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World Health Organization

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Agenda Item 4 **NFSDU/43 CRD 2**

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

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REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA STRUCTURE AND PREAMBLE

Prepared by New Zealand

1 INTRODUCTION

The 42nd Session of the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU42) agreed that a discussion paper would be prepared by New Zealand to address the remaining aspects in the review of the *Standard for Follow-up Formula* (CXS 156-1987): structure and Preamble of the revised standard(s). The paper was agreed to be circulated for comments through a Circular letter.

The Committee further agreed that New Zealand would analyse the responses and prepare a paper to present to CCNFSDU43 for further discussion and decision in order for the Committee to complete its work on the review of the *Standard for Follow-up Formula*.

CCEXEC82 held in June 2022 recommended extension of the deadline for completion of the review of the *Standard for Follow-up Formula* (CXS 156-1987) to 2023 and urged completion of the work by CCNFSDU43 (Para 14 REP22/EXEC1).

1.1 Circular letter

The Circular letter (CL 2022/24/OCS-NFSDU) was issued in March 2022 with comments sought by 31 August 2022 via the Codex Online Commenting system.

Please note the following abbreviations used throughout this paper:

CM: Codex Member
CMO: Codex Member Organisation
CO: Codex Observer
EWG: Electronic Working Group
CL: Circular letter

Infant Formula Standard: Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-181)

1.2 Conclusions

New Zealand has analysed the responses from Committee members to the questions in the CL. Appendix I contains the analysis of the responses and recommendations covering the structure of the standard and wording for a Preamble for the Committee's consideration at CCNFSDU43.

In total 47 responses were received (38 CM, 1 CMO, 8 CO) but not all respondents replied to all questions. Appendix II lists of the respondents to CL 2022/24/OCS-NFSDU.

1.3 Recommendations

The Committee is invited to consider Recommendations 1 and 2 as presented in Appendix I.

APPENDIX I: DISCUSSION ON THE RESPONSES TO CL 2022/24/OCS-NFSDU AND RECOMMENDATIONS FOR THE COMMITTEE

1 STRUCTURE

1.1 Background

To facilitate the review of the *Standard for Follow-up Formula* the standard has been presented as one standard with two parts; Section A: Follow up formula for older infants; and Section B: Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children, or Product for young children (hereafter referred to collectively as 'product for young children' throughout this paper).

The structure was part of the terms of reference of the 2018 electronic working group (EWG) and two rounds of consultations were conducted which are summarised in Agenda Paper (CX/NFSDU 18/40/5) to CCNFSDU40. However, due to time constraints, CCNFSDU40 did not consider the work of the 2018 EWG on the structure of the standard(s).

To date, the Committee has not discussed or taken any decisions on the structure of the standard.

1.2 Committee views on the structure

The discussion paper circulated to the Committee through CL 2022/24/OCS-NFSDU in March 2022 asked the following questions regarding the structure of the standard(s):

1. Now that the standard has been completed, please indicate your preferred structure approach, and clearly state why you do, or do not, support each option:

    a. One standard with two parts: Part A covering Follow-up Formula for Older Infants and Part B covering Product for Young Children.
    b. Two separate standards: One standard for Follow-up Formula for Older Infants, and one standard for Product for Young Children.
    c. Can support either approach.
    d. Support a different structure approach – please describe the approach and provide your justification.

2. Do you have any further comments on the structure?

In total 46 respondents (37 CM, 1 CMO, 8 CO) indicated their preferred structure option. A clear majority of the respondents (26 CM, 1 CMO, 4 CO) preferred *Option a. One Standard with Two parts: Part A covering Follow-up Formula for Older Infants and Part B covering Product for Young Children.* Three respondents (2 CM, 1 CO) who preferred Option a. also mentioned that they could support *Option b. Two separate standards* should that be the option preferred by the Committee.

Option b. Two separate standards: One standard for Follow-up Formula for Older Infants, and one standard for Product for Young Children, was the preferred option of 11 respondents (10 CM, 1 CO). Three of those (2 CM and 1 CO) also mentioned they were not opposed to *Option a. One standard with two parts* and could support it. Six respondents (1 CMO, 2 CM, 3 CO) specifically mentioned that they do not support or that they oppose *Option b. Two separate standards.*

Three respondents (3 CO) supported an alternative structure option; to create one standard covering four products; Infant Formula, Infant Formula for Special Dietary Use, Follow-up Formula for Older Infants, and Product for Young Children. All three mentioned *Option a. One Standard with Two Parts* as their second preference. The same alternative structure option was also mentioned by one respondent as their second preference, their first preference being *Option a. One standard with two parts.* Another two respondents commented that infant formula, which can in some cases be necessary, and follow-up formula for older infants and products for young children, which are unnecessary, should not be combined in one standard. Two respondents specifically mentioned that they do not support discussion on other options for the structure apart from *Option a. One standard with two parts* and *b. Two separate standards*. A further one respondent could support all structure options.

Justification for Option a. One Standard with Two parts: Part A covering Follow-up Formula for Older Infants and Part B covering Product for Young Children

The common justification provided for supporting *Option a. One Standard with Two parts: Part A covering Follow-up Formula for Older Infants and Part B covering Product for Young Children* was that this is in line with how the Committee has approached and conducted the review of the standard, and that while the two products have differing compositions and are intended for two distinct age groups, they are based on a similar concept as being a liquid part of the diversified diet of either older infants or young children. One standard with two parts was seen as an adequate approach to distinguish the two products. Some also mentioned that there is not enough justification to separate the two products even though their composition differs. Several respondents further noted that a precedent has been set in the Infant Formula Standard (CXS 72-1981) which covers two compositionally distinct but conceptually similar products in one standard with two parts, and that there are also other Codex texts that cover both of the age groups.

A group of respondents noted that given that both products are recognized and used as breastmilk substitutes, defined as breastmilk substitutes in the International Code of Marketing of Breast-Milk Substitutes, and that both are not necessary products, they should be covered in one standard.

Respondents whose preference was *Option a. One Standard with two parts* also noted that most of the provisions and requirements are aligned for the two products, and that Option a. is a pragmatic way forward and will facilitate the completion of the standard.

Justification for Option b. Two separate standards: One standard for Follow-up Formula for Older Infants, and one standard for Product for Young Children

Those in support of *Option b. Two separate standards: One standard for Follow-up Formula for Older Infants, and one standard for Product for Young Children* mentioned this approach to be justified based on the different compositions, and the products being for two different age groups with differing nutritional requirements. Another reason given in support of two separate standards was that follow- up formula for older infants is a breastmilk substitute but product for young children is not and thus they are substantially different. *Option b. Two separate standards* was also seen as less confusing, more logical, and to better facilitate future review and revision, allowing that to happen separately for both products. It was further noted that Option b. would not affect the timeline for the completion of the standard nor have procedural implications.

Procedural implications of the different options

The first 2018 EWG consultation paper presented four options for the structure of the standard(s). The paper also presented the Codex procedural implications for each option, which were included with the guidance of the Codex Secretariat. New Zealand has confirmed with the Codex Secretariat that the implications are still relevant. Both *Option a. One standard with two parts* and *Option b. Two separate standards* are within the current mandate of the review of the Standard for Follow-up Formula agreed to by Codex Alimentarius Commission (CAC, at its 36th session in 2013) and do not have any procedural implications. The alternative approach proposed by three respondents to the CL 2022/24/OCS-NFSDU, which would see the creation of one standard covering four products, would require approval for new work, if the approach necessitated substantial changes to parts of the Infant Formula Standard. A project document would need to be prepared for CAC's approval and CAC would need to be informed that work on the Standard for Follow-Up Formula was discontinued. Once work on the new standard covering the four products was completed, the current Standards for Infant Formula and Follow-on Formula should be revoked. Choosing this approach would also mean that a new timeline for the work would need to be set.

1.3 Recommendation on the structure

Based on the clear majority preference of the respondents to CL 2022/24/OCS-NFSDU it is recommended that the Committee agree to one standard with two parts, Part A covering Follow-up Formula for Older Infants and Part B covering Product for Young Children. This option has no procedural implications and will allow CCNFSDU43 to submit the complete revised Standard for Follow-up Formula for adoption by the Commission (Step 8).

Recommendation 1
That CCNFSDU agree to one standard with two parts, Part A covering Follow-up Formula for Older Infants and Part B covering Drink for Young Children with Added Nutrients, or Product for Young Children with Added Nutrients, or Drink for Young Children, or Product for Young Children.

2 PREAMBLE

2.1 Introduction

Whilst a decision has yet to be taken on the Preamble, discussions have been had at previous meetings as to what a Preamble should or should not include, notably relating to the need to reference WHO/WHA documents.

The Codex Procedural Manual does not provide guidance on the purpose of a Preamble and what it should include. The Format for Codex Commodity Standards contained within the Procedural Manual does not require a Preamble section.

Any country can use Codex standards as they see fit, Codex standards being voluntary in nature. Codex standards do however serve in many cases as a basis for national legislation. In terms of the World Trade Organization's (WTO) Agreement on Technical Barriers to Trade (TBT), if a dispute arises, Codex standards are an important reference point for the dispute settlement mechanism. Note that the Preamble, as well as any annexes or appendices, are an integral part of a Codex standard and contribute to the entire content of the standard.

2.2 Background

In 2017, the EWG considered WHO/WHA referencing within the *Standard for Follow-up Formula*. Due to polarised views within the EWG for and against referencing WHO/WHA documents, the EWG Chair engaged with the Codex Secretariat and WHO to progress this issue and find a workable solution. The result was the concept of a Preamble that could include reference to relevant documents. The intent was that this approach would replace the need to list or reference specific documents or resolutions within different sections of the Standard itself as the Preamble is applied to the Standard as a whole.

At CCNFSDU39, there were some inconclusive discussions on the Preamble. Whilst Preamble wording had been drafted and presented in the agenda paper, the Committee did not discuss the recommendation or take a position on the text. The CCNFSDU Chair noted that several fundamental questions needed to be answered on whether to have specific references to WHA resolutions and WHO guidelines or whether to have a more general reference; that some of the WHA resolutions went beyond the mandate of Codex and therefore were inappropriate to reference; and whether guidance from the CCEXEC or CAC might be needed before the wording of the Preamble could be refined.

In 2018, CCEXEC75 (and reaffirmed by CCEXEC77) provided advice on references to WHO/WHA documents in the draft Follow-up Formula Standard:

a. references should be considered on a case-by-case basis;
b. references may provide context and additional information to assist members in understanding and use of standards;
c. concepts and technical information could be incorporated into the text of the standard itself, rather than referencing sources external to Codex; and
d. references must be relevant to the scope of the standard itself, fall within the mandate of Codex, have a scientific basis, and have been developed through a transparent process.

Codex Members are encouraged to familiarise themselves with CRD 2 from CCNFSDU42. CRD2 was prepared as a way of providing background to the Committee on the evolution of the scope, definition and labelling sections of the *Standard for Follow-up Formula*. It presents a timeline of discussions, considerations and decisions relating to how relevant concepts and technical guidance in WHO/WHA documents have informed the labelling and other provisions within the draft standard(s). The table contained within CRD 2 illustrates how during the review of the *Standard for Follow-up Formula*, the EWG and Committee has followed the advice of CCECEX75, specifically recommendations a), c), and elements of d).

Given the Committee has now agreed on the labelling provisions and taken into account the advice from CCEXEC, the decision has been made to consider the Preamble based on the responses to the 2022 Circular Letter (CL 2022/24/OCS-NFSDU), and to not build on Recommendation 9 as presented in the 2017 Agenda Paper (CX/NFSDU 17/39/4 Rev.1).

2.3 Approaches to a Preamble in other CCNFSDU texts

Different approaches have been taken to the Preamble for different Codex standards. The current *Standard for Follow-up Formula* (CXS 156– 987), the *Standard for Processed Cereal-based Foods for Infants and Young Children* (CXS 74–1981), and the *Standard for Canned Baby Foods* (CXS 73–1981) do not have a Preamble. The *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72–1981) has a simple Preamble which states that the Standard is divided into two sections; Section A refers to Infant Formula, and Section B deals with Formulas for Special Medical Purposes Intended for Infants.

The most recently drafted Preamble was that for the *Guidelines for Ready-to-Use Therapeutic Foods*. The decision taken at CCNFSDU42 (REP22/NFSDU paras 102 – 109) was to keep the Preamble simple yet refer to the basic composition, the target age group, and that RUTF is a recommended option for the dietary management of severe acute malnutrition.

In relation to the discussion on the revised Preamble for the *Guidelines for Ready-to-Use Therapeutic Foods* that was had at CCNFSDU42, the Chairperson clarified that the Preamble should set the scene by providing the overall context but not specify any product requirements which are found within the main body of the 'Guidelines'. The Codex Secretariat further clarified that the Preamble should not address matters outside the scope of Codex and that discussion on the Preamble should be guided by the *General Principles of the Codex Alimentarius*. The Committee was advised of Section 3 of these Principles: *Nature of Codex Standards* which states that;

> *Codex standards and related texts are not a substitute for, or alternative to national legislation. Every country's laws and administrative procedures contain provisions with which it is essential to comply.*

Thus, issues not addressed in the 'Guidelines' were still subject to countries' laws and requirements.

The advice of CCEXEC75 on referencing WHO/WHA documents, and CCEXEC78 on references to other standards setting organisations was taken into account when revising the RUTF Preamble. This was to ensure a minimum number of references as they require ongoing monitoring.

2.4 Committee views on the Preamble

In the Circular letter (CL 2022/24/OCS-NFSDU) issued in March 2022 Codex Members were reminded that any Preamble text should not conflict with, or be more stringent than, the composition and labelling aspects of the Standard(s) (as these have already been agreed by the Committee). Further, if there is to be a Preamble, members were reminded that as per the guidance provided by the CCNFSDU Chair in relation to RUTF, Preamble text should set the scene by providing the overall context but does not need to specify any product requirements which are found within the main body of the Standard(s).

The Circular letter asked the following questions:

- Do you think this Standard(s) requires a Preamble? Yes/No
- If so, what is the purpose of having a Preamble for this Standard(s)? Please provide rationale and justification for your thinking.
- What detail should the Preamble contain? Please provide rationale and justification for your thinking.

Of the 31 respondents who support *Option a. One standard with two parts,* 21 (19 CM, 2 CO) responded that a Preamble should be included, with an additional two respondents (1 CMO, 1 CM) commenting that they are not opposed to a Preamble if supported by the Committee. Eight respondents (6 CM, 2 CO) did not support a Preamble. Of these eight, five indicated they could support a simple statement to say that the Standard is divided into two parts if there was support from the Committee for a Preamble statement.

In addition, a further five respondents (4 CM, 1 CO) who had a preference for two separate standards, said that they could support a simple Preamble statement (to say that the Standard is divided into two parts), if the Committee preference is for one standard with two parts. The three Codex Observers who supported an alternative structure option; to create one standard covering four products; Infant Formula, Infant Formula for Special Dietary Use, Follow-up Formula for Older Infants, and Product for Young Children, commented that they could also support one standard and with all three of the view that a Preamble is necessary.

Of those members who supported a Preamble, (or who could support a Preamble if this was the preference of the Committee), respondents were almost equally split between those who preferred a simple statement to say that the Standard is divided into two parts vs those who supported more detailed text that incorporates content of applicable WHO/WHA guidance and resolutions and/or specific references to these documents.

From those submissions supporting a more detailed Preamble, many communicated that the premise for incorporating WHO/WHA documents and resolutions into the Preamble is largely based on policy coherence as it acts as a prompt to countries that in addition to the Standard itself, other guidance material and international instruments exist, and these references assist countries in putting the Standard into context, as well as facilitating application of the Standard. A reference to the WHO International Code of Marketing of Breast-milk Substitutes was the most frequently cited document to include in the Preamble.

Counter to this, those supporting a simple Preamble statement (or no Preamble statement at all), were primarily of the view that the Committee has followed the advice of CCEXEC75 and incorporated the applicable concepts and guidance from WHO/WHA documents and resolutions into the Standard itself, making reference to these within the Preamble unnecessary. Comment was also made that as per the Codex Procedural Manual, a preamble is not required.

2.5 Recommendation on the Preamble

As per Recommendation 1, that is the Committee agree to one standard with two parts, the Preamble text options have been drafted for this structure preference. The text proposals may also be relevant if the preference of the Committee is to have two separate standards, each with a separate Preamble.

This starting point is a compromised position and an attempt to capture the differing views of those who submitted responses to the CL.

In the development of the text proposals, the following aspects have been taken into account, alongside the responses received to the CL:

- Guidance provided by the CCNFSDU Chair and Codex Secretariat on RUTF at CCNFSDU42, notably that Preamble text should set the scene by providing the overall context but does not need to specify any product requirements which are found within the main body of the Standard(s), and that the Preamble should not address matters outside the scope of Codex.
- The advice of CCEXEC75 (and reaffirmed by CCEXEC77) on references to WHO/WHA documents in the draft Standard for Follow-up Formula.
- The need to ensure any Preamble text is not in conflict with, or more stringent than, the composition and labelling aspects of the Standard(s), as these have already been agreed by the Committee.
- The need to avoid duplication of content already covered within the body of the Standard itself.

Recommendation 2
That CCNFSDU consider and discuss the following Preamble text options:
This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants, and Section B deals with Drink for Young Children with Added Nutrients, or Product for Young Children with Added Nutrients, or Drink for Young Children, or Product for Young Children. [The application of this Standard should be consistent with national health and nutrition policies and relevant national/regional legislation and take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes, as per the national context].

[Relevant World Health Organization (WHO) guidelines and policies and World Health Assembly (WHA) resolutions were considered in the development of this Standard and may provide further guidance to countries].

APPENDIX II: LIST OF RESPONDENTS TO CL 2022/24/OCS-NFSDU

Codex Members & Codex Member Organisation

1. Australia
2. Brazil
3. Burkina Faso
4. Cambodia
5. Canada
6. Chile
7. Colombia
8. Costa Rica
9. Cuba
10. Ecuador
11. Egypt
12. The European Union
13. Guatemala
14. Indonesia
15. Iran
16. Kenya
17. Malaysia
18. Mali
19. Mexico
20. Morocco
21. Nepal
22. New Zealand
23. Niger
24. Nigeria
25. Norway
26. Paraguay
27. Peru
28. The Philippines
29. Republic of Korea
30. Saudi Arabia
31. Senegal
32. South Africa
33. Switzerland
34. Thailand
35. Uganda
36. United Kingdom
37. The United States of America
38. Uruguay
39. Vietnam

Codex Observers

1. Association européenne pour le droit de l'alimentation / European Food Law Association (AEDA - EFLA)
2. Consumers International (CI)
3. European Network of Childbirth Associations (ENCA)
4. Helen Keller International (HKI)
5. Institute of Food Technologies (IFT)
6. International Baby Food Action Network (IBFAN)
7. International Special Dietary Foods Industries (ISDI)
8. The United Nations Children's Fund (UNICEF)