CODEX ALIMENTARIUS COMMISSION





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Agenda Item 4

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

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REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA

Prepared by New Zealand

Relevant concepts and technical guidance in WHO/WHA documents and the labelling provisions in the draft standard for follow-up formula

This CRD has been prepared by New Zealand (Chair of the Electronic Working Group (EWG) for the Review of the Follow-up Formula Standard), at the request of the Chair of CCNFSDU. The purpose of this paper is to provide the Committee with the history and background on previous work that may assist and facilitate the discussion on the Preamble at CCNFSDU41.

Introduction

It is apparent from comments received in previous EWG's and from the discussions at CCNFSDU39/40 that CCNFSDU is polarised in its views on whether World Health Organization (WHO) documents and World Health Assembly (WHA) resolutions should be referenced in Codex standards (namely the Standard for Follow-up Formula), and if so, previous EWG's have been unable to agree to which documents/resolutions should be referenced and are appropriate for all Member Countries.

Significant progress has been made on the composition and labelling provisions of follow-up formula for older infants and [name of product] for young children, and further progress is dependent on a decision and progress on the structure, definitions and the preamble for the standard(s) and resolution of the outstanding WHO/WHA referencing issue.

This document provides an overview and summary of the issue of referencing WHO/WHA documents including where and how the development of the draft Standard for Follow-up Formula has taken into consideration the content of WHO/WHA documents and resolutions.

Background

In 2016, the EWG was asked to consider whether there was a need to make specific reference to WHO/WHA documents or resolutions in the Codex Standard for Follow-up Formula, and if so, how and where. Information and detail on relevant WHO/WHA documents and resolutions was provided in the EWG consultation papers and the <u>Agenda Paper</u> at CCNFSDU38 as background for future considerations on this matter.

The 2017 EWG¹ further considered WHO/WHA referencing within the Follow-up Formula Standard and were provided with detail on the relevant documents and resolutions. Within the 2017 EWG, strong positions were presented for and against referencing WHO/WHA documents and resolutions and determination of which documents may be appropriate and applicable proved to be challenging. Electronic working group views ranged from those who do not support the inclusion of any WHO/WHA documents or resolutions in Codex Standards to those members who favour listing all WHO/WHA documents and resolutions that may in some part be applicable to infant and young child feeding.

The EWG Chair consequently engaged the support of the Codex Secretariat and WHO to progress this issue and find a workable solution. At that point in time there was an option proposed, with general support from WHO and the Secretariat, to the concept of a Preamble that could include reference to relevant documents and/or resolutions. The intent was that this approach to the Preamble would replace the need to list or reference specific documents or resolutions within different sections of the Standard itself as the Preamble is applied to the Standard as a whole.

¹ 2017 1st Consultation Paper – Scope and Labelling of Follow-up Formula for Older Infants and [Name of Product] for Young Children

The <u>Agenda Paper</u> at CCNFSDU39 put forward Recommendation 9 which included draft text for a Preamble statement that included specific reference to relevant WHO documents and WHA resolutions. This draft text was a result of the Chairs' request for assistance on progressing the issue of WHO/WHA referencing within the Standard, and consequently CCNFSDU was asked to agree to the draft Preamble statement.

At CCNFSDU39, 'The Committee confirmed its decision to have a preamble to the standard. However, the chair noted that several fundamental questions needed to be answered first on whether to have specific references to WHA resolutions and WHO guidelines or whether to have a more general reference; that some of the WHA resolutions went beyond the mandate of Codex and therefore was inappropriate to reference them; and whether guidance from the CCEXEC or CAC might be needed before the wording of the preamble could be refined' (REP18/NFSDU para 67).

Consequently the Committee noted the various views made by delegations but did not take any decisions, and recommended to keep in brackets the preamble for further discussion at the next session of the CCNFSDU.

At CCNFSDU40, the decision was taken to defer discussion on Section B: product definition and labelling of [product] for young children (Appendix IV), the structure of the Standard(s) and preamble(s) to CCNFSDU41.

CCEXEC75 advice

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:

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

Furthermore, the Strategic Plan to advance the mandate of the Codex Alimentarius Commission during the period 2020-2025 states:

In conducting its work, the Commission takes into account, where appropriate, the relevant policies, strategies and guidelines of FAO and WHO, and of other intergovernmental organizations such as the World Organization for Animal Health (OIE), consistent with fulfilling its unique mandate to protect the health of consumers and promote fair practices in the food trade through the development of international food standards.

International food safety standards established by the Commission are explicitly recognized in the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS Agreement). Codex standards also serve as references under the WTO Agreement on Technical Barriers to Trade (WTO TBT Agreement).

CCEXEC/CAC

At CCEXEC77, the Executive recommended to CAC42 to adopt the draft scope, description and labelling for follow-up formula for older infants (Section A) of the proposed revised *Standard for Follow-up Formula (CX 156-1987)* at Step 5 as endorsed and amended by CCFL noting in particular that the part on restriction of cross-promotion had not been endorsed by CCFL and required further discussion in CCNFSDU.

Consequently, CAC42 i. adopted the proposed draft text (scope, definition and labelling – as endorsed and amended by CCFL), and noted that the last part of section 9.6.4 on cross-promotion would be further considered by CCNFSDU; and ii. noted that CCEXEC77 had recalled and reaffirmed the advice given by CCEXEC75 regarding use of references to WHO documents and WHA resolutions.

Supporting Information

To assist discussions at CCNFSDU41, the Chair of the Follow-up Formula EWG has prepared this document and included <u>Table 1</u>: Concepts and guidance from WHO and WHA documents that have been incorporated into draft standard text. The table illustrates how in the review of the Follow-up Formula Standard the EWG and Committee have followed the advice of CCEXEC75, specifically recommendations a), c) and elements of d) as below:

- a. references should be considered on a case-by-case basis;
- b. references may provide context and additional information to assist members in understanding and use of standards;

c. concepts and technical information could be incorporated into the text of the standard itself, rather than referencing sources external to Codex; and

d. references must be relevant to the scope of the standard itself, fall within the mandate of Codex, have a scientific basis, and have been developed through a transparent process.

Whilst the Standard on Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72 – 1981) incorporates within the Scope the following provision; 'The application of this section of the Standard should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2' this approach need not be considered the precedent for such referencing matters, especially given that the CCEXEC75 guidance was not available at the time of Infant Formula Standard review, and CCEXEC75 has communicated that incorporation of relevant concepts and technical information is considered an alternative approach to referencing sources external to Codex (recommendation c).

In introducing the labelling recommendations for follow-up formula for older infants at CCNFSDU40, the Chair of the EWG did bring to the attention of the Committee those recommendations that incorporate concepts (and in some instances direct wording) of relevant WHO and WHA documents. This was noted in Para 39 and 45 of the Final Report as replicated below:

- **39.** To concerns on how the WHO *International Code of Marketing of Breastmilk Substitutes*, the *Global Strategy for Infant and Young Child Feeding* and relevant WHA resolutions would be addressed, if not in the scope, it was clarified that these could be addressed through the provisions in the labelling section and in the future discussion on the preamble.
- **45.** The Committee noted that this section was largely based on Article 9 of the WHO International Code of Marketing of Breastmilk Substitutes, and Recommendation 4 of the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children (specifically provision 9.6.2); and in some cases the provision used the wording as contained within the Guidance.

Whilst referencing WHO/WHA documents and resolutions and the Preamble were not specifically discussed at CCNFSDU40, comments received would indicate that the views of Committee members on this matter remain polarised.

Referencing in other Codex Standards

The referencing of WHO/WHA documents and resolutions does occur in other Codex standards, including the *Standard on Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72 – 1981), and this is being presented by some Codex members as a precedent for its use in the review of the Follow-up Formula Standard. The labelling provisions in the draft standard for follow up formula could be considered more prescriptive than the Infant Formula Standard, picking up on many of the labelling recommendations in WHO/WHA documents and resolutions, and could therefore be considered a deviation from this benchmark, and in-line with the advice provided by CCEXEC75.

Summary

The Committee must now consider the WHO/WHA referencing issue and discuss whether the incorporation of WHO and WHA concepts and technical information into the text of the standard itself, overrides the need for generic referencing.

Table 1: Concepts and guidance from WHO and WHA documents that have been incorporated into draft standard text

Document	Draft text is as per CCNFSDU40 report Appendix III and IV. Text for Follow-up formula for older infants has been agreed to by the Committee, endorsed by CCFL and CAC and is at Step 6.Text for [name of product] for young children in <i>blue italics</i> is at Step 3 and yet to be agreed to by CCNFSDU. Note: CCFL45 endorsed the labelling sections for Follow-up Formula for Older Infants with amendments to 9.2.2, 9.3 and 9.4.1 (i) and (ii) and 9.4.2. The changes proposed by CCFL are presented in strikethrough / bold underlined font. With regard to 9.6.4, the Committee endorsed the first sentence and agreed to return the last sentence on cross-promotion for further consideration by CCNFSDU.			
WHO International Code of Marketing of Breast- milk Substitutes	Follow-up Formula for Older infants		[Name of Product] for Young children	
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.	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.	9.5.2	Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that formula [product] remaining after feeding should be discarded, shall appear on the label.
	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:		
		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.		
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: (a) the words "Important Notice" or their equivalent;	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) a statement of the superiority of breastfeeding;	9.6.1 k	o) 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 be used only on the advice of a health worker as to the need for its use and the proper method of use;	9.6.1	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) instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation	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. The label shall carry clear graphic instructions illustrating the method of preparation of the product.	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 [product] remaining after feeding should be discarded, shall appear on the label. The label shall carry clear graphic instructions illustrating the method of preparation of the product. [Pictures of feeding bottles are not permitted on labels of (name of product) for young children.]
	9.5.4	The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use.	9.5.4	[The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use].
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.	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;	<i>{</i> 9.6.1	The label of [name of product] for young children shall have no image, text or representation f,including pictures of feeding bottles,]—that could undermine or discourage breastfeeding or which idealises the use of [name of product] for young children. The terms 'humanized', 'maternalized' or other similar terms must not be used on the label.]
The terms "humanized", "maternalized" or similar terms should not be used.	9.6.3	The terms "humanized", "maternalized" or other similar terms shall not be used.		

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.	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.	{9.5.6	The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a [diversified] [balanced] diet.]
9.4 The label of food products within the scope of this Code should also state all the following points: (a) the ingredients used;	9.2.1	A complete list of ingredients shall be declared on the label	9.2.1	A complete list of ingredients [including optional ingredients] shall be declared on the label
(b) the composition/analysis of the product;	9.3	Declaration of Nutritive Value	9.3	Declaration of Nutritive Value
		This section includes requirements for full declaration of the nutritional values of the product		ection includes requirements for full declaration of ritional values of the product
(c) the storage conditions required; and		The date marking and storage instructions shall be in accordance with section 4.7.1 of the General Standard for the Labelling of Prepackaged Foods. a practicable, storage instructions shall close proximity to the date marking	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.
(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.		The date marking and storage instructions shall be in accordance with section 4.7.1 of the General Standard for the Labelling of Prepackaged Foods. Practicable, storage instructions shall close proximity to the date marking	9.4.1	(i) The "Best Before Date" or "Best Quality Before Date shall be declared
10.1 The quality of products is an essential element for the protection of the health of infants and therefore should be of a high recognized standard.	All ingressafe ar	sed text to be discussed at CNFSDU41: redients shall be clean, of good quality, and suitable for ingestion by [older] is from the 6th month on and young on. They shall conform with their normal	All ingr	ed text to be discussed at CCNFSDU41: edients shall be clean, of good quality, safe and e for ingestion by infants from the 6th month on ung children. They shall conform with their

	quality and od	requirements, such as colour, flavour our.	normal odour.	quality requirements, such as colour, flavour and
10.2 Food products within the scope of this Code should, when sold or otherwise distributed, meet applicable standards recommended by the Codex	Proposed text to be discussed at CNFSDU41: 6.HYGIENE		Proposed text to be discussed at CCNFSDU41: 6.HYGIENE	
Alimentarius Commission and also the Codex Code of Hygienic Practice for Foods for Infants and Children.	It is no second and the title and direct second		It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the <i>General Principles of Food Hygiene</i> (CXC 1- 1969), and other relevant Codex texts such as the <i>Code of Hygienic Practice for Powdered Formulae for Infants and Young Children</i> (CXC 66-2008) [the <i>Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods</i> (CXC 40- 1993) and the <i>Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods</i> (CXC 23- 1979)] The products should comply with any microbiological criteria established in accordance with the <i>Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods</i> (CXG 21- 1997).	
Guidance on ending the inappropriate promotion of foods for infants and young children	Fo	llow-up Formula for Older infants		[Name of Product] for Young children
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 importance of	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.	<i>{</i> 9.5.6	The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a {diversified} {balanced} diet.}
continued breastfeeding for up to two years or beyond and the importance of not introducing				

recommend or promote bottle feeding:

be construed as an endorsement by a

been specifically approved by relevant

authorities.

convey an endorsement or anything that may

professional or other body, unless this has

national, regional or international regulatory

8 complementary feeding before 6 months of Labels should not discourage 9.6.1 breastfeeding. Each container label shall have a clear, conspicuous and include the appropriate age of introduction of easily readable message which the food (this must not be less than 6 months); includes the following points: be easily understood by parents and other a) the words "important notice" or caregivers, with all required label information being visible and legible. 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 The label shall have no pictures of 9.6.2 **f9.6.1** The label of [name of product] for young Messages should not: infants, young children and women children shall have no image, text or representation include any image, text or other representation nor any other picture, text, or **f.including pictures of feeding bottles. 1** that could that might suggest use for infants under the representation that might: undermine or discourage breastfeeding or which age of 6 months (including references to idealises the use of [name of product] for young 9.6.2.1 idealize the use of follow-up milestones and stages); children. The terms 'humanized'. 'maternalized' or other formula for older infants: include any image, text or other representation similar terms must not be used on the label. that is likely to undermine or discourage 9.6.2.2 suggest use for infants under [9.6.2] Products shall be labelled in such a way as to breastfeeding, that makes a comparison to the age of 6 months (including avoid any risk of confusion between infant formula, breast-milk, or that suggests that the product references to milestones and stages); follow-up formula for older infants, [name of product] for is nearly equivalent or superior to breast-milk; 9.6.2.3 recommend or promote bottle young children, and formula for special medical

9.6.2.4 undermine or discourage

suggests that the product is similar,

equivalent to or superior to breast-

breastfeeding; or that makes a

comparison to breast-milk, or

feeding;

milk;

purposes[, and to enable consumers to make a clear

distinction between them, in particular as to the text,

images and colours used].]

		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.	
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 mascots 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).	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.	
WHA 69.9 Ending inappropriate promotion of foods for infants and young children	Follow	-up Formula for Older infants	[Name of Product] for Young children
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	guidelir the Inte milk Su Assemi	wn above, 'full consideration to WHO nes and recommendations, including trnational Code of Marketing of Breast- bstitutes and relevant Health oly resolutions' has been given and ts incorporated within the labelling ons.	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.

recommendations, including the International Code of Marketing of Breast-milk Substitutes and relevant Health Assembly resolutions		
WHA 63.32	Follow-up Formula for Older infants	[Name of Product] for Young children
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 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.	The prohibition on nutrition and health claims on foods for infants and young children is contained within the <i>Guidelines for Use of Nutrition and Health Claims</i> (CXG 23-1997) which are referenced in the introductory paragraph to the Labelling Section. [9. Labelling The requirements of the Codex 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.
WHA 54.2	Follow-up Formula for Older infants	[Name of Product] for Young children
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 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.	The prohibition on nutrition and health claims on foods for infants and young children is contained within the <i>Guidelines for Use of Nutrition and Health Claims</i> (CXG 23-1997) which are referenced in the introductory paragraph to the Labelling Section. [9. Labelling The requirements of the Codex 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.

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, the labelling section of the product has taken into consideration the International Code and WHA resolutions

As shown above, the labelling section of the product has taken into consideration the International Code and WHA resolutions