

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
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ORGANIZATION



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

Agenda Item 6

CX/NFSDU 01/06
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Twenty-third Session
Berlin, Germany, 26-30 November 2001

DRAFT REVISED STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN ¹ *- Comments at Step 4 of the Procedure -*

Comments from:

ARGENTINA
AUSTRALIA
BRAZIL
CANADA
CHINA
CUBA
FRANCE
GERMANY
HUNGARY
INDIA

INDONESIA
ITALY
JAPAN
KOREA, REPUBLIC OF
MALAYSIA
MEXICO
NORWAY
PARAGUAY
POLAND
SENEGAL

SINGAPORE
SOUTH AFRICA
SRI LANKA
SWITZERLAND
THAILAND
UNITED KINGDOM
UNITED STATES OF AMERICA
URUGUAY

AOECS - ASSOCIATION OF EUROPEAN COELIAC SOCIETIES
EUROPEAN COMMUNITY
ENCA - EUROPEAN NETWORK OF CHILDBIRTH ASSOCIATIONS
IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK
IFAC - INTERNATIONAL FOOD ADDITIVES COUNCIL
IFOAM - INTERNATIONAL FEDERATION OF ORGANIC AGRICULTURE MOVEMENTS
ILCA - INTERNATIONAL LACTATION CONSULTANT ASSOCIATION
ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES
WHO - WORLD HEALTH ORGANIZATION

¹ This document reproduces all comments previously published in CX/NFSDU 00/7, its addendums, and CRDs section by section

OTHER COMMENTS

KOREA, REPUBLIC OF

- 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.

1. SCOPE

ARGENTINA

We propose removing the square brackets so that the passage reads "from the age of 4 to 6 months onwards". This is justified in that the official recommendation of WHO (Weekly Epidemiological Record No 17, pp 119-120, 20 April 1995) calls for exclusive breast feeding of infants from birth to the age of 4 to 6 months. After this time, breast feeding should be continued and supplemented by the feeding of safe complementary foods in accordance with nutritional requirements. WHO emphasises that complementary feeding should not be introduced either too early or too late.

This recommendation was made following the WHO resolution of 1994.

At the last session of the CCNSFDU in Berlin, the WHO representative pointed out that WHO's position regarding the introduction of complementary feeding at the age of four to six months had not changed as there was no scientific evidence to justify any change at this stage. The representative furthermore announced that a scientific study into this matter is now under way that will take account of data collected from various regions of the world. The study will be completed in the year 2002.

Our position is that the Codex should remain consistent with the WHO recommendation. If this recommendation is modified in future on the basis of new scientific evidence, then the Codex should be amended accordingly.

AUSTRALIA

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.

BRAZIL

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

CANADA

Canada supports deletion of the square brackets around „4 to 6 months“ in line with recommendations made by the WHO.

CHINA

We agree with the comments of Australia that the square brackets should be removed.

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.

FRANCE

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.

GERMANY

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 5th 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 ...*".

INDIA

India has been consistently taking a stand in the past two Codex Committee on Nutrition and Foods for Special Dietary Uses meetings held at Bonn in 1996 and at Berlin in 1998, and the 23rd Session of the Codex Alimentarius Commission at Rome in 1999 **against the following two major issues in the proposed draft revised standard for processed cereal based foods for infants and young children** as has also been reflected in the respective reports:

i) Inclusion of starchy roots and tubers in the formulation of cereal based foods for infants and young children replacing part of the cereal, and

ii) Specifying the age of '4-6 months' for introduction of these foods to infants.

(...)

There is now sufficient scientific, including epidemiological evidence for supporting the age of six months as the appropriate age for introduction of complementary foods in the infant's diet and India strongly supports the same.

The rationale for keeping the age 'of about 6 months' for introduction of complementary foods in the standard for cereal based foods for infants and young children, is as under:

❖ A global consensus has evolved in recent years defining optimal feeding of infants and children: exclusive breastfeeding from birth to about six months, followed by introduction of complementary foods drawn

from the local diet at about six months. Breastfeeding should be sustained well into or beyond the second year of life, with increasing amounts of complementary foods.

- ❖ Early introduction of complementary foods leads to early cessation of breast feeding, thus depriving the child of all the innumerable advantages of breast feeding.
- ❖ Breast milk provides all the nutrients a baby needs during the first six months of life. Other foods, however good these may be, are nutritionally inferior to breast milk. Breast milk is relatively high in fat content compared to most complementary foods and is, thus, the key source of both energy and essential fatty acids. Further, the nutritional density of cereal based foods is far lower than breast milk specially for vitamin A, riboflavin and calcium.
- ❖ Breast milk reduces interference with the bio-availability of key nutrients such as zinc and iron. Early introduction of complementary foods will interfere with this advantage provided by breast milk.
- ❖ Breast milk is free. Substitution of breast milk by other foods will strain the already meagre incomes of most families in developing world.
- ❖ It is well established that exclusive breast feeding is associated with the delay in the return of maternal fertility post partum. The Lactational Aemorrhoea Management (LAM) is an important method of fertility control in poor communities and helps in achieving a longer average birth interval which in turn has a positive impact on child health.
- ❖ Supplementing breast feeding with other foods at an early age undermines breast feeding and substantially increases the risk of illness and death from diarrhoea, specially among infants living in poor and unhygienic conditions. On the other hand, continuing exclusive breast feeding upto six months reduces the risk of diarrhoea and acute respiratory infections which are a major cause of infant and young child mortality and morbidity.
- ❖ The recommendation of 4-6 months leads to confusion in the minds of anxious parents and in their enthusiasm and concern for the well being of the child they start complementary foods from the age of even three months. The literature suggests that this leads to increased morbidity and mortality.
- ❖ The phrase '4-6 months' used in the Innocenti Declaration of 1990 predates the knowledge about the damaging effects of early complementation upon both breast milk intake and infant morbidity. Current knowledge adequately represented upto date refers to 'about 6 months' phrasing. No current studies could be identified that would justify the general recommendation of complementary foods from 4-5 months; all newer studies suggest that such a recommendation would have deleterious effect on child health without any compensating advantage on growth.
- ❖ Importance of breast feeding is now well established. WHA 34.22 Resolution on International Code of Marketing of breast milk substitutes at the 34th World Health Assembly reiterated that "Breast feeding is the only natural method of infant feeding and that it must be actively protected and promoted in all countries. The working group on breast feeding, American Academy of Pediatrics also considers exclusive breast feeding as ideal nutrition and sufficient to support optimal growth and development for approximately the first 6 months after birth.
- ❖ The WHO's publication titled "Complementary Feeding of Young Children in Developing Countries : A review of current scientific knowledge" (WHO/NUT/98.1) while reviewing the current scientific knowledge concludes that 'there are several advantages in keeping the age of about six months rather than the average age of 4-6 months' for the introduction of complementary feeding. It further concludes that 'full term infants with appropriate weight for gestational age should be exclusively breast fed until about 6 months of age'. The more recent work in Honduras further indicates that no growth advantage is seen even in low birth weight infants when complementary foods are introduced before 6 months (American Journal of Nutrition, 1999, 69(4))
- ❖ WHO/UNICEF Technical Consultation on Infant and Young Child Feeding that took place in March 2000 at Geneva issued a statement regarding the duration of exclusive breast feeding, recommending the duration of exclusive breast feeding as 'about 6 months'.

- ❖ The original Codex standard for processed cereal based foods for infants and children, Codex Stan 74-1981 (amended in 1981, 1987, 2989, 1991) does not specify any age for introduction of processed cereal based foods in the diet of infants under the **SCOPE** of the standard. Further, the essential composition of this standard does not include starchy roots or stem.

Thus, **India strongly recommends that the Standard for Processed Cereal Based Foods for Infants and Young Children should refer to the age of “about 6 months” as the appropriate age for the introduction of such foods/complementary foods** in the infant’s diet and that the reference to starchy roots and stems should be deleted from the composition of such foods.

The parawise comments on draft revised Standard for Processed Cereal Based Foods for Infants and Young Children (CL1999/20-NFSDU) are as under:

- The most important changes needed to improve the draft are as under:

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)

In view of the World Health Assembly’s Resolution and a number of countries supporting the expression of ‘about six months’, there is no reason to ignore the words about six months. India reiterates the following:

- The words ‘4 to 6 months’ in square brackets should be replaced by words ‘about six months’.
- It is important for India and the developing world to insist on about six months since the mention of 4-6 months may mislead the consumers to introduce these foods at four months or may be earlier than that which is not desirable under the socio-economic conditions prevailing in these regions. The use of diluted feeds prepared unhygienically, may endanger the health of vast majority of already malnourished infants. This would also given leeway to manufacturers to promote their products to unassuming parents earlier than 4 months.

Under these circumstances, India strongly recommends the use of words ‘about 6 months’ in the interest of the health of vast majority of infants of the developing world. Inclusion of ‘about 6 months’ words will support the efforts of India and the developing world to promote exclusive breast-feeding upto the age of 4-6 months.

INDONESIA

In accordance with the recommendation of the World health Organisation (weekly Epidemiological Record No. 17, page 119-120, 20th 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 save 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”.

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).

JAPAN

It is proposed adding the next sentence to SCOPE to clear that the rice gruel products which are the weaning foods of our country are not contained in this standard.

"This standard does not cover simple cereals products reconstituted with water."

KOREA, REPUBLIC OF

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.

MALAYSIA

Malaysia proposes to delete the square brackets and accept the text "4 to 6 months". This is to be in line with the official WHO recommendation regarding the age of introduction of cereal-based foods.

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)

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

NORWAY

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

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.

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.

SWITZERLAND

There was controversy during the 23rd 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.**

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.

UNITED STATES OF AMERICA

We recommend proceeding with all components of this proposed standard except for the issue of age of introduction of weaning foods. We recommend that this issue be deferred pending resolution by currently on-going technical consultancies being conducted under the auspices of the WHO, UNICEF and other collaborators.

URUGUAY

The scope of the standard is very important. Therefore this category of food is contained in our national nutrition directive ("Reglamento Nacional de Bromatología" (Decreto 315/94)) in the chapter **Foodstuffs for Infants as of the Age of Six Months and for Young Children ("Alimentos para lactantes de seis meses y más y para niños de corta edad")**. This chapter covers foodstuffs other than breast-milk and infant formulas which serve the gradual adjustment of the nutrition of the children concerned to that appropriate for older children. This group of foodstuffs includes cereal-based foods, which are the subject of our discussion. Attention is drawn to the fact that most of our infants are given foods of this type on medical advice after they have reached the age of six months, i.e. in the second six months of life. When drafting the relevant chapter of Uruguay's national nutrition directive ("Reglamento Bromatológico Nacional de Uruguay"), national paediatric authorities were consulted. In addition, the valid national standard for infant nutrition during the first year was taken into account. Therefore we believe that this should be expressed in the **Scope** of the Codex Standard, i.e. that the details in square brackets should read "as of the age of six months or in the second six

months of life". This comment applies to all the statements regarding the age range concerned. Moreover, stating an age range of 4–6 months on the label is too imprecise to be correctly interpreted by the public.

Therefore Uruguay requests that:

the square brackets be deleted and that the age at which this food may be used be clearly stated: "as of the age of six months" or "as of the second six months of life".

This viewpoint was put forward by the governments of Bolivia, Ghana, India, Indonesia and Tanzania, which were also supported in this by many other delegations who expressed concerns in this respect. The statement that complementary foods can be introduced at the age of "about six months" corresponds to the correct age and is in accordance with the resolutions of the World Health Assembly from 1992 and 1994. In WHA Resolution 47.5 (1994), the Member States are urged 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*").

During the World Health Assembly in 1996, further concerns were raised regarding this topic. Therefore the Member States drew up Resolution 49.15, in which the Member States were urged "*to ensure that complementary foods are not marketed for or used in ways that undermine exclusive and sustained breast-feeding*".

A scientific revision recently launched by WHO and UNICEF and determined that complementary foods can be introduced at the age of about six months (Complementary Feeding of Young Children in Developing Countries: a review of the scientific knowledge, WHO 1998).

AOECS - ASSOCIATION OF EUROPEAN COELIAC SOCIETIES

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

EUROPEAN COMMUNITY

Scientific evidence is in favour of maintaining the reference to 4 to 6 months for the introduction of supplementary feeding in order to satisfy the nutritional requirements of all infants. Therefore the text in the square brackets should be maintained and the square brackets should be deleted.

ENCA - EUROPEAN NETWORK OF CHILDBIRTH ASSOCIATIONS

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 hydrolysed, 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
- Vandenas 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.

IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK

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)

ILCA - INTERNATIONAL LACTATION CONSULTANT ASSOCIATION

Delete brackets and change 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 onward“ (A) „and for feeding young children as part of their progressively diversified diet.“ (B)

Rationale: (A) Exclusive breastfeeding for about the first 6 months of life promotes optimal infant health and growth. Even among those babies most at risk for growth faltering, there is no demonstrable growth advantage when complementary foods are added before 6 months.² Results of a comprehensive review of complementary feeding in developing countries³ indicate that:

- „Growth rates of fully breast-fed infants in developing countries are generally similar to those of their counterparts in more affluent populations during the first six months of life.“
- „In affluent populations, growth rates of infants who are exclusively breast-fed during the first six months or more are similar to those of infants given solid foods between four and six months, probably because of displacement of breast milk by complementary foods“
- „In disadvantaged populations...none of these studies showed a growth advantage of complementary feeding of breast-fed infants prior to six months“
- „The risk of diarrhoeal morbidity in poor populations is 2-fold to 13-fold higher when breast-fed infants are given complementary foods between four and six months than when they are exclusively breast-fed“

² Dewey, K.G., Cohen, R.J, Brown, K.H. et al. Age of Introduction of Complementary Foods and Growth of Term, low-birth-weight breast-fed infants: A Randomized Intervention Study in Honduras. *Am J Clin Nutrition*, 1999; 69 (4): 679-686

³ WHO/NUT/98.1 Complementary Feeding of Young Children in Developing Countries: A Review of Current Scientific Knowledge, 1998

Other sources indicate that a period of six months exclusive breastfeeding is protective against allergies.⁴ A recent WHO/UNICEF publication⁵ cites several studies to support its position that „there is abundant evidence that exclusive breastfeeding for around the first six months reduces both morbidity and mortality and these beneficial effects are more pronounced where infection rates are greatest and hygiene and sanitation are poor“

The WHO/UNICEF Integrated Management of Childhood Illness (IMCI) materials are also very clear on this point: „Most babies do not need complementary foods before 6 months of age“.

These WHO and UNICEF statements and, equally important, the research on which they rest, have been the basis for the decisions by the Ministries of Health in a great many countries around the world⁶ to adopt „around 6 months“ as the age at which complementary foods should be introduced into the diets of most children. To the partial list cited in the footnotes can be added Norway and Paraguay - which have put in writing their countries' views that „about 6 months“ is the appropriate age for complementary feeding to begin - and Brazil which will be taking the same view at this meeting. The United States does not have an official policy on this, but it is worth noting that the prestigious American Academy of Pediatrics also recommends exclusive breastfeeding for about 6 months.

These public health recommendations do not, in any way, preclude clinical decisions made jointly by health care providers and the family which involve a different timetable for complementary feeding of a individual infant with special needs.

For consistency, changes should also be made to 3.8.1 to read „other ingredients suitable for infants who are more than six months of age“ and to 8.5.4 to read „The label shall clearly state that the product is not recommended for use below 6 months“

Rationale (B) The phrase in the current text „when...breastfeeding alone...is no longer sufficient to satisfy nutritional requirements „ does not reflect what is known about the physiology of human lactation. „Maternal milk production is finely tuned to the demand of the infant....and (experience) suggests that human lactation is quite plastic“⁷ is - that is, there is human beings no predetermined capacity to produce milk. „It is probably quite futile to use energy requirements as the basis for deciding when to introduce complementary foods at the population level“⁸

Nor does there seem to be widespread risk of specific nutritional deficiencies when exclusive breastfeeding continues for the full half year.

- Protein density in the first year of life is unrelated to growth.⁹
- The risk of iron deficiency anaemia among exclusively breastfed normal birth weight infants is low before nine months¹⁰ and experience with low-birth weight infants indicates that „the provision of iron-fortified

⁴ Kajosaari M. Saarinen V. Prophylaxis of atopic disease by six months total solid food elimination. *Acta Paediatr Scand* 1983; 72:411-5

⁵ WHO/UNICEF Guidelines on Complementary Feeding and Control of Iron Deficiency for 0-3 Year olds in the WHO European Region, 1999

⁶ Armenia, Belarus, Czech Republic, Kazakhstan, Kyrgyzstan, Uzbekistan, Slovakia, Georgia, Tajikistan; Micronesia, Mongolia, India; Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Guatemala, Haiti, Honduras, Nicaragua, Panama, Paraguay, Peru, Uruguay, Venezuela; Cameroon, Cape Verde, Central African Republic, Cote d'Ivoire, the Gambia, Ghana, Guinea, Liberia, Niger, Nigeria, Eritrea, Malawi, Mozambique, Rwanda, Sao Tome, Principe, South Africa, Uganda, Zambia and Zimbabwe

⁷ WHO/NUT/98.1 Complementary Feeding of Young Children in Developing Countries: A Review of Current Scientific Knowledge, 1998

⁸ Ibid.

⁹ Heinig, MJ et al. (1993) Energy and protein intakes of breast-fed and formula-fed infants during the first year of life and their association with growth velocity: The DARLING study. *American Journal of Clinical Nutrition*, 58:152-161

¹⁰ WHO/NUT/98.1 Complementary Feeding of Young Children in Developing Countries: A Review of Current Scientific Knowledge, 1998

complementary foods (does) not appreciably reduce the risk of anaemia at 6 months.“¹¹ Other strategies including late clamping of the cord and supplementary iron drops appear to make more sense for these special needs infants.

- Zinc deficiency does not appear to be a problem among infants who are exclusively breastfed for six months.¹²
- A review of the evidence on vitamin deficiencies indicates that „there are very few situations in which nutritional deficiencies are observed in exclusively breast-fed infants during the first six months...and „in all of the...situations, improving the mother’s diet or giving her supplements...or giving vitamin drops directly to the infant...is the recommended strategy to prevent deficiencies, as it cannot be guaranteed that complementary foods will have sufficient nutrient density and they may increase the risk of morbidity“¹³

ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES

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

¹¹ Ibid.

¹² Hambidge, KM et al (1979) Plasma zinc concentrations of breast-fed infants. *Journal of Pediatrics*, 94:607-608

¹³ WHO/NUT/98.1 Complementary Feeding of Young Children in Developing Countries: A Review of Current Scientific Knowledge, 1998

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.

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.¹⁴

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.

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

¹⁴ Including statements by the Representative of WHO at the 20th and 21st sessions of the CCNFSU. See also Appendix V, Statement of WHO on the recommended age range for the introduction of complementary foods, to the report of the 23rd session of the Codex Alimentarius Commission (ALINORM 99/37).

physical status.¹⁵ 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.¹⁶ In contrast, weight and growth velocity begin to fall at about 5 months of age when judged against a trial breastfed growth reference.¹⁷ On this basis the Committee urged the development of a new growth reference reflecting the current feeding recommendation.¹⁸ 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.¹⁹

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.

One of the most frequently cited studies – by Cohen et al. in Honduras²⁰ – 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 review²¹ 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

¹⁵ WHO Expert Committee on Physical status: the use and interpretation of anthropometry. World Health Organization, 1995 (WHO Technical Report Series, No. 854).

¹⁶ *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.

¹⁷ *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.

¹⁸ For a summary of latest developments in this connection, see: WHO Executive Board, 105th 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.

¹⁹ WHO *Expert Committee on Physical status*, op. cit., p. 249.

²⁰ 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.

²¹ Frongillo EA and Habicht JP. Investigating the weaning's dilemma: lessons from Honduras. *Nutrition Reviews* 1997;55:390-95.

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.²² 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”.²³

A commentary on solid feeding guidelines published in *The Lancet* in November 1998²⁴ 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.

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.²⁵ 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.²⁶

The WHO multicentre growth reference study²⁷

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.

²² 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).

²³ 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.

²⁴ Werk LN and Alpert JJ. Solid feeding guidelines. Commentary. *The Lancet* 1998;352:1569.

²⁵ The draft global strategy will be submitted, after consultation, to the World Health Assembly in May 2002.

²⁶ 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.

²⁷ WHO Executive Board, op. cit.

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.*

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 breastfeeding²⁸ 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*.²⁹ 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 feeding³⁰ 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 IMCI³¹ formulation "at least 4 months and if possible 6 months", which UNICEF previously accepted.

²⁸ 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>

²⁹ 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.

³⁰ Breastfeeding: foundation for a healthy future. New York, United Nations Children's Fund, Division of Communication, August 1999.

³¹ Integrated Management of Childhood Illness (document WHO/CHD/97.3). Geneva, World Health Organization, Department of Child and Adolescent Health and Development.

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 1984,³² 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.

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.*³³

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

(... see 8.5.4 ...)

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.

2. DESCRIPTION

AUSTRALIA

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.

³² Resolution WHA37.30, in document WHA37/1984/REC/1, page 19.

³³ Resolution WHA39.28, in document WHA39/1986/REC/1, page 29.

BRAZIL

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.

CANADA

• Name of Standard

If this standard continues to encompass foods which are primarily legumes, starchy roots and stem products, the name of the standard should be "**Standard for Processed Foods Based on Cereals, Legumes, Starchy Roots or Stem Products for Infants and Young Children**". This change should also be introduced throughout the standard wherever reference to all of cereals and/or legumes and/or starchy roots and/or stem products is made.

- The minimum amount of milled cereal and/or legumes and/or starchy root or stem products in these foods should be 60% on a dry weight basis.

The words „final mixture“ should be changed to „product“.

CHINA

We agree to include "starchy roots or stem products" as the basis of cereal-based complementary food. Although these food ingredients may lower the nutritional density of the products, considering that the food sources vary significantly in different countries, these foods should be allowed to use, as long as the final products meets the criteria for quality and protein content.

CUBA

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.

GERMANY

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.

INDIA

India has been consistently taking a stand in the past two Codex Committee on Nutrition and Foods for Special Dietary Uses meetings held at Bonn in 1996 and at Berlin in 1998, and the 23rd Session of the Codex Alimentarius Commission at Rome in 1999 **against the following two major issues in the proposed draft revised standard for processed cereal based foods for infants and young children** as has also been reflected in the respective reports:

- i) Inclusion of starchy roots and tubers in the formulation of cereal based foods for infants and young children replacing part of the cereal, and
- ii) Specifying the age of '4-6 months' for introduction of these foods to infants.

India supported by many other developing countries desired deletion of starchy roots and stems from the composition of the cereal based foods for infants and wanted the age for introduction of these foods to be at 'about 6 months' so that the interests of infants and young children in the developing world could be protected.

(...)

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.

Starchy roots and starchy stems should be deleted from the essential composition

Starchy roots can never replace cereals, legumes or pulses as the later are rich in various nutrients like carbohydrate, protein, minerals and certain vitamins while starchy roots can provide only starch (carbohydrate) to the infant.

The argument of making up the protein content of these foods with synthetic amino acids is not acceptable to India.

Codex standards applicable for these foods will be a binding for all countries and manufacturers will misuse this clause for their own benefit.

The problem of malnutrition is a matter of serious concern in the developing world. Various studies have indicated that malnutrition sets in around six months of age and reaches its peak by 24 months. This is the time when cereal-based foods are needed for infants. It is, therefore, important to ensure that good quality and nutritious food items like cereal and pulses are used in formulation of these foods. India very strongly objects to the mention of starchy roots in the essential composition.

(...)

In addition to above important issues, India also recommends that Cereal Based complementary foods should have more than 25% cereal content. Infact it should be more than 50%. The standard should also specify the degree of milling under product description as germ part of grain is a more important nutrient source.

MEXICO

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 propose to the Committee that Paragraph 2 be clarified regarding the ingredients to which the remaining 75% of the product applies, as the text simply mentions that the proportion of cereals and starchy stem products must be 25%. In principle these ingredients could be any optional ingredients. However, we suggest pointing out that the remaining ingredients must be a mixture of these optional ingredients in order to ensure

that cereals and starchy stem products still form the main basis, i.e. that the share of individual components may not exceed 25%.

SENEGAL

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.

UNITED KINGDOM

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

ENCA - EUROPEAN NETWORK OF CHILDBIRTH ASSOCIATIONS

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

IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK

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.

2.1. Product Definitions

CANADA

2.1.1 and 2.1.4

It is suggested that consideration be given to the inclusion of breastmilk as an alternative liquid for reconstitution of the products that are subject to this Standard, i.e. „Reconstituted with breastmilk, milk or other...“

MEXICO

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

2.2 Other Definitions

- no comments -

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

BRAZIL

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 papers.

URUGUAY

In our opinion, under the essential composition and quality factors, the content of dietary fibre should be limited to 5g/100g of the food (on a dry matter basis).

3.1 Essential Composition

3.1.1

BRAZIL

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.

CHINA

We agree to include "starchy roots or stern products" as the basis of a cereal-based complementary food in 3.1.1. The reason is stated in the previous bullet.

INDIA

Delete "and/or starchy roots (such as arrow root, yam or cassava) and starchy stems "and "soybean". Reword to read: Dry cereals, rusks, biscuits and pasta 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.

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 and hence does not need to be mentioned again.

KOREA, REPUBLIC OF

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

MEXICO

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.

POLAND

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 used, but they should not be genetically modified.

SRI LANKA

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.

URUGUAY

Delete the addition "starchy roots" or "starchy stems".

The addition of these products will directly impair the energy density and quality of cereal-based products.

IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK

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.

3.1.2

MEXICO

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

3.2 Energy Density

AUSTRALIA

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.

GERMANY

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)**.

KOREA, REPUBLIC OF

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

MEXICO

Regarding Paragraph 3.2, we suggest that the energy density of the product quoted at 0.8 kcal/100 g be checked since the calorific value of products sold in Mexico before preparation in accordance with the manufacturer's instructions is 350 kcal/100 g.

UNITED KINGDOM

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.

3.3 Protein

NORWAY

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 ... (see below 3.3.1 and 3.3.2).

3.3.1

AUSTRALIA

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.

BRAZIL

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.

CANADA

Change the term „chemical index“ to „amino acid score“.

The second sentence in 3.3.1, „In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the protein mixture, and only in the proportions necessary for that purpose.“ should be deleted. Allowing addition of amino acids encourages the use of low quality protein.

GERMANY

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**".

INDIA

Add: "The protein content of the product 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.

NORWAY

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.

URUGUAY

The following should be added: "The protein content must amount to at least 10% on a dry matter basis."

We must assume that in many countries and regions of the world in which animal milk is not available or not part of the local diet, cereal-based products will be mixed with water. The processing of the cereal-based foods should be limited to retain a protein content as high as possible. This also ensures that micro-nutrients are retained.

IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK

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.

3.3.2

NORWAY

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).

3.3.3

- no comments -

3.3.4

ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES

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

3.4 Carbohydrates**3.4.1**

AUSTRALIA

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).

INDIA

3.4.1 and 3.4.2 Delete "honey"

KOREA, REPUBLIC OF

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.

MEXICO

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

IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK

3.4.1 and 3.4.2 Delete "honey".

3.4.2

GERMANY

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.

HUNGARY

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).

INDONESIA

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, glukose, glocose 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)

KOREA, REPUBLIC OF

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.

SWITZERLAND

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).

UNITED KINGDOM

Section 3.4.2 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**).”

EUROPEAN COMMUNITY

There is a mistake concerning the amount of permitted added carbohydrate (Section 3.4.2, 1 st indent). The wording is in contradiction with paragraph 63 of the report of the 21 st session of the Codex Committee on nutrition and foods for special dietary uses.

ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES

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)**.

3.5 Lipids

CANADA

This section should include a prohibition against the use of partially hydrogenated oils in any of the products that are subject to this standard.

3.5.2 (new) Products described in Sections 2.1.1 to 2.1.4 must not contain partially hydrogenated fats as ingredients.

INDIA

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.

SRI LANKA

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

THAILAND

We propose that

- lauric acid, myristic acid and palmitic acid should be included in the draft revised standard and each of mentioned fatty acid should not exceed 10% of total lipid content.
- the amount of linolenic acid should be 10% of linoleic acid
- the amount of trans-fatty acid should not exceed 4% of total fat content.

IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK

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

ARGENTINA

The square 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.

AUSTRALIA

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.

CHINA

We agree with the sodium content of the products described in 3.6.1.

GERMANY

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 ...*".

HUNGARY

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.

INDIA

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.

INDONESIA

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.

NORWAY

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).

SWITZERLAND

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

THAILAND

The amount of sodium in this section should be 70 mg/100 kcal. The sentence should be read as follows:-
“The sodium content of the products described in sections 2.1.1 to 2.1.4 of this standard shall not exceed 70 mg/100 kcal of the ready to eat product, and also in the case of the products intended for children over one year of age, where the sodium content shall not exceed 70 mg/100 kcal.”

UNITED KINGDOM

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.”

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

URUGUAY

Retain square brackets. The sodium content of complementary foods should be as low as possible. Various studies have shown that an inordinately high sodium content in infant formula is harmful, and that infants and young children may acquire a preferred taste for salty foods when fed salty foods during infancy and early childhood.

EUROPEAN COMMUNITY

The exemption for products for children over one year of age is not acceptable. The relevant part of the section (“, except ... 200mg/100 kcal”) should be deleted. The figure of 100 mg/100kcal should be retained and the square brackets be deleted.

IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK

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.

ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES

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

3.6.2

CANADA

The need for specifying a minimum calcium content is questioned.

3.6.3

AUSTRALIA

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.

CANADA

The need for specifying a minimum calcium content is questioned.

3.7 Vitamins

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.*

3.7.1

ARGENTINA

The square brackets in section 3.7.1 should be deleted.

AUSTRALIA

The square brackets in section 3.7.1 should be deleted.

CANADA

The need for a minimum vitamin B₁ requirement is questioned. Furthermore, this section is inconsistent with 3.7.3.

CHINA

We agree with the amount of vitamin B₁ (thiamin) in 3.7.1.

FRANCE

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

HUNGARY

This statement is acceptable, brackets should be deleted.

SWITZERLAND

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.

UNITED KINGDOM

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.

EUROPEAN COMMUNITY

“Vitamin B1”: The figure of 25 µg/100 kJ (100 µg/100 kcal) is preferred.

IFOAM - INTERNATIONAL FEDERATION OF ORGANIC AGRICULTURE MOVEMENTS

IFOAM is supporting the Vitamine B1 (thiamine) content of 0.06mg /100 kcal (15 mg/100kJ), which is proposed by the Codex Commission. This content is lower than the one in the EU Commission Directive 96/5/EC of February 1996 (No. L49, 28.2. 1996). Our organisation is very much in favour of such a lower minimum content, which allows to cover the minimum need of thiamine in organically produced foods by natural sources. We propose to take the brackets away.

Detailed comment of our expert person regarding the Vitamin B 1 (thiamine) Content in Processed Cereal Based Foods for Infants and Young Children (Point 3.7.1. in CL 1999/20-NFSDU)

Cereal based baby foods are an excellent nutritional basis for babies. Cereals, especially whole grain cereals are rich in natural thiamine. Codex proposes a thiamine content of 0.06mg /100 kcal (15 mg/100kJ). **This recommendation covers the need of the babies and should not be changed.**

The reasons:

1. Recommendations**Necessary daily intake of vitamin B1**

The organisations responsible state a need for vitamin B1 in relation to energy needed. The following is relevant:

<u>Adults – intake per kJ/kcal</u>	Vitamin B1 per 1000 Joules	Vitamin B1 per 1000 kcal
WHO/FAO	0.1 mg	0.42 mg
DGE (German society for nutrition)	0.12 mg	0.5 mg

Daily intake for children

The prescribed daily intake of vitamin B1 has the following values

DGE	0.4 mg
USA	0.6 mg

From this follows in relation to the recommended energy intake:
per 100 kcal

Infants, 3 - 5 months old,
energy intake 700 kcal / day

DGE	0.057 mg
-----	----------

<u>Codex proposes</u>	0.060 mg
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2. The natural content of thiamine is also sufficient for babies

According to our search in literature no lack of vitamin B1 is recorded with healthy babies and small children. **The natural content of thiamine in processed cereal based baby food is sufficient.**

3. What would a level higher than 15 µg/100kJ mean?

It would mean that artificial thiamine would have to be added to all cereal based baby foods. There is good reason to question what the consequences of too high vitamin contents in food, especially in baby food are.

As for organic food, consumers expect that organic food is all natural. They would not understand and accept that artificial thiamine should be added.

3.7.2 and 3.7.3**CANADA**

3.7.2: Canada suggests that this section be deleted. All vitamin and mineral additions to the products subject to this standard should be left to the decision of individual countries. Consequently, section 3.7.3 should be reworded as follows:

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

MEXICO

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.

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

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 Optional Ingredients

3.8.1

ARGENTINA

In line with the comments under Section 1 Scope, the square brackets should be deleted.

AUSTRALIA

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

BRAZIL

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

CHINA

We suggest that the square brackets in 3.8.1 [four to six months of age] should be removed.

FRANCE

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

GERMANY

We suggest to delete the **square brackets** around "*four to six months of age*".

INDIA

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 manufactures to add just about any ingredient they choose. A standard for infant and young child foods should not allow unspecified optimal ingredients.

MALAYSIA

The square brackets in 3.8.1 should be deleted to be in line with the comments under Scope and accept the text "4 to 6 months of age".

MEXICO

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

SWITZERLAND

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

URUGUAY

Delete the entire paragraph. The text as it now reads allows the usage of any ingredient suitable for children aged 4–6 months in addition to those specified in Paragraph 3.1. Moreover, the age range of "4–6 months" is repeated.

A standard for foods for infants and young children must not allow the optional addition of unspecified ingredients.

EUROPEAN COMMUNITY

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

IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK

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.

ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES

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

3.8.2

AUSTRALIA

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".

MEXICO

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

3.8.3

BRAZIL

Change "after 9 months" for "after 12 months".

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

INDIA

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.

KOREA, REPUBLIC OF

Change "after 9 months" to "**after one year of age**"

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

MEXICO

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.

NORWAY

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).

URUGUAY

Change "...after nine months" to "after 18 months". Cocoa can cause allergic reactions and should only be introduced into children's diet after 18 months. This is stipulated in the national legal regulations on this product.

IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK

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.

3.8.4**HUNGARY**

Gluten containing cereals or materials can be used only in products to be consumed after six month of age.

3.9 Quality Factors**3.9.1****THAILAND**

We propose that this section should be read as follows: - "All ingredients, including optional ingredients, shall be clean, safe, suitable and of good quality according to GMP if applicable."

3.9.2

- no comments -

3.9.3

- no comments -

3.10 Consistency and Particle Size**3.10.1****ARGENTINA**

We propose amending the sentence as follows: "Cuando se prepare de acuerdo a las instrucciones de uso, los alimentos procesados a base de cereales, deberían tener una textura apropiada para la alimentación de lactantes o niños pequeños de la edad para la que el producto está destinado". (*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.*) In effect we propose deleting the reference to "spoon feeding" and replacing it simply with the word "feeding" to reflect the fact that the standard also covers rusks, biscuits and other foods not fed by spoon.

AUSTRALIA

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'

BRAZIL

Delete: brackets.

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

CHINA

We suggest that "[spoon feeding] of" in 3.10.1 be deleted.

FRANCE

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.

GERMANY

We suggest to delete the square brackets around "spoon feeding".

HUNGARY

The words "spoon feeding" may be used and even may be omitted.

INDIA

Delete brackets.

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

INDONESIA

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.

MALAYSIA

Malaysia proposes to delete the square brackets in section 3.10.1 and adopt the text "spoon feeding" so as to discourage the use of milk bottles in feeding cereal-based foods.

SENEGAL

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.)"

SWITZERLAND

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.

URUGUAY

Section 3.10.1 should be reworded as follows: “*When prepared according to the label directions for use, the cereal-based foods described in Paragraphs 2.1.1 and 2.1.2 should have a texture appropriate for the spoon feeding of infants or young children of the age for which the product is intended.*”

ENCA - EUROPEAN NETWORK OF CHILDBIRTH ASSOCIATIONS

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

IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK

Delete brackets.

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

ILCA - INTERNATIONAL LACTATION CONSULTANT ASSOCIATION

Keeping in mind the concerns expressed by Argentina, Australia, Indonesia and Switzerland that the phrase „spoon feeding“ did not make provision for feeding cereal-based products such as rusks and biscuits, ILCA suggests that this might be rephrased to read „When prepared according to the label directions for use, processed cereal-based food should have a texture appropriate for spoon or finger feeding of infants or young children of the age for which the product is intended“

3.10.2

- no comments -

3.11 Specific Prohibition

- no comments -

4. FOOD ADDITIVES

THE USE OF ADDITIVES IN PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN

Prepared by the Netherlands, Canada, China, France, Germany, Romania, Spain, Switzerland, United Kingdom, the United States of America (USA), Uruguay, Slovakia, EC, and ISDI

Since the present standard on processed cereal-based foods for infants and young children (Codex stan 74-1991) came into effect, there has been a tremendous product development. This means that the present paragraphs on additives do not reflect the situation on the market any more.

Regarding the lay-out of the paragraphs in the annex it can be noted that the additives which are part of the present paragraphs on additives are presented in the annexes in regular characters. Following the room documents of the last meeting of the Committee and the request of several delegations new additives have been inserted in italics. The comments of the working group regarding the use of specific additives are given in the annexes preceded by an asterisk. ISDI suggested a number of additives to be added to the paragraphs, these

insertions are marked with two asterisks. The working group did not have the opportunity to comment these additions.

Besides the comments regarding specific additives the working group has the following comments of a more general nature.

1. The general view is that the use of additives in foodstuffs for young children should be as restricted as possible. The question is whether this should be achieved by limiting the absolute number of additives permitted in these foodgroups or whether the insertion of several additives with a comparable function is acceptable.
2. Many remarks concerned the units to be used in which the use of additives is expressed. Most members of the working group supported the use of mg/kg or mg/l of ready to use formula or babyfood. The presentation has been adapted to this suggestion.
3. The use of flavours, nature identical or artificial in infant food showed to be controversial and, more in particular the acceptable amount of ethyl vanillin was questioned.
4. Further information on the chemical nature, function and safety of malt carbohydrases is considered necessary.

ANNEX

Proposed draft revised Standard for Processed Cereal-based foods for infants and young children (CODEX STAN 74-1991)

Paragraph 4: Food additives, flavours and enzymes

		INS:	Per kg as consumed	Status/ remarks
4.1	Emulsifiers			
4.1.1	Lecithin	322	1.5 g * 10 g	ADI: n.l.
4.1.2	Mono- and diglycerides	471	1.5 g *5 g singly or in combination with 472a, b and c	ADI: n.l.
<i>new</i>	<i>Acetic acid esters of mono- and diglycerides</i>	<i>472a</i>	<i>5 g/kg singly or in combination with 472a, b and c</i>	<i>ADI: n.l.</i>
<i>new</i>	<i>Lactic acid esters of mono- and diglycerides</i>	<i>472b</i>	<i>5 g/kg singly or in combination with 472a, b and c</i>	<i>ADI: n.l.</i>
<i>new</i>	<i>Citric acid esters of mono- and diglycerides</i>	<i>472c</i>	<i>5 g/kg singly or in combination with 472a, b and c</i>	<i>ADI: n.l.</i>
**new 4..	Thickening agents			
**new	<i>Locust bean gum</i>	<i>410</i>	<i>10 g individually or in combination with 412, 414, 415, 440 20 g for gluten-free cereals, individually or in combination with 412, 414, 415, 440</i>	<i>ADI: n.s.</i>

		INS:	Per kg as consumed	Status/ remarks
**new	<i>Guar gum</i>	412	10 g individually or in combination with 410, 414, 415, 440 20 g for gluten-free cereals, individually or in combination with 412, 414, 415, 440	ADI: n.s.
**new	<i>Acacia gum (gum Arabic)</i>	414	10 g individually or in combination with 410, 414, 415, 440 20 g for gluten-free cereals, individually or in combination with 412, 414, 415, 440	ADI: n.s.
**new	<i>Xanthan gum</i>	415	10 g individually or in combination with 410, 414, 415, 440 20 g for gluten-free cereals, individually or in combination with 412, 414, 415, 440	ADI: n.s.
**new	<i>pectins</i>	440	10 g individually or in combination with 410, 414, 415, 440 20 g for gluten-free cereals, individually or in combination with 412, 414, 415, 440	ADI: n.s.
**new	<i>Oxidized starch</i>	1404	50 g	
**new	<i>Monostarch phosphate</i>	1410	50 g	
**new	<i>Distarch phosphate</i>	1412	50 g	
**new	<i>Phosphated distarch phosphate</i>	1413	50 g	ADI: n.s.
**new	<i>Acetylated distarch phosphate</i>	1414	50 g	ADI: n.s.
**new	<i>Acetylated starch</i>	1420	50 g	
**new	<i>Acetylated distarch adipate</i>	1422	50 g	
**new	<i>Starch sodium octenyl succinate</i>	1450	50 g	
4.2	PH Adjusting Agents			
**new	<i>Acetic acid</i>	260	GMP	ADI: n.l.
**new	<i>Potassium acetate</i>	261	GMP	ADI: n.l.
**new	<i>Sodium acetate</i>	262	GMP	ADI: n.l.
**new	<i>Calcium acetate</i>	263	GMP	ADI: n.l.
**new	<i>L(+) malic acid</i>	296	GMP	ADI: n.l.
**new	<i>L(+) sodium lactate</i>	325	GMP	ADI: n.l.
**new	<i>L(+) potassium lactate</i>	326	GMP	ADI: n.l.
**new	<i>L(+) calcium lactate</i>	327	GMP	ADI: n.l.
**new	<i>Hydrochloric acid</i>	507	GMP	ADI: n.l.
**new	<i>Sodium citrates</i>	331	GMP	ADI: n.l.

		INS:	Per kg as consumed	Status/ remarks
**new	<i>Potassium citrates</i>	332	GMP	ADI: n.s.
**new	<i>Sodium carbonate</i>	500i	GMP	ADI: n.l.
**new	<i>Sodium hydroxide</i>	524	GMP	ADI: n.l.
**new	<i>Potassium hydroxide</i>	525	GMP	ADI: n.l.
**new	<i>Calcium hydroxide</i>	526	GMP	ADI: n.l.
4.2.1	Sodium hydrogen carbonate	500ii	GMP, within limits for sodium *delete	ADI: n.s.
4.2.2	Potassium hydrogen carbonate	501ii	GMP *delete	ADI: n.s.
4.2.3	Calcium carbonate	170i	GMP	ADI: n.s.
4.2.4	L(+) Lactic acid	270	1.5 g *GMP	ADI: n.l.
4.2.5	Citric acid	330	2.5 g *GMP	ADI: n.l.
new	<i>Sodium phosphate</i>	339iii	1 g/kg singly or in combination with 340 and 341 iii, expressed as P2O5	Mtdi 70 mg/kg b.w. day
new	<i>Potassiumphosphate</i>	340	1 g/kg singly or in combination with 340 and 341 iii, expressed as P2O5	Mtdi 70 mg/kg b.w. day
new	<i>Calciumphosphate</i>	341iii	1 g/kg singly or in combination with 340 and 341 iii, expressed as P2O5	Mtdi 70 mg/kg b.w. day
4.3	Antioxidant			
4.3.1	Tocopherol mix	306b	300 mg/kg fat, singly or in combination	Group ADI: 0,15-2 mg
new	<i>Alpha-tocopherols</i> <i>Gamma-tocopherols</i> <i>Delta-tocopherols</i>	307 308 309	*100 mg/kg in fat containing food singly or in combination (304 included)	
4.3.3	L-Ascorbyl palmitate	304	200 mg/kg fat *100 mg/kg in fat containing food singly or in combination with tocopherols	ADI: 1,25 mg
4.3.4	L-Ascorbic acid and its sodium and potassium salts	300 301 303	50 mg, expressed as ascorbic acid, within the limits for sodium and potassium	Group ADI: n.s.
new	<i>Calcium L-ascorbate</i>	302	*20 mg/100 g 3 g/100 g *2 g/100 g *0,2 mg/100 g	
4.4	Flavours			<i>An inventory is made of the use of flavours by CCFAC</i>
4.4.1	Vanilla extract		GMP	
4.4.2	Ethyl vanillin		7 mg/100 g *1 mg	ADI: 3 mg
4.4.3	Vanillin		7 mg/100 g	ADI: 10 mg
**new	<i>Natural fruits extracts</i>		GMP	

		INS:	Per kg as consumed	Status/ remarks
4.5	Enzymes			<i>Enzymes are not yet being dealt with in codex</i>
4.5.1	Malt carbohydrases		GMP	ADI: n.l.
4.6	Leavening agents			
4.6.1	Ammonium carbonate	503i	GMP	ADI: n.s.
4.6.2	Ammonium hydrogen carbonate	503ii	GMP	ADI: n.s.
4.7	Anti-caking agents			
<i>new</i>	<i>Siliciumdioxide</i>	<i>551</i>	<i>2 g/kg *0,2 g *for dry cereals</i>	<i>ADI: n.s.</i>
** new 4.8	Packaging gases			
<i>**new</i>	<i>Carbon dioxide</i>	<i>290</i>	<i>GMP</i>	
<i>**new</i>	<i>Argon</i>	<i>938</i>	<i>GMP</i>	
<i>**new</i>	<i>Helium</i>	<i>939</i>	<i>GMP</i>	
<i>**new</i>	<i>Nitrogen</i>	<i>941</i>	<i>GMP</i>	
<i>**new</i>	<i>Nitrous oxide</i>	<i>942</i>	<i>GMP</i>	
<i>**new</i>	<i>Oxygen</i>	<i>948</i>	<i>GMP</i>	

ARGENTINA

We request the inclusion of the natural fruit flavours permitted under the Codex standard for follow-on foods (CODEX STAN 156-1997).

SRI LANKA

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

UNITED STATES OF AMERICA

Addendum 1: The Use of Additives in Processed Cereal-Based Foods for Infants and Young Children:

We are concerned about the lack of a defined set of criteria and process for determining the safety and appropriateness of additives for processed cereal-based foods for infants and young children. Prior to considering the listing in Addendum 1, we strongly recommend that a more thorough consideration of the following issues be undertaken:

1. Identification of the specific components required to demonstrate a “safe use” status for foods for infants and young children;
2. Description of the types of scientific evidence and/or documentation of safe history of use needed to support inclusion in a positive list;
3. Clarification of the relationship of this process to evaluations and policies of JECFA and the CFAC;
4. Clarification of the CCNFSDU process for providing and evaluating the scientific evidence and rationale for a positive list of this type.

EUROPEAN COMMUNITY

Will collaborate with relevant Working Group.

IFAC - INTERNATIONAL FOOD ADDITIVES COUNCIL

IFAC's Gums Committee also comments in support of CX/NFSDU 00/7 adding five new thickening agents (Locust Bean Gum, Guar Gum, Acacia Gum (Gum Arabic), Xanthan Gum and Pectins) at 10 grams alone or in combination in cereal based foods and at 20 grams for gluten free cereals.

ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES

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.

4.1 Emulsifiers

POLAND

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.

4.2 pH Adjusting Agents

MEXICO

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)

4.3 Antioxidants

MEXICO

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)

POLAND

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.

4.4 Flavours

BRAZIL

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.

GERMANY

It should be suggested to only admit *natural* and *nature-identical flavours*.

INDIA

Delete reference to flavors

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

MEXICO

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).

POLAND

p.4.4.2 Polish food legislation doesn't permit synthetic ethyl vanillin in products for infants and children up to 3 yers. 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.

IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK

Delete reference to flavors

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

4.5 Enzymes

- no comments -

4.6 Leavening Agents

MEXICO

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

5. CONTAMINANTS

SRI LANKA

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.

5.1 Pesticide Residues

GERMANY

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"*.

INDIA

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 pesticides the cumulative pesticide load is unclear and may present a health hazard to babies and young children.

SENEGAL

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."

URUGUAY

This paragraph should be reworded and its content stated clearly:

"The product shall be prepared ... under good manufacturing practices ... or if technically unavoidable, the product as sold may not contain more than 0.01mg/kg per substance."

This standard should have a stated maximum level for residues and pesticides and not vague phrases such as in the present text. There are 200 known pesticides found in baby foods.

EUROPEAN COMMUNITY

The Scientific Committee for Food (SCF), in a recent opinion on the subject (4 June 1998), expressed doubts whether all existing ADIs set within the EU or by the Joint Meeting on Pesticide Residues (JMPR) are adequate to protect the health of infants and young children. They said that there is doubt as to whether all existing ADIs have been set using databases that include all the "core" tests (multigeneration studies, developmental toxicity (teratology) studies, short-term toxicity studies, long-term chronic toxicity/carcinogenicity studies and neurotoxicity studies) now considered necessary for risk assessment for infants and young children. In addition, the SCF identified three relatively new areas of toxicity (particular endocrine and reproductive effects, developmental neurotoxicity and immunotoxicity) that deserve special consideration in relation to infants and young children. The core tests may indicate potential problems in these relatively new areas and trigger further studies. However, some substances could have effects in these areas in the absence of any warning from the results of existing core studies.

As long as uncertainty of the adequacy of ADI exists, the residues of pesticides in foods intended for infants and young children have to be as low as possible. Therefore it is proposed that a second sentence is added to

the second paragraph of the section (“The products covered ... by the Codex Alimentarius Commission”) as follows:

“These limits shall take into account the specific nature of the products concerned and the specific population group for which they are intended”.

IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK

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

CANADA

The term „practically free“ should be changed to „to the maximum extent possible“ in line with section 5.1. In addition, as in section 5.1, this section should indicate that products need to comply with relevant Codex standards.

„The product shall be free from residues of hormones **and** antibiotics as determined by means of agreed methods of analysis and from other contaminants, especially pharmacologically active substances, **to the maximum extent possible.**

The products covered by the provisions of the Standard shall comply with those maximum residue limits established by the Codex Alimentarius Commission.“

INDIA

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

IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK

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

GERMANY

We suggest to replace "*recommended*" by "*shall*".

INDIA

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, 1977), 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.

SENEGAL

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).

IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK

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.

6.2

GERMANY

We suggest to replace "*should*" by "*shall*".

6.3 - section does not exist in the draft

INDIA

6.3 (a) Reword to read: “shall be free from pathogenic microorganisms”

6.3 (b) Reword to read: “shall be free from parasites”

7. PACKAGING

MEXICO

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

8. LABELLING

INDIA

Add the following two texts:

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

Label graphics should be 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 nutrition 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.

MEXICO

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.

UNITED KINGDOM

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.

IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK

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.

ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES

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 2nd sentence.

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

8.1 The Name of the Food

CANADA

Canada suggests that a minimum amount of cereal should be required in a product that is designated as „cereal“. For example, 60 % of the weight of the product as sold. This section would then be worded as follows:

„The name of the food shall be „Dry Cereal for Infants (and/or Young Children)“, **provided the food contains no less than 60 % cereal by weight as sold**“.

8.2 List of Ingredients

SWITZERLAND

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

ARGENTINA

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

In section 8.3.1(b), the reference should be to sections 3.6 and 3.7, not to 3.2.2.

AUSTRALIA

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.”

HUNGARY

ad 8.3.1. (b) There is no Section 3.22. in this draft.

INDONESIA

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).

JAPAN

To avoid the risk of the imprudent use of honey in the home, the following sentence should be added in labeling section.

8.3 The labeling that the product is manufactured and/or processed in the way as not to contain live spores of Clostridium botulinum in the product, where appropriate, should be made if products intended for infants contain honey.

MALAYSIA

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

In the last part of section 8.3.1 (b), should read as added according to Section 3.7 shall be declared per 100g

SRI LANKA

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

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.

UNITED KINGDOM

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’

EUROPEAN COMMUNITY

Paragraph 77 of the report of the 21 st session states that section 8.3 was amended as proposed by the observer from the EC. This however does not appear in the proposed draft revised standard appearing in Annex IV.

The proposal, which was read and agreed by the Committee, was based on the EC comments (CX/NFSDU 98/6 – Add 2, page 6) and took into account the comments of other participants, in particular the text suggested by Canada for paragraph 8.3.1.a. It also took into account the fact that customarily for solid food 100 g is a reference amount for nutrient declaration while for liquid food 100 ml is a reference amount. The proposed text which has been accepted by the Committee should read as follows:

“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), and the amount of protein, carbohydrate and fat expressed in grammes (g) per 100 g or 100 ml of the food as sold, and where appropriate, as per specified quantity of the food as suggested for consumption;

(b) the average amount of each vitamin and mineral for which specific levels are defined in section 3.6 and 3.7 expressed in numerical form per 100 g or 100 ml of the food as sold and, where appropriate, as per specified quantity of the food as suggested for consumption;

c) any other nutritional information required by national legislation.

8.3.2 The labelling may bear the average amount of the vitamins and minerals when their declaration is not covered by the provisions of section 8.3.1.(b) expressed in numerical form per 100 g or 100 ml of the product as sold and, where appropriate, per specified quantity of the food as suggested for consumption.

ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES

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 Date Marking and Storage Instructions**8.4.1**

AUSTRALIA

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).

8.4.2

- no comments -

8.4.3

GERMANY

This item can be **deleted**, it has been regulated in the Codex Standard 1-1985.

ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES

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 Information for Utilization**8.5.1**

- no comments -

8.5.2

ARGENTINA

We recommend that section 8.5.2 should be written as: "Leche o fórmula y *no sólo agua* será usada para diluir o mezclar" (*Milk or formula but not water alone shall be used for dilution or mixing.*)

AUSTRALIA

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

CANADA

Consideration should be given to including breastmilk as an alternative to reconstitute the food in the directions, i.e. „*Breastmilk, milk or formula but no water shall be used for dilution or mixing*“ or an equivalent statement.“

CHINA

We suggest that "but no water" in 8.5.2 be deleted.

GERMANY

We suggest to change the sentence into "... *but not water alone shall be used for...*".

UNITED KINGDOM

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

ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES

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

AUSTRALIA

The square brackets in section 8.5.3 can be deleted.

BRAZIL

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.

CHINA

We suggest that 8.5.3 be deleted as it is already specified above.

FRANCE

The square brackets should be deleted.

GERMANY

We suggest to remove the square brackets (and also to delete the word "in" subsequent to "on").

HUNGARY

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.

INDIA

Remove square brackets

MEXICO

We propose emphasizing in Paragraph 79 of the Report of the 21st Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses that the 75% in the rule specified in the proposal by the Association of Official Analytical Chemists (AOACS) corresponds to the 25% rule, since the relevant statement in the report is unclearly worded. (Translator's note: The author probably refers to the Association of European Coeliac Societies (AOECS)).

SWITZERLAND

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

UNITED KINGDOM

The UK considers the text at section 8.5.3 acceptable and propose that the square brackets are deleted.

AOECS - ASSOCIATION OF EUROPEAN COELIAC SOCIETIES

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).

EUROPEAN COMMUNITY

The square brackets should be deleted.

ENCA - EUROPEAN NETWORK OF CHILDBIRTH ASSOCIATIONS

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

IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK

Remove square brackets

ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES

ISDI favours the deletion of the square brackets.

8.5.4

AUSTRALIA

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.

BRAZIL

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

CANADA

We would support the WHO's recommendation to change the 2nd sentence of this section to „The label shall clearly state that the product is recommended for use from the age of about 6 months and not before 4 months.“

CHINA

We suggest that "to begin complementary feeding" be revised as "to begin complementary feeding in infants over 4 to 6 months of age" in 8.5.4.

FRANCE

The square brackets should be deleted.

GERMANY

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 3rd sentence the word "*precisely*" should be deleted. It is impossible to precisely indicate the beginning of complementary feeding.

HUNGARY

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.

INDIA

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

INDONESIA

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

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 preciseley 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.

MALAYSIA

To delete the square brackets in section 8.5.4 and adopt the text, to be in line with WHO recommendation.

MEXICO

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.)

MEXICO

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.

SWITZERLAND

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

UNITED KINGDOM

The UK considers the text at section 8.5.4 acceptable and propose that the square brackets are deleted.

URUGUAY

Apart from the explanation that the product may be introduced at the age of six months, the label must contain the following **specific instruction** in clearly visible letters: "To be used on doctor's advice."

The **label** should clearly state what “young children” means as defined in the present standard. We also agree that the label should always state the presence or absence of gluten in the food.

We would also like the following three statements to be included in the section on “Labelling”:

1. “The label shall have no pictures of infants or young children which idealizes the use or suggests an inappropriate age of introduction of these products.”

2. “No health claims are permitted regarding the properties of the products covered by this Standard.”

Health-promoting properties are used to idealize the nutritional and health-related aspects of processed infant foods. Statements of this kind serve advertising purposes and are very liable to mislead consumers. They must therefore be prohibited in order to protect the consumer’s right to make an informed choice not based on alleged properties.

3. “IMPORTANT NOTICE: For best child nutrition and health, breast-feeding should continue after the introduction of complementary foods as of the age of about six months.”

EUROPEAN COMMUNITY

The square brackets should be deleted.

ENCA - EUROPEAN NETWORK OF CHILDBIRTH ASSOCIATIONS

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

IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK

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

See Scope for rationale.

ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES

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

WHO - WORLD HEALTH ORGANIZATION

Proposed improvements in the draft revised Codex standard

Although the present Codex Standard for Processed Cereal-based Foods for Infants and Children³⁴ does not include a specific indication of the recommended age of use of products, the draft revised Standard does.³⁵

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:

³⁴ CODEX STAN 74–1981 (amended 1985, 1987, 1989, 1991). Codex Alimentarius, Vol. 4, 1994.

³⁵ 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.

8.5.5

INDIA

8.5.5. Add: "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.

IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK

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.

8.6 Additional Requirements

ARGENTINA

We recommend deleting the square brackets in this section. The products covered by the Scope of this standard are complementary foods and not substitutes for breast milk. This concept is in line with the WHO's International Code of Marketing of Breast-Milk Substitutes.

AUSTRALIA

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

Removal of all brackets.

CANADA

Delete both square brackets.

CHINA

We suggest that the square brackets in 8.6 [not] be removed.

FRANCE

The square brackets should be deleted.

GERMANY

Both square brackets have to be removed.

HUNGARY

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

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.

MALAYSIA

Malaysia proposes to delete the square brackets in both places in section 8.6 and adopt the text in the brackets.

MEXICO

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."

SWITZERLAND

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.

THAILAND

We propose that this section should be read as follows:- “ The products covered by this standard are not breast-milk substitutes and shall not be presented as such.”

UNITED KINGDOM

The UK considers the text at section 8.6 acceptable and propose that the square brackets are deleted.

EUROPEAN COMMUNITY

The text as it stands is acceptable. The square brackets should be deleted.

This section can hardly be justified by the content. It is suggested that this sentence is moved to the “SCOPE” section.

ENCA - EUROPEAN NETWORK OF CHILDBIRTH ASSOCIATIONS

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.

ILCA - INTERNATIONAL LACTATION CONSULTANT ASSOCIATION

If changes are made to paragraphs 1, 3.81 and 8.5.4 to indicate that cereal-based weaning foods are intended for use from age 6 months, then ILCA would support the removal of the brackets from this paragraph. It would then read „The products covered by this standard are not breast-milk substitutes and shall not be presented as such“

If, however, such changes are not made, then ILCA supports retaining the word „not“ and altering the wording in this section so that it reads: „The products covered by this standard are in some instances breast-milk substitutes and shall be presented as such.“

Rationale: The designation of a product as a breast-milk substitute depends not only on the content but also on the marketing of that product. Thus a cereal-based product marketed for infants from age 3 months, would be a breast-milk substitute because it would be replacing, in part, the breast-milk which should be the infant’s exclusive diet at that age, while the same product marketed for infants over 6 months would not be a breast-milk substitute when marketed as complementary to continued breastfeeding.

ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES

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.

9. METHODS OF ANALYSIS AND SAMPLING

- no comments -