

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

**Agenda Item 5**

**CX/NFSDU 05/27/5**  
**September 2005**

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES Twenty-seventh Session

**Bonn, Germany, 21 - 25 November 2005**

#### PROPOSED DRAFT REVISED STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN

*- Comments at Step 6 of the Procedure -*

#### Comments from:

**ARGENTINA**  
**AUSTRALIA**  
**BRAZIL**  
**CHINA**  
**INDIA**  
**MEXICO**  
**TURKEY**  
**UNITED STATES OF AMERICA**  
**VENEZUELA**

**AAC – Association des amidonneries de céréales de l'UE**  
**ENCA – European Network of Childbirth Associations**  
**IACFO – International Association of Consumer Food Organisations**  
**IBFAN – International Baby Food Action Network**  
**ISDI – International Special Dietary Foods Industries**  
**IWGA – International Wheat Gluten Association**

## ARGENTINA

**Article 4:** From Argentina's point of view, it could be convenient to include only those elements in the board of additive elements which are technologically absolutely necessary in order to avoid any possible surpass of the mentioned values, because these aliments will be used by young children and infants.

**Article 4.10:** It would be adequate to eliminate the square brackets, taking into account that it is reasonable to consider that in the technological process it is difficult to eliminate these components.

**Article 8.6.3:** Argentina supports the elimination of the square brackets.

## AUSTRALIA

### Section 8 Labelling

- The numbering is should be 8.1, 8.2 etc.
- If retained, the sentence referring to nutrition claims should be assigned its own paragraph.

### Paragraph 8.1

Should include the identification code for the *Guidelines for use of nutrition and health claims*, consistent with the other mentioned texts.

### Paragraph 8.6.1

Directions for use and storage instructions should be shown on the label affixed to the container; therefore reference to the accompanying leaflet should be deleted.

### Paragraph 8.6.3

The option to label a food 'gluten free' should remain with the manufacturer rather than being a requirement. It is likely that manufacturers, whose products meet the criteria for gluten free, would declare it on the label. Perhaps a cross reference to Section 5.1 of the Codex Draft Revised Standard for Gluten-Free Foods could be useful once the revised Gluten-free Foods Standard is adopted.

## BRAZIL

Observations: - proposals of additions to the text are underlined  
 - proposals of elimination of the text are ~~erossed~~  
 - explanations and justifications are *in italic* and in **bold**.

### **Title:**

*Brazil suggests to request the Codex Committee on Food Labeling-CCFL about the need of revision of the norm title, considering the approved description for the product: "... cereal-based foods" and "the proportion of at least 25% of final mixture of cereals defined for the product".*

*Justification: The use of the expression "cereal-based foods" can lead the consumer to a misunderstanding, considering the cereal percentage presented in the product.*

## **4. FOOD ADDITIVES**

### **TABLE – WORKING GROUP'S PROPOSALS**

*The guar (INS 412), carob bean (410) and carrageenan (407) gums must not be used in Infant Formula.*

*Justification: Studies on safety and use for lactant and young children must be elaborated to justify their use on Infant Formula. In Brazil, these gums are not allowed to infant formula.*

*The phosphates (INS 338, INS 339i, 339ii and 339iii, INS 340i, 340ii and 340iii) have numerical ADI and must present the numerical limit of use.*

*Sodium acetates (INS 262ii) has numerical ADI and must present the numerical limit of use.*

*To exclude sorbates (INS 334, INS 335i, 335ii, 336 e 337) and tartrates (INS 334, INS 335i, INS 335ii, INS 336 and INS 337).*

*Justification: There is no technological necessity for these additives uses in infant formula due to their composition.*

## **8. LABELING**

**8.1.1.** "Nutrition Claims shall be permitted for foods for infants and young children where they have been demonstrated in rigorous studies with adequate scientific standards."

*Brazil would like to request for a clarification concerning the item 8.1.1, since the Nutrition Claims are part of the Codex Standard (CAC/GL 23-1997).*

8.6.3. To keep the item in the square brackets

**Justification:** *The item 8.6.3 must take into consideration the advances of the Draft Standard for Gluten Free Foods and the analytical method definition.*

1. Proposed Draft Formulas for Special Medical Purposes Intended for Infants (ALINORM 05/28/26 para 100 and Appendix IV (Section B)).

9.6.4 To keep the item and to remove the square brackets

9.6.5 To keep the item and to remove the square brackets.

## CHINA

Alinorm 05/28/26, Appendix V	JUSTIFICATION
<b>2. DESCRIPTION</b>	
Processed cereal-based foods are prepared <b>primarily</b> from one or more milled cereals, which should constitute at least 25% of the final mixture on a dry weight basis	Delete the word “primarily” as there are other very nutritive ingredients such as milk or pulses that can be used in these products.
<b>3.1 ESSENTIAL COMPOSITION</b>	
<b>3.1.1</b> The four categories listed in 2.1.1 to 2.1.4 are prepared <b>primarily</b> from one or more milled cereal products, such as wheat, rice, barley, oats, rye, maize, millet, sorghum and buckwheat, <b>legumes (pulses), or oilseed</b> . They may also contain <b>legumes (pulses)</b> , starchy root (such as arrow root, yam or cassava) or starchy stems <del>or oil seeds</del> in smaller proportions.	Delete “primarily” in accordance with section 2. Description. <u>Reasons:</u> – Legumes and pulses, such as soy and cowpea, are high quality and quantity protein ingredients and thus valuable sources of nutrition. – Moreover legumes historically have been covered by this standard and should remain so.
<b>3.4 CARBOHYDRATES</b>	
<b>3.8 OPTIONAL INGREDIENTS</b>	
<b>3.8.3 Only L(+) producing lactic acid cultures may be used.</b>	<u>Add</u> this provision to keep consistency with the Standard for Infant Formula
<b>4. FOOD ADDITIVES</b>	
<b>4.2 pH-adjusting agents</b> <b>4.2.4 Request for L(+) lactic acid producing cultures at GMP<sup>3</sup></b>	<b>We fully support this request. As stated under footnote 3, cultures are not considered as food additives. Therefore they should appear under “Optional ingredients”, see above comment under 3.8.3.</b>
<b>4.10 Carry-over of Food Additives</b>  <b>No food additives shall be present as a result of carry-over from raw materials and other ingredients with the exemption:</b> <b>(a) of the food additives listed under Sections 4.1 to 4.9 of this standard within the limits of the maximum levels stipulated in this standard; and</b> <b>(b) [of the carrier substances mentioned in the Advisory List of Vitamin Compounds for Use in Foods</b>	CODEX <i>Principle Relating to Carry-over of Additives into Foods</i> shall apply to infant formula. To restrict all carry-over of food additives is not practicable, and also makes it difficult to develop new formula with certain desired beneficial qualities.

<p>for Infants and Children within the limits of the maximum levels stipulated in that List]</p> <p>CODEX Principle Relating to Carry-over of Additives into Foods shall apply.</p>	
<p><b>8. LABELLING</b></p>	
<p><b>8.1.1 Nutrition and health cClaims shall be permitted for foods for infants and young children where they have been demonstrated in rigorous studies with adequate scientific standards.</b></p>	<p><b><u>Add "health claims" to this provision.</u></b>  <b><u>Rationale:</u></b>  <b>It is of the <u>outmost importance</u> that information on the dietary properties of processed-cereal based products for infants and young children can be communicated as:</b></p> <ul style="list-style-type: none"> <li>- The lack of appropriate information on these adapted foods may orient the parent to choosing non-adapted and inappropriate foods for their infants and young children.</li> <li>- Health claims, such as nutrition function claims, are important and true statements regarding the dietary properties of the foods and provide important information to parents.</li> <li>- Justified health claims and nutritional claims are recognized nutrition knowledge and should be linked to the food consumers choose every day. Otherwise, these knowledge will never be widely applied in consumers' diet.</li> <li>- We acheive an important target of nutrition education when nutrition knowledge on labels help consumers understand the dietary property of the foods and choose the foods they need.</li> <li>- Provisions ensuring that claims for foods for special dietary uses are appropriately used, have already been detailed in Section 3.1 of Codex STAN 146-1985 (Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses).</li> <li>- There is no justification for denying them information that is based on scientific substantiation.</li> </ul>
<p><del>8.1.2 Any indication required in the labelling should be made in the appropriate language(s) of the country in which the product is sold.</del></p>	<p><del>Delete this section. General Laelling Standard (CODEX STAN 1-1985) has covered it.</del></p>
<p><b>8.5 DATE MARKING AND STORAGE INSTRUCTIONS</b></p>	
<p><del>8.5.3 Where practicable, storage instructions shall be in close proximity to the date marking.</del></p>	<p><del>Delete this section. General Standard for the Labelling of and Claims for prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985) have such provisions already.</del></p>
<p>8.6.3 [when the product is composed of gluten-free ingredients and food additives, the label should show the statement "gluten-free"]</p>	<p>Delete the sentence. Allergen declaration must the same as prescribed in Codex <i>General Standard for the Labelling of Prepackaged Foods</i>.</p>

## INDIA

### 1. SCOPE

The WHO has already recommended adding a reference to the WHO Global Strategy on Infant and young Child Feeding, WHA Resolution 55.25 (2002). It is important to add these references so that production and marketing of these products are governed by the provisions of these global recommendations in the interest of nutrition and health of infants and young children of the world.

The Scope may be reworded as under:

“This standard covers processed cereal based foods intended for feeding infants and young children as complementary foods from the age of six months as part of their progressively diversified diet in accordance with World Health Assembly Resolutions WHA 54.2(2001) and WHA 55.25 (2002).

### 2. DESCRIPTION

The name of the product suggests that the Cereal content should be the primary base of this product.

Paras 84-85 of Alinorm 03/41, the proceeding of 27<sup>th</sup> Session of CAC, refers to the concern expressed by the Delegations of India & Egypt in this respect and the commission adopted the proposed draft revised Standard at Step 5 with the understanding that the comments of these delegations would be considered by the CCNFSDU.

India has been recommending a minimum of 50% of cereals in this product during the last five sessions of the CCNFSDU. A product having only 25% of cereals cannot be termed as cereal based food. India, therefore, strongly recommends keeping a minimum of 50% cereals in the Standard for Processed Cereal based Foods for Infants and Young Children.

### 3. ESSENTIAL COMPOSITION AND QUALITY FACTORS.

#### 3.1 Essential Composition

**3.1.1** Starchy roots will have an adverse impact on the quality of product, as it would dilute the proportion of essential nutrients present in the food, lowering the nutritional density in terms of energy, protein and other nutrients and is, therefore, incompatible with infant’s nutritional requirements.

Hence, starchy roots and stems should be deleted and the clause may be reworded as under:

“The four categories listed in 2.1.1 to 2.1.4 are primarily from one or more milled cereal products such as wheat, rice, barley, oats, rye, millet, sorghum and buckwheat. It may also contain legume (pulses) and/ or oilseeds”.

Milk should also be added in the composition.

#### 3.2 Energy Density

The energy density of cereal-based foods has to be sufficiently high as infants and young children are to be provided energy dense foods. The energy density of 0.8 Kcal/g is too low and needs to be increased to 4 to 5 Kcal/g.

The energy density of such foods in India ranges from 385 to 470 Kcalories per 100 gm on dry weight basis.

#### 3.1 Protein

**3.3.2** These foods could be diluted with water or protein free liquids as per clause 2.1.2. The cereal-based foods should, therefore, have adequate protein content. India, therefore, recommends that the following clause be added at the end to read as:

“The minimum protein content of the product shall not be less than 15%.

Further, the clauses 3.3.2 and 3.3.3 should have protein content per 100 g. of the product also and clause 3.3.4 should be deleted in the light of comments for clause 2.1.4.

#### 3.4 Carbohydrates

##### 3.4.1 and 3.4.2 Delete the word “honey”

Reason: the addition of honey increases the risk for microbial contamination.

### 4. FOOD ADDITIVES

#### 4.2 pH adjusting agents

It is desirable to exclude all the phosphate containing additives in as it upsets the calcium phosphate ratio, which has adverse effect on bone metabolism.

Phosphoric acid and its salts should not be permitted as pH adjusting agents.

#### **4.7 Thickening agents**

Delete all thickening agents of low nutritional value.

#### **4.8 Anti-caking agents**

The addition of Silicon dioxide should be prohibited due to its adverse effects.

#### **4.9 Packaging gas (Propellants)**

The relative risk/benefit of gases other than Nitrogen need safety evaluation. It is preferable to use nitrogen gas of food grade quality.

### **8. LABELING**

**8.1.1** The following sentence may be added:

“The use of pictures is prohibited in the label of any food meant for infants and young children as per International Code for Protection & Promotion of Breast Feeding”

#### **8.2 The Name of the Food**

Remove the brackets and replace the words by “and/or Young Children” by the words “and young children”.

“Cereal based Energy Foods for infants and young children” would be more appropriate name for such foods.

#### **8.4 Declaration of Nutritive Value**

**8.4.1** (a) & (b) and 8.4.2 Delete “or 100 ml.” as these foods are sold in dry form and not as liquid foods.

#### **8.6 Information for Utilization**

**8.6.4** Complementary feeding should begin at six months of age as per WHA Resolutions 54.2 & 55.25.

Reword the entire clause as under:-

“The label shall indicate clearly that the product is recommended for use from the age of six months only”

**8.6.5** Add **8.6.5**. to read:

The label shall contain the following statement

“ Important notice: For optimal child nutrition and health, breastfeeding should continue along with the feeding of complementary foods”

#### **8.7 Additional Requirements**

Breastfeeding needs to be continued upto the age of 2 years & beyond alongwith adequate complementary feeding started at six months of age, as per WHA Resolutions.

Parents should be advised not to stop breastfeeding and therefore the label should contain the following important notice:-

“Important Notice: Breastfeeding be continued for best child nutrition and health”.

## **MEXICO**

### **2. DESCRIPTION**

We propose deleting the word “primarily” from the text.

#### **3.1 Essential Composition**

Note: The nutritional values are expressed per 100 kJ, but no equivalent value per 100 kcal is given.

- In section 3.1.1, we suggest deleting the word “primarily” and adding “legumes (pulses), or oil seed” after „buckwheat“.

- In section 3.5, we suggest ending the sentence with a full stop after the bracket: “(4.5 g/100 kcal).”

- In section 3.4.2, where it reads that the amount of added carbohydrates from these sources (sucrose, fructose, glucose, glucose syrup or honey) shall not exceed 2 g/100 kJ (8.4 g/100 kcal), we suggest changing this to 1.2 g/100 kJ (5 g/100 kcal), as these values were proposed at the 26 Session of the Committee.

- In section 3.9.1, we suggest to delete the wording “Including optional ingredients”.

- In section 8.1.1, we suggest referring to CODEX STAN. 146-1985 instead of CODEX STAN 1 1985.

- In section 8.5.3 we suggest reformulating the wording “Where practicable, storage instructions...” into “Storage instructions shall be...”

## TURKEY

PROPOSED MODIFICATION OF ALINORM 05/28/26, Appendix V	JUSTIFICATION
<b>2. DESCRIPTION</b>	
Processed cereal-based foods are prepared <del>primarily</del> from one or more milled cereals, which should constitute at least 25% of the final mixture on a dry weight basis.	<u>Delete</u> the word “ <i>primarily</i> ”. <u>Rationale:</u> There are other very nutritive ingredients such as milk or pulses that can be used in these products.
<b>3. ESSENTIAL COMPOSITION AND QUALITY FACTORS</b>	
<b>3.1 ESSENTIAL COMPOSITION</b>	
<b>3.1.1</b> The four categories listed in 2.1.1 to 2.1.4 are prepared <del>primarily</del> from one or more milled cereal products, such as wheat, rice, barley, oats, rye, maize, millet, sorghum and buckwheat, <b>legumes (pulses), or oilseed</b> . They may also contain <del>legumes (pulses),</del> starchy root, (such as arrow root, yam, or cassava) or starchy stems <del>or oil seeds</del> in smaller proportions.	<u>Delete</u> “ <i>primarily</i> ” in accordance with section 2. Description. <u>Rationale:</u> – Legumes and pulses, such as soy and cowpea, are high quality and quantity protein ingredients and thus valuable sources of nutrition. – Moreover legumes historically have been covered by this standard and should remain so.
<b>3.4 CARBOHYDRATES</b>	
<b>3.4.2</b> If sucrose, fructose, glucose, syrup or honey are added to products mentioned in points 2.1.2 - the amount of added carbohydrates from these sources shall not exceed <del>≥ 1.2 g/100kJ (8.4 5 g/100kcal)</del>	<u>Change</u> “2” into “1.2” <u>Rationale:</u> The original proposal for this section was based on the European Directive (96/5/EEC) which indicates a level of 1.2 g/100kJ. There must be a typing error in the ALINORM.
<b>3.7.1</b> The amount of vitamin B <sub>1</sub>	Change 12,5 µg/100 kJ into 12.5 µg/100 kJ
<b>4. FOOD ADDITIVES</b>	
<b>4.4 Flavours</b>  4.4.1 Vanilin extract GMP 4.4.2 Ethyl vanillin 7 mg on an “as consumed basis” 4.4.3 Vanillin 7 mg on an “as consumed basis”  Components of chocolate and part of the characterising flavour. Other flavours may be needed, further discussion is necessary.	Add Flavours
<b>4.10 CARRY-OVER OF FOOD</b>	

<b>ADDITIVES</b>	
<p>No food additives shall be present as a result of carry-over from raw materials and other ingredients with the exception: (a) of the food additives listed under Sections 4.1 to 4.9 of this standard within the limits of the maximum levels stipulated in this standard; and (b) [of the carrier substances mentioned in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979) within the limits of the maximum levels stipulated in that List.]</p>	<p><u>Delete</u> [ ]</p> <p><u>Rationale:</u> We acknowledge that CCFAC is currently considering to establish a new additive functional class for nutrient carriers. However, we believe that the list of nutrient carriers should remain as presently the case, namely at the end of the advisory list of mineral salts and vitamin compounds for the use in foods for infants and young children. As this list is currently under revision by CCNFSDU we consider that this list of nutrient carriers should also be reviewed.</p>
<b>8. LABELLING</b>	
<p>8.1.1 Nutrition <b>and health c</b>laims shall be permitted for foods for infants and young children where they have been demonstrated in rigorous studies with adequate scientific standards.</p>	<p><u>Add</u> "health claims" to this provision.</p> <p><u>Rationale:</u> It is of the <b>outmost importance</b> that information on the dietary properties of processed-cereal based products for infants and young children can be communicated as:</p> <ul style="list-style-type: none"> <li>- The lack of appropriate information on these adapted foods may orient the parent to choosing non-adapted and inappropriate foods for their infants and young children.</li> <li>- Health claims, such as nutrition function claims, are important and true statements regarding the dietary properties of the foods and provide important information to parents.</li> <li>- We are not aware of any study showing that parents of infants and young children are more readily persuaded by health claims than other adults.</li> <li>- Some countries already allow certain health claims, namely nutrient function claims, in labelling of formulas and foods intended for healthy infants.</li> <li>- Provisions ensuring that claims for foods for special dietary uses are appropriately used, have already been detailed in Section 3.1 of Codex STAN 146-1985 (Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses).</li> </ul> <p>Finally, there is <b><u>no reason to prohibit</u></b> the communication of relevant information through labelling and literature if it complies with the above mentioned criteria and as long as this <b><u>communication remains in line</u></b> with national practices and the WHO International Code on the Marketing of Breast-milk Substitutes. The aim of the Code on the Marketing of Breast-milk Substitutes is to <i>“contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding, and by ensuring the proper use of breast milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution”</i>. This section is adequately covered in section 8 of CODEX 146-1985 and in section 8.2 of the General Standard (CODEX STAN 1-1985).</p>



8.3.1 ...these <b>may</b> may be	Change “bold character” into “normal character”
8.4.1 ... <del>which should be</del> which should be	Change “bold characters” into “normal characters”
<b>8.5 DATE MARKING AND STORAGE INSTRUCTIONS</b>	
8.5.3 <del>Where practicable, storage instructions shall be in close proximity to the date marking.</del>	<u>Delete</u> this section <u>Rationale:</u> This type of provisions is fully described in the General Standard for the Labelling of and Claims for prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985) and is not needed here.
<b>8.6 INFORMATION FOR UTILIZATION</b>	
8.6.3 [When the product is composed of gluten-free ingredients and food additives, the label should show the statement "gluten-free".]	<u>Delete</u> brackets <u>Rationale:</u> The labelling of the presence of ingredients containing gluten is already obligatory according to section 4.2.1.4 of Codex Standard CODEX STAN 1-1985. The absence of gluten is regulated by Codex Standard for Gluten-free foods 118-1981 rev. 1983.

## UNITED STATES OF AMERICA

### I. General Comments

We are submitting comments on the Draft Revised Standard for Processed Cereal Based Foods for Infants and Young Children except for Section 4 (Food Additives) that was referred to the Codex Committee on Food Additives and Contaminants (CCFAC) for endorsement. We anticipate further comments on Food Additives may be forthcoming pending the response from CCFAC.

### II. Specific Comments

#### 8.6 Information for Utilization

**8.6.3** [When the product is composed of gluten-free ingredients and food additives, the label ~~should~~ **may** show the statement “gluten-free”.]

Comment: We suggest the wording change shown above. The provision to indicate that gluten is not present on the label in the existing Codex standard for “Gluten-Free Foods” (Codex Stan 118-1981-amended 1983) appears to be voluntary. For example, Sec 5.1 in that standard states that a food prepared according to Section 3.1 **may** be called a “gluten-free food.” Section 5.1 in the draft revision of the gluten-free foods standard (currently at Step 7) contains similar language.

## VENEZUELA

PROPOSED CHANGES TO ALINORM 05/28/26 APPENDIX V	JUSTIFICATION
<b>2. DESCRIPTION</b>	
Processed cereal-based foods are prepared <del>primarily</del> from one or more milled cereals, which should constitute at least 25% of the final mixture on a dry weight basis.	Delete the word “primarily”. <u>Explanation:</u> There are other nutritious ingredients such as milk and pulses which can be used in these products.
2.1 Product definitions	
2.1.2 Cereals with an added high protein food which are or have to be prepared for	Change the text as proposed in bold letters.

consumption with water or other appropriate protein-free liquid. <b>Cereals with additions of high protein ingredients which are or have to be prepared for consumption with water or other appropriate protein-free liquid.</b>	
2.2 Other definitions	
2.2.1 The term infant means a person not more than 12 months of age. <b>The term infant means a person up to 12 months of age.</b>	Substitute “ <b>hasta los/up to</b> ” for “ <b>de menos de</b> ” ... (Applies to Spanish version only. Translator’s note) Explanation: Change the wording in order to include 12-months-old children as they would not be covered by the definition of young children either.
<b>3. ESSENTIAL COMPOSITION AND QUALITY FACTORS</b>	
<b>3.1 Essential Composition</b>	
<b>3.1.1</b> The four categories listed in 2.1.1 to 2.1.4 are prepared <del>primarily</del> from one or more milled cereal products, such as wheat, rice, barley, oats, rye, maize, millet, sorghum, buckwheat, legumes (pulses) or oil seeds. They may also contain starchy roots (such as arrow root, yam or cassava) or starchy stems in smaller proportions.	Delete “primarily” in line with section 2. Description: Explanation: There are legumes (pulses) rich in high-quality protein, which are a good nutrition source.
<b>3.3 Protein</b>	
3.3.1 “The chemical index of the added protein shall be equal to at least 80% of that of the reference protein casein or the Protein Efficiency Ratio (PER) of the protein in the mixture shall be equal to at least 70% of that of the reference protein casein.” The chemical index of the added protein shall be equal to at least 80% of that of casein <b>as the reference protein, or the Protein Efficiency Ratio (PER)...</b>	Modify the text as proposed.
<b>3.8 Optional Ingredients</b>	
<b>3.8.3 Only L(+) producing lactic acid cultures may be used.</b>	Include this proposition.
3.10 Consistency and Particle Size	
3.10.1 When prepared according to the label directions for use, processed cereal-based foods should have a texture appropriate for the spoon feeding of infants or young children of the age for which the product is intended.	Delete []
3.10.2 Rusks and biscuits may be used in the dry form so as to permit and encourage chewing or they may be used in a liquid form, by mixing with water or other suitable liquid, that would be similar in consistency to <del>dry</del> cereals <b>as described in 2.1.1 and 2.1.2 when prepared according to the label directions of use.</b>	Delete “dry” and complete the sentence as proposed in bold letters.
<b>8. LABELLING</b>	
<del>8.1.2 Any indication required in the labelling should be made in the appropriate language(s) of the country in which the product is sold.</del>	Delete this section. Explanation: Such a provision is contained in section 8

	of Codex Standard 146-1985 and in section 8.2 of the General Standard (CODEX STAN 1-1985
8.6.3 <del>Where practicable, storage instructions shall be in close proximity to the date marking.</del>	Delete this section. Explanation: As such a provision is contained in section 8 of Codex Stan 146-1985, there is no need to include it in this document.
8.6 Information for Utilization	
8.6.3 <del>When the product is composed of gluten-free ingredients and food additives, the label should show the statement “gluten free”.</del>	Delete this section. Explanation: The labelling of the presence of gluten containing ingredients is mandatory in line with section 4.2.1.4 of the General Standard (CODEX STAN 1-1985). The absence of gluten is regulated by the Codex Standard for “Gluten-free Foods” (CODEX STAN 118-1981 (amended 1983)).
8.6.4 “The label shall indicate clearly ...in consultation with a <del>health worker</del> , based on...”	Substitute “ <b>pediatrician</b> ” for “ <b>health worker</b> ”.

## AAC – Association des amidonneries de céréales de l’UE

Section 8.1.1 of the Proposed Draft Revised Standard specifies that the requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 Rev. 1-1991) apply to this standard.

Section 8.6.3 specifies that „*When the product is composed of gluten-free ingredients and food additives, the label should show the statement ‘gluten-free’*”.

The AAC believes that the additional mandatory indication of the absence of gluten, in a standard for a particular food not specially prepared to meet the dietary needs of persons intolerant to gluten as covered by the Codex Standard for „Gluten-Free Foods” is not consistent with the risk management option of Codex in the context of allergenicity and intolerance.

The Codex General Standard for the Labelling of Prepackaged Foods as amended, provides for a list of foods and ingredients that are known to cause hypersensitivity and that shall always be declared. With the adoption in 1999 of these requirements, allergenicity and intolerance were adequately addressed by the Codex Alimentarius Commission, in a consistent way, as a horizontal measure.

Foods which have specially prepared to meet the dietary needs of persons intolerant to gluten, are regulated through the Codex Standard for „Gluten-Free Foods” (Codex Stan 118-1981, amended 1983).

**The European Cereal Starch Industry Association is therefore in favour that the relevant section 8.6.3 is removed from the standard.**

## ENCA - European Network of Childbirth Associations

### 1. Scope

ENCA support the text as it is, but suggests 2 changes to improve the clarity of the text.

- Delete in the second line:” taking into account infants’ individual nutritional requirements”.  
Because, this cannot be handled in an international standard.
- **Restore the text “and WHA 55.25 (2002)” at the end of the text. This is critically important to mention as this Resolution contains the following important sentence:**

“the introduction of micronutrient interventions and the marketing of nutritional supplements do not replace, or undermine support for the sustainable practice of, exclusive breastfeeding and optimal complementary feeding” (WHA 55.25, May 2002).

## 2. Description

It is very unclear what the other 75% should or can be as the name of the product is processed cereal-based foods. Cereals should be the main ingredient on a dry weight base. This description is in contradiction with 3.1.1 (essential composition) ENCA supports a minimum of over 50% of milled cereals and would favour even a higher minimum content.

## 3.4. Carbohydrates

**3.4.1. and 3.4.2.** The sugar content should be lower in order not to favour a preference for sweet food.

## 3.6. Minerals

**3.6.1.** The sodium content should be lower as children could acquire a preferred taste for salty food.

## 3.8 Optional Ingredients

**3.8.1.** A standard for infants and young children should not allow unspecified optional ingredients. All ingredients should be specified and meet Codex standards. Scientific proof should exist from independent research that their use is safe in infants and young children. If this is not the case precaution should be applied until the evidence is available.

**3.8.2.** Delete “if present” and add “ and should be labelled for use after 12 months.”

**Reinsert 3.8.3.** Products containing cocoa should be used only after 12 months.

Following the decision in point 116 of the CCNFSDU 2003 report ENCA submits this compilation of scientific data to give the rationale why ENCA asks to have cocoa only allowed as ingredient after 12 months or even later.

### Infants and cocoa

A medline search has shown abundant literature on ingestion of cocoa and its main CNS (central nervous system) active substances methylxanthine theobromine and caffeine for mice, rats, racehorses and racing greyhounds. The following effects of the active substances were detected:

- ✓ Theobromine inhibited body weight gain in rats. Sertoli cells in testes seem to be the primary target for the theobromine toxicity. (1)
- ✓ Avoidance reactions were decreased while ambulation was increased in mice. (2)
- ✓ Caused vacuolation within the Sertoli cells, abnormally shaped spermatids and alters testis structure (3)
- ✓ Decrease of relative length of limbs and decrease in bone vascular endothelial growth factor in offspring of mice. (4)

For human beings there are less published papers, but the findings can raise some concerns as to exposing infants of a young age to this CNS active ingredient.

**We could not find a single paper that demonstrates the safety of cocoa use in products for infants and young child feeding.** Here some quotes of what the literature says:

- ✓ The results suggest that a usual dietary portion of chocolate would produce behaviorally discriminable plasma levels. (5)
- ✓ A normal portion of chocolate exhibits psychopharmacological activity. (6)
- ✓ The paper concludes with a call for caution in the use of caffeine and theobromine pending further and more elaborate investigations (7)

(1) Wang Y Theobromine toxicity on Sertoli cells...Toxicol Lett 1994

(2) Kuribari H Behavioral effects of cocoa and its main active compound theobromine... 1992

(3) Wang Y Reproductive toxicity of theobromine and cocoa extracts in male rats Reprod Toxicol 1992

(4) Skopinski P Chocolate feeding of pregnant mice ... Pol J Vet Sci 2003

(5) Mumford GK Absorption rate of methylxanthines.. Eur J Clin Pharmacol 1996

(6) Skopinski P Methylxanthines are the psycho-pharmacological active constituents of chocolate Psychopharmacology 2004

(7) Eteng MU Recent advances in caffeine and theobromine toxicities; a review Plant Foods Hum Nutr 1997

#### 4. Food additives

This section should be as short as possible to protect infants and young children from the exposure to a wide range of additives.

We welcome the fact that this section contains no allowed synthetic flavours as those should not be permitted as they can cause allergic reactions and shape children taste unilaterally to synthetic flavours.

#### 4.7 Thickening agents

Delete all thickening agents as they are of low nutritional value.

As this is a cereal-based product, the thickening should be provided by cereals and not by thickening agents of low nutritional value.

#### 5. Contaminants

The maximum values as set in the directive of the European Commission should be applied here, as this offers the best achievable protection of infants and young children from pesticide and other contaminants leftovers.

#### 6. Hygiene

As *Enterobacter sakazakii* has now even been shown to be present in cereal based food of category 2.1.2, special hygiene measures should be drafted and information for care givers should be included in labelling provisions of products of category 2.1.2.

#### 8. Labelling

**8.1.1.** The last sentence of the first para should be replaced to read: The label shall have no pictures or text which idealizes or suggest an inappropriate age of introduction of these products. (See 8.1.2 for the use of pictograms in the instructions for preparation)

Delete the last sentence in 8.1.1 as nutrition claims could divert parents from feeding their infants with safe indigenous family foods. The promotion of packaged foods for infants can place too great a financial burden on families exacerbating family poverty and increasing the risks of malnutrition of other family members.

*The World Health Assembly has repeatedly stressed how infant and young-child mortality can be reduced by: “exclusive breastfeeding for the first six months with nutritionally adequate and safe complementary feeding through the introduction of safe and adequate amounts of indigenous foodstuffs and local foods while breastfeeding continues up to the age of two years or beyond” (WHA Resolution 54.2, May 2001)*

**8.1.2** Add the following: Pictograms explaining the whole mode of preparation must be added to the written instructions for preparation.

**8.1.3** Add the following text to read:

The use of or the addition of genetically modified ingredients shall be clearly indicated on the label.

*It is preferable that they not be permitted. If they are permitted then the above statement is needed.*

#### 8.3 List of ingredients

**8.3.1** Insert the words “outside panel”. A complete list of ingredients shall be declared on the outside panel of the label....

*All vital information must be available to parents at point of purchase. They should not have to purchase a product in order to read the ingredients list.*

#### 8.6 Information for utilisation

**8.6.1** Delete “or on the accompanying leaflet” as information to purchasers should be available before buying to allow an informed choice of the product.

This information should be available to every person (different care givers) preparing food from the package, therefore the directions as to the preparation shall be on the outside panel.

**8.6.2** Add “breastmilk” to the liquids to be added to the dry product, as this is practised by mothers.

**8.6.4** We support the existing wording of the 2 first lines and ask for deletion of the rest of the paragraph.

If the rest of the paragraph is not deleted then the word “**independent**” or “**free from commercial influence**” must be inserted before the term ‘*health worker*’.

If the word ‘independent’ is used it must be defined.

The following statement must also be included:

Important notice: This product is not sterile, discard leftovers to protect infants from health hazards.

#### **8.6.5 Additional paragraphs to be included:**

Important notice:

For optimum child nutrition and health, breastfeeding should continue along with feeding this food.

This sentence is an important safeguard which will make sure that these products do not replace breastmilk.

## **IACFO - International Association of Consumer Food Organisations**

IACFO supports all the comments made by IBFAN on this standard

## **IBFAN - International Baby Food Action Network**

### **1. Scope**

IBFAN supports the text as it is written, but suggests 2 changes to improve its clarity to read:

**Delete** text starting in the second line, taking into account infants' individual nutritional requirements.

**Restore** the text and WHA 55.25 (2002) and change to read:

*This standard covers processed cereal-based foods intended for feeding infants as a complementary food generally from the age of 6 months onwards, and for feeding young children as part of a progressively diversified diet, in accordance with the Global Strategy for Infant and Young Child feeding, and subsequent World Health Resolutions including WHA 54.2 (2001 and WHA 55.25 (2002)).*

**Rationale:** Individual nutritional requirements cannot be considered in an international standard.

This Codex Standard should take particular note of all WHA Resolutions on this subject and in order to keep pace with marketing developments and scientific knowledge. Steps should be taken to ensure that revisions are made whenever any significant public health measure on infant and young child feeding is adopted by the WHA.

**It is highly important that Resolution WHA 55.25 is retained as it contains the following safeguard:**

“the introduction of micronutrient interventions and the marketing of nutritional supplements do not replace, or undermine support for the sustainable practice of, exclusive breastfeeding and optimal complementary feeding” (WHA 55.25, May 2002).

### **2. Description**

**Change** "25 %" to read "75%".

**Rationale:** If a complementary food is named "cereal-based" it should have more than 25% cereal content. This would bring the description in agreement with the essential composition as defined in 3.1.1 which states pulses and starchy roots or oil seeds can be present in “smaller proportions”. The amounts of the other ingredients can only be smaller if the amount of cereal required is higher.

*Also if a product is labelled as a cereal food it would be misleading to parents to have only 25% of the product as cereal.*

*The degree of milling should be specified in the product description. A large part of the nutritional benefits of cereal grains are lost when only the starchy endosperm and not the germ part of the cereal grain is included in the product.*

### **3. Essential Composition and Quality Factors**

#### **3.1 Essential composition**

**3.1.1** Delete the word “products” and insert “grains” and “to contain a minimum of 75% grains on a dry weight basis”.

**Change** to read:

*The four categories listed in 2.1.1 to 2.1.4 are prepared primarily from one or more milled cereal grains such as wheat, rice, barley, oats, rye, maize, millet, sorghum and buckwheat to contain a minimum of 75% on a dry weight basis. They may also contain legumes (pulses), starchy roots (such as arrowroot, yam or cassava) or starchy stems or oil seeds in smaller proportions.*

### 3.4 Carbohydrates

#### 3.4.1 and 3.4.2 Delete: "honey".

**Rationale:** *The addition of honey presents additional risks for microbial contamination of these products which infants should not be exposed to.*

**Reduce** the amounts of added sugars to 3.8g/100kcal and 4.2g/100kcal.

**Rationale:** *The sugar content should be lower. In both cases the added sugars should not be as high as approximately 30% of calories. The WHO recommends that intakes of added refined sugars should be less than 10% of total calories consumed. Taste preferences are a learned behaviour and the high levels of 7.5g/100kcal to 8.4g/100kcal would encourage the development of preferences for sweetened foods.*

### 3.6 Minerals

#### 3.6.1 The sodium content should be lower.

**Rationale:** Children could acquire a preferred taste for salty food.

### 3.8 Optional Ingredients

#### 3.8.1 Change to read

In addition to the ingredients listed under 3.1, other **specified** ingredients suitable for infants who are more than six months of age or for young children may be used. **The specified permitted optional ingredients must meet Codex standards and must have been demonstrated by independently-funded and systematically reviewed research to be safe for consumption by infants. This standard must be revised at the earliest opportunity to include the new specified ingredients. Minimum and maximum amounts must be stated for each permitted optional ingredient.**

**Rationale:** *What is the point of having a "standard" if it allows the addition of unspecified optional ingredients?*

#### 3.8.2 Delete "if present" and add the words: **If honey or maple syrup is present then the product must be labelled for use after 12 months.**

**Rationale:** If these ingredients are present, then the food may be contaminated and unfit for consumption by infants and young children. To eliminate any risk of contamination it is preferable to prohibit these ingredients as sweeteners for foods for infants under 12 months of age.

**If cocoa is present then the product must be labelled for use after 12 months.**

**Rationale:** IBFAN is very concerned about the addition of cocoa to cereals for infants and young children for a number of reasons.

Cereals with added cocoa generally contain high levels of sugar and therefore have the potential to create dietary preferences in favour of chocolate and other sweet foods. The WHO Global Strategy on Diet, Physical Activity and Health recommends that the sugar consumption in an individual's diet should not exceed 10% of total calories in order to reduce the incidence of obesity, cardiovascular disease and diabetes. These diet-related, chronic diseases are prevalent in industrialized countries and are becoming an emerging nutritional problem in developing countries.

Cocoa added to cereals for infants and young children may also add to the allergenicity of cereal foods. Cocoa and high sugar cereal-based foods for infants and young children have a low nutrient to calorie ratio, yet these products are aggressively marketed for and to young children at a time when nutritional status should be optimal to support the highest attainable standard of growth, development and health. There is abundant literature on the ingestion of cocoa and its main CNS (central nervous system) active substances methylxanthine theobromine and caffeine for mice, rats, racehorses and racing greyhounds. The following effects were detected:

- ✓ Theobromine inhibited body weight gain in rats. Sertoli cells in testes seems to be the primary target for the theobromine toxicity. (1)
- ✓ Avoidance reactions were decreased while ambulation was increased in mice. (2)
- ✓ Caused vacuolation within the Sertoli cells, abnormally shaped spermatids and alters testis structure (3)
- ✓ Decrease of relative length of limbs and decrease in bone vascular endothelial growth factor in offspring of mice. (4)

For human beings there are less published papers, but the findings can raise some concerns as to exposing infants of a young age to this CNS active ingredient. **We could not find a single paper that demonstrates the safety of cocoa use in products for infants and young child feeding.** Here some quotes of what the literature says:

- ✓ The results suggest that a usual dietary portion of chocolate would produce behaviourally discriminable plasma levels. (5)
- ✓ A normal portion of chocolate exhibits psychopharmacological activity. (6)
- ✓ The paper concluded with a call for caution in the use of caffeine and theobromine pending further and more elaborate investigations (7)

### 3.9.1 Change to read:

All ingredients, including **specified, permissible** optional ingredients shall be clean, safe, suitable and of good quality.

## 4. Food additives

### 4.4 Flavours

Delete the reference to flavours.

**Rationale:** *Flavours should not be permitted as they can cause allergic reactions and accustom children to synthetic tastes instead of real food tastes.*

### 4.7 Thickening agents

Delete all thickening agents of low nutritional value.

**Rationale:** As this is a cereal-based product, the thickening should be provided by cereals and not by added thickening agents.

## 5. Contaminants

### 5.1 Pesticide residues

**Reword** to read: The product shall be prepared with special care under good manufacturing practices, so that residues of those pesticides which may be required in the production, storage or processing of the raw materials or the finished food ingredient do not remain, or if technically unavoidable, ~~are reduced to the maximum extent possible~~ **do not exceed a maximum level of 0.01mg/kg for each substance in the product as sold.**

**Rationale:** *This standard should have a stated maximum level for pesticides and not vague phrases such as the present text, "reduced to the maximum extent possible". There are 200 known pesticides found in baby foods. By not stating the maximum allowable levels for each pesticide the cumulative pesticide load is unclear and may present a health hazard to babies and young children. Children are now exposed to more than 50,000 high-production volume synthetic chemicals. Young children are uniquely vulnerable to pesticide exposure and certain cancers have been linked to their presence in foods.*

*The maximum values as set in the Commission Directive on processed cereal-based foods and baby foods for infants and young children<sup>1</sup> can be applied here, as this offers an achievable protection of infants and young children from pesticide ingestion.*

## 6. Hygiene

**Reword** to read:

~~It is recommended that~~ The products covered by the provisions of this standard **shall** be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1 1969, Rev.3, 1997), and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.

**Rationale:** *Stating that the product shall be manufactured in accordance with these Codes of practice is stronger than a recommendation that the product be made in accordance with them.*

*As the pathogen Enterobacter sakazakii has been shown to be present in cereal-based foods supplemented with powdered infant formula, special hygienic measures should be taken during the manufacturing process and warnings placed on the labels to inform caregivers of the risk of microbial contamination of these products.*

## 8. Labelling

8.1.1 Replace the first paragraph with the following text:

***“Nutrition and health claims shall not be permitted for foods covered by the scope of the provisions of this standard. The label shall have no pictures OR TEXT – either on the label or in the Name of the Product which suggests a health advantage, product, idealizes it or suggests an inappropriate age of introduction for these products. Terms which suggest that the product is like human milk should not be permitted.*”**

<sup>1</sup> Commission Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children, as amended by Commission Directive 1998/36/EC Commission Directive 1999/39/EC and Commission Directive 2003/13/EC;



If the existing text is retained referring to the Codex General Standard then the final sentence must be changed to include the word – “**..and text**” to read

“.....National jurisdictions may further restrict the use or pictorial devices **and text**.”

**DELETE:** “~~Nutrition claims shall be permitted for foods for infants and young children where they have been demonstrated in rigorous studies with adequate scientific standards.~~”

**Rationale:** No scientific evidence or logic has been presented to support the removal of the safeguard which prevented the product being presented (through text or pictures) as suitable for an inappropriate age. **This text must be reinstated.**

Health and nutrition claims as text have the potential to deceive parents to think that these products have a nutritional advantage over safe indigenous family foods. Claims have the potential outcome of placing infants and young children at risk for nutritional deficiencies related to intakes of excessive sugar, other low-nutrient food ingredients and food additives and contaminants characteristic of many of these products. As well, claims can lead to early complementation of breastmilk and seriously compromise an infant’s nutritional and immunological needs.

Nutrition claims are marketing tools which violate the aims and spirit of the International Code and its subsequent relevant Resolutions. Even though we welcome the safeguards in 3.10.1 regarding particle size and spoon feeding, the promotional impact of claims is still likely to persuade caregivers to use these products inappropriately and will increase the danger of cereal-based foods being fed through feeding bottles and used as breastmilk substitutes at too early an age, undermining the optimum period of exclusive breastfeeding. The promotion of processed packaged foods for infants with nutrition claims will undermine confidence in safe, indigenous family foods, exacerbating family poverty and increasing the risks of malnutrition.

The **World Health Assembly** supports the use of indigenous foods. It has repeatedly stressed how infant and young-child mortality can be reduced by: “**exclusive breastfeeding for the first six months with nutritionally adequate and safe complementary feeding through the introduction of safe and adequate amounts of indigenous foodstuffs and local foods while breastfeeding continues up to the age of two years or beyond**” (WHA Resolution 54.2, May 2001).

**The Assembly has also warns that:** “the introduction of micronutrient interventions and the marketing of nutritional supplements do not replace, or undermine support for the sustainable practice of, exclusive breastfeeding and optimal complementary feeding” (WHA Resolution 55.25, May 2002).

Nutrition and health claims are not the same as nutrition information (which is essential) and are intended to create a perceived advantage, or to “idealize” commercial foods for infants and young children over indigenous foods. Since nutrition and health claims are not permitted for infant formulae, they should not be permitted for any other food for infants and young children.

The scientific articles used to justify claims are invariably funded and/or authored by product manufacturers. In the case of infant feeding this is far to risky.

The above changes will be in accordance with the **Guidelines for Use of Nutrition and Health Claims**

**8.1.2 ADD** the following text: **Pictograms explaining the whole mode of preparation must be added to the written instructions for preparation.**

**8.1.3 Add** the following text to read:

The use of or the addition of genetically modified ingredients shall be clearly indicated on the label.

**Rationale:** It is preferable that GMO food ingredients not be permitted. If they are permitted then the above statement is needed.

### **8.3 List of ingredients**

**8.3.1 Insert** the words “**outside panel**”.

A complete list of ingredients shall be declared on the **outside panel** of the label....

**Rationale:** All vital information must be available to parents at point of purchase. They should not have to purchase a product in order to read the ingredients list.

### **8.6. Information for utilisation**

**8.6.1 Delete** the words: “**or on the accompanying leaflet**”. Information to purchasers should be available prior to purchasing the product to allow for informed choice.

**8.6.2 Add** the word “breastmilk” to the liquids to be added to the product, to read “...the label shall state, **breastmilk** or formula, but no water, shall be used for the dilution or mixing”.

**8.6.4** We support the existing wording of the 2 first lines and ask for deletion of the rest of the paragraph. If this recommendation is not taken up the word “**independent**” or “**free from commercial influence**” must be inserted before the term ‘**health worker**’.

If the word '*independent*' is used it must be defined as being free from commercial influence..

Insert the following statement:

Important notice: This product is not sterile, discard leftovers to protect infants from health hazards.

**8.6.5 Add** 8.6.5 to read:

**“The label shall contain the following statement: ‘Important notice: For optimal child nutrition and health, breastfeeding should continue along with the feeding of complementary foods’.”**

**Rationale:** Parents should be notified that the introduction of complementary foods does not signal a need to stop breastfeeding. Breastmilk continues to be the most important source of nutrition after six months of age. WHO and UNICEF policy encourage mothers to breastfeed for 2 years and beyond.

## ISDI – International Special Dietary Foods Industries

N.B: there needs to be consistency in the way energy is expressed, in order to be in line with the Infant Formula Standard, ISDI suggests expressing all energy values in kcal (kJ).

ISDI PROPOSAL	JUSTIFICATION
<p><b><u>2. DESCRIPTION</u></b>            Processed cereal-based foods are prepared <del>primarily</del> from one or more milled cereals, which should constitute at least 25% of the final mixture on a dry weight basis</p>	<p><u>Delete</u> the word “primarily”  <u>Rational:</u> there are other very nutritive ingredients such as milk or pulses that can be used in these products.</p>
<p><b><u>3.1. Essential Composition</u></b>  <b>3.1.1</b> The four categories listed in 2.1.1 to 2.1.4 are prepared <del>primarily</del> from one or more milled cereal products, such as wheat, rice, barley, oats, rye, maize, millet, sorghum and buckwheat, <b>legumes (pulses), or oilseed</b>. They may also contain <del>legumes (pulses),</del> starchy root, (such as arrow root, yam, or cassava) or starchy stems <del>or oil seeds</del> in smaller proportions.</p>	<p><u>Delete</u> the word “primarily”  <u>Rational:</u> there are other very nutritive ingredients such as milk or that can be used in these products   <u>Add</u> change place of “legumes (pulses), or oilseed”  <u>Rational:</u> pulses and pulses such as soy, are high protein content ingredients and thus are valuable sources of nutrition. Moreover legumes historically have been covered by this standard and should remain so.</p>
<p><b><u>3.4 Carbohydrates</u></b>  <b>3.4.2</b> If sucrose, fructose, glucose, syrup or honey are added to products mentioned in points 2.1.1 and 2.1.4            - the amount of added carbohydrates from these sources shall not exceed <del>2</del> <b>1.2</b> g/100kJ (<del>8.4</del> <b>5</b> g/100kcal)</p>	<p><u>Change</u> “2” into “1.2”  <u>Rational:</u> the original proposal for this section was based on the European Directive which indicates a level of 1.2 g/100kJ. There must be a typing error in the Alinorm;</p>
<p><b><u>3.8 Optional ingredients</u></b>  <b>3.8.1</b> In addition to the ingredients listed under 3.1, other ingredients suitable for infants who are more than 6 months of age <del>or as appropriate</del> and for young children can be used.</p>	<p><u>Add</u> “or as appropriate”  <u>Rational:</u> it brings this section more in line with the scope of this standard.</p>
<p><b>3.8.3 Only L(+) producing lactic acid cultures may be used.</b></p>	<p><u>Add</u> a new provision  <u>Rationale:</u> consistency with the Standard for Infant Formula.</p>
<p><b><u>3.9. Quality factors</u></b>  <b>3.9.1</b> All ingredients, <del>including optional ingredients,</del> shall be clean, safe, suitable and of good quality.</p>	<p><u>Delete</u> “including optional ingredients”  <u>Rational:</u> the wording “all ingredients” already cover them</p>
<p><b><u>4. FOOD ADDITIVES</u></b>  <b>4.2 pH-Adjusting Agents</b></p>	<p>ISDI supports this request.  <u>Rationale:</u> Cultures are natural way to reduce pH.</p>

<p><b>4.2.4 Request for L(+) producing lactic acid producing cultures at GMP<sup>3</sup></b></p>	<p>Decreases risk of contamination from undesirable bacteria, the add taste and have a long history of safe use as acidifier. They are authorised in the Codex Standard on Infant formula and in EU legislation in foods for infants and young children.</p>
<p><b>4.10 Carry-over of Food Additives</b>  <del>No food additives shall be present as a result of carry over from raw materials and other ingredients with the exception:</del>  <del>(a) of the food additives listed under Sections 4.1 to 4.4 of this standard within the limits of the maximum levels stipulated in this standard; and</del>  <del>(b) [of the carrier substances mentioned in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children within the limits of the maximum levels stipulated in that List.]</del></p> <p><b>Section 3 of the “principle relating to the Carry-over of Food Additives into Food” as set forth in Codex Alimentarius Volume 1, shall apply.</b></p>	<p><u>Delete</u> the proposed provision and keep the wording found in the current Codex Standard.  <u>Rational:</u> there is no reason not to apply the carry-over principle to these products if their manufacture follows good manufacturing practices.</p>
<p><b>8. LABELLING</b>  <b>(current) 8.1.1</b>        8.1.1 The requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev. 1-1991), Codex Alimentarius Volume 1), the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985 (Rev. 1-1993) and the Guidelines for Use of Nutrition and Health Claims apply to this standard. With specific reference to section 7 of the Codex General Standard for the Labelling of Prepackaged Foods national jurisdictions may further restrict the use of pictorial devices.</p> <p>Nutrition <b>and health</b> Claims shall be permitted for foods for infants and young children where they have been demonstrated in rigorous studies with adequate scientific standards.</p>	<p><u>Add</u> “health”  <u>Rational:</u> It is of the utmost importance that information on the dietary properties of infant formula can be communicated as</p> <ul style="list-style-type: none"> <li>• claims explain the specific nutritional characteristics of these foods and draw the attention of parents and caregivers to the fact that they are suitable for the baby</li> <li>• If health claims on these foods were prohibited, this would encourage a switch to the consumption of regular foods as they can bear claims. However, as regular foods are not nutritionally adapted to the needs of infants and young children such switch could cause health risk to this vulnerable population</li> <li>• Provisions ensuring that claims for foods for special dietary uses are appropriately used, have already been detailed in Section 3.1 of Codex STAN 146-1985.</li> </ul>
<p><b>8.1.2 The name of the food</b>  <del>Any indication required in the labelling should be made in the appropriate language(s) of the country in which the product is sold.</del></p>	<p><u>Delete</u> this section  <u>Rational:</u> this is adequately covered in section 8 of CODEX 146-1985 and in section 8.2 of the General Standard (CODEX STAN 1-1985).</p>
<p><b>8.5 Date marking and storage instructions</b>  <del>8.5.3. Where practicable, storage instructions shall be in close proximity to the date marking.</del></p>	<p><u>Delete</u> this section  <u>Rational:</u> this type of provisions is fully described in the General Standard for the Labelling of and Claims for prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985) and is not needed</p>

	here.
<b>8.6 Information for utilization</b>	
<b>8.6.2.</b> For products covered by 2.1.1, directions on the label shall state “Milk or formula but no water <b>alone</b> shall be used for dilution or mixing” or any equivalent statement.	<u>Add</u> “alone” <u>Rational:</u> water is used in the reconstitution of infant formula, which is one of the nutritious liquids recommended for the dilution of cereals.
<b>8.6.3.</b> <del>[When the product is composed of gluten free ingredients and food additives, the label should show the statement “gluten free”.]</del>	<u>Delete</u> this section <u>Rational:</u> the labelling of the presence of ingredient containing gluten is already obligatory according to section 4.2.1.4 of Codex Standard CODEX STAN 1-1985. The absence of gluten is regulated by Codex Standard for Gluten free foods 118-1981 rev 1983.
<b>8.6.4.</b> The label shall indicate clearly from which age the product is intended for use. <del>This age shall not be less than 6 months for any product.</del> In addition the label shall include a statement indicating that the decision when precisely to begin complementary feeding, including any exception to six months of age, should be made in consultation with a health worker, based on the infant specific growth and development needs. Additional requirements in this respect may be made in accordance with the legislation of the country in which the product is sold.	<u>Delete</u> second sentence. <u>Rational:</u> it is already covered in the scope of this standard. In order to reflect the conclusion of the WHO Expert Consultation on “The optimal duration of exclusive breastfeeding” as referred to in the WHA Resolution 54.2., point 8.6.4 must be re-worded to ensure that the individual needs of all infants and young children are met.

## IWGA – International Wheat Gluten Association

The International Wheat Gluten Association (IWGA) would like to reiterate its request already expressed last years, to delete the requirement for “gluten-free” labelling under section 8.6.3 of the above mentioned draft revised standard.

Section 8.1.1 of the Proposed Draft Revised Standard specifies that the requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 Rev. 1-1991) apply to this standard.

Section 8.6.3 specifies that “*When the product is composed of gluten-free ingredients and food additives, the label should show the statement ‘gluten-free’*”.

Foods which have been specially prepared to meet the dietary needs of persons intolerant to gluten, are regulated through the Codex Standard for “Gluten-Free Foods” (Codex Stan 118-1981, amended 1983). This Standard does not apply to foods which in their normal form do not contain gluten.

The Codex General Standard for the Labelling of Prepackaged Foods as amended, provides for a list of foods and ingredients that are known to cause hypersensitivity and that shall always be declared. With the adoption in 1999 of these requirements, allergenicity and intolerance were adequately addressed by the Codex Alimentarius Commission, in a consistent way, as a horizontal measure.

The requirement for the additional mandatory indication of the absence of gluten, in a standard for a particular food not specially prepared to meet the dietary needs of persons intolerant to gluten as covered by the Codex Standard for “Gluten-Free Foods”, consequently, is redundant.

The International Wheat Gluten Association therefore asks the Codex Committee on Nutrition and Foods for Special Dietary Uses to delete section 8.6.3 on the indication of the absence of gluten.