International Special
Dietary Foods Industries

Appendix III

Relevant concepts and guidance from WHO and WHA documents that have been incorporated into the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981).

Guidance on
Infant formula

Introduction

This appendix provides illustrative examples of how relevant concepts and provisions from key World Health Organization (WHO) guidance documents, World Health Assembly (WHA) resolutions, and the WHO International Code of Marketing of Breast-milk Substitutes have been considered and incorporated into the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981).

The comparisons presented in this appendix demonstrate that many of the policy objectives reflected in WHO and WHA texts have already been translated into specific Codex requirements, particularly in relation to labelling, product information, safe use, and the protection and promotion of breastfeeding.

This appendix is intended to provide additional context on the relationship between these WHO/WHA instruments and the Codex standard:

- WHO International Code of Marketing of Breast-Milk Substitutes
- WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children
- WHA 69.9 Ending the Inappropriate Promotion of Foods for Infants and Young Children
- WHA 63.23 Infant and Young child Nutrition
- WHO Global Strategy for Infant and Young Child Feeding and WHA 54.2 Infant and Young Child Nutrition
- WHA 61.20 Infant and Young Child Nutrition: Biennial Progress Report

WHO International Code of Marketing of Breast-Milk Substitutes

https://www.who.int/publications/i/item/9241541601

WHO International Code of Marketing of Breast-milk Substitutes (extracts referring to labelling)	Codex Standard for Infant Formula (CXS 72-1981)	ISDI Comment
9.1 Labels should be designed to provide the necessary information about the appropriate use of the product, and so as not to discourage breast-feeding	*Section 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.* *Section 9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.* *Section 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.* *Section 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 an independent health worker as to the need for its use and the proper method of use.* *Section 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.* *Section 9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.*	ISDI notes that the labelling section of the Infant Formula Commodity Standard product has taken the WHO International Code of Marketing of Breast-milk Substitutes into consideration.
9.2 Manufacturers and distributors of Infant Formula should ensure that each container as a clear, conspicuous, and easily readable and understandable message printed on it, or on a label which cannot readily become separated from it, in an appropriate language, which includes all the following points:	*Section 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:*	ISDI notes that the labelling section of the Infant Formula Commodity Standard product has taken the WHO International Code of Marketing of Breast-milk Substitutes into consideration.
(a) the words "Important Notice" or their equivalent;	*Section 9.6.1 a) the words "important notice" or their equivalent;*	ISDI notes that the labelling section of the Infant Formula Commodity Standard product has taken the WHO International Code of Marketing of Breast-milk Substitutes into consideration.

WHO International Code of Marketing of Breast-milk Substitutes (extracts referring to labelling)	Codex Standard for Infant Formula (CXS 72-1981)	ISDI Comment
(b) a statement of the superiority of breastfeeding;	*Section 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;*	ISDI notes that the labelling section of the Infant Formula Commodity Standard product has taken the WHO International Code of Marketing of Breast-milk Substitutes into consideration.
(c) a statement that the product should be used only on the advice of a health worker as to the need for its use and the proper method of use;	*Section 9.6.1 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.*	ISDI notes that the labelling section of the Infant Formula Commodity Standard product has taken the WHO International Code of Marketing of Breast-milk Substitutes into consideration.
(d) instructions for appropriate preparation, and a warning against the health hazards of in- appropriate preparation	*Section 9.5.4 The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.*	ISDI notes that the labelling section of the Infant Formula Commodity Standard product has taken the WHO International Code of Marketing of Breast-milk Substitutes into consideration.
Neither the container nor the label should have pictures of infants, nor should they have other pictures or text which may idealize the use of Infant Formula. They may, however, have graphics for easy identification of the product as a breastmilk substitute and for illustrating methods of preparation.	*Section 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.* *Section 9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.* *Section 9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.*	ISDI notes that the labelling section of the Infant Formula Commodity Standard product has taken the WHO International Code of Marketing of Breast-milk Substitutes into consideration. ISDI also notes that considering the importance of the safe use of the products and of proper information for use, the Codex Alimentarius commodity Standards goes a step further than the WHO International Code of Marketing of Breast-milk Substitutes with section 9.5.3 of labelling require- ments by making graphic instructions illustrating the method of preparation of the product mandatory. This section 9.5.3 was strongly supported by ISDI when adopted by the Codex Alimentarius.
The terms "humanized", "maternalized" or similar terms should not be used	*Section 9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.*	ISDI notes that the labelling section of the Infant Formula Commodity Standard product has taken the WHO International Code of Marketing of Breast-milk Substitutes into consideration.

WHO International Code of Marketing of Breast-milk Substitutes (extracts referring to labelling)	Codex Standard for Infant Formula (CXS 72-1981)	ISDI Comment
9.3 Food products within the scope of this Code, marketed for infant feeding, which do not meet all the requirements of an Infant Formula, but which can be modified to do so, should carry on the label a warning that the unmodified product should not be the sole source of nourishment of an infant. Since sweetened condensed milk is not suitable for infant feeding, nor for use as a main ingredient of Infant Formula, its label should not contain purported instructions on how to modify it for that purpose.	*Section 1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard would be accepted for marketing as IF. No product other than IF may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life.* *Section 2.1.1 Infant Formula means a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding.* *Section 2.1.2 The product is so pro- cessed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.* *Section 7.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. When in liquid form, the product shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as packing media.* *Section 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.*	ISDI notes that the Infant Formula Commodity Standard product has taken the WHO International Code of Marketing of Breast-milk Substitutes into consideration. In line with the Codex Standard ISDI considers that only products that comply with the criteria laid down in the provisions of the Codex Standard can be accepted for marketing as Infant Formula. The elements that frame how the products should be reconstituted - where necessary – are also strictly limited in the Codex Standard.
9.4 The label of food products within the scope of this Code should also state all the following points: (a) the ingredients used;	*Section 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.*	ISDI notes that the Infant Formula Commodity Standard product has taken the WHO International Code of Marketing of Breast-milk Substitutes into consideration. In line with the Codex Standard ISDI considers that only products that comply with the criteria laid down in the provisions of the Codex Standard can be accepted for marketing as Infant Formula. The elements that frame how the products should be reconstituted – where necessary – are also strictly limited in the Codex Standard.

WHO International Code of Marketing of Breast-milk Substitutes (extracts referring to labelling)	Codex Standard for Infant Formula (CXS 72-1981)	ISDI Comment
(b) the composition/analysis of the product;	*9.3 Declaration of Nutritive Value* *The declaration of nutrition information 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 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.* *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.* *c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted*	ISDI notes that the Infant Formula Commodity Standard product has taken the WHO International Code of Marketing of Breast-milk Substitutes into consideration.
(c) the storage conditions required; and	*Section 9.4.2 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.*	ISDI notes that the Infant Formula Commodity Standard product has taken the WHO International Code of Marketing of Breast-milk Substitutes into consideration. In more recent Codex Standards, the specific commodity Standard cross reference the requirements from section 4.7.1 of the General Standard for the Labelling of Prepackaged Foods, as these requirements are common to prepackaged foods.
(d) the batch number and the date before which the product is to be consumed, taking into account the climatic and storage conditions of the country concerned.	*Section 9.4.1 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.*	ISDI notes that the Infant Formula Commodity Standard product has taken the WHO International Code of Marketing of Breast-milk Substitutes into consideration (cf. lot identification, date marking & storage instructions).

WHO International Code of Marketing of Breast-milk Substitutes (extracts referring to labelling)	Codex Standard for Infant Formula (CXS 72-1981)	ISDI Comment
10.2 Food products within the scope of this Code should, when sold or otherwise distributed, meet applicable standards recommended by the Codex Alimentarius Commission and also the Codex Code of Hygienic Practice for Foods for Infants and Children.	*Section 6. HYGIENE* *Section 6.1 It is recommended that the product covered by the provi- sions of this standard be prepared and handled in accordance with the appropriate sections of the Gener- al Principles of Food Hygiene (CXC 1-1969), and other relevant Codex texts such as the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CXC 66-2008).* *Section 6.2 The products should comply with any microbiological criteria established in accordance with the Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CXG 21-1997).*	ISDI notes that the Infant Formula Commodity Standard product has taken the WHO International Code of Marketing of Breast-milk Substitutes into consideration.

WHO GUIDANCE ON ENDING THE INAPPROPRIATE PROMOTION OF FOODS FOR INFANTS AND YOUNG CHILDREN

https://www.who.int/publications/i/item/9789241513470

WHO Guidance on ending the inappropriate promotion of foods for infants and young children	Codex Standard for Infant Formula (CXS 72-1981)	ISDI Comment
Recommendation 4 The messages used to promote foods for infants and young children should support optimal feeding and inappropriate messages should not be included. Messages about commercial products are conveyed in multiple forms, through advertisements, promotion and sponsorship, including brochures, online information and package labels. Irrespective of the form, messages should always: include a statement on the im- portance of continued breast- feeding for up to two years or beyond and the importance of not introducing complementary feeding before 6 months of age; include the appropriate age of introduction of the food (this must not be less than 6 months); be easily understood by parents and other caregivers, with all required label information being visible and legible.	*Section 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.* *Section 9.1.1 The text of the label and all other information accompanying the product shall be written in the ap- propriate language(s).* *Section 9.6.1 Labels should not discourage breastfeeding.* *Section 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;*	ISDI notes that the Infant Formula Commodity Standard has taken the WHO Guidance on ending the inappropriate promotion of foods for infants and young children into consideration.

WHO Guidance on ending the inappropriate promotion of foods for infants and young children	Codex Standard for Infant Formula (CXS 72-1981)	ISDI Comment
Messages should not: include any image, text or other representation that might suggest use for infants under the age of 6 months (including references to milestones and stages); include any image, text or other representation that is likely to undermine or discourage breast- feeding, that makes a compar- ison to breast-milk, or that suggests that the product is nearly equivalent or superior to breast-milk; recommend or promote bottle feeding; convey an endorsement or anything that may be construed as an endorsement by a professional or other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.	*Section 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 an independent health worker as to the need for its use and the proper method of use.* *Section 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.* *Section 9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.* *Section 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.*	ISDI notes that the Infant Formula Commodity Standard has taken the WHO Guidance on ending the inappropriate promotion of foods for infants and young children into consideration. ISDI notes that other elements in this section of the WHO Guidance on ending the inappropriate promotion of foods for infants and young children are of a policy nature and not relevant per se for the specific commodity requirements and often covered otherwise in the broader local context.
Recommendation 5 There should be no cross-promotion to promote breast-milk substitutes indirectly via the promotion of foods for infants and young children. • The packaging design, labelling and materials used for the promotion of complementary foods must be different from those used for breast-milk substitutes so that they cannot be used in a way that also promotes breastmilk substitutes (for example, different colour schemes, designs, names, slogans and mas- cots other than company name and logo should be used). • Companies that market breast-milk substitutes should refrain from engaging in the direct or indirect promotion of their other food products for infants and young children by establishing relationships with parents and other caregivers (for example through baby clubs, social media groups, childcare classes and contests).	*Section 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*	ISDI notes that the elements from the WHO Guidance on ending the inappropriate promotion of foods for infants and young children that are of relevance for the commodity standard and label have been taken into account. ISDI members comply with all laws and regulations in the countries in which they operate and have extensive internal approval and audit processes in place to ensure their online and offline content meets all legal, regulatory and nutritional science requirements. In addition, manufacturers of infant and young child nutrition have their own internal and external mechanisms for policy compliance. Furthermore, some BMS manufacturers raise awareness of the WHO Code among the main online marketplaces and search engines. They also actively raise awareness among third party retailers of the WHO Code and applicable laws through education and training and monitor independent websites to identify regulatory and compliance issues. ISDI Members further support efforts by national governments to ensure compliance with all national laws and regulations.

WHA 69.9 ENDING THE INAPPROPRIATE PROMOTION OF FOODS FOR INFANTS AND YOUNG CHILDREN

https://iris.who.int/server/api/core/bitstreams/ade914c6-86e9-475f-a963-959940b1924d/content

WHA 69.9 Ending the inappropriate promotion of foods for infants and young children	Codex Standard for Infant Formula (CXS 72-1981)	ISDI Comment
Recognizing that the Codex Alimentarius Commission is an intergovernmental body which is the principal organ of the joint FAO/ WHO food standards programme and that it is the appropriate body for establishing international standards on food products, and that reviews of Codex standards and guidelines should give full consideration to WHO guidelines and recommendations, including the International Code of Marketing of Breast-milk Substitutes and relevant Health Assembly resolutions		ISDI notes that as shown above, 'full consideration to WHO guidelines and recommendations, including the International Code of Marketing of Breast-milk Substitutes and relevant Health Assembly resolutions' has been given and concepts incorporated within the labelling provisions and other provision of the relevant Codex Standard. ISDI would also emphasise the advice and conclusions of CCEXEC75: In June 2018, the Codex Executive Committee ("CCEXEC") recommended to CCNFSDU that only references consistent with the mandate of Codex that have scientific relevance should be considered: • With regard to references to WHO/ WHA documents in the draft CCNFSDU text on follow-up formula, CCEXEC75 provided the following advice intended to assist CCNFSDU in moving forward: > references should be considered on a case-by-case basis; > references may provide context and additional information to assist members in understanding and use of Standards; > concepts and technical information could be incorporated into the text of the Standard itself, rather than referencing sources external to Codex; and > 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.

WHA 63.23 INFANT AND YOUNG CHILD NUTRITION

https://apps.who.int/gb/ebwha/pdf_files/wha63/a63_r23-en.pdf

WHA 63.23 Infant and young child nutrition	Codex Standard for Infant Formula (CXS 72-1981)	ISDI Comment
and to ensure that nutrition and health claims shall not be permitted for foods for infants and young children, except where specifically provided for in relevant Codex Alimentarius standards or national legislation	*9. LABELLING* *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 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 specifically provided for in relevant Codex Standards or national legislation.*	ISDI notes that the elements of resolution WHA 63.23 of relevance for the Infant Formula commodity standard and label are reflected in the Codex Standard.

WHO GLOBAL STRATEGY FOR INFANT AND YOUNG CHILD FEEDING AND WHA 54.2 INFANT AND YOUNG CHILD NUTRITION

https://www.who.int/publications/i/item/9241562218; https://apps.who.int/gb/ebwha/pdf_files/wha54/ea54r2.pdf

WHO Global Strategy for Infant and Young Child Feeding and WHA 54.2 Infant and Young Child Nutrition	Codex Standard for Infant Formula (CXS 72-1981)	ISDI Comment
conscious of the need for the Codex Alimentarius Commission to take the International Code and subsequent relevant Health Assembly resolutions into consideration in dealing with health claims in the development of food standards and guidelines;	*9. LABELLING* *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 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 specifically provided for in relevant Codex Standards or national legislation.*	ISDI notes that the elements of the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA 54.2 (2001) of relevance for the infant formula commodity standard and label are reflected in the Codex Standard.
strengthen national mechanisms to ensure global compliance with the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions, with regard to labelling as well as all forms of advertising, and commercial promotion in all types of media, to encourage the Codex Alimentarius Commission to take the International Code and relevant subsequent Health Assembly resolutions into consideration in developing its standards and guidelines; and to inform the general public on progress in implementing the Code and subsequent relevant Health Assembly resolutions		As shown above, ISDI notes that the labelling section of the product has taken into consideration the International Code and WHA resolutions.

WHA 61.20 INFANT AND YOUNG CHILD NUTRITION: BIENNIAL PROGRESS REPORT

https://apps.who.int/gb/ebwha/pdf_files/a61/a61_r20-en.pdf

WHO Global Strategy for Infant and Young Child Feeding and WHA 54.2 Infant and Young Child Nutrition	Codex Standard for Infant Formula (CXS 72-1981)	ISDI Comment
3) to implement, through application and wide dissemination, the WHO/ FAO guidelines on safe preparation, storage and handling of powdered infant formula in order to minimize the risk of bacterial infection and, in particular, ensure that the labelling of powdered formula conforms with the standards, guidelines and recommendations of the Codex Alimentarius Commission and taking into account resolution WHA58.32;		ISDI notes that the labelling section of the Codex Infant Formula commodity standard has taken into consideration the elements highlighted by the resolution WHA 61.2.

INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)

Sq. de Meeûs 35
1000 Brussels, Belgium

E-mail: secretariat@isdi.org
Web: www.isdi.org

International Special
Dietary Foods Industries