180-1991)

No immediate need for revision/amendment

- *Guidelines on formulated complementary foods for older infants and young children* (CXG 8-1991)
- *General principles for the addition of essential nutrients to food* (CXG 9-1987)
- *Standard for special dietary foods with low-sodium content (including salt substitutes)* (CXS 53-1981)
- *Standard for formula foods for use in very low energy diets for weight reduction* (CXS 203-1995).

21. It should be noted that the list above is indicative only, is not presented in any order of prioritization and should not be considered as new work proposals nor does it mean that more in-depth review should not be considered. Formal proposals for new work are still required in accordance with general Codex procedures and additional procedures specific to CCNSDU.

Conclusion

22. CCNFSDU has developed many standards since its inception and has undertaken several amendments/revisions over the years to bring them up to date or in line with general decisions of CAC relevant to all Codex standards. The full revision of the *Standard for follow-up formula* (renamed *standard for follow-up formula for older infants and product for young children*) being the most recent work.

23. 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 2020⁷, and 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

⁷ [CL 2020/30-NFSDU](#); [CL 2024/52-NFSDU](#)

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 (see para. 11 of the draft guidelines in [CL 2024/52-NFSDU](#)).

24. The screening summaries in Appendix I provide a starting point for further consideration/review or submission of proposals for new work within the general Codex procedures and working procedures applied by the Committee.

Recommendations

25. CCNFSDU is invited to consider the following recommendations:

- 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. In doing so, the 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 (available [here](#)) 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*” (see [CL 2024/52-NFSDU](#)) (Agenda item 6).

Appendix I

Summary of Screening exercises

Standard for infant formula and formulas for special medical purposes intended for infants (CXS 72-1981)

Consequential amendments to correct conversion between kilocalories and kilojoules and to align with corrections made to the revised CXS 156-1987 could require immediate submission to CAC while further review could be done in future to consider any other amendments that might be relevant in view of the revised CXS 156-1987, outcomes of the Joint FAO/WHO update of nutrient intake values for infants and young children from birth through 3 years of age (in publication), outcomes of the CCNSFDU EWG on the use of fructans, beta-carotene and lycopene as optional ingredients, or any other relevant information.

Standard for canned baby foods (CXS 73-1981)

The review has highlighted gaps and developments that warrant the attention of CCNFSDU. Several areas have been identified for further consideration, such as, but not limited to, clarifying the scope (e.g. clarifying that products covered by CXS 156 are excluded from this Standard), compositional requirements and the target group of the foods covered by the Standard and other amendments to the section on flavourings, and the section on labelling (to align with other relevant standards).

Standard for processed cereal-based foods for infants and young children (CXS 74-1981)

The review has highlighted gaps and developments that warrant the attention of CCNFSDU. The current version of the Standard especially provisions for macronutrients, including maximum amounts for added sugar and sodium, but also requirements for vitamins and minerals should be revised based on recent international recommendations and guidelines. The sections on optional ingredients and labelling should also be considered.

Standard for special dietary foods with low sodium content (including salt substitutes) (CXS 53-1981)

The review of the Standard took into account the WHO guideline on salt substitutes and from this perspective, there does not appear to be a need to update this Standard because the standard pertains to foods for special dietary uses.

Standard for foods for special dietary use for persons intolerant to gluten (CXS 118-1979)

The review has indicated that the Standard remains relevant and effective, but that CCNFSDU may want to consider several updates to the definition (gluten-free foods), i.e. removing oats from the list of sources of gluten, several other amendments to sections 2.1.2, 2.2.2 and 5.1. It is recommended that CCNFSDU consider aligning the Standard with global practices, which could involve removing gluten-free foods from the FSDU framework and potentially integrating relevant provisions into broader food labelling standards and that the Standard be updated to reflect advances related to gluten detection, amongst others.

Standard for labelling of and claims for foods for special medical purposes (CXS 180-1991)

The review has indicated that this Standard remains relevant for FSMP and does not require updating right away. However, there are ongoing discussions that may necessitate revision in future. To help better align the Standard with current practices, consideration could be given to conduct a review in future to help determine the need to scope in more specific compositional requirements for FSMP, mainly those formulated to provide a sole source of nutrition and those that are not currently captured under CXS 72, CXS 203 and CXG 95.

Standard for formula foods for use in weight control diets (CXS 181-1991)

The review seems to suggest that there is some technical justification for updating the Standard and that a more in-depth review should be undertaken to identify further areas for updating the Standard. The current review suggests that other essential micronutrients, such as pantothenic acid, vitamin K, biotin, molybdenum, manganese and selenium for which NRVs has been set should also be mandatorily required in the foods covered by this Standard and that section 3.2.3.2 should be revised.

Standard for formula foods for use in very low energy diets for weight reduction [\(CXS 203-1995\)](#)

The analysis and reports from VLED manufacturers indicated an update of CXS 203 is not needed at this time. CXS 203 continues to be both nutritionally adequate and safe while also technically feasible with minimal barriers to the supply of VLED globally.

Guidelines on formulated complementary foods for older infants and young children [\(CXG 8-1991\)](#)

While a possible amendment has been identified for section 4.1 no other developments / information have been identified to warrant further review and revision of the Guidelines at this time.

General principles for the addition of essential nutrients to food [\(CXG 9-1987\)](#)

The review did not find any information to warrant changes to the Guidelines at this time.

Guidelines for vitamin and mineral food supplements [\(CXG 55-2005\)](#)

The review of the Guidelines has highlighted several significant developments and gaps that warrant the attention of CCNFSD. The identified gaps, particularly in the provision of comprehensive guidance for FSDU and the blurring line between conventional foods and dietary supplements, underscore the necessity for action. It is recommended that CCNFSDU considers the options presented for addressing these gaps and may want to consider new work in the coming years. The review of the Guideline, in addition to other Codex texts, identified a gap in the compositional recommendations for FSDU, and a potential need to either expand the scope of current Codex texts or develop a new Codex text to provide guidance for products that do not fall within the scope of existing texts, such as supplemented foods and FSDU. Several options were identified that CCNFSDU could consider to address the gaps identified.