

29 August 2019

Review of the Standard for Follow-up Formula (CXS 156-1987): Draft Scope, Description and Labelling for Follow-up Formula for older infants¹

ISDI reply to Circular Letter (CL 2019/77-NFSDU) at STEP 6

General comments

ISDI concurred with CCFL45's endorsement of sections 9.1 to 9.6.3 (with amendments to 9.2.2, 9.3 and 9.4.1 (i) and (ii) and 9.4.2) on labelling and CCFL45's decision to return of the last sentence on paragraph 9.6.4 on cross promotion for further consideration at step 3. ISDI supports CCFL45 delegations that favoured the deletion of the sentence.

ISDI does still also have reservations on the following aspects and recommends changes at step 6 to eliminate inconsistencies and conflicts within this section of the Standard and thus improve clarity.

Specific comments

(9) LABELLING	
9.4	Date Marking and Storage Instructions
9.4.1	(i) The “Best Before Date” or “Best Quality Before Date” shall be declared by the day, month and year except that for products with a shelf life of more than three months, [at least] the month and year [shall be declared] [The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).]
	(ii) In the case of products requiring a declaration of month and year only, the date shall be introduced by the words “Best before end <insert date>; or “Best Quality before end <insert date>].-
<u>The date marking and storage instructions shall be in accordance with section 4.7.1 of the <i>General Standard for the Labelling of Prepackaged Foods</i>.</u>	
9.4.2	In addition to the date, any special conditions for the storage of the food shall be indicated if [where they are required to support the integrity of the food and, where] the validity of the date depends thereon.-
Where practicable, storage instructions shall be in close proximity to the date marking.	

ISDI Comment

ISDI takes note of the changes made by CCFL45 to this section.

ISDI would like to highlight the Codex Standard for Infant Formula and Formulas for Special Medical Purposes

¹ For the background information, please refer to REP19/NFSDU (paras 37 - 50 and para. 57 and Appendix III); REP19/FL (paras 24 - 28) and REP19/CAC (paras 81 - 84 and Appendix III).

Intended for Infants (CODEX-STAN 72-1981) stipulates the date of minimum durability that is expressed by "Best Before" with clear indications on how to declare it.

(9.6.) Additional Labelling Requirements
(9.6.1) Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:
a) the words "important notice" or their equivalent;
b) the statement "Breast-milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast-milk;
c) a statement that the product should only be used on advice of a health worker as to the need for its use and the proper method of use.
d) the statement; 'The use of this product should not lead to cessation of continued breastfeeding'.

ISDI Comment

ISDI would like clarification on 9.6.1.d) and the compatibility with 2.1 and 2.1.1, where the product is defined as a breast milk substitute so per definition this product is to be used as a substitute to breast milk – in a context of either partial or total cessation of breast feeding. The statement is confusing and is properly covered already by 9.6.1.b).

ISDI continues to favour an approach stating that the label of Follow-up Formula for Older Infants should not discourage breastfeeding. Further, mandated statements deserve careful consideration of how consumers will interpret or react to the statement. Proposed new statements should, ideally, be subject to research or pilot studies to determine if the intended meaning or outcome is likely to be achieved.

Based on the above comments, ISDI recommends the following replacement wording:

d) the statement; "exclusive breastfeeding is recommended from birth to 6 months of age, and that breastfeeding should continue to two years of age or beyond".

(9.6.2.) The label shall have no pictures of infants, young children and women nor any other picture, text, or representation that might:
9.6.2.1 idealize the use of follow-up formula for older infants;
9.6.2.2 suggest use for infants under the age of 6 months (including references to milestones and stages);

ISDI Comment

ISDI considers that the phrase "(including references to milestones and stages)" in 9.6.2.2 should be deleted as it could lead to consumers' confusion regarding the appropriate age range for different products.

ISDI proposes the following text instead:

9.6.2.2 should read "suggest use for infants under the age of 6 months."

Rationale

Section 9.5.6 states that "The label of follow-up formula for older infants shall include a statement that the product shall not be introduced before 6 months of age, is not to be used as a sole source of nutrition and that older infants should receive complementary foods in addition to the product." References to milestones and stages are intended to facilitate consumers' understanding of the intended users of the product. Any stage and milestone information stated should not conflict with the very clear age of introduction (not before 6 months) to avoid any confusion.

9.6.2.3 recommend or promote bottle feeding;

ISDI Comment

ISDI would like clarification on the compatibility of this requirement and 9.5.1, 9.5.2 and 9.5.3. ISDI considers that this requirement is in contradiction with the above-mentioned sections and should be deleted or further clarified for concrete implementation.

9.6.2.4 undermine or discourage breastfeeding; or that makes a comparison to breast milk, or suggests that the product is similar, equivalent to or superior to breast milk;

ISDI Comment

ISDI would like CCNFSDU to clarify the need for 9.6.2.4 and its consistency with 9.6.1.b (the statement "Breast-milk is the best food for your baby" or a similar statement).

9.6.2.5 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body unless this has been specifically approved by relevant national or regional regulatory authorities.

ISDI Comment

ISDI notes that this section does not exist in the current Follow-up Formula Standard or in the Infant Formula Standard. ISDI considers that such section is a national authority competence, which would explain why it is not considered in other Standards and texts. Further, if Codex supports this as a principal ISDI considers that it would be more appropriately included within General Labelling Standards or Guidelines than in product Standards.

Specific comments – last sentence in 9.6.4.

9.6.4. Products shall be distinctly labelled in such a way as to avoid any risk of confusion between infant formula, follow up formula for older infants, (name of product) for young children, and formula for special medical purposes, in particular as to the text, images and colours used, to enable consumers to make a clear distinction between them, Cross promotion between product categories is not permitted on the [label/labelling] of the product.

ISDI Comment

ISDI recalls the discussion at CCFL45 and continues to support delegations that favoured the deletion of the last sentence on "cross-promotion" in this paragraph. ISDI believes that restricting cross-promotion is not supported by the evidence, is outside Codex' mandate and is inconsistent with countries' international obligations.

To achieve their purpose, labelling provisions must be based on science. It is important to have a clear distinction between the labelling of infant formula, follow-up formula for older infants and [name of the product] for young children, and formula for special medical purposes.

Rationale

ISDI supports draft Article 9.6.4 – with the exception of the last sentence on cross-promotion, where ISDI suggests its deletion for the following reasons:

- Our industry enables parents and caregivers to easily rely on the same family of products as the child grows. Expert use of text, images and colours fully supports the goal of providing distinctly labelled products, specifically to avoid the risk of consumer confusion between infant formula, Follow-up Formula, and Food for Special Medical Purposes ("FSMP"). Restricting cross-promotion may lead to consumer confusion in identifying safe, legitimate, nutritious

products for young children. It could have the unintended consequence of depriving mothers and caregivers of the necessary information to make appropriate nutrition decisions for their young children. Governments noted similar concerns at the last CCFL45 meeting.

- Restricting cross-promotion goes beyond the mandate of Codex. References to additional labelling provisions and marketing prohibitions go beyond the provisions of the Codex Procedural Manual.² In addition, the restriction differs significantly from the established provisions for food labelling in Codex Standards.³ There is no justification, neither scientific nor market based, for the substantial deviation from Codex norms in the labelling section. Governments noted similar concerns during a recent meeting of the Codex Committee on Food Labelling (“CCFL”).⁴
 - The general principles (section 3) of the Codex General Standard for the labelling of prepackaged foods (Codex STAN 1-1985) already set rules that apply to all foods not to confuse consumers. Similar provisions exist for FOODS FOR SPECIAL DIETARY USES in (CODEX STAN 146-1985). It is permitted to add optional labelling elements providing they are not in conflict with the General principles. One of the general principles states that “Prepackaged food shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.”⁵
- There is insufficient scientific evidence that restricting promotion would contribute to promoting public health through increasing breast feeding rates of infants. A Parliamentary enquiry in Australia found that “[t]he reasons why women do not breastfeed for the recommended period are complex and multifaceted. They include consistency of advice, timing and quality of breastfeeding education, perceptions about infant formula, and the level of community support”.⁶ In addition, a 2014 study conducted by Malaysia’s Ministry of Health found that “there was no retrievable evidence that evaluate the direct effect of promoting ...formula on breastfeeding practice”.⁷ A literature review on Breastfeeding Rates & Pattern in the Malaysian Context further concluded that whilst “advertising was one of the factors reported, the evidence for the relationship between advertising and breastfeeding (BF) rates remains tenuous”.⁸ Even more importantly, that literature review found that “[n]one of the studies related advertising of complementary food to breastfeeding rates”⁹.
 - The feeding of infants and young children is a complex and careful transformation from a milk centric towards the household / solid diet. Infant feeding choices are complex. In high income countries the feeding choice can be very personally motivated but usually the socio-economic realities across all countries determine the feeding choice.
- Restrictions on cross-promotion are incompatible with the established rules for international trade and could result in trade impediments and infringe intellectual property rights. Such restrictions would be considered more trade restrictive than necessary to meet the legitimate objective of protecting human health and increase breastfeeding rates (contrary to Article 2.2 of the TBT Agreement); and the proposed restriction on the use of trademarks to prevent cross promotion, would amount to an unjustifiable encumbrance on trademarks by special requirements (contrary

² Procedural Manual, 26th edition, Section II – Relations between commodity standards and general subject committees, p.49: Where commodity committees are of the opinion that the general provisions are not applicable to one or more commodity standards, they may request the responsible general subject committees to endorse deviations from the general provisions of the Codex Alimentarius. Such requests should be fully justified and supported by available scientific evidence and other relevant information. Sections on food [...]labelling [...] which contain specific provisions or provisions supplementing the General Standards, Codes or Guidelines shall be referred to the responsible general subject committees at the most suitable and earliest time in the Procedure for the Elaboration of Codex Standards and Related Texts, though such referral should not be allowed to delay the progress of the standard to the subsequent Steps of the Procedure.

³ General Standard for the Labelling of Prepackaged Foods (CX STAN 1-1985) ([link](#)) and General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CX STAN 146-1985) ([link](#)).

⁴ Report of the Forty-Fifth Session of the Codex Committee on Food Labeling, 13-17 May 2019 ([link](#)).

⁵ FAO, General principles of food labelling - <http://www.fao.org/ag/humannutrition/foodlabel/76333/en/>

⁶ The Parliament of the Commonwealth of Australia, House of Representatives, Standing Committee on Health and Ageing, “The Best Start: Report on the inquiry into the health benefits of breastfeeding,” 2017, p. 2 ([link](#)).

⁷ Effect of Promoting Formula Milk for Toddler and Pregnant as well as Breastfeeding Mothers on the Breastfeeding Practice, Malaysia MOH, Health Technology Assessment Section, p. 4 (2014).

⁸ Literature Review on Breastfeeding Rates & Pattern in the Malaysian Context, Azmi Burhani Consulting for FIFEC, p. 40 (15 November 2014).

⁹ *Id.*

to Article 20 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"). Governments noted similar concerns at the last CCFL meeting.¹⁰

- The proposed restrictions may also lead to legal uncertainties, since the draft section is inconsistent in itself and establishes contradictory provisions.¹¹ Governments noted similar concerns during the last CCFL meeting.¹²
- The proposed restrictions do not provide sufficient clarity for regulatory enforcement, nor for industry compliance, as they include undefined terms such as "Cross Promotion".

Additional arguments

ISDI notes that the WHO technical guidance on "Ending the inappropriate marketing practices of foods for infants and young children" refers to cross promotion¹³. The technical guidance was welcomed with appreciation but not endorsed recommends to prohibit the promotion of breast-milk substitutes indirectly via the promotion of foods for infants and young children.¹⁴ "The purpose of WHO documents and WHA resolutions is to help determine public health policies. These documents are recommendation and provide direction and guidance for governments in developing their own national public health policies in accordance with their national context."¹⁵ ISDI recalls that Follow-up formula for older infants has been defined as a Breast Milk Substitute at CCNFSDU40. Therefore, its promotion is already prohibited according to the WHO Code on Breast Milk Substitute.

Where and when necessary, the use of follow up formula for older infants is consistent with the aim of the WHO Code as it helps give older infants who are not breastfed an equal chance of survival, enabling them to grow and thrive. "Provision of safe and adequate nutrition for infants, by protection and promotion of breast-feeding, and ensuring the proper use of breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution".¹⁶

¹⁰ Report of the Forty-Fifth Session of the Codex Committee on Food Labeling, 13-17 May 2019 ([link](#)).

¹¹ An example is Section 9.6.2.3, which prohibits to "recommend or promote bottle feeding." on the other hand, Section 9.5.2 requests "adequate directions for the appropriate preparations and use of the product" for bottle feeding, with Section 9.5.3 requesting "clear graphic instructions illustrating the method of preparation of the product."

¹² Report of the Forty-Fifth Session of the Codex Committee on Food Labeling, 13-17 May 2019 ([link](#)).

¹³ WHO Technical Guidance - http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_R9-en.pdf

¹⁴ CX/NFSDU 17/39/3 - http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-39%252Fnf39_03e.pdf

¹⁵ CX/NFSDU 17/39/4 52

¹⁶ WHO Code, 1981, Article 1- https://www.who.int/nutrition/publications/code_english.pdf