

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 7

**CX/NFSDU 03/7
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Twenty-fifth Session

Bonn, Germany, 3- 7 November 2003

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

- Comments at Step 3 of the Procedure -

Comments from:

**AUSTRALIA
BRAZIL
SPAIN**

**AAC – ASSOCIATION DES AMIDONNERIES DE CÉRÉALES DE L'UE
ISDI – INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES
IWGA – INTERNATIONAL WHEAT GLUTEN ASSOCIATIONS
WHO – WORLD HEALTH ORGANIZATION**

AUSTRALIA

GENERAL COMMENTS

Australia notes that references to particular Sections or numbered items in the standard are not consistent. For example in Sections 3.3.2 – 3.3.4 reference is made to ‘point’ whereas Section or the numbered item is used elsewhere. It is recommended that consistent language be used in the draft standard. Similarly Australia suggests that references to nutrient density values in the standard be consistently written. For example in some cases values are presented as kcal (kJ) (e.g. Section 3.2) and in other Sections (e.g. Section 3.3) as kJ (kcal).

PRODUCT DEFINITION

We note a minor editorial error in that a semicolon is missing from the end of 2.1.2.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

Australia acknowledges the work of the Compositional Working Group (chaired by Malaysia) but strongly encourages that further work be undertaken to review essential composition.

In regards to Sections 3.6 (minerals) and 3.7 (vitamins), we would like to reiterate our support for a risk-based approach being used in the review process with regard also being given to the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987). Australia’s recent review of the regulation of infant foods permitted restoration of vitamins and minerals found naturally in cereals but mandated the addition of iron to reduce the risk of infant anaemia.

ESSENTIAL COMPOSITION

We suggest that for grammatical reasons the second sentence of this section be slightly amended as follows:

They may also contain legumes (pulses), starchy roots (such as arrowroot, yam or cassava) or starchy stems or oil seeds in smaller proportions.

ENERGY DENSITY

We assume that the correct interpretation of this requirement is on a ‘ready to eat’ basis rather than ‘as sold’. Therefore, we support the previous comments of the European Network of Childbirth Associations (ENCA) and propose to include, for clarity purposes, the following bolded additions to this Section:

*The energy density of cereal-based foods should not be less than 0.8 kcal/g (3.3 kJ/g) **when prepared according to directions for use or in the ready to eat product.***

LIPIDS

For consistency with the terminology being considered for Section 3.1 - Essential Composition of the draft revised standard for infant formula (Annex 1 of CL2003/4-NFSDU), Australia suggests that the title of Section 3.5 is changed from ‘Lipids’ to ‘Fats and Fatty Acids’.

MINERALS

Australia supports the maximum levels for sodium as proposed. It is suggested that values per mg/kJ are also included. In addition, ‘ready to eat’ can be interpreted as either ‘as sold’ or when prepared according to directions. Given that the sodium limits are energy based and other sources of sodium can be added during preparation, we suggest that including ‘in the ready to eat product’ is problematic. ‘Therefore for clarity we suggest the following amendments as indicated:

- 3.6.1 The sodium content of the products described in Sections 2.1.1 to 2.1.4 ~~of this standard~~ shall not exceed 100mg/ 100kcal (**24 mg/100kJ**), ~~in the ready-to-eat product~~, except in the case of products intended for children over one year of age, where the sodium content shall not exceed 200 mg/100 kcal (**48 mg/100 kJ**).

VITAMINS

See comments under 3.

OPTIONAL INGREDIENTS

Australia supports removal of the brackets around 'nine' months.

3.10 CONSISTENCY AND PARTICLE SIZE

- 3.10.1 Australia supports the removal of 'spoon' as it is not relevant to all foods regulated by the standard eg. rusks.

FOOD ADDITIVES

There is an incorrect number for xanthan gum – it should be 415 rather than 425.

LABELLING

- Standard 2.9.2 Foods for Infants from the *Australia New Zealand Food Standards Code* contains a number of labelling requirements that we believe could be included in the Codex Standard. These are:

the labelling of honey as 'sterilised' to reflect Section 3.8.2, which allows use of honey following processing to destroy *Clostridium botulinum*. For example, *where honey is used as an ingredient, the word 'sterilised' must be used in association with the word 'honey'*;

the labelling of a food as 'sweetened' if the food has more than a certain level of added sugar. In Australia and New Zealand this level is 4g/100g for all infant foods. For example, *where the added sugars content of a food exceeds 4g/100g, the word 'sweetened' be included on the label*; and prohibiting labels from recommending that a food can be added to bottle feeds of infant or follow-up formula.

There should be a sub-heading included for Section 8.1.

- 8.1.1 Australia considers that the first option provides flexibility that accommodates the varying circumstances of member countries on this issue. This option satisfies Australian requirements. However if there continues to be lack of consensus on this issue we suggest that only the second sentence of the first option be placed in brackets to ensure that the reference to the Codex General Standard remains.

On the inclusion of an additional sentence related to nutrition and health claims, Australia notes that there was agreement at the 31st session of the Codex Committee on Food Labelling (ALINORM 03/22A, para 66) to advance the proposed Draft Guidelines for Use of Nutrition and Health Claims to Step 8. Section 1.4 of the Guidelines prohibits the use of nutrition and health claims on foods for infants and young children except where provided for in relevant Codex standards or national legislation. Australia supports the use of health and nutrition claims according to a national legislation. Therefore, providing that the aforementioned Draft Guidelines are approved/adopted by the Codex Alimentarius Commission in mid 2003, we support amendment of the bracketed text so

that reference is made to the draft guidelines and more specifically to the provisions permitting use of health and nutrition claims according to national legislation. This Section should be number as 8.1.3.

DECLARATION OF NUTRITIVE VALUE

There is a minor editorial error in this section where 8.3.1 (b) should read 8.4.1(b).

8.6 INFORMATION FOR UTILIZATION

8.6.3 Whilst recognising the Committee's previous decision to require labelling of the presence or absence of gluten (para 83), Australia suggests that this decision should be revisited following the outcome of further discussions on the Draft Standard for Gluten-free Foods (at Step 7) scheduled for the 25th session of CCNFSDU.

Given that the agreed scope of the standard takes into account the individual variation of infants, there appears potential for contradiction between the first and second sentences of this Section. In Australia and New Zealand, Standard 2.9.2 – *Foods for Infants* of the *Australia New Zealand Food Standards Code* prevents labelling that recommends a food as suitable for below four months of age. This requirement recognises that the introduction of complementary foods prior to four months of age presents a higher level of risk to all infants. Additionally it could be argued that age is not the only way to indicate for who the product is intended. For example, labelling that is linked to the developmental milestones of infants e.g. 1st foods, 2nd foods etc. rather than 'age' can also indicate the appropriateness of a food. The last sentence of the Section is considered unnecessary and should be deleted.

BRAZIL

2. DESCRIPTION

Suggestion:

We suggest to substitute in item 2: "at least 25%" for "above of 50%". The text would be read as follow:

"Processed cereal-based foods are prepared primarily from one or more milled cereals, which should constitute ~~at least 25%~~ above of 50% of the final mixture on a dry weight basis."

Justification: *We suggest the substitution to guarantee the nutritional quality of the product (energy and protein density, among other characteristics), and to avoid misunderstanding among consumers regarding the basic composition of the product.*

3.11 SPECIFIC PROHIBITION

- To include the item with the following writing:

"The product and its components shall not have been contain GMOs".

Justification:

1) The British Royal Society, in the report "Genetically modified plants for use and human health-an update" (2002), points out special recommendations in the introduction of genetically modified foods on diet of specific and vulnerable groups such as infants, children, pregnant and lacting women.

2) *The item # 49 of the Ad Hoc Codex Intergovernmental Task Force on Foods derived from Biotechnology document: “Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, reports that:*

“Attention should be paid to particular physiological characteristics and metabolic requirements of specific population groups such as infants, children, pregnant and lactating women, the elderly and those with chronic diseases or compromised immune systems”.

3) *The use safety of genetically modified ingredients in foods destined for infants should be evaluated in order reach a scientific consensus on the subject, reinforcing the necessity to guarantee that these components will not be used in Infant Formula elaboration.*

8. LABELLING

8.6. INFORMATION FOR UTILIZATION

8.6.4

- To keep the expression: “The label shall indicate clearly from which age the product is intended for use. The label shall clearly state that the product is not recommended for use below 6 months.”

- To delete the whole phrase “ In addition (...) is sold”. To eliminate the square brackets of the hole phrase. The text would be read as follows:

[8.6.4 The label shall indicate clearly from which age the product is intended for use. The label shall clearly state that the product is not recommended for use below 6 months. ~~In addition, the label shall include a statement indicating that the decision when precisely to begin complementary feeding, including any exception from that age limit, 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. The labelling should not be in conflict with the provisions of this paragraph.~~

SPAIN

1. SCOPE

In the Spanish version, we propose to replace the term “*tomando*” by “*teniendo*”, as it is more correct.

2.1. PRODUCT DEFINITIONS

We assume that “2.1.5” is a typing error; the section should be numbered “**2.1.4**”. (*Applies to Spanish version only. Translator’s note*)

3.1. ESSENTIAL COMPOSITION

As rice is not a starchy root, but a cereal, the corresponding reference to it should be deleted (Translator's note: Applies to Spanish version only. A mistake has apparently been made due to the similarity between the English word "arrow" in "arrow root" and the Spanish word "arroz", meaning rice.).

3.5. LIPIDS

We support the inclusion of the wording in square brackets and suggest to delete the square brackets.

3.6. MINERALS

3.6.1.

We support the following wording: **“The sodium content of the products described in Sections 2.1.1 to 2.1.4 of this Standard shall not exceed 100mg/100kcal of the ready-to-eat product.”**

3.8. OPTIONAL INGREDIENTS**3.8.1.**

We support the following wording: **“In addition to the ingredients listed under 3.1, other ingredients suitable for infants who are more than six months of age can be used.”**

3.8.3.

We support the following wording: **“Cocoa can be used only in products to be consumed after 12 months of age, and at the maximum level of 1.5% m/m in the ready-to-eat product.”**

It has to be taken into account that from that age onwards a child is no longer considered an infant.

3.10. CONSISTENCY AND PARTICLE SIZE**3.10.1.**

We propose to remove the square brackets and to incorporate “*spoon feeding*” in the text.

4. FOOD ADDITIVES**4.1. Emulsifiers****4.1.1. Lecithin (322)**

We suggest to follow the guidelines put forward by the SCF which establishes a maximum intake of 10 g/kg for this kind of products.

4.1.2. Mono- and diglycerides of fatty acids (471)

The SCF states that in weaning foods for healthy infants and young children a maximum concentration of 5 g/kg is sufficient. Higher amounts are only required for use in combination with other emulsifiers in amino acid and peptide-based nutritionally complete foods for special medical purposes containing lipids.

4.5. Enzymes**4.5.1. Malt carbohydrases**

Due to its function, this enzyme should be listed under a separate heading named “technological additives”, and its use should be restricted to rusks and biscuits.

4.6. Leavening Agents

The name of this heading should be replaced by “raising agents”.

4.9. Packaging Gas (Propellants)

European Parliament and Council Directive 95/2/EC of 20 February 1995 on Food Additives other than Colours and Sweeteners lays down in Article 2(3b): “*foods for infants and young children as referred to in Directive 89/398/EEC, including foods for infants and young children not in good health; these foodstuffs are subject to the provisions of Annex VI*”.

Given the fact that the gases contained in this section are additives listed in Annex I of the Directive 95/2, they may not be used for infant nutrition.

8. LABELLING

8.1.1.

We support the second proposal, which reads: “The label shall have no pictures or text which idealizes or suggests an inappropriate age of introduction of these products.

No nutrition and health claims shall be made regarding the dietary properties of the products covered by the provisions of this standard.”

8.1.2.

We support the proposed text and therefore suggest to delete the square brackets. (*Change applies to the Spanish version only. Translator’s note*)

8.4. Declaration of Nutritive Value

8.4.1.

Paragraph b)

The reference made to section 3.2.2. is not correct and should be replaced by references to sections 3.6. and 3.7. (*Change applies to the Spanish version only. Translator’s note*).

Paragraph c)

The reference to section 8.3.1.b) is not correct as this section does not appear in the document subject to analysis. (*Applies to the Spanish version only. Translator’s note*).

8.4.2.

Same comment as for the preceding paragraph c).

8.6.4.

We support the text contained in square brackets and suggest to delete the square brackets.

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 “*the presence or absence of gluten should be indicated on the label*”.

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. Nevertheless, one could admit that specific rules regarding all substances known to cause hypersensitivity (not only gluten) apply to foods intended to a specific category of population, such as infants and young children. In this context, the AAC encourages the Committee to consider this principle of mandatory indication from a general point of view.

We believe however that the additional mandatory indication of the absence of one specific substance, gluten, in a Standard for a food not specially prepared to meet the dietary needs of persons intolerant to gluten as covered by the Codex Standard for gluten-free foods (Codex stan 118-1981), is not consistent with the risk management

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option of Codex in the context of allergenicity and intolerance. The mandatory indication of the absence of allergens can be further considered from a general perspective if required.

The AAC therefore would be in favour that the section 8.6.3 reads “the presence of gluten should be indicated on the label” and would suggest to complete this section by a scientific substantiation of the reasons why, among all the substances known to cause hypersensitivity, only the presence of gluten has to be thus mentioned for processed cereal-based foods for infants and young children.

ISDI – INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES

ESSENTIAL COMPOSITION

ISDI PROPOSAL	JUSTIFICATION
<p>3.1.1 The four categories listed in 2.1.1 to 2.1.4 are prepared primarily from one or more milled cereal products, such as wheat, rice, barley, oats, rye, maize, millet, sorghum and buckwheat, legumes (pulses), or oilseed. It may also contain legumes (pulses), starchy root, (such as arrow root, yam, or cassava) or starchy stems or oil seeds in smaller proportions.</p>	<p>“primarily” should be removed because there are other very nutritive ingredients such as milk or that can be used in these products</p> <p>Indeed, 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>3.5 Lipids</p> <p>For products mentioned in point 2.1.2 2.1.2 the lipid content shall not exceed 1.1g/100kJ (4.5g/100kcal). If the lipid content exceeds 0.8g/100kJ (3.3g/100kcal):</p> <ul style="list-style-type: none"> - the amount of linoleic acid (in the form of triglycerides=linoleates) shall not be less than 70mg/100kJ (300mg/100kcal) and shall not exceed 285mg/100kJ (1200mg/100kcal) the amount of lauric acid shall not exceed 15% of the total lipid content - the amount of myristic acid shall not exceed 15% of the total lipid contentthe The use of partially hydrogenated fats for these products is prohibited <p>[Product category 2.1.2 2.1.1 and 2.1.4 should have a minimum maximum lipid content of 3.3g/100kcal (0.8g/100kJ).]</p>	<p>2.1 should be 2.1.2 (cereals with an added high protein food) as it is the case in Europe (Directive 96/5/EC).</p> <p>Remove the square brackets.</p> <p>There is no reason to have such a high minimum lipid level. This represents an increase of around 50% more lipid that in present products, although no justification is provided. With the increase in child obesity around the world, it could be desirable in some countries to permit lower lipid content of cereals. Instead ISDI proposes to set a maximum level for category 2.1.1 and 2.1.4 as it is the case in the EU.</p>
3.6 Minerals	

ISDI PROPOSAL	JUSTIFICATION
The sodium content of the products described in Sections 2.1.1 to 2.1.4 of this standard shall not exceed {100mg/100kcal} (25mg/100 kJ) of the ready-to-eat product, except in the case of products intended for children over one year of age, where the sodium content shall not exceed {200mg/100kcal} (50mg/100kJ) .	ISDI agrees with the levels proposed and suggest expressing them also per 100kJ.
3.8 Optional ingredients 3.8.1 In addition to the ingredients listed under 3.1, other ingredients suitable for infants who are more than 6 months of age or as appropriate and for young children can be used. 3.8.3 Cocoa can be used only in products to be consumed after {nine} months of age, and at the maximum level of 1.5% m/m in the ready-to-eat product.	Add “or as appropriate” brings this section more in line with the scope of this standard. Delete the square brackets to retain “nine months” which is in the original standard. There is no reason to increase the age of introduction of cocoa to greater than 9 months.
3.9. Quality factors 3.9.1 All ingredients, including optional ingredients , shall be clean, safe, suitable and of good quality.	“including optional ingredients” should be deleted since the wording “all ingredients” already cover them

IWGA – INTERNATIONAL WHEAT GLUTEN ASSOCIATION

The International Wheat Gluten Association (IWGA) would like to comment to section 8-Labeling of the above mentioned draft revised standard as circulated in Alinorm 03/26A - Appendix III.

Section 8.1.1 of the Proposed Draft Revised Standard specifies that the requirements of the Codex General Standard for the Labeling of Prepackaged Foods (CODEX STAN 1-1985 Rev. 1-1991) apply to this standard. Section 8.6.3 specifies that *“the presence or absence of gluten should be indicated on the label”*.

The Codex General Standard for the Labeling 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 reference under Section 8.6.3 to the mandatory indication of the presence of gluten, therefore, is redundant.

The additional mandatory indication of the absence of substances known to cause hypersensitivity, is not consistent with the risk management option of Codex in the context of allergenicity and intolerance, i.e. the positive labeling of the presence of these substances. In this perspective, the mandatory indication of the absence of one specific substance, 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 justified.

If the Committee decides that the additional mandatory indication of the absence of substances known to cause hypersensitivity in a specific product group is required, it should be considered from a general perspective, and include all substances that can potentially be used in the products. Section 8.6.3. could then be amended as follows:

“In addition to the requirements of the Codex General Standard for the Labeling of Prepackaged

Foods as referred to in Section 8.1.1, the absence of substances known to cause hypersensitivity and that can be used in these products, shall be indicated on the label.”

WHO

1. SCOPE

As with the draft revised standard for infant formula, it is recommended that the scope provision end with a reference to the Global Strategy for Infant and Young Child Feeding and resolution WHA55.25 by which the Global Strategy was formally endorsed. The text (changes in italics) would thus read:

This standard covers processed cereal-based foods intended for feeding infants as a complementary food generally from the age of 6 months onwards, taking into account infants' individual nutritional requirements, 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 World Health Assembly resolution WHA55.25 (2002).*

8. LABELLING

Concerning **paragraph 8.6.4**, it is suggested that the text read as follows (new text in italics):

The label shall indicate clearly from which age the product is intended for use. The label shall clearly state that the product is not recommended for use below six months *of age*. The label shall also 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 *individual infant's* 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. The labelling should not be in conflict with the provisions of this paragraph.