

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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**Agenda Item 7**

**CX/NFSDU 00/7**  
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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

**CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES**  
**Twenty-second Session**  
**Berlin, Germany, 19-23 Juni 2000**

**DRAFT REVISED STANDARD FOR PROCESSED CEREAL-BASED FOODS**  
**FOR INFANTS AND YOUNG CHILDREN**  
**- Comments at Step 3 of the Procedure-**

### **Comments from:**

AUSTRALIA  
BRAZIL  
CUBA  
FRANCE  
GERMANY  
HUNGARY  
INDONESIA  
ITALY  
KOREA, REPUBLIC OF  
MEXICO  
NORWAY  
PARAGUAY  
POLAND  
SENEGAL  
SINGAPORE  
SOUTH AFRICA  
SRI LANKA  
SWITZERLAND  
UNITED KINGDOM

AOECS - ASSOCIATION OF EUROPEAN COELIAC SOCIETIES  
ENCA - EUROPEAN NETWORK OF CHILDBIRTH ASSOCIATIONS  
IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK  
ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES  
WHO - WORLD HEALTH ORGANIZATION

## **AUSTRALIA**

### **Section 1 Scope**

Australia believes that prescribed age range in the Codex draft standard should be consistent with the prevailing World Health Organization (WHO) recommendation. The current recommendation, for exclusive breast feeding from birth to 4 to 6 months of age, was made in 1995 (Weekly Epidemiological Record No 17, 1995), a year later than the World Health Assembly Resolution adopted in 1994. This is also consistent with Australian federal government policy.

Australia notes that at the previous Session of CCNFSDU, the WHO representative indicated “there was no change in the current WHO position concerning the introduction of complementary feeding between four and six months”.

The square brackets therefore should be deleted and the text “4 to 6 months” adopted. The consequential amendments pertaining to this age group elsewhere in the draft Standard should therefore be retained.

### **Section 2 Description**

Australia accepts the rationale to support the inclusion of starchy roots and stems, but recognises that such ingredients are likely to be nutritionally inferior to cereal or legume sources. This issue could be resolved by conditionally retaining starchy roots and stems, but prescribing appropriate protein content and quality criteria for foods made from these ingredients.

### **Section 3.2 Energy density**

The unit reference for the minimum energy density is incorrectly given as 100grams and should be corrected to a unit gram. The criterion should read 3.3 kJ/g (0.8 kcal/g). Note that the order of kilojoules and kilocalories is reversed to be consistent with the remainder of similarly expressed parameters in the draft Standard.

### **Section 3.3 Protein**

The reference protein is not identified. In previous versions of the draft Standard, the text “casein as defined in Annex 1” is inserted immediately after the first mention of reference protein. Annex 1 is currently missing. Efficiency is also misspelled.

### **Section 3.4 Carbohydrates**

The last Session’s attempt to correct a previous error for the carbohydrate levels in 3.4.2 has resulted in the added fructose limit exceeding the limit for the group of added carbohydrates. Australia believes that the original error in agenda paper CX/NFSDU 98/6 was that the value of 1.2 g/100kcal should have read 1.2g/100kJ. There is internal consistency in 3.4.2 and between 3.4.1 and 3.4.2 if “the amount of added carbohydrates from these sources shall not exceed” 1.2g/100kJ (5.0 g/100 kcal).

### **Section 3.6 Minerals**

The brackets in section 3.6.1 should be deleted. The proposed sodium content of 100mg/100kcal is safe for infants and 200mg/100kcal for the ready to eat product is safe for products intended for children over one year of age.

It is not clear whether the reference to ‘milk’ in 3.6.3 refers to milk added to products used directly, or after the food has been pulverized with milk.

### **Section 3.7 Vitamins**

The square brackets in section 3.7.1 should be deleted.

### **Section 3.8 Optional ingredients**

In line with Australia's comments under Section 1 Scope, the square brackets in 3.8.1 should be deleted.

The text in 3.8.2 should refer to the honey and maple syrup ingredients rather than the final food product and be expressed in terms of outcome, rather than process. This could be achieved by "Honey and maple syrup used as ingredients should be free of *Clostridium botulinum* spores, after appropriate processing where necessary".

### **Section 3.10 Consistency and particle size:**

The aim of provision 3.10.1 is to ensure that the semi-solid or solid food's texture is suitable for infant feeding. 'Spoon' was introduced to clarify that feeding of these foods via the bottle was not appropriate. 'Spoon' can be applied to all product categories except rusks and biscuits intended for direct consumption. Moreover, texture appropriate to spoon feeding does not preclude 'lumpy' foods that may be hazardous to infants.

Australia suggests that 'spoon' in the square brackets be deleted and 'feeding] of' be followed by 'of semi-solids and solids to'

### **Section 8.3 Declaration of nutritive value**

In section 8.3.1(a) the word "calories" should be replaced by "kilocalories".

The last part of section 8.3.1(b) should be consistent with 8.3.1(a) and (c) and modified to read: "... added according to section 3.7 shall be declared per 100g of the food as sold, and where appropriate, per specified quantity of the food as suggested for consumption."

### **Section 8.4 Date marking and storage conditions**

Section 8.4.1 can be deleted and substituted by a cross reference to section 7.2 of the Codex General Labelling standard (1-1985).

### **Section 8.5 Information for use**

Australia recommends that section 8.5.2 should be written as "... but not water alone shall be ....", instead of "... but no water shall ....".

The square brackets in section 8.5.3 can be deleted.

The square brackets in section 8.5.4 can be deleted. This provision is in line with the WHO recommendation and should be adopted given that the manufacturer can choose the wording of the statement. Australia queries the need for products intended for use by infants and young children older than 6 months to carry the label statement of unsuitability below 4-6 months.

### **Section 8.6 Additional requirements**

Australia believes that the square brackets should be deleted. The products covered by this standard are weaning foods and are not breast-milk substitutes. In this context, it is useful to recall the definition given in the International Code of Marketing of Breast-milk Substitutes for complementary food: "Complementary food" means any food, whether manufactured or locally prepared, suitable as a complement to breast milk or to infant formula, when either becomes insufficient to satisfy the nutritional requirements of the infant. Such food is commonly called "weaning food" or "breast-milk supplement". This definition corresponds exactly with the Scope of the standard. For this reason processed cereal-based foods for infants and young children are weaning foods (or complementary foods) and not breast-milk substitutes and should not be presented as such.

## BRAZIL

### 1 SCOPE

We support the deletion of the square brackets and adoption of the wording from four to six months.

### 2 DESCRIPTION

Delete: “and/or starch root and stem products” and change 25% to 75%.

Justification: To allow starchy roots and stem products as the basis of cereal-based complementary food can potentially lower the nutritional density, protein and micronutrients. It could contribute to insufficient nutrient density.

If a complementary food is named cereal-based it should have 75% of cereal content.

### 3.1 ESSENCIAL COMPOSITION

#### 3.1.1. Delete: “and/or starchy roots (such as arrowroot, yam or cassava) or starchy stems” and “soybean”.

Justification: Should be deleted because of their low nutritional content. The addition of starchy roots will have a negative impact on the nutritional density and quality of cereal products. Soybean is already included in pulses.

Reword to read: “cereal based foods are prepared primarily from one or more milled cereal products such as wheat, rice, barley, oats, rye, maize, millet, sorghum and buckwheat and/or legumes (pulses) and sesame.

### 3.3 PROTEIN

#### 3.3.1. Delete: “In all cases, the addition of amino acids is permitted only for the purpose of improving the nutritional value of the protein mixture, and only in the necessary proportions for that purpose. Only natural forms of L-amino acids should be used.”

Add: “the minimum content of the product protein shall be not less than 10% on a dry weight basis”.

Justification: The addition of amino acids to this type of products is unnecessary.

The ingredients used in the production of the products should have an adequate protein quality.

ITEMS: 3.3.2; 3.3.3; 3.3.4; 3.4.1; 3.4.2; 3.5.1; 3.6.2; 3.6.3.

g/100 kJ (g/100Kcal) should be rewritten as g/100 Kcal (g/100KJ) in line with placement in 3.2 energy definition and in other Codex pipers.

### 3.8 OPTIONAL INGREDIENTS

We suggest removing the square brackets, for the same reason already mentioned under “scope”.

#### 3.8.3 Change “after 9 months” for “after 12 months”.

Justification: Cocoa can cause allergic reactions and should be introduced as late as possible.

### 3.10 CONSISTENCY AND PARTICLE SIZE

#### 3.10.1. Delete: brackets.

Justification: A complement to breast milk or infant formulas should be spoon-fed.

#### 4.4. FLAVOURS

Delete: reference to flavors (4.4.1 – 4.4.3)

Justification: Added flavors shall not be allowed in a standard for infants; these substances can cause them allergic reaction.

#### 8.5.3. INFORMATION FOR UTILIZATION

Delete: the sentence “if the intended age of use is below six months”

Justification: Considering that the individual sensible to the gluten is it during all the life phases and that the gluten presence should necessarily be declared in the label, as the Brazilian legislation explicit, it is recommended the removal of the sentence.

8.5.4. Removal of all brackets and incorporation of the text to the norm.

8.6. Removal of all brackets.

## CUBA

We accept the wording of the Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children at Step 3 of the Procedure concerning the introduction of complementary feeding "from the age of 4 to 6 months onwards" because this takes account of variations in the individual development of infants. Fixing the minimum age at six months would not allow for the flexibility required to adapt the diet to each infants' individual needs.

We further propose to retain the wording "starchy roots or stem products" in connection with the composition of cereal-based foods, so that each region may make use of the raw materials at its disposal.

## FRANCE

### 1- Section 1 Scope

Scientific evidence clearly demonstrates that psychomotility, digestion and metabolism are from the age of four to six months of life so well developed as to allow for the introduction of complementary feeding.

Moreover, this recommendation for introducing complementary feeding from the age of four and six months onwards is in agreement with current WHO recommendations on this topic.

For these reasons, the French delegation suggests to retain the reference to "4 to 6 months" under Scope and to remove the square brackets.

### 2 – Section 3.7.1 Vitamin B1

We suggest to set the amount at 25µg/100kJ (100µg/100kcal).

### 3 – Section 3.8.1

The square brackets should be deleted and the enclosed text retained.

#### **4 – Section 3.10.1**

The reference to spoon feeding should be deleted because these preparations are in many countries, including France, bottle-fed to children well beyond the age of six months.

#### **5 – Section 8.5.3 Gluten**

The square brackets should be deleted.

#### **6 – Section 8.5.4**

The square brackets should be deleted.

#### **7 - Section 8.6**

The square brackets should be deleted.

## **GERMANY**

### **ad 1: Scope**

Germany cannot agree to the proposal of specifying the age as of which these products can be used by indicating "*approximately six months*".

During the session of the Codex Alimentarius Commission 1999 the representatives of the WHO already made clear that the statement "*from the age of 4 to 6 months onwards*" complied with the basic recommendation of the WHO. There are both reasons of nutritional and developmental physiology for specifying the age to begin with processed foods.

We suggest to delete the square brackets around "*4 to 6 months*".

To make it clear that the beginning of the 5<sup>th</sup> month of life is the earliest recommended age for starting with processed food, it could also read: "*from the age of 4 to 6 **completed** months*".

To clarify that both breast milk and infant formula alone can be insufficient as of this age, the second part of the sentence should be reworded to read "*when ... breastfeeding or infant formula alone are no longer sufficient to satisfy nutritional requirements ...*".

### **ad 2: Description and 3.1.1 Essential Composition**

We can understand the objections of some member states towards "*starchy root or stem products*" only with regard to naming the products (cereal), not with regard to the nutritive valence. In this context, it should be made clear whether

- a) the title of the standards has to be adjusted according to the envisaged extension to "*starchy root or stem products*" or
- b) the restriction to the "*cereal-based foods*" has to be maintained with the appropriate consequences.

Irrespective of the fact which ingredients are used, the standard prescribes requirements as to the protein content and quality, carbohydrates, fat content and content of certain mineral salts and vitamins for all products. It does not at all prohibit the addition of other substances than the aforesaid mineral salts and vitamins for reasons of nutritional physiology.

**ad 3: Composition**

- ad 3.2:** Energy density: instead of *0.8 kcal/100 g (3.3 kJ/100 g)* it has to read **0.8 kcal/g (3.5 kJ/g)**.
- ad 3.3.1:** In this section the name of the **reference protein** is **missing**. In the version of ALINORM 99/26 Annex IV, casein was indicated as reference protein; however, **Annex 1** concerning the pattern of amino acids of casein **was missing**. We assume that this is a mistake, particularly as pursuant to section 62 of ALINORM 99/26 it has been intended to maintain casein as reference protein and to include it in Annex 1. We agree to that.
- We suggest to replace "*chemical index*" by "**amino acid score**".
- ad 3.4.2:** Instead of "*0.48 g/100 kJ (2.0 g/100 kcal)*" it should read "**1.2 g/100 kJ (5.0 g/100 kcal)**" according to EU Directive 96/5.
- ad 3.6.1:** We do not see any necessity to permit a sodium content of 200 mg/100 kcal in cereal-based products intended for children over one year of age. This would correspond to an amount of sodium chloride (NaCl) of 0.5 g/100 kcal and would no longer be different from the amount of sodium chloride in normal foods.
- We suggest to delete the square brackets** around 24 mg/100 kJ (100 mg/100 kcal) and also the second part of the sentence beginning with "*except in the case of ...*".
- ad 3.8.1:** We suggest to delete the **square brackets** around "*four to six months of age*".
- ad 3.10.1:** We suggest to **delete** the **square brackets** around "spoon feeding".
- ad 4:** **Additives for technological purposes**
- ad 4.4:** It should be suggested to only admit *natural* and *nature-identical flavours*.
- ad 5.1:** Based on an EU Regulation we suggest the following text: "*The product shall be prepared with special care ... so that residues of those pesticides which may be required ... do not remain, or if technically unavoidable, do not exceed a maximum level of 0.01 mg/kg each in the ready-to-eat product*".
- ad 6.1:** We suggest to replace "*recommended*" by "*shall*".
- ad 6.2:** We suggest to replace "*should*" by "*shall*".
- ad 8.4.3:** This item can be **deleted**, it has been regulated in the Codex Standard 1-1985.
- ad 8.5.2:** We suggest to change the sentence into "*... but not water alone shall be used for...*".
- ad 8.5.3:** **We suggest to remove the square brackets** (and also to delete the word "in" subsequent to "on").
- ad 8.5.4:** **We suggest to remove the square brackets**. The second sentence should be changed into: "*The label shall clearly state that the product is not to be used below the age of 4 months*".
- In the 3<sup>rd</sup> sentence the word "*precisely*" should be deleted. It is impossible to precisely indicate the beginning of complementary feeding.
- ad 8.6:** Both **square brackets** have to be **removed**.

## HUNGARY

First of all let us allow to give you some information on the legislation in Hungary concerning this subject.

In 1998 the Committee on Codex Alimentarius Hungaricus accepted the regulation N<sup>o</sup> 1-3-96/5 on „Processed cereal base foods and baby foods for infants and young children”. This is equivalent in technical content to Commission Directive 95/5 EC.

As concerns the questions:

- ad 3.4.2. The value 0,48 g/100 kJ (2.0 g/100 kcal) seems to be a mistake. These values aren't conform with the maximum quantity of fructose in the following point. The mentioned values in the Directive 95/5 EC are 1,2 g/100 kJ (5 g/100 kcal).
- ad 3.6.1. We agree with the limit for sodium content at a level of 100 mg/100 kcal, and we do not think that an other value "200 mg/100 kcal" is needed for children over one year of age.
- ad 3.7.1. This statement is acceptable, brackets should be deleted.
- ad 3.8.4. Gluten containing cereals or materials can be used only in products to be consumed after six month of age.
- ad 3.10.1. The words "spoon feeding" may be used and even may be omitted.
- ad 8.3.1. (b) There is no Section 3.22. in this draft.
- ad 8.5.3. Our proposal is as follows: The products intended for use below six month should not contain gluten.  
The presence or absence of gluten should be indicated in the label of foods for infants.
- ad 8.5.4. We think that the first sentence of this para is very important. We propose the next sentences as follows:  
The label shall indicate clearly from which age the product is intended for use. The label may clearly state that the product is not recommended for use below 4 to 6 months. In addition, the label may include a statement indicating that the decision when precisely to begin complementary feeding 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.
- ad 8.6. It is proposed to use this statement obligatory as follows:  
The products covered by this standard are not breast-milk substitutes and shall not be presented as such.

## INDONESIA

### 1. SCOPE

“This standard covers processed cereal-based foods intended for feeding infants as a complement to breast milk or infant formula when, from the age of (4 to 6 months) onwards, breast feeding alone or infant formula is no longer sufficient to satisfy nutritional requirements and for feeding young children as part of their progressively diversified diet.”



**Comments :**

In accordance with the recommendation of the World Health Organisation (weekly Epidemiological Record No. 17, page 119-120, 20<sup>th</sup> April 1995; see annex 3) is for exclusive breast feeding from birth to 4 to 6 months of age and after this initial period of exclusive breast feeding, children should continue to be breast fed while receiving nutritionally adequate and safe complementary feeding too early or too late is both undesirable (emphasis by WHO). This recommendation is posterior to WHO resolution, which is adopted in 1994 (annex 4). It must therefore be concluded that this is the preferred wording.

At the CCNSFDU session in Berlin the representative of WHO indicated that “ there was no change in the current WHO position concerning the introduction of complementary feeding between four and six months, as current scientific evidence did not support an amendment at this stage; the range was an essential element as it reflected the need to take the diversity of needs of the individual infant into account. The representative informed the Committee that a comprehensive study, to be concluded in 2002, had been initiated to revise the current International Growth reference Standards, on the basis of data collected in several regions on scientific basis for considering this issue in the future.” (ALINORM 99/26 para 53).

We propose to delete the square brackets above, so the sentence of the SCOPE become :

**“This standard covers processed cereal-based foods intended for feeding infants as a complement to breast milk or infant formula when, from the age of 4 to 6 months onwards, breast feeding alone or infant formula is no longer sufficient to satisfy nutritional requirements and for feeding young children as part of their progressively diversified diet”.**

**3.4 CARBOHYDRATES**

**3.4.2** If sucrose, fructose, glucose, glucose syrup or honey are added to products mentioned in point 2.12 :

- the amount of added carbohydrates from these sources shall not exceed 0.48g/100k J(2.0g/kcal)

**Comments:**

there are any mistakes in the typing, see at the report of the meeting of Codex Committee on NFSDU ALINORM 99/26 para 63 , should be :

**3.4.2** If sucrose, fructose, glucose, glucose syrup or honey are added to products mentioned in point 2.12 :

- **the amount of added carbohydrates from these sources shall not exceed 2 g/100 kJ (8.4 g/kcal)**

**3.6 MINERALS**

**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 (100 mg/100kcal) 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).

**Comment**

We propose to delete the square brackets because the sodium content of 100 mg/kcal is safe for infants and the 200 mg/kcal of the ready -to- eat product is safe for products intended for children over one year of age. Point 3.6.1 become :

**3.6.1 The sodium content of the products described in Section 2.1.1 to 2.1.4 of this standard shall not exceed 100 mg/100 kcal 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 200 mg/kcal.**

### **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.

We propose the word **spoon and the bracket** to be deleted because the standard covers also products like pasta, rusk and biscuits, which are not eaten with a spoon. The section becomes as follows :

**3.10.1 When prepared according to the label directions for use, processed cereal-based foods should have a texture appropriate for the feeding of infants or young children of the age for which the product is intended.**

### **8.3 DECLARATION OF NUTRITIVE VALUE**

8.3.1 The declaration of nutrition information shall contain the following information in the following order :

(a) the energy value, expressed in calories(kcal) or kilojoules(kj)

**Comment :**

**8.3.1 The declaration of nutrition information shall contain the following information in the following order :**

**(a) the energy value, expressed in kilocalories(kcal) or kilojoules(kj).**

8.5.4 (The 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 4 to 6 months. In addition, the label shall include a statement indicating that the decision when precisely to begin complementary feeding should be made in consultation with a health worker, based on the infant specific growth and development needs. Additional requirements of this respect may be in accordance with the legislation of the country which the product is sold.)

**Comment:**

In accordance with the WHO as in the part 1. SCOPE, we propose to delete the brackets point 8.5.4 become :

**8.5.4 The shall indicate clearly from which age the products is intended for use. The label shall clearly state that the product is not recommended for use below 4 to 6 months. In addition, the label shall include a statement indicating that the decision when precisely to begin complementary feeding should be made in consultation with a health worker, based on infant specific growth and development needs. Additional requirements of this respect may be made in accordance with the legislation of the country which the product is sold.**

### **8.6 ADDITIONAL REQUIREMENTS**

The products covered by this standard are (not) breast-milk substitutes and shall not be presented as such.

**Comment:**

In accordance with the scope of this standard clearly declare that the products covered by this standard are not breast-milk substitutes. Because of that we propose to delete the brackets, the sentence become :

**The products covered by this standard are not breast-milk substitutes and shall not be presented as such.**

**ITALY**

Further to the request of comments on the above mentioned draft revised standard (CL 1999/20-NFSDU), as far as the age of introduction of cereal-based foods is concerned, on our opinion *the official WHO recommendation should be followed.*

During the last Codex Commission held in Rome in June-July 1999 the WHO representatives reminded that "the current WHO recommendation was that complementary feeding should start at between four and six months of age for most infants. *Therefore, the references to the age range of four to six months in the proposed Draft revised Standard for processed Cereal-Based Foods for Infants and Young Children (Alinorm 99/26, appendix IV) were consistent with the current WHO recommendation*".

Therefore Italy supports the deletion of the square brackets and the adoption of the wording "from four to six months" in the scope of the Standard (and consequently square brackets should also be deleted at point 3.8.1 and 8.5.4).

**KOREA, REPUBLIC OF****1. SCOPE**

We are now in the position to support in introduction of age "**from the age of 4 to 6 months**" for the cereal-based foods for infants and young children.

**3. ESSENTIAL COMPOSITION AND QUALITY FACTORS****3.1 ESSENTIAL COMPOSITION**

3.1.1 where in the sentence "starchy roots (such as arrow...)" to be read as "starchy roots (such as **potato**, arrow...)

**3.2 ENERGY DENSITY**

"0.8 kcal/100g(3.3g/kJ/100g)" should be read as "**0.8 kcal/g(3.3kJ/g)**"

**3.4 CARBOHYDRATES**

3.4.1 All kinds of mono and di-saccharides should be included, sugars such as lactose and maltose should be classified same in this category, and the term "added carbohydrates" be referred to be "**added sugars**" or "**added saccharides**" instead.

3.4.2 Instead of “2.0g/100kcal” for added carbohydrates should be corrected to **“5.0g/100kcal”** in accordance with the rule applied in 3.4.1.

### 3.8 OPTIONAL INGREDIENTS

Change “after 9 months” to **“after one year of age”**

3.8.3 Cocoa can be used only in products to be consumed **after one year of age**, and at the maximum....

### OTHER COMMENTS

- When the age of introduction for cereal-based foods from 4 to 6 months is to be fixed, the starting month of feeding from 6 month for the follow-up formula should be adjusted to match the criterion for cereal-based foods since in the standard there is defining follow-up formula be fed as liquid part of weaning foods.
- In using terms in this revision, “point x.x.x”, “section x.x.x”, and singly “x.x.x” are confusedly used. That should be unified in one form.

## MEXICO

In Section 1, "Scope", it reads "...a partir de los cuatro o seis meses de edad..." (from the age of four or six months onwards). As we are dealing here not with an option but with an age span, we propose replacing this with "...cuatro a seis meses de edad..." (from the age of four to six months). (Applies to Spanish version only, the Translator)

In Section 2 we propose deleting "legumes (pulses)" and placing this in the "Optional Ingredients" section. Keeping "legumes (pulses)" in Section 2 would give the impression that these items are an essential ingredient in this type of food.

We accept that starchy roots or stem products should be included under these rules.

We accept the proposal for setting the age of introduction of these foods as "four to six months".

In Sections 2.1.1 and 2.1.2 we propose replacing the word "reconstituido" (reconstituted) with "preparado" (prepared).

In Section 3.1.1 the word "arroz" (rice) following "raíces amiláceas" (starchy roots) should be deleted, because rice is a grain and not a starchy root. (Translator's note: A mistake was apparently made due to the similarity between the English word "arrow" in "arrow root" and the Spanish word "arroz", meaning rice.) We further propose including items such as potatoes, yucca, sweet potatoes (batata), salsify and tapioca.

In Section 3.1.2 the word "nutrientes" should be replaced by "nutrimentos". (Applies to Spanish version only, the Translator)

In Section 3.4 "carbohidratos" should be replaced by "hidratos de carbono". (Applies to Spanish version only, the Translator)

In Section 3.7.2 vitamin A should be expressed in "µg equivalentes de retinol". (Applies to Spanish version only, the Translator). Following vitamin D the unit of expression should be given in brackets "(µg cholecalciferol)", for it is in this form that the physiological effect of this vitamin is measured.

In Section 3.8.1 we propose replacing the words "suitable for" with "that are not harmful to".

In Section 3.8.3 we propose replacing the word "cacao" with "cocoa (Applies to Spanish version only, the Translator). We further propose permitting the use of cocoa only in products to be consumed after twelve months of age, and not after nine months of age.

In Section 3.8.2 the words "if present" should be deleted.

In Section 4.2.1 and 4.2.2 we propose replacing the words "Hidrogen-carbonato de sodio" with "carbonato de sodio-hidrogenado" and using "Hidrogen-carbonato de potasio" instead of "carbonato de potasio hidrogenado". (Applies to Spanish version only, the Translator)

In Section 4.3.1 "Concentrado de varios tocoferoles" should be replaced with "Mezcla de tocoferoles". (Applies to Spanish version only, the Translator)

In Section 4.3.4 "...expresados en..." should be replaced with "...expresados como...". (Applies to Spanish version only, the Translator)

In Section 4.4 we propose using the heading "saborizantes y aromatizantes" (flavours and aromas).

In Section 4.4.2 "100g" should be deleted and, in conformity with the maximum permitted amount given in the English version, "con respecto al consumo" should be replaced with "sobre la base de consumo" (on an as consumed basis).

In Section 4.6 we propose replacing "levaduras" (yeasts) with "leudantes" (leavening agents), as this is the generic term for this type of additive. (Applies to Spanish version only, the Translator)

In Section 4.6.2 "Hidrogencarbonato de amonio" should be replaced with "Carbonato de amonio hidrogenado". (Applies to Spanish version only, the Translator)

In Section 7.1 the term "calidades" should be replaced with "propiedades". (Applies to Spanish version only, the Translator)

In Section 8.5.4 we propose rewriting the passage "that the product is not recommended for use below 4 to 6 months" to read " ... that the product is not recommended for use below 4 months". We propose this change because confusion could result through the indication of two minimum ages and the final decision must be made by a paediatrician.

We propose adding a Section 8.6.1 as follows: "The label shall not bear images of infants or young children and shall not contain any wording that idealizes the use of this product or suggests an improper age at which feeding of the product may begin. Labels on products from which edible substances of smooth consistency are prepared shall indicate that this substance is to be spoon-fed."

In Section 8, "Labelling", a provision should be added stating that the label on products containing bee's honey must include a statement indicating that this product may only be fed to young children over twelve months.

In the "Information for Utilization" section, paragraph four, line two, we propose the following text: "No se recomienda la utilización del producto antes de cuatro a seis meses de edad". (The product is not recommended for use below four to six months.)

## NORWAY

### *General comments on addition of vitamins and minerals*

Norway will emphasize that traditions and practices with regard to the feeding of infants and young children vary considerably from country to country. The nutrient requirements which are appropriate will depend on the infants dietary practices in the country concerned. Therefore it is not appropriate to lay down requirements

regarding the specific contents of certain nutrients in such a standard. Norway considers that the addition of essential nutrients, as stated in the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987) should be the responsibility of national authorities, depending upon the particular nutritional problems to be corrected, the characteristics of the target populations and the food consumption patterns of the area.

Norwegian scientists have estimated the influence of the maximum limits given in the Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children on the nutrient intake of Norwegian infants. A dietary survey has recently been conducted at the Institute for Nutrition Research at the University in Oslo involving a group of approximately 300 infants. Using the data from food intakes and the maximum limits suggested in the Proposed Draft Revised Standard for Processed Cereal-based Foods for Infants and Young Children, the maximum intake of some nutrients has been examined and evaluated.

A considerable proportion of Norwegian infants have a high intake of processed cereals. Given a maximum addition of protein, vitamin D and vitamin A, the intake of these nutrients will be excessive and even potentially harmful (1). Preliminary results from a nation wide dietary survey among 6 months old infants (n = 2383) support the data on intake levels of processed cereal based food presented in that study.

#### *Vitamin A*

In Norway infants are traditionally given cod-liver oil or multi-vitamin supplements to ensure sufficient intake of vitamin D. A daily doses of cod-liver oil contains approximately 1080 µg retinolekv. Infants with a high cereal intake (95 percentile) could reach an intake of retinol of more than 2600 µg per day (1). Such an intake is three times higher than the level specified by EU's Scientific Committee for Food (1993) for a potentially harmful intake of retinol. For infants from 6 to 11 months old and young children from 1 to 3 years old, potentially harmful intake levels are 900 and 1800 µg per day respectively. Even without vitamin supplements, the intake in the examples (1550-2200 µg per day) is twice the maximum limit specified and commensurate with the upper limit for prophylactic intake in the literature (1800-3000 µg retinol per day).

*Conclusion:* Addition of vitamin A in processed cereal-based foods for infants and young children should not be mandatory.

#### *Vitamin D*

The greatest concern involves the maximum limits for vitamin D. The intake of vitamin D in Norwegian infants with a high intake of baby cereals (that is the 95 percentile for intake) can be calculated to be as high as 40 µg per day including vitamin D intake from cod-liver oil and vitamin supplements. Even without vitamin supplements, the intake can be as high as 30 µg per day (1).

The literature shows that there is an enhanced risk of vitamin D toxicity in infants at an intake of 25 µg per day. High doses of vitamin D are toxic and can lead to infantile hypercalcaemia with a risk of calcium deposits in the kidney (renal calcinosis) and vascular system, as well as skeletal changes. Other organs may also be affected. Just as there are a great variations in responses to vitamin D, there appear to be significant individual variations in susceptibility to the development of hypercalcaemia following the intake of vitamin D. Accordingly, it is not possible to determine an absolute lower limit for toxicity.

A standard for foods for infants and young children should not allow a vitamin D content in products that could lead to a large group of infants having an intake which is associated with risk of vitamin D toxicity.

*Conclusion:* Addition of vitamin D in processed cereal-based foods for infants and young children should not be mandatory.

*This conclusion implies the following changes in the Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children*

3.7.1 *Delete the paragraph* (the addition of vitamins should not be mandatory).

3.7.2 *Delete the paragraph* (the addition of vitamins should not be mandatory).

Change the wording in 3.7.3 to

**3.7.3 The addition of vitamins and minerals shall be in conformity with the legislation of the country in which the product is sold.**

***or***

keep the text in 3.7.1 and 3.7.2, and change the wording in 3.7.3 to

**3.7.3 The addition of vitamins and minerals is not mandatory, but if added, the addition shall be in conformity with the legislation of the country in which the product is sold.**

#### *General comments on protein*

The kidneys' ability to concentrate urine is not fully developed during early infancy. Accordingly infants' protein intake should not exceed 10% of the total energy intake prior to the age of 6 months. It is recommended that infants of 6 to 12 months of age get 7 to 10 % of their energy from protein (0,4 to 0,6 g per 100 kJ) while children from 1 to 3 years old should get 10 to 15% of their energy from protein (0,6 to 0,9 g per 100 kJ). Using the intake data from the study mentioned above, the maximum limit for protein will result in as many as 50% of Norwegian infants of 9 months of age receiving more than 15% of their energy from protein (1). The recommended protein intake in this age-group is 7-10% of the energy.

A high protein intake has been associated with an increased risk of kidney haemorrhage, the development of Type 1 (juvenile) diabetes and overweight in children, increased loss of calcium, and elevated levels of homocystein. In a French study, an intake of more than 18% was associated with an increased risk of overweight in children.

Intakes of more than 15% (> 0,9 g per 100 kJ) of the energy from protein puts a heavy burden on the kidneys and may also have other harmful effects.

*Conclusion:* The maximum limit for protein should not exceed 15% of the energy (0,9 g per 100 kJ).

*This conclusion implies the following changes in the Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children*

3.3.1 Delete the last two sentences in this section. The addition of amino acids to this type of products is unnecessary. The ingredients used in production of the products should have an adequate protein quality.

3.3.2 For the products mentioned in Sections 2.1.2 and 2.1.4, the protein content shall not exceed 0.9 g/100 kJ (3.75g/100 kcal).

#### *Other comments on the Proposed Draft Revised Standard for Processed Cereal-based Foods for Infants and Young Children*

1. Delete the content in the square brackets and replace with the age of about 6 month.

3.6.1 The sodium content of the products described in Sections 2.1.1 to 2.1.4 in this Standard shall not exceed 24 mg/100 kJ (100 mg/100 kcal) of the ready-to-eat product. (Norway suggests the deletion of the rest of the sentence).

**3.8.3** Cocoa can be used only in products to be consumed after 2 years of age, and at the maximum level of 1.5% m/m in the ready-to-eat product. (because cocoa inhibit the absorption of iron).

#### **Reference**

Commission Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children - Nutritional consequences in Norway. National Nutrition Council of Norway 1998.

## PARAGUAY

Paraguay is in favour of fixing the age of about 6 (six) months as the minimum age for the complementary feeding of infants with cereal-based foods in order to protect the interests of infants and young children in developing countries. Otherwise we accept the Standards as presented.

## POLAND

**p.3.1.1** We propose to consider use of sesame seeds because it may contain the saponins (a possible reason of haemolysis). The maize and soybean can be genetically modified, so use of them should be also considered.

**p.4.1.1 and 4.1.2** We propose to add “singly or in combination”.

**p.4.1.2** The full name should be mono- and diglycerides of fatty acids.

**p.4.3.1** Mixed tocopherols concentrate should be no more than 100 mg/kg of product for human consumption.

**p.4.3.3** Contain of L-Ascorbyl palmitate should be no more than 10 mg/l of product for human consumption.

**p.4.4.2** Polish food legislation doesn't permit synthetic ethyl vanillin in products for infants and children up to 3 yrs. Ethyl vanillin haven't the full toxicological evaluation and its ADI is 0-5 mg/kg weight body/day.

This document contains general information about chemical contaminations. Product for infants and children up to 3 years, also raw materials should to meet requirements of health quality. According to our food legislation, we propose to add a list of the maximum limits of heavy metals:

Pb – 0,10 mg/kg

Cd – 0,01 mg/kg

Hg – 0,01 mg/kg

As – 0,10 mg/kg

Sn – 10,0 mg/kg

Zn – 50,0 mg/kg

Cu – 20,0 mg/kg.

## SENEGAL

1. With reference firstly to the designation cereal-based foods and secondly to the existence of dietary models, such as cereal-based models typical of certain geographic regions, where cereals represent 60 to 70% of total energy intake, while in other regions nutritional models prevail where the same share is covered by roots and tubers, we request that the reference to starchy root products be deleted in Sections 2 ("DESCRIPTION") and 3.1 ("and/or starchy roots ..... cassava") of this Standard, which in our opinion relates specifically to cereals.



In countries where cereals are a major source of energy, roots and tubers are classed and used as vegetables and are thus not considered a basic foodstuff.

2. As concerns section 3.10.1, we propose adopting the following wording: "(When prepared according to the label directions for use, processed cereal-based foods should have a homogenous texture appropriate for the spoon feeding of infants ..... for which the product is intended."
3. As concerns section 5.1, we propose, in the interest of greater clarity, adopting the following wording: "The product shall be prepared with special care under good manufacturing practices (GMP), so that ready-to-use finished products strictly conform to the limits set by the Codex Commission for pesticide residues."
4. As concerns section 6.1, the beginning of the last line should read "Textes pertinents du Codex" and not "Textes du Codex pertinents". (Translator's note: This correction applies only to the French version of the text).

## **SINGAPORE**

Singapore supports WHO's recommendation on the introduction of cereal-based foods to infants from 4 to 6 months.

## **SOUTH AFRICA**

South Africa supports the current WHO recommendation of "four to six months". The set recommendation of about six months is difficult to quantify in scientific studies. An age of four, five or six months is, on the contrary definitely quantifiable.

## **SRI LANKA**

3.1.1 – Sri Lanka does not agree to the use of "Starchy Roots" (such as arrow, yam or cassava).

"Arachis" which was in the previous standard should be included in the new standard too.

### **3.5 LIPIDS**

The upper lipid content appears to be a little too high. If products with this upper limit are manufactured, it can lead to obesity.

### **4. FOOD ADDITIVES**

Value against each additive is presumed to be the recommended maximum. This may be stated in the standard.

### **5. CONTAMINANTS**

Under this section it may be desirable to mention about the absence of mycotoxin (aflatoxin) and if data is available to fix a limit as the products are based on the use of cereal and pulses.

## EDITORIAL CORRECTION

Section 8.3.1 (b) should read as

" In addition to any other nutritional information required by national legislation, the total quantity in the final product of each vitamin and mineral added according to section 3.7.4....." and not section 3.2.2.

In section (c) in the last sentence the words "after sold and were" should be corrected read " after sold and where"

## SWITZERLAND

### 1. Scope

There was controversy during the 23<sup>rd</sup> Session of the Codex Alimentarius Commission last year regarding the scope of the draft revised standard for processed cereal-based foods for infants and young children. As reported by the records, Switzerland was in favour of the proposal to define the scope of the standard as covering “processed cereal-based foods intended for feeding infants as a complement to breast milk or infant formula, when from the age of 4 to 6 months onwards, breast feeding alone or infant formula is no longer sufficient to satisfy nutritional requirements and for feeding young children as part of their progressively diversified diet”. We would also like to refer to the statement of the WHO representative who confirmed the age of introduction as being 4 to 6 months. **We therefore strongly endorse the given proposal and would like to suggest that the square brackets be deleted.**

### 3.4 Carbohydrates

**3.4.2** We would like to highlight what is in our view **a typing error in the first indent of 3.4.2:** it should read “the amount of added carbohydrates from these sources shall not exceed **2 g/100kJ (8.4 g/100kJ)**, instead of 0.48 g/kJ (2.0 g/100kcal) ( See para 63 of the report).

### 3.6 Minerals

**3.6.1** The sodium content of 100mg/100 kcal seems quite safe for infants. We therefore **propose that the square brackets [100 mg/100kcal] be removed.**

### 3.7 Vitamins

**3.7.1** The amount of vitamin B1 (thiamin) shall not be less than [15 µg/100 kJ (60 µg/100 kcal.)] **We would like to endorse this provision and recommend that the square brackets be deleted.** Furthermore, our country wishes to have a discussion on the value of 15 µg/100 kJ as we have reasons to believe that a lower level would be more appropriate. The natural thiamin content in certain cereals is lower than 15 µg/100 kJ which means that in order to reach a level higher than 15 µg/100 kJ, artificial thiamin has to be added to the cereal preparation.

### 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 [four to six months] of age and for young children can be used”.

We would like to refer to our comments under section 1: Scope and **recommend that the square brackets be deleted.**

### 3.10 Consistency and particle size

**3.10.1** In this section, the words “spoon feeding” are in square brackets. **We propose that the square brackets as well as the word “spoon” be deleted.** However, the word feeding should be retained since the standard covers also products which are not necessarily served with a spoon like pasta, rusks and biscuits. The section should therefore read: **When prepared according to the label directions for use, processed cereal-based foods should have a texture appropriate for the feeding of infants or young children of the age for which the product is intended.**

## 8. Labelling

**8.2** We would like to propose a change in the wording by replacing “should” by “shall”. Labelling is essential for consumer information and in this particular case, it is important as it ensures the protection of the target group which is a high risk group. Therefore, the provision should read: Any indication required in the labelling **shall** be made in the appropriate language of the country in which the product is sold.

### 8.3 Declaration of nutritive value

**8.3.1 (a)** The word “calories” should **be replaced by “kilocalories (kcal)”** so that the provision reads: the energy value, expressed in **kilocalories (kcal)** or kilojoules (kJ), ... for consumption;

**8.3.1 (b)** We propose that the last part of this section **be modified to read: ... added according to section 3.7 shall be declared per 100 g and where appropriate as per specified quantity of the food as suggested for consumption.**

### 8.5 Information for utilisation

**8.5.3** The square brackets “[below six months] **should be deleted.**

**8.5.4.** We propose that **the square brackets which apply to this whole section be deleted.**

### 8.6 Additional requirements

This section reads: “The products covered by this standard are [not] breast-milk substitutes and shall [not] be presented as such”. The square brackets were added in 1998. **We recommend that these square brackets be deleted.** The products covered by this standard are weaning foods and are not breast-milk substitutes. We would like to recall the definition given in the International Code of Marketing of Breast-milk Substitutes for complementary food: Complementary food means any food, whether manufactured or locally prepared, suitable as a complement to breast milk or to infant formula, when either becomes insufficient to satisfy the nutritional requirements of the infant. Such food is also commonly called “weaning food” or breast-milk supplement”. In our view, this definition corresponds with the scope of the standard. Therefore, processed cereal-based foods for infants and young children are weaning foods (or complementary foods) and not breast-milk substitutes and we believe that they should not be presented as such.

## UNITED KINGDOM

The UK feel strongly that the age of introduction of supplementary feeding should reflect the WHO recommendations of “4 to 6” months. Inclusion of an age range is essential to reflect the variations in infant growth rates worldwide and any recommendation which would lead to a delay in weaning until 6 months could have consequences for infant development. The UK recommend that the current text is adopted but that the age of introduction of feeding be reviewed in light of the findings of the WHO study of International Growth Reference Standards in 2002. The square brackets should be removed from section 1 and 3.8.1.

The inclusion of starchy roots and stems should remain in the standard and is supported by independent scientific advice from European experts.

### Section 3.2 : Energy Density

The proposed minimum energy density of 0.8 kcal/100 g (3.3 kJ/100g) appears extremely low. The UK consider this figure to be insufficient to provide an adequate minimum energy intake. The range of energy contents observed for UK products is 97-113 kcal/100g.

### Section 3.6.1 : Minerals

The proposed limit for sodium of 100mg/100g should apply to all products without exception. This section should be revised to read: “The sodium content of the products described in Sections 2.1.1 to 2.1.4 of this Standard shall not exceed [100 mg/100 kcal] of the ready-to-eat product.”

### Section 3.7.1 Vitamins

The UK request that the proposed minimum thiamin content of foods be increased to 25 µg/100kJ (100µg/100kcal) in line with existing European Community legislation.

The UK considers the text at sections 8.5.3 , 8.5.4 and 8.6 acceptable and propose that the square brackets are deleted.

I have provided in the attached Annex a list of typographical errors and minor proposals to improve the consistency of the text for your consideration.

## ANNEX

### Section 3.4.2 : Carbohydrates

This section contains a transcription error and should be replaced by : “The amount of added carbohydrates from these sources shall not exceed 2.0g/100kJ (**8.4g**/100kcal).”

### Section 3.6.1: Minerals

The limit for sodium expressed in kJ should be added, namely (25 mg/100kJ).

### Section 8 : Labelling

At section 8.1 the reference to Codex Stan 1-1985 may be insufficient and could be replaced by Codex Stan 146-1985, which contains a number of provisions applicable to processed cereal-based foods and also refers back to the General Standard for Labelling where appropriate. Section 8.2 of this section might also be deleted if this amendment is made.

### Section 8.3 : Declaration of Nutritive Value

8.3.1 (a) The word ‘kilo’ should be added before calories

8.3.1 (b) The reference to 3.2.2 should be removed as this section no longer exists. It should be replaced by a reference to sections 3.6 and 3.7

8.3.1 (c) 'were appropriate' should be replaced by 'where appropriate'

8.5.2 The wording should be amended to read "Milk or formula but not water alone shall be.....".

## AOECS - ASSOCIATION OF EUROPEAN COELIAC SOCIETIES

### 1. SCOPE

We suggest to add the sentence "*The definition of gluten corresponds to the Codex Standard of gluten-free foods*".

### 8.5 INFORMATION FOR UTILIZATION

Point 8.5.3 should be read: "*The presence of gluten has to be indicated in the label.*" (According to the "Recommendations for the Labelling of Foods that can Cause Hypersensitivity" – Amendment to the General Standard for the Labelling of Prepackaged Foods).

## ENCA - EUROPEAN NETWORK OF CHILDBIRTH ASSOCIATIONS

### 1. Scope

We support as age for introduction about six months because:

- The American Academy of Paediatrics in its leading policy statement, after consultation of many scientific studies recommend exclusive breastfeeding for approximately 6 months and gradual introduction of iron-enriched solid foods in the second half of the first year to complement breastfeeding. (Breastfeeding and the Use of Human Milk AAP Pediatrics Vol 100 Wo 6 Dez 97 1035-1039)

- In the light of this statement and best allergy prevention we support "about 6 months"

The following medical studies recommend a diversification of the diet only after 6 months

- Effects of a dietary and environmental prevention programme on the incidence of allergic symptoms in high atopic risk infants: three years follow-up
- A Marini, M Agosti, G Motta and F Mosca Division of Neonatology, Ist Department of Paediatrics, University of Milan, Italy Acta Paediatrics Suppl 414; 1-22. 1996
- Marini A, Agosti M, Motta G, et al Prevenzione dietetica in neonati ad alto rischio atopico: follow-up 0-36 mesi: valutazioni cliniche e di laboratorio. Riv Ital Pediatr (IJP) 1990; 16:391-8
- Chandra RK, Hamed A. Cumulative incidence of atopic disorders in high risk infants fed whey hydrolysate, soy, and conventional cow milk formulas. Ann Allergy 1991; 87:129-32
- Businco L., Marchetti F, Pellegrini G, et al. Prevention of atopic disease in "at risk newborns" by prolonged breast feeding. Ann Allergy 1983; 51: 296-9

- Vandenplas Y, Hauser B, Van de Borre. et al. Effect of a whey hydrolysate prophylaxis of atopic disease. Ann Allergy 1992; 68:419-24
- Kajosaari M. Saarinen V. Prophylaxis of atopic disease by six months total solid food elimination. Acta Paediatr Scand 1983; 72:411-5
- Chirico, G. et al: Immunogenicity and antigenicity of a partially hydrolysed cow's milk infant formula. In: Allergy 52, S. 82-88, 1997

To be consistent the age for introduction should also be changed in point 3.8.1.

## 2. Description

We support to delete "starchy roots and stems" because the nutritional quality and density will not be enhanced by these components.

### 3.10 Consistency and particle size

delete brackets around "spoon-feeding", processed cereal-based products are intended to prepare infants for a progressively diversified diet eaten by spoon.

Then the products are not breastmilk substitutes and the International Code of Marketing BMS could not apply to labelling provision

**8.5.3.** Delete the last part of the sentence "if the intended age of use is below [six months]"

**8.5.4.** Delete the brackets around this section and change the age range to about 6 months to be consistent with comments given in the section 1. Scope

**8.6.** If our comments to 1.Scope are respected then the brackets around not can be removed.

If the age range of 4 to 6 months will stay in the scope then [not] have to be deleted to read!

The products covered by this standard are breastmilk substitutes and shall be presented as such.

## IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK

\* = the most important changes needed to improve the draft

### \* 1. Scope

Delete brackets, and change to read "about 6 months". Also delete "when" and the phrase, "breastfeeding alone or infant formula is no longer sufficient to satisfy nutritional requirements

Reword text to read **"This standard covers processed cereal-based foods intended for feeding infants as a complement to breast milk or infant formula from the age of about 6 months and for feeding young children as part of their progressively diversified diet."**

*The age of "about six months" for the appropriate age for the introduction of complementary foods is in line with World Health Assembly resolutions of both 1992 and 1994 which state that complementary foods should begin at "about 6 months" of age. Resolution 47.5 (1994) states "The forty-seventh World Health Assembly urges member States to ...promote sound infant and young child nutrition...by...fostering appropriate complementary feeding practices from the age of about six months, emphasizing continued breast-feeding and frequent feeding with safe and adequate amounts of local foods". A recent comprehensive WHO-UNICEF review of current scientific*

*findings concluded that the appropriate age of introduction of complementary foods was about 6 months. (Complementary Feeding of Young Children in Developing Countries: a review of the scientific knowledge, WHO 1998)*

\* 2. Description

delete "**and/or starchy root and stem products**" and change "**25%**" to "**75%**".

*Allowing starchy roots and stem products as the basis of a cereal-based complementary food can potentially lower the nutritional density, especially energy, protein and some micro-nutrients. It could further contribute to their frequent insufficient nutrient density. Manufacturers could then try to raise the protein level by adding amino acids.*

*If a complementary food is named "cereal-based" it should have more than 25% cereal content. 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 grain is included in the product.*

3. Essential composition and quality factors

3.1 Essential composition

\* Delete "and/or starchy roots (such as arrow root, yam or cassava) or starchy stems" and "soybean". Reword to read: "**Dry cereal is prepared primarily from one or more milled cereal products such as wheat, rice, barley, oats, rye, maize, millet, sorghum and buckwheat and/or legumes (pulses) and sesame.**"

*The item "starchy roots (such as arrow root, yam or cassava) or starchy stems" should be deleted because of their low nutrition content. The addition of starchy roots will have a negative impact on the nutritional density and quality of the cereal products. Soybean is already included in pulses.*

3.3 Protein

3.3.1 Add: "**The minimum content of the product protein shall be no less than 10% on a dry weight basis.**"

*One has to assume that in many situations where animal milks are not available or are not part of the local diet that cereal-based foods will be mixed with water. The processing of the cereal-based foods should be limited to retain the minimum protein content. This also ensures that micro-nutrients are retained and not lost in the milling.*

3.4 Carbohydrates

3.4.1 and 3.4.2 Delete "honey".

3.5 Lipids

\* Add: "**No hydrogenated fats containing trans fatty acids shall be added to the products defined as cereal-based foods intended for infants and young children.**"

*Trans fatty acids are undesirable ingredients which have been implicated in impairing the metabolic conversions of linolenic and linoleic acids to DHA and AA. There are concerns that trans fatty acids may be incorporated into developing brain and retinal tissue and alter optimal physiological function.*

### 3.6 Minerals

#### 3.6.1 Retain brackets

*The sodium content of complementary foods should be as low as possible. Research has shown that infants and young children acquire a preferred taste for salty foods when fed salty foods during infancy and early childhood.*

### 3.8 Optional ingredients

#### 3.8.1 Delete (If this sentence is retained, delete brackets and reword to "about six months".)

*The text as it now reads ("In addition to ingredients listed under 3.1, other ingredients suitable for infants who are more than four to six months of age and for young children can be used.") allows manufacturers to add just about any ingredient they choose. A standard for infant and young child foods should not allow unspecified optional ingredients.*

#### 3.8.3 Change "...after 9 months..." to "...after 12 months...".

*Cocoa can cause allergic reactions and should be introduced into the young child's diet as late as possible, at the very least after 12 months.*

### 3.10 Consistency and particle size

#### \* 3.10.1 Delete brackets.

*Bottle-feeding complementary foods is a harmful practice which undermines breast-feeding and should be discouraged.*

## 4. Food additives

### 4.4 Delete reference to flavors

*These substances can cause allergic reactions in children less than 12 months of age.*

## 5. Contaminants

5.1 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, **do not exceed a maximum level of 0.01 mg/kg for each substance in the product as sold.**"

*This standard should have a stated maximum level for pesticides and not vague phrases such as the present text "pesticides...are reduced to the maximum extent possible". There are 200 known pesticides found in baby foods. By stating the maximum allowed level for each pesticide the cumulative pesticide load is unclear and may present a health hazard to babies and young children.*

### 5.2 Other Contaminants

Delete "**practically**" to read: "The product shall be free from residues of hormones, antibiotics as determined by means of agreed methods of analysis and free from other contaminants, especially pharmacologically active substances."



## 6. Hygiene

6.1 Reword to read: "**The product 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."

*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..*

## 8. Labelling

\* Add the following two texts:

**"The label shall have no pictures of infants or young children or text which idealizes the use or suggests an inappropriate age of introduction of these products."**

*Label graphics should be for product identification not for product promotion. By showing a very young infant's image parents can be misled to feed the product to infants before about 6 months.*

\* **"No health claims, nutrient content claims or nutrient function claims shall be made regarding the dietary properties of the product."**

*Health claims, nutrient content claims and nutrient function claims are used to idealize the health and nutritional aspects of processed infant foods. Such claims are promotional and have a high potential for misleading consumers. Claims should not be permitted in order to protect consumers from making infant feeding choices based on unsubstantiated and misleading information.*

### 8.5 Information for Utilization

\* 8.5.3 Remove square brackets

\* 8.5.4 Remove square brackets. Change "before 4 to 6 months" to "**before about 6 months**".

*See Scope for rationale.*

\* Add: **8.5.5 "Labels shall contain the following statement: 'Important notice- For best child nutrition and health, breastfeeding should continue along with feeding complementary foods'"**.

*Parents should be warned that the introduction of complementary foods does not signal a need to stop breastfeeding. Breast milk continues to be an important source of excellent nutrition. WHO and UNICEF policy encourages mothers to breastfeed 2 years and beyond.*

## **ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES**

### **1. SCOPE**

ISDI is of the opinion that regarding the age of introduction of cereal-based foods the **official** WHO recommendation should be followed. During the last Codex commission held in Rome in

June-July 1999 the WHO representatives reminded that "the current WHO recommendation was that complementary feeding should start at between four and six months of age for most infants. **Therefore, the references to the age range of four to six months in the proposed Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children (Alinorm 99/26, appendix IV) were consistent with the current WHO recommendation.**"

This recommendation was published in 1995 in the Weekly Epidemiological Record, No17. It may be useful to recall the text:

*"The World Health Organization recommends that infants should be fed exclusively on breast milk from birth to 4 to 6 months of age; that is, they should be given no other liquids or solids than breast milk, or even water, during this period. Given the worldwide variation in growth velocity, an age range is an essential element of this feeding recommendation. Mean growth Z-scores are indeed observed to begin falling at different points within this 4-to-6-month range in breast-fed infants from different populations worldwide. WHO and its partners are in the process of refining the definition of "optimal" growth, as measured by accepted functional indicators of infant health and well-being.*

*After this initial 4-to-6-month period of exclusive breast-feeding, children should continue to be breast-fed for up to 2 years of age or beyond, while receiving nutritionally adequate and safe complementary foods. Starting complementary feeding too early or too late are **both** undesirable. Ideally, the decision when precisely to begin will be made by a mother, in consultation with her health worker, based on her infant's specific growth and development needs."*

Dr Brundtland, Director-General of WHO has repeatedly confirmed that WHO has not changed this recommendation and will not change it until such time as the weight of new scientific evidence makes this not only possible but also necessary. The above recommendation has been published after the WHA resolution 47.5 in which the words "the age of about 6 months" are used. The only possible conclusion is that the 4-to-6-month range is preferred by WHO, and therefore should be included in the Codex Standard.

ISDI is aware of the fact that WHO has initiated a study to revise the current International Growth Reference Standards. This study will not be completed before 2002. It may or may not lead to a change in the WHO recommendation.

ISDI would like to underline that the Codex Standard should take into account nutritional requirements of worldwide countries, this includes feeding habits in developing **and** developed countries. For this reason the wording "from four to six months" is particularly well adapted to cover all biological and feeding discrepancies in the world. The Codex Standard should not restrict any feeding practice without sound reasons scientifically based. ISDI also underlines that each country has the right and the opportunity to restrict this age of introduction of complementary feeding at national level in order to comply with the nutritional pattern of its population.

In the meantime, in order to avoid any delay in the advancement of this Standard and in absence of any scientific evidence to not doing so, **ISDI strongly supports the deletion of the square brackets and the adoption of the wording "from four to six months"**. In the future, if the WHO change its recommendation, the Standard should be modified accordingly.

### 3.3. PROTEIN

3.3.4. The remaining square bracket at the end of the sentence should be deleted

### 3.4. CARBOHYDRATES

#### 3.4.2. ISDI has noted a mistake in the calculation of the carbohydrate content (first bullet).

As mentioned in the session report (point 63, page 9) the carbohydrate level has been modified and raised from 1.2 g to 2 g/100kJ. This level was mistranscribed in the draft Standard and the value of 2g is given for 100 kcal instead of 100kJ and then divided by 4.18 to obtain the value per kJ ( $2 / 4.18 = 0.48$ ).

Consequently the sentence should read:

The amount of added carbohydrates from these sources shall not exceed **2 g/100 kJ (8.4g/100 kcal)**.

### 3.6 MINERALS

#### 3.6.1. ISDI proposes to delete square brackets and to add the value per kJ (24mg /100 kJ)

#### 3.7.4. ISDI strongly favours the revision of the Advisory Lists of Mineral Salts and Vitamin Compounds for use in Foods for Infants and Young Children (CAC/GL 10-1979). This task has been mentioned in the "summary status of work" (p18). ISDI has already forwarded a list of substances (attached to this document) which are presently missing and is ready to collaborate in the revision of this list.

#### 3.8.1. For the same reasons already mentioned under "scope" square brackets should be deleted.

## 4. FOOD ADDITIVES

The revision of the list of food additives has been officially decided during the last Codex session. ISDI supports this revision and suggests adding additives already evaluated by scientific bodies such as the European Scientific Committee on foods. This committee has already evaluated the technological needs and the nutritional safety of several additives that are needed in the manufacture of foods for infants and young children.

Furthermore, natural fruits extracts and natural identical flavouring substances should be added in this Standard (natural fruit extracts are already authorised in the Follow-up formulae Standard). Risks of allergic reactions from flavouring substances are negligible. This was concluded in the authoritative article The role of flavouring substances in food allergy and intolerance by Steve I. Taylor and Erin Stafford Dormedy; Advances in Food and Nutrition Research Vol 42.

## 8. LABELLING

Because all labelling provisions in this Standard have to be endorsed by CCFL, CCNFSDU should formulate the labelling section as carefully as possible in order to avoid any refusal from the CCFL. ISDI therefore proposes to refer to CODEX STAN 146-1985 instead of CODEX STAN 1-1985.

Consequently, ISDI proposes to change the first sentence as follows:

***In addition to the requirements of the Codex General Standard for the Labelling and claims for prepackaged foods for special dietary uses (CODEX STAN. 146-1985) the following specific provisions apply:***

*Explanatory note:* It is insufficient to refer to the General Standard for Labelling of Prepackaged Foods (CODEX STAN 1-1985) because Codex STAN 146-1985 contains a number of specific

provisions, which also apply to processed cereal-based foods. Therefore reference should be made to Codex Stand. 146-1985, which refers back to the General Standard for Labelling (CODEX STAN 1-1985) where appropriate, or has specific provisions. These are also applicable to processed cereal-based foods for infants and young children.

**In addition, ISDI proposes to delete the 2<sup>nd</sup> sentence.**

This is adequately covered in section 8 of CODEX 146-1985 respectively section 8.2 of the General Standard (CODEX STAN 1-1985).

**8.3.1. (a).** The word "*kilo*" is missing is before "calories"

**8.3.1. (b).** This paragraph should refer to Section 3.6 and 3.7 and not to 3.2.2, which does not exist any more. In addition, ISDI proposes to replace the wording "as well as" by "***and may be given***". The declaration per serving size should not be mandatory as this serving size varies from country to country and with the infant age.

**8.3.1. (c).** The wording "were appropriate" should be replaced by "***where*** appropriate"

**8.4.3.** This type of provisions is fully described in the General Standard for Labelling (CODEX STAN 1-1985) and is not needed here. For simplification purpose, ISDI suggests deleting this Section

**8.5.2.** ISDI requests the addition of the word "***alone***" after "water". Indeed, water is used in the reconstitution of infant formulae, which is one the nutritious liquids recommended for the cereals dilution.

**8.5.3.** ISDI favours the deletion of the square brackets.

**8.5.4.** ISDI agreed on the wording as it is written and suggests deleting brackets.

**8.6.** ISDI fully supports the wording of this paragraph and is of the opinion that the square brackets are to be deleted. The products covered by this standard are weaning foods and are not breast-milk substitutes. In this context it is useful to recall the definition given in the International Code of Marketing of Breast-milk Substitutes for complementary food: "*Complementary food*" means any food, whether manufactured or locally prepared, suitable as a complement to breast milk or to infant formula, when either becomes insufficient to satisfy the nutritional requirements of the infant. Such food is also commonly called "*weaning food*" or "*breast-milk supplement*". This definition corresponds exactly with the Scope of the Standard. For this reason processed cereal-based foods for infants and young children are weaning foods (or complementary foods) and not breast-milk substitutes and should not be presented as such.

## WHO - World Health Organization

### INTRODUCTION

This note is in reply to CL 1999/20-NFSDU of September 1999, which requested comments and information on the proposed draft revised standard in reference. This note is limited to matters touching on the *age of introduction of these foods*, and it should be read in conjunction with information that WHO has presented elsewhere in this connection.<sup>1</sup>

The optimal duration of **exclusive breastfeeding** – and thus the optimal timing of when **complementary feeding** should begin – is an important public health issue that WHO keeps under continual review. Based on available scientific and epidemiological evidence, WHO's current infant-feeding recommendation may be summarized as follows:

*During the first four to six months of life, no food or liquid other than breast milk, not even water, is required to meet the normal infant's nutritional requirements. Thereafter, children should continue to be breastfed for up to two years of age or beyond, while receiving nutritionally adequate and safe complementary foods that will meet their changing nutritional requirements.*

### BACKGROUND

#### A summary of the supporting scientific and epidemiological evidence

Adequacy of infant **growth** is the main scientific criterion for assessing how long exclusive breastfeeding should be maintained and, consequently, when complementary feeding should begin. Other important considerations include functional outcomes, especially **morbidity**, **mortality**, **development** and **behaviour**; and the **quality** and **safety** of available complementary foods, the level of **environmental contamination**, and the **child-spacing benefits** of exclusive breastfeeding.

It is imperative to distinguish carefully between articulating a population-based recommendation covering *all infants everywhere*, and applying this recommendation to meet the nutritional needs of an *individual* infant within a *specific* environment.

Furthermore, given the worldwide variation in growth velocity and other health and development outcomes, an *age range* is an essential element of WHO's infant-feeding recommendation. In this connection, it should be noted that starting complementary feeding too early or starting it too late are both undesirable. Ideally, the decision when *precisely* to begin complementary feeding:

- will be made by a mother,
- in consultation with her health worker,
- based on her infant's specific growth and development needs.

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<sup>1</sup> Including statements by the Representative of WHO at the 20<sup>th</sup> and 21<sup>st</sup> sessions of the CCNFSDU. See also Appendix V, Statement of WHO on the recommended age range for the introduction of complementary foods, to the report of the 23<sup>rd</sup> session of the Codex Alimentarius Commission (ALINORM 99/37).

Based on research coordinated by WHO, important additional scientific evidence regarding the timing of the introduction of complementary foods was published in 1995 in the report of the WHO Expert Committee on physical status.<sup>1</sup> The evidence showed that, in predominantly breastfed infants, weight and growth velocity begin to fall at 3 months of age when judged against the current NCHS/WHO reference.<sup>2</sup> In contrast, weight and growth velocity begin to fall at about 5 months of age when judged against a trial breastfed growth reference.<sup>3</sup> On this basis the Committee urged the development of a new growth reference reflecting the current feeding recommendation.<sup>4</sup> Moreover:

*[t]he Expert Committee recognized that future scientific advances and worldwide improvements in sanitation may make it necessary to modify recommendations, but considered that current [WHO feeding] recommendations are based on the best wisdom available.<sup>5</sup>*

### **Further research and perspectives**

Since the publication of the Committee's findings in 1995, there have been a number of additional studies and reviews. While contributing in a variety of important ways to the growing body of knowledge on the topic, results have not, by themselves, warranted any change, up or down, in WHO's current infant-feeding recommendation.

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<sup>1</sup> WHO *Expert Committee on Physical status: the use and interpretation of anthropometry*. World Health Organization, 1995 (WHO Technical Report Series, No. 854).

<sup>2</sup> *Ibid.*, p. 238. The current WHO/National Center for Health Statistics (Washington, DC) reference was developed by combining two distinct data sets representing different age groups compiled in different decades. The reference reflects the growth of children who were fed primarily with infant formula and who were of restricted genetic, geographic, and socioeconomic background. The combined effect of these limitations so seriously flaws the present international reference on both technological and biological grounds as to interfere with the sound health and nutritional management of individual infants and young children, and provides inaccurate community estimates of over- and undernutrition.

<sup>3</sup> *Ibid.*, pp. 236–237. This conclusion was based on analysis of pooled data concerning infants predominantly breastfed for at least 4 months, and partially breastfed to at least 12 months, from 7 North American and European studies; deprived communities in India and Peru; 7 centres in 5 countries (the WHO/HRP data set from Chile, Egypt, Hungary, Kenya and Thailand); and formula-fed infants in affluent populations. For additional detail in this regard, see: WHO Working Group on Infant Growth. An evaluation of infant growth (document WHO/NUT/94.8). World Health Organization, Geneva, 1994.

<sup>4</sup> For a summary of latest developments in this connection, see: WHO Executive Board, 105<sup>th</sup> Session. Infant and young child nutrition: the WHO multicentre growth reference study. Document EB/105/INF.DOC./1. Geneva, World Health Organization, 16 November 1999.

<sup>5</sup> WHO *Expert Committee on Physical status*, op. cit., p. 249.

One of the most frequently cited studies – by Cohen et al. in Honduras<sup>1</sup> – found that there was no advantage to introducing complementary foods before 6 months of age. However, the study was unfortunately flawed methodologically by the high pre-intervention refusal rate (66%) and the highly uneven dropout rate among groups following randomization.

A 1997 review<sup>2</sup> of the Honduras study highlighted these methodological weaknesses; it also noted that, as a result of the study, UNICEF had suggested changing the current infant-feeding recommendation to stipulate exclusive breastfeeding through the sixth month of life. The authors concluded, however, that before any global change in the present 4–6-month recommendation could be made, further well-designed studies would have to be undertaken under different cultural, social and biological conditions.

In 1998 WHO published a state-of-the-art review of scientific knowledge about complementary feeding of young children in developing countries.<sup>3</sup> In the review, the primary authors (who were among the principal investigators of the Honduras study) acknowledged two prevailing points of view regarding the duration of exclusive breastfeeding: a 4–6-month range and “about 6 months”. The primary authors nevertheless concluded that “full-term infants with appropriate weight-for-gestational age should be exclusively breastfed until about six months of age”.<sup>4</sup>

A commentary on solid feeding guidelines published in *The Lancet* in November 1998<sup>5</sup> concluded that:

*In the light of scientific evidence, age 4–6 months seems to be a reasonable time to introduce solids and seems to impose no known harm. Human milk remains the ideal source of nutrition for babies, and encouragement of breastfeeding promises the greatest benefit. Investigation of the long-term nutritional consequences of modification of early diet and of the complex interactions leading to food hypersensitivity will facilitate greater understanding of the best time to introduce solid feeds.*

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<sup>1</sup> Cohen RJ, Brown KH, Canahuati J, Landa Rivera L, Dewey KG. Effects of age of introduction of complementary foods on infant breast milk intake, total energy intake, and growth: a randomised intervention study. *The Lancet* 1994;343:288-93.

<sup>2</sup> Frongillo EA and Habicht JP. Investigating the weanling’s dilemma: lessons from Honduras. *Nutrition Reviews* 1997;55:390-95.

<sup>3</sup> WHO, UNICEF, University of California (Davis), ORSTOM. Complementary feeding of young children in developing countries: a review of scientific knowledge (document WHO/NUT/98.1).

<sup>4</sup> This review, unlike the report of the WHO Expert Committee on physical status, is not a formal WHO publication; the views expressed therein are thus solely the responsibility of the authors. This important distinction allows WHO to ensure that a full spectrum of ideas can be aired on scientific and policy issues of major public health importance, irrespective of whether they represent formal WHO policy.

<sup>5</sup> Werk LN and Alpert JJ. Solid feeding guidelines. Commentary. *The Lancet* 1998;352:1569.

In addition to current research that WHO is coordinating (see below), a number of reviews are under way examining timing, nutritional adequacy, morbidity and mortality, and sociocultural practices associated with the introduction of complementary foods. This includes a systematic review of the scientific literature, for the period after the work of the WHO Expert Committee on physical status to the present, that is being undertaken in the context of the development of a new global strategy for infant and young child feeding.<sup>1</sup> The results of these reviews will be all the more important in the light of the fact that, worldwide, on average only about 34% of infants are still being exclusively breastfed at the age of 4 months.<sup>2</sup>

### The WHO multicentre growth reference study<sup>3</sup>

Consistent with the recommendation of the Expert Committee on physical status, WHO is currently conducting a multi-country study involving more than 12 000 children from geographically and ethnically diverse sites. The study combines a longitudinal component from birth to 24 months with a cross-sectional study from 18 to 71 months. The aim is to establish a new international growth reference that reflects growth patterns of healthy breastfed infants and children living in environments that do not constrain growth. The new reference will establish the breastfed infant as the normative model against which *all* alternative-feeding methods must be measured in terms of growth, health and development. The study is expected to contribute to improved understanding of the **age range** during which breast milk alone is sufficient to meet the healthy infant's nutritional requirements for growth and development.

### A differing view, and WHO's response

Since 1994 some have begun calling into question the validity of WHO's current infant-feeding recommendation. Initially, this was based on a misreading of the significance, the same year, of World Health Assembly resolution WHA47.5, which urged the "fostering of appropriate complementary feeding practices from the age of about six months". As noted repeatedly, this message is identical to that contained in the second half of the full recommendation cited in the preamble to resolution WHA45.34, which had been adopted two years earlier:

*Reaffirming that during the first four to six months of life no food or liquid other than breast milk, not even water, is required to meet the normal infant's nutritional requirements, and that **from the age of about six months** infants should begin to receive ... locally available foods ... in addition to breast milk.*

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<sup>1</sup> The draft global strategy will be submitted, after consultation, to the World Health Assembly in May 2002.

<sup>2</sup> The WHO Global Data Bank on Breastfeeding. Department of Nutrition for Health and Development, World Health Organization, 1211 Geneva 27, Switzerland. Contact: [saadehr@who.int](mailto:saadehr@who.int).

<sup>3</sup> WHO Executive Board, op. cit.



Indeed, both messages are consistent with:

- the recommended period of exclusive breastfeeding, expressed as a range, and
- the approximate timing, as a function of this range, of the start of complementary feeding that WHO has consistently recommended since 1979 based on a continual review and reappraisal of available scientific evidence.

For example, UNICEF recently issued a statement on the recommended length of exclusive breastfeeding<sup>1</sup> in which it “maintains that the infant feeding recommendations in general are for breastfeeding to be exclusive for about 6 months”. The statement describes as “outdated terminology” the wording “all infants should be fed exclusively on breast milk from birth to 4–6 months of age” used in the *Innocenti Declaration*.<sup>2</sup> This wording, the UNICEF statement notes, “predates the evolution of knowledge about the damaging effects of early complementation upon both breast milk intake and infant morbidity”. The latest UNICEF publication on infant feeding<sup>3</sup> repeats the recommendation for breastfeeding to be exclusive “for about the first six months of life”. However, the publication goes a significant step further by saying that “Except in the rarest cases, no additional foods and fluids are necessary...” during this period.

Based on the available scientific and epidemiological evidence, WHO considers both inaccurate and excessively rigid the “about 6 months” formulation for the recommended length of exclusive breastfeeding. In the absence of a “standard infant”, a global feeding recommendation requires an **age range** that will accommodate *all* of the nearly 130 million babies born in the world every year. **More importantly, however, the too categorical formulation “about 6 months” poses a serious risk of interfering with the sound health and nutritional management of some infants in terms of inappropriately delaying the start of complementary feeding based on their specific needs.** Pending new evidence, WHO supports the continued use of the agreed IMCI<sup>4</sup> formulation “at least 4 months and if possible 6 months”, which UNICEF previously accepted.

### Implications for the marketing of complementary foods

Faulty complementary feeding practices compounded by nutritionally inadequate, and frequently contaminated, foods often introduced too early (in developing and developed countries) or too late (in developing countries) remain a major cause of malnutrition. As the World Health Assembly noted in 1984,<sup>5</sup> inappropriate marketing practices contribute to this malnutrition in at least two ways:

- through the promotion of products that are unsuitable for infant feeding and
- through the promotion of infant foods for use at too early an age.

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<sup>1</sup> Lhotska L and Armstrong H. UNICEF’s recommended length of exclusive breastfeeding. New York, United Nations Children’s Fund, 22 November 1999. Accessible at: <http://www.bftopics.org/docs/doc2.htm>

<sup>2</sup> The Innocenti Declaration on the Protection, Promotion and Support of Breastfeeding was adopted by participants at the WHO/UNICEF policy-makers’ meeting on “Breastfeeding in the 1990s: a Global Initiative” held at the Spedale degli Innocenti, Florence, Italy, on 30 July–1 August 1990.

<sup>3</sup> Breastfeeding: foundation for a healthy future. New York, United Nations Children’s Fund, Division of Communication, August 1999.

<sup>4</sup> Integrated Management of Childhood Illness (document WHO/CHD/97.3). Geneva, World Health Organization, Department of Child and Adolescent Health and Development.

<sup>5</sup> Resolution WHA37.30, in document WHA37/1984/REC/1, page 19.

Both can be detrimental to infant and young child health.

In 1986 the Health Assembly once again drew attention to the fact that “many products unsuitable for infant feeding are none the less being promoted and used for this purpose”, and observed that:

*any food or drink given before complementary feeding is nutritionally required may interfere with the initiation and maintenance of breastfeeding and therefore should neither be promoted nor encouraged for use by infants during this period.*<sup>1</sup>

Three key principles governing infant feeding that are mentioned above are equally relevant in the context of the marketing of complementary foods:

- It is imperative to distinguish between a population-based recommendation covering all infants and its application to meet the needs of individual infants in specific environments.
- Given the worldwide variation in growth velocity and other health and development outcomes, an age range is an essential element of WHO’s infant-feeding recommendation.
- Starting complementary feeding too early or starting it too late are both undesirable.

When complementary foods are being marketed, it is thus essential that product labels and related informational materials scrupulously observe both the lower *and* the upper end of the 4–6-month age range for exclusive breastfeeding. In fact – and despite the consistent age-based recommendation for the last two decades concerning the nutritional adequacy of breast milk – cereal-based complementary foods the world over are still frequently marketed as suitable for use “from 4 months”. Moreover, since the legend “from 4 months” on product labels is typically understood by health workers and the general public alike to mean “from the end of the third month”, it can serve to encourage products’ premature introduction.

### **Proposed improvements in the draft revised Codex standard**

Although the present Codex Standard for Processed Cereal-based Foods for Infants and Children<sup>2</sup> does not include a specific indication of the recommended age of use of products, the draft revised Standard does.<sup>3</sup> Paragraph 8.5.4 of the draft reads as follows:

*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 4 to 6 months. In addition, the label shall include a statement indicating that the decision when precisely to begin complementary feeding should be made in consultation with a health worker, based on the 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.*

WHO proposes the following alternate wording for the second sentence of this paragraph to make it consistent with the remainder of the paragraph – by phrasing it positively – and to call attention to the importance of not promoting infant foods for use at too early an age:

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<sup>1</sup> Resolution WHA39.28, in document WHA39/1986/REC/1, page 29.

<sup>2</sup> CODEX STAN 74–1981 (amended 1985, 1987, 1989, 1991). Codex Alimentarius, Vol. 4, 1994.

<sup>3</sup> Codex Alimentarius Commission, ALINORM 99/26, pages. 40–45.

*The label shall clearly state that the product is recommended for use from the age of about 6 months and not before 4 months.*

Paragraph 8.5.4 represents a significant improvement over the original standard. Not only is the language consistent with the available scientific evidence in terms of the recommended period of exclusive breastfeeding and, consequently, when complementary feeding should begin; but it also provides two “safety nets” to help ensure the standard’s appropriate application in specific environments.

- The **second sentence** of the draft provision reflects the current *worldwide population-based recommendation*.
- For applying this recommendation to meet the needs of the *individual* infant, emphasis, in the **third sentence**, is on dialogue between a mother and her health worker in the light of her infant’s *specific* needs.
- The provision goes still further, in the **fourth sentence**, by explicitly acknowledging the prerogative of governments to adopt additional, presumably *more stringent*, requirements if the *particular* circumstances of the country or population in question warrant it.

## CONCLUSION

The optimal duration of **exclusive breastfeeding** – and thus the optimal timing of when **complementary feeding** should begin – is an important public health issue that WHO keeps under continual review. Based on available scientific and epidemiological evidence, and pending the accumulation of new evidence that may require a change, WHO reaffirms the validity of its current infant-feeding recommendation.