

2 April 2019

ISDI position on the labelling section

Revision Codex Standard on Follow-up formula (CX/STAN 156-1987)

ISDI is of the opinion that section 9 on labelling of Follow-up formula for older infants is not ready for endorsement by CCFL.

Since 2013, the nutrition committee of Codex (CCNFSDU¹) has been working on the revision of the Follow-up formula Standard (CX/STAN 156-1987). Amongst other proposals, at the last session of the CCNFSDU in November 2018, a provision on cross-promotion was introduced. The proposal states as follows:

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.**²

The CCNFSDU⁴⁰ referred the draft on the labelling for older infants for “endorsement/advice” to the labelling committee (CCFL³).

ISDI is of the opinion that section 9 is not ready for endorsement by CCFL for the following reasons:

- Section 9 differs significantly from the established provisions for food labelling in Codex Standards⁴,
- There is no justification, neither scientific nor market based, for the substantial deviation from Codex norms in the labelling section.
- References to additional labelling provisions and marketing prohibitions go beyond the provisions of the Codex Procedural Manual⁵.

¹ Codex Committee on Nutrition and Foods for Special Dietary Uses

² Emphasis added

³ Codex Committee on Food Labelling

⁴ General Standard on Food Labelling (CX STAN 1-1985) and General Standard on Labelling and Claims of Foods for Special Dietary Uses (CX STAN 146-1985)

⁵ [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.

- The proposed section is inconsistent as it establishes contradictory provisions⁶
- The proposed section does not provide sufficient clarity for regulatory enforcement, nor for industry compliance, and includes undefined terms such as “Cross Promotion”.
- If adopted, it will not be in accordance with international trade obligations (technical barriers to trade and intellectual property rights).

In line with the above, ISDI is of the opinion that Section 9 (labelling) is not ready for endorsement by CCFL.

You will find below:

1. Further details on the different rationale supporting the ISDI position.
2. Appendix A: comparative table
3. Appendix B: ISDI proposed wording for section 9

⁵ Particularly example is Section 9.6.2.3 prohibits to “recommend or promote bottle feeding” whereas section 9.5.2 requests “adequate directions for the appropriate preparations and use of the product” where 9.5.3 requests “clear graphic instructions illustrating the method of preparation of the product”.

⁶ Particularly example is Section 9.6.2.3 prohibits to “recommend or promote bottle feeding” whereas section 9.5.2 requests “adequate directions for the appropriate preparations and use of the product” where 9.5.3 requests “clear graphic instructions illustrating the method of preparation of the product”.

SECTION 9 INCONSISTENT WITH KEY CODEX STANDARDS AND GUIDELINES

References to other relevant CODEX texts

The labelling section 9 of the draft CODEX Standard for Follow-up Formula (CX/STAN 156-1987) needs to be consistent with other relevant Codex texts including the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985), and the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985).

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.

For detailed comments on this see Appendix A but as an example we would highlight the section 9.6.2.5 stipulates that the label shall not *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.*. The wording of this section is stricter than the ones in the current FUF Standard or in the Infant Formula Standard for example. ISDI considers that such section is

- a. either a national authority competence, which would explain why it is not considered in other Standards and texts,
- b. or is already covered by the provisions and principles established in the relevant general Standards or Guidelines in relation to labelling.

Extensive increase of labelling requirements compared to other CODEX texts

The draft labelling section of the future standard is very extensive (see Appendix A – additional elements highlighted in green). According to the Procedural Manual, information specified should normally be limited to the following:

- A statement that the product shall be labelled in accordance with the General Standard for the Labelling of Pre-packaged Foods (Codex Stand 1-1985)
- The specified name of the food
- Date marketing and storage instructions. [...] ⁷

Section 9.6, as drafted, provides an overview of statements which should be added on the label. Those statements aim to achieve an international public health objective in order to protect/ promote breastfeeding.

The Procedural Manual further states that, “where appropriate, [...] other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade” will be regarded. However, “the food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of

⁷ Procedural Manual, 26th edition, p60.

the food supply.”⁸

Although these statements are the proposed text from CCNFSDU40 ISDI recalls that a few options were proposed in the 2017 eWG consultations. 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. Stating “The use of this product should not lead to cessation of continued breastfeeding.” may infer that it is not suitable for use as a breastmilk substitute and result in some caregivers turning to using unsafe alternatives. Follow-up formula is used by non-breastfeeding mothers. In the case of mothers providing a mixed-feeding, it would be more appropriate that a message supporting the continuation of breastfeeding is conveyed, in line with public health recommendation.

ISDI recommends CCFL that all relevant scientific information should be thoroughly reviewed prior any further statement is added when necessary according to Codex process.

LACK OF CONSISTENCY WITHIN THE SECTION

The labelling section 9 of the draft CODEX Standard for Follow-up Formula (CX/STAN 156-1987) needs to **be consistent within itself**.

A reading of the draft labelling section of the Draft Standard in its entirety (see Appendix A) highlights **inconsistencies or even contradictions** that will become highly challenging for the industry but also for national authorities in terms of implementation and controls.

Please see Appendix A for detailed comments on each sub sections of the draft labelling section, but as an example we would highlight:

Example 1

- section 9.6.2.2 prohibits references to “milestones and stages”
- however, section 9.6.4 reads, in part, “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”

ISDI considers that the contradiction between 9.6.2.2 and 9.6.6 could potentially lead to consumer confusion.

Example 2

- section 9.6.2.3 prohibits to “recommend or promote bottle feeding”

⁸ Procedural Manual, 26th edition, Statement of Principle Concerning The Role Of Science In the Codex Decision-Making Process and the Extent to which Other Factors are taken into account

- while section 9.5.2 requests “adequate directions for the appropriate preparations and use of the product” and 9.5.3 requests “clear graphic instructions illustrating the method of preparation of the product”.

MORE STRINGENT THAN THE INFANT FORMULA STANDARD

The labelling section 9 of the draft CODEX Standard for Follow-up Formula (CX/STAN 156-1987) should not be more stringent than the Infant Formula Standard (CODEX STAN 72-1981).

One of the concepts promoted by the eWG during the progression of the revised Standard was that the FUF 6-12 would not be more stringent than the Infant Formula Standard, and the draft additional labelling requirements (highlighted in green in Appendix A) do not reflect such a principle.⁹

ISDI recommends to assess any new provisions in line with these concepts.

NOT MEETING THE OBJECTIVES OF JUSTIFIED, CLEAR, IMPLEMENTABLE & ENFORCEABLE

The proposed **deviation from general labelling requirements** considered in the labelling section 9 of the draft CODEX Standard for Follow-up Formula (CX/STAN 156-1987) must be **justified**. The requirements must also be **clear, implementable and enforceable**.

We also note that a **Codex Standard on Follow Up Formula is already in place with labelling requirements** which would be deemed sufficient with the additions proposed by ISDI (see Appendix B).

ISDI raises **concerns with the labelling section as drafted** (see below & Appendix A). **A holistic approach on the additional labelling requirements that are proposed is needed in order to ensure that they are justified, clear, implementable and enforceable**.

ISDI QUESTIONS THE ISSUE OF CROSS PROMOTION TO BE INSERTED IN THE LABELLING SECTION

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.”¹⁰

⁹ CX/NFSDU 17/39/4

¹⁰ FAO, General principles of food labelling - <http://www.fao.org/ag/humannutrition/foodlabel/76333/en/>

Cross-promotion is referred to in the WHO technical guidance on “Ending the inappropriate marketing practices of foods for infants and young children”¹¹. This technical guidance which 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.¹²

“The purpose of WHO documents and WHA resolutions is to help determine public health policies. These documents should provide direction and guidance for governments in developing their own national public health policies in accordance with their national context.”¹³

ISDI also clarifies 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 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 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”.¹⁴

The concept of cross promotion was introduced as a new concept for the labelling provisions during the plenary session of CCNFSDU. It had not been included in the consultations undertaken by the eWG on the labelling sections. Consequently many delegates were unprepared to address this issue adequately during this meeting.

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.

Moreover the feeding of infants and young children is a complex and careful transformation from a milk centric towards the household / solid diet. Parents and caregivers should be able to count on manufacturers accompanying and guiding them on this journey which usually takes 2-3 years. Manufacturers produce a set of nutritional products which supports this journey.

It is the duty of Codex and manufacturers to clearly distinguish between products for different age groups in order to avoid confusion and misuse.

ISDI anticipates that the term “cross promotion” will be implemented differently at national level. This would lead to legal and regulatory inconsistencies and obstacles in international trade and therefore against the Codex’ aim to facilitate international trade of safe foods thanks to harmonized norms.

In the existing publicly available literature the term is either loosely defined or covers different concepts to the meaning conveyed by the WHO Representative at CCNFSD40: “that the intent of the provision on cross-promotion was to avoid messages on labels that a product for a particular age group was also suitable for another age group or that reference was made to a similar product for

¹¹ WHO Technical Guidance - http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_R9-en.pdf

¹² 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

¹³ CX/NFSDU 17/39/4 52

¹⁴ WHO Code, 1981, Article 1- https://www.who.int/nutrition/publications/code_english.pdf

another age group¹⁵." It is subjective and leads to interpretation that will create potential obstacles to trade (TBT). While some member states may have legitimate interests to add provisions to a Codex texts to suit to their local environment, these should not restrict commercial freedom. Cross-promotion statement added has also other meaning that the initial sentence proposed in 9.6.4

ISDI considers that the initial wording for 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" for which statement on "text, images and colours" has been added at CCNFSDU40 is sufficient. However, ISDI would encourage to ensure that this statement does not bring confusion to consumers especially for illiterate ones who heavily rely on features such as colour or image.

ISDI further notes that legislation and regulations are usually based on what is permitted and allowed instead of outlining what should not be permitted. ISDI is of the opinion that the first section of 9.6.4. sufficiently addresses concerns expressed.

In addition ISDI is of the view that providing facts (information) about the appropriate products for infants and young children of different ages is useful information for parents and caregivers and should be permitted providing that it is not promotional in nature.

ISDI therefore recommends CCFL to delete the reference to cross promotion and to consider ISDI's proposal for section 9.6.4 (see Appendix B).

CONCLUSION

The Section 9 of the draft CODEX Standard for Follow-up Formula (CX/STAN 156-1987) as a whole is not ready for adoption at step 5 and should be reworked in line with the Codex Alimentarius principles to ensure that consistent, justified and clear wording will provide the foundation to facilitate trade and protect the health of infants.

¹⁵ CCNFSDU40 report, §50

APPENDIX A – COMPARISON BETWEEN LABELLING SECTIONS

	INFANT FORMULA	Follow Up Formula Standard	Draft for Follow Up Formula for older Infant (6-12) Standard	ISDI COMMENTS
	Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981)	Standard for Follow-up formula (CODEX STAN 156-1987)		
	Revised in 2007 Amended in 2016 Currently applicable	Amended in 2017 Currently applicable	Under negotiation	
Labelling	The requirements of the <i>General Standard for the Labelling of Prepackaged Foods</i> (CODEX STAN 1-1985), the <i>Guidelines on Nutrition Labelling</i> (CAC/GL 2-1985) and the <i>Guidelines for Use of Nutrition and Health Claims</i> (CAC/GL 23-1997) apply to infant formula and formula for special medical purposes for infants. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where	In addition to the requirements of the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985), the following specific provisions apply:	The requirements of the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985), the Guidelines on Nutrition Labelling (CXG 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) apply to follow-up formula for older infants. These requirements include a prohibition on the use of nutrition and health claims for foods for infants except where specifically provided for in relevant Codex Standards or national legislation.	ISDI would request for CCFL to confirm the consistency with relevant CODEX texts

	specifically provided for in relevant Codex Standards or national legislation. In addition to these requirements the following specific provisions apply:			
9.1	The Name of the Food	The Name of the Food	The Name of the Product	
9.1.1	The text of the label and all other information accompanying the product shall be written in the appropriate language(s).	The name of the food shall be "Follow-up Formula". In addition thereto, any appropriate designation may be used in accordance with national usage.	The text of the label and all other information accompanying the product shall be written in the appropriate language(s).	
9.1.2	The name of the product shall be either "Infant Formula" or any appropriate designation indicating the true nature of the product, in accordance with national usage.	Those products which are prepared from whole or skimmed milk in accordance with Section 3.3.1.2 and where 90% or more of the protein is derived from whole or skimmed milk as such, or with minor modification that does not substantially impair the vitamin and mineral content of the milk, may be labelled "Follow-up Formula based on milk".	The name of the product shall be Follow-up Formula for Older Infants as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national [or regional] usage.	
9.1.3	The sources of protein in the product shall be clearly shown on the label.	All sources of protein shall be clearly shown on the label in close proximity to the name of the food in descending order of proportion by weight.	The sources of protein in the product shall be clearly shown on the label. a) If [name of animal] milk is the only source of protein[*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of animal] milk [protein]. b) If [name of plant] is the only source of protein[*], the product may be	In 9.1.3 ISDI requests advice from CCFL for simplification including potential cross reference to relevant CODEX texts.

			<p>labelled 'Follow-up Formula for Older Infants Based on [name of plant] [protein].</p> <p>c) If [name of animal] milk and [name of plant] are the sources of protein[*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of animal] milk protein and [name of plant] protein' or 'Follow-up Formula for Older Infants Based on [name of plant] protein and [name of animal] milk protein'.</p> <p>* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.</p>	
9.1.4	If cows' milk is the only source of protein, the product may be labelled "Infant Formula Based on Cows' Milk".	A product which contains neither milk nor any milk derivative may be labelled "contains no milk or milk products" or an equivalent phrase.	A product which contains neither milk nor any milk derivative shall be labelled "contains no milk or milk products" or an equivalent phrase.	<p>ISDI questions the imposition of a negative statement for FUF 6-12 by replacing "may" with "shall"– when if there is no "milk or milk product", this would be clear both from the name/description of the product and the list of ingredients.</p> <p>ISDI would request clarification from the CCFL on the best approach.</p>
9.1.5	A product which contains neither milk nor any milk derivative shall be labelled "contains no milk or milk products" or an equivalent phrase.		See 9.1.4	

9.2	List of Ingredients	List of Ingredients	List of Ingredients	
9.2.1	A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.	The declaration of the list of ingredients shall be in accordance with Sections 4.2.1, 4.2.2 and 4.2.3 of the General Standard for the Labelling of Prepackaged Foods except that in the case of added vitamins and added minerals, these ingredients shall be arranged as separate groups for vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.	A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.	
9.2.2	The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate class names for these ingredients and additives may be included on the label.	-	The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate functional classes for these ingredients and additives may be included on the label. The food additives INS number may also be optionally declared.	
9.3	Declaration of Nutritive Value	Declaration of Nutritive Value	Declaration of Nutritive Value	
	The declaration of nutrition information shall contain the following information which should be in the following order:	The declaration of nutrition information shall contain the following information in the following order:	The declaration of nutrition information [for follow-up formula for older infants] shall contain the following information which should be in the following order:	

	<p>a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes or per 100 millilitres of the food as sold as well as per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.</p> <p>b) the total quantity of each vitamin, mineral, choline as listed in paragraph 3.1.3 and any other ingredient as listed in paragraph 3.2 of this Standard per 100 grammes or per 100 millilitres of the food as sold as well as per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.</p> <p>c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.</p>	<p>(a) The amount of energy, expressed in Calories (kcal) and/or kilojoules (kJ) per 100 g of the food as sold as well as per specified quantity of the food as suggested for consumption.</p> <p>(b) The number of grammes of protein, carbohydrate and fat per 100 g of the food as sold as well as per specified quantity of the food as suggested for consumption. In addition, the declaration per 100 calories (or per 100 kilojoules) is permitted.</p> <p>(c) The total quantity of each vitamin, mineral and any optional ingredient, as listed in Section 3.3.2 of this standard per 100 g of the food as sold as well as per specified quantity of the food as suggested for consumption. In addition, the declaration per 100 calories (or per 100 kilojoules) is permitted.</p>	<p>a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold [as well as] [or] per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.</p> <p>b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section A and any other ingredient as listed in paragraph 3.2 of Section A per 100 grams or per 100 millilitres of the food as sold as well as per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.</p> <p>c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.</p>	
9.4	Date Marking and Storage Instructions	Date Marking and Storage Instructions	Date Marking and Storage Instructions	
-	-	In addition to the declaration of date marking and storage instructions in accordance with Sections 4.7.1 and 4.7.2 of the General Standard for the Labelling of Prepackaged Foods, the following provisions apply:	-	

9.4.1	<p>The date of minimum durability (preceded by the words "best before") shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, the month and year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer. In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative</p>	<p>Storage of Opened Food</p> <p>Storage instructions of opened packages of a food for special dietary uses shall be included on the label if necessary to ensure that the opened product maintains its wholesomeness and nutritive value. A warning should be included on the label if the food is not capable of being stored after opening or is not capable of being stored in the container after opening.</p>	<p>(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).]</p> <p>(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>].</p>	<p>ISDI requests advice from CCFL for simplification including potential cross reference to relevant CODEX texts.</p>
9.4.2	<p>In addition to the date, any special conditions for the storage of the food shall be indicated if the validity of the date depends thereon. Where practicable, storage instructions shall be in close proximity to the date marking.</p>	-	<p>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.</p>	

9.5	Information for Use	Information for Utilization	Information for Use	
9.5.1	Products in liquid form may be used either directly or in the case of concentrated liquid products, must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.	Directions as to the preparation and use of the food, and its storage and keeping after the container has been opened shall appear on the label.	Ready to use products in liquid form should be used directly. Concentrated liquid products and powdered products, must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.	
9.5.2	Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that formula remaining after feeding should be discarded, shall appear on the label and in any accompanying leaflet.	The labelling of a Follow-up Formula shall include a statement that Follow-up Formula shall not be introduced before the 6th month of life.	Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that product remaining after feeding should be discarded, shall appear on the label.	
9.5.3	The label shall carry clear graphic instructions illustrating the method of preparation of the product.	Information that infants and children fed Follow-up Formula shall receive other foods in addition to the food shall appear on the label.	The label shall carry clear graphic instructions illustrating the method of preparation of the product.	

9.5.4	The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.	-	The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use.	
9.5.5	Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label and in any accompanying leaflet.	-	Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.	
9.5.6	-	-	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.	
9.6	Additional Labelling Requirements	Additional Requirements	Additional Labelling Requirements	
		The products covered by this standard are not breast-milk substitutes and shall not be presented as such.		
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:	-	Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:	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

	<p>a) the words "important notice" or their equivalent;</p> <p>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;</p> <p>c) a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use.</p>		<p>a) the words "important notice" or their equivalent;</p> <p>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;</p> <p>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.</p> <p>d) the statement; 'The use of this product should not lead to cessation of continued breastfeeding'.</p>	<p>of either partial or total cessation of breast feeding.</p> <p>The statement is confusing and is properly covered already by 9.6.1.b</p> <p>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.</p> <p>See Appendix B for ISDI proposal.</p>
9.6.2	The label shall have no pictures of infants and women nor any other picture or text which idealizes the use of infant formula.	-	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 strongly opposes the following requirements in 9.6.2.2 as drafted and considers that the phrase "(including references to milestones and stages)"

				<p>should be deleted as it could lead to consumers confusion regarding the appropriate age range for different products.</p> <p>ISDI proposes the following text instead:</p> <ul style="list-style-type: none">• 9.6.2.2 should read <i>"suggest use for infants under the age of 6 months."</i> <p>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."</p> <p>Regarding the reference to milestones and stages, ISDI would also like to clarify the compatibility of 9.6.2.2 with 9.6.4. The labels of the products should clearly distinguish the products but cannot stress the existence of other categories that would be appropriate for the age range, while having to flag that complementary foods should be given.</p>
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				ISDI would like CCFL to clarify the need for and consistency of 9.6.2.2.
9.6.2.3	-	-	recommend or promote bottle feeding;	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 would like CCFL 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 as to the superiority of breastfeeding or breast-milk). Follow-up formula is used by non-breastfeeding mothers. In the case of mothers providing a mixed-feeding, it would be more appropriate that a message supporting the continuation of breastfeeding is conveyed, in line with public health recommendation. (see comments in 9.6.2.2)
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	This section does not exist in the current FUF Standard or in the Infant Formula Standard. ISDI considers that such section is either a national authority competence, which would explain

			national or regional regulatory authorities.]	why it is not considered in other Standards and texts, or is already covered by the provisions and principles established in the relevant general Standards or Guidelines in relation to labelling.
9.6.3	The terms "humanized", "maternalized" or other similar terms shall not be used.	-	The terms "humanized", "maternalized" or other similar terms shall not be used.	
9.6.4	Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.	-	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.	See cross promotion comments above. ISDI strongly advises to delete the statement referring to cross-promotion for the reason explained above.
9.6.5	The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula, and formula for special medical purposes.	-		

APPENDIX B – PROPOSAL OF ISDI FOR SECTION 9

	Draft for Follow Up Formula for older Infant (6-12) Standard	ISDI comments & proposals
9 Labelling	The requirements of the General Standard for the Labelling of Prepackaged Foods (CXG 1-1985), the Guidelines on Nutrition Labelling (CXG 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) apply to follow-up formula for older infants.	ISDI recommends to review the consistency with relevant CODEX texts
9.1	The Name of the Product	
9.1.1	The text of the label and all other information accompanying the product shall be written in the appropriate language(s).	
9.1.2	The name of the product shall be Follow-up Formula for Older Infants as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national [or regional] usage.	
9.1.3	<p>The sources of protein in the product shall be clearly shown on the label.</p> <p>a) If [name of animal] milk is the only source of protein[*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of animal] milk [protein].</p> <p>b) If [name of plant] is the only source of protein[*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of plant] [protein].</p> <p>c) If [name of animal] milk and [name of plant] are the sources of protein[*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of animal] milk protein and [name of plant] protein' or 'Follow-up Formula for Older Infants Based on [name of plant] protein and [name of animal] milk protein'.</p> <p>* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.</p>	In 9.1.3 ISDI would like to emphasize the complexity of these provisions and request to assess the consistency with other CODEX texts.
9.1.4	A product which contains neither milk nor any milk derivative may be labelled "contains no milk or milk products" or an equivalent phrase.	<p>ISDI questions the imposition of a negative statement for FUF 6-12 by replacing "may" with "shall" – when if there is no "milk or milk product", this would be clear both from the name/description of the product and the list of ingredients.</p> <p>In addition this is not in line with other Codex texts (See Appendix A).</p>

		ISDI suggest to retain the term "may".
9.2	List of Ingredients	
9.2.1	A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.	
9.2.2	The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate functional classes for these ingredients and additives may be included on the label. The food additives INS number may also be optionally declared.	
9.3	Declaration of Nutritive Value	
	The declaration of nutrition information [for follow-up formula for older infants] shall contain the following information which should be in the following order: a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold [as well as] [or] per 100 millilitres of the food ready for use, when prepared according to the instructions on the label. b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section A and any other ingredient as listed in paragraph 3.2 of Section A per 100 grams or per 100 millilitres of the food as sold as well as per 100 millilitres of the food ready for use, when prepared according to the instructions on the label. c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.	
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>].	ISDI recommends to review the consistency with relevant CODEX texts
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.	
9.5	Information for Use	
9.5.1	Ready to use products in liquid form should be used directly. Concentrated liquid products and powdered products, must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding,	

	according to directions for use. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.	
9.5.2	Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that product remaining after feeding should be discarded, shall appear on the label.	
9.5.3	The label shall carry clear graphic instructions illustrating the method of preparation of the product.	
9.5.4	The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use.	
9.5.5	Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.	
9.5.6	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.	
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; "exclusive breastfeeding is recommended from birth to 6 months of age, and that breastfeeding should continue to two years of age or beyond".	Based on comments in Appendix A, ISDI suggest the following wording.
9.6.2	The label shall have no pictures of infants, young children and women nor any other picture, text, or representation that might idealize the use of follow-up formula for older infants;	Based on comments in Appendix A, ISDI suggest the following wording.
9.6.3	The terms "humanized", "maternalized" or other similar terms shall not be used.	
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.	Based on comments in Appendix A, ISDI suggest the following wording.

