

# International Baby Food Action Network (IBFAN)

## IBFAN Comment on Option A

**General Remark:** *IBFAN supports the position put forward in Draft A: that one standard is needed for **all** infant formulas. It is our position the option put forward in Draft B presents significant risks for infant health.*

### **IBFAN supports draft A for the following reasons:**

*A single standard significantly reduces the risk of confusion regarding the grey area between “normal” and “specific” infant formula. Two standards would lead to increased confusion in choice by consumers as well health care worker needing to prescribe these formulas.*

*Alterations in composition can easily be met for the few situations where the use of infant formulas is medically indicated and these can readily be accommodated under the current standard.*

*Infants who have special medical needs, other than those with PKU, galactosemia and Maple Sugar Syndrome would be at greater risk for adverse effects of formula feeding, such as necrotising enterocolitis, gastroenteritis and acute respiratory disease This vulnerable sector of infants should receive human milk, either through breastfeeding, feeding of expressed human milk or the provision of banked human milk.*

*A single standard would prevent the proliferation of infant feeding trials. Compositional changes would require infant feeding trials for infants with special medical needs. Issues of conflict of interest for medical researchers and the ethical considerations of infant feeding trials for infants with special medical needs are increasingly topics of concern.*

*A proliferation of infant formulas for various spurious “medical needs and normal infant feeding behaviours - regurgitation, colic and slow growth - risks increased use of unsubstantiated health and nutrient claims. The current status of misleading claims for infant formulas is already serious, increased “uses” would only worsen this situation.*

*Increased marketing through free samples, free supplies, promotional brochures, direct advertising to the public would directly compete directly with breastfeeding, compromising optimal infant and young child health.*

*From the consumer’s point of view it is essential that the same safeguards on marketing apply to these products as to ‘normal’ formulas. In both cases the marketing must be consistent with the International Code and subsequent, relevant Resolutions of the WHA. **All babies, and especially sick babies, need the protection of the International Code and subsequent relevant WHA Resolutions.***

*It is worth noting that in any case only a very small number of infants need specialised ‘medical’ formulas. (For an estimate see the WHO review of the Physiological Basis of Infant Feeding.) The purpose of the Codex Committee on Nutrition and Foods for special Dietary Use is to form global standards for trade purposes. According to its terms of reference it is:*

*(a) to study specific nutritional problems assigned to it by the Commission and advise the Commission on **general** nutrition issues; (emphasis added)*

*(b) to draft **general** provisions, as appropriate, concerning the nutritional aspects of all food; (emphasis added)*

*It is not logical, cost effective or reasonable to have a separate standard for such a small number of products. The justification for a separate standard for FSMP for infants (especially one where the restrictions on labeling and promotion are less stringent, as they are in Draft B) has simply not*

been made. The additional labeling requirements outlined in 9.6.5 in Draft A should ensure that sufficient warning is placed on the products to safeguard appropriate use, especially where consumption of the product may cause a health hazard.

The reference to the ban of advertising to the general public in 9.6.7 of both drafts is confusing, unnecessary and inadequate. The International Code and Resolutions incorporate more comprehensive safeguards, which cover all classifications of marketing to the public and to health workers.

UNICEF and WHO affirm that all breastmilk substitutes come under the scope of the International Code

It is also far more reasonable to consistently use the term "Infant Formula" rather than "food." The Codex Standard 180-1991 covers FSMP for general use by the whole population. In this case we are dealing with Infant Formulas intended only for infants. Consequently, throughout the entire text, wherever FSMP are mentioned, the term "Food" should be replaced by the term "Infant Formula" and the [...] around "Infant Formula" should be deleted. (Probably the abbreviation IFSMP (Infant Formula for Special Medical Purposes) is appropriate.)

## **PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA INCLUDING FOODS [INFANT FORMULA] FOR SPECIAL MEDICAL PURPOSES [INTENDED FOR INFANTS]**

**IBFAN PROPOSES THE FOLLOWING TITLE:**

**PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA INCLUDING INFANT  
FORMULA FOR SPECIAL MEDICAL PURPOSES**

**RATIONALE: THIS ALLOWS CONSISTENCE BETWEEN TITLE AND 1.1**

### **1. SCOPE**

1.1. *IBFAN proposes that the word 'normal' is deleted.*

#### **RATIONALE**

'normal' nutritional requirements can only be met by breastmilk, which are biologically tailored to meet all these requirements. Infant formula, as a breastmilk substitute, can only meet general nutritional requirements.

1.2. **Change to read:** The provisions in this standard are also intended for ~~[foods]~~ **[infant formula]** for special medical purposes ~~[for infants]~~, formulated according to the description and general principles of Codex Standard 180-1991, except for certain compositional provisions which must be modified to meet the special nutritional requirements deriving from the disease(s), disorder(s) or medical condition(s) for whose dietary management the food is formulated, labelled and presented.

1.4. **Change to read:** The application of the Standard ~~should~~ **shall be in conformity with** ~~take into account~~ the recommendations given to countries under the International Code of Marketing of Breast-milk Substitutes and ~~subsequent~~ the World Health Assembly resolutions.

### **2. DESCRIPTION**

#### **2.1 PRODUCT DEFINITIONS**

***IBFAN's proposal: Delete the word 'normal' and insert the word 'six':***

2.1.1 **Infant formula** means a breast-milk substitute specially manufactured to satisfy, by itself, the ~~normal~~ nutritional requirements of infants during the first **six** months of life up to the

introduction of appropriate complementary feeding. Only products that comply with the criteria laid down in this Standard may be presented as infant formula. (*for rationale see 1.1.*)

2.1.2 **Change to read: ~~Foods [Infant formula] for special medical purposes [intended for infants]~~ are** **is** a category of **foods infant formula** for special dietary uses which **are** **is** specially processed and/or formulated and presented for the dietary management of infant patients and **shall** ~~may~~ be used only under medical supervision. They are intended for the exclusive or partial feeding of infant patients with limited or impaired capacity to take, digest, absorb or metabolize breast-milk, ordinary infant formula [~~or complementary food~~], or certain nutrients contained therein, or who have other special medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal infant diet, by other foods for special dietary uses, or by a combination of the two.

***IBFAN Comment: Including complementary food into this standard for infant formula will bring confusion. Changing ‘may’ to ‘shall’ makes it clear that the dietary management of these infants requires medical supervision***

2.1.3 When in liquid form, both types of product may be used either directly or prepared with safe, and previously boiled water before feeding according to directions for use. In powdered form, both types of product also require safe, and previously boiled water for preparation. Products mentioned under 2.1.2 may need the addition of calculated amounts of other foods before feeding, according to medically determined directions.

2.1.4 Both types of products are so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

## 2.2 OTHER DEFINITIONS

The term *infant* means a person not more than 12 months of age.

## 3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

### 3.1 ESSENTIAL COMPOSITION

3.1.1 **Infant formula** is a product based on milk of cows or other animals and/or other edible constituents of animal, including fish, or plant origin, which have been proved to be suitable for infant feeding. ***Please take into consideration IBFAN’s comments submitted to the WG on essential composition***

3.1.2 ~~Foods [Infant formula] for special medical purposes [intended for infants]~~ **are** **is** based on ingredients of animal and/or plant origin or on synthetic compounds suitable for human consumption.

3.1.2.1 The formulation of ~~foods [infant formula]~~ for special medical purposes [~~intended for infants~~] should be based on sound medical and nutritional principles. Their use should have been demonstrated, by **independent** scientific evidence **and peer reviewed**, to be safe and beneficial in meeting the nutritional requirements of the infants for whom they are intended.

*Independent means independent from commercial interest or a conflict of interest with one of the sponsors of the study*

### 3.2 OPTIONAL INGREDIENTS

**Change to read:** —

3.2.1 In addition to the compositional requirements listed under 3.1, other [nutrients/ingredients] may be added when required in order to provide [nutrients/substances] ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrition for the infant or for

the dietary management of the disease(s), disorder(s) or medical condition(s) for which a ~~feed~~ **[an infant formula]** for special medical purposes ~~[intended for infants]~~ is formulated.

3.2.2 **remove brackets and add:** [The usefulness/suitability/beneficial effect] for the particular nutritional uses of infants and safety of these nutrients shall be scientifically demonstrated] **and peer reviewed**

**4.6 Change to read:** For ~~foods~~ [infant formula] for special medical purposes ~~[intended for infants]~~ described in Section 1.2 of this Standard the following additional food additives are permitted when required: (*-to be determined*) -

## 6. HYGIENE

6.1 It is recommended that the products covered by the provisions of this standard 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 the Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979).

6.2 The products should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997)

**Add the following phrase:**

**6. 3** In the case of infant formulas sold in powdered form there shall be a notification on the label that this is not a sterile product. Additionally warnings must be placed on the label informing parents that the product must be prepared shortly before consumption and that any left-over, prepared product must be discarded after feeding. Such precautions are necessary to prevent the growth of microbial contaminants.

*These measures are essential to reduce the risk of death or serious illness caused by the presence of such pathogens as Enterobacter sakazaki.*

## 9. LABELLING

The text of the label and all other information accompanying the products shall be written in the appropriate language(s).

**IBFAN Rationale: In many cases several languages are needed..**

### 9.5 **ADD TO READ: LABELLING OF ALL INFANT FORMULA**

*Add **all** in the heading to make it clear that these provisions apply to all types of formula*

#### 9.5.6 **ADDITIONAL LABELLING REQUIREMENTS FOR ALL INFANT FORMULA**

*Add **all** in the heading to make it clear that these provisions apply to all types of formula*

9.5.6.1 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

a) the words "important notice" or their equivalent;

b) **delete the brackets and change to read:** a statement of the superiority of breastfeeding ~~or breastmilk~~, for example the statement: **Breastfeeding** ~~Breastmilk~~ is **the best food** for your baby, it protects against diarrhea and other illnesses;

**IBFAN Rationale: The International Code requires labels to refer to the superiority of 'breastfeeding' which is a process that is proven to protect infant health. The Standard should not allow deviation from this.**

c) a statement that the product should only be used on advice of a independent health worker as to the need for its use and the proper method of use;

d) instructions for appropriate preparation;

Change to read:

e) a warning against the health hazards of inappropriate preparation; **a warning that the product is not sterile and that the formula must be prepared just before feeding and that left-over prepared product** remaining after each feeding **must** be discarded.

**Change to read:** 9.5.6.2 The label shall have no pictures of infants and women nor any other picture or text which idealizes **the artificial feeding of infants** ~~the use of infant formula~~. The label shall have graphics illustrating the methods of preparation of the product and methods of feeding **including cup-feeding**.

IBFAN Comment: REMOVE BRACKETS on 9.5.6.5. to read:

9.5.6. The products shall be labelled in such a way as to avoid any risk of confusion between infant formula and follow-up formula.

**9.5.7** No health claims, shall be made regarding the dietary properties of the products covered by this Standard. This sentence in square brackets in Alinorm 03/26A, has totally disappeared from the present draft, IBFAN insist on keeping it in because:

*Infant formula manufacturers are increasingly using health claims to market their products. Such claims could be used to undermine breastfeeding by creating a misleading perception that breastmilk and infant formula are similar or equal. In general, claims are used to idealize the product rather than inform the consumer. This form of idealization is contrary to the International Code and therefore should not be permitted.*

*Moreover health claims are not permitted under the Codex Draft Guidelines for Use of Nutrition Claims (Alinorm 97/22 appendix II).*

CHANGE TO READ: **9.6 ADDITIONAL LABELLING OF FOODS [INFANT FORMULA] FOR SPECIAL MEDICAL PURPOSES** ~~[INTENDED FOR INFANTS]~~

9.6.1 The name of the product shall be "**Food [Infant Formula]** for Special Medical Purposes ~~[Intended for Infants]~~" or any appropriate designation indicating the true nature of the product, in accordance with national usage.

This section can be deleted as 9.1.1. already gives the complete list of ingredients ~~9.6.3 In addition, information on the nature of the animal or plant proteins or protein hydrolysates should be provided.~~

9.6.4 ~~Foods~~ **[infant formula]** for special medical purposes ~~[intended for infants]~~ in which the essential characteristic involves a specific modification of the content or the nature of the proteins, fats or carbohydrates shall bear a description of this modification and information on the amino acid, fatty acid or carbohydrate profile, when necessary.

**Add other to read:** **OTHER** Additional Labelling Requirements for ~~Foods~~ [Infant formula] for special medical purposes ~~[intended for infants]~~

**Add only to read:** 9.6.5.1 A prominent statement "USE UNDER MEDICAL SUPERVISION **ONLY**" shall appear on the label in bold letters in an area separated from other written, printed or graphic information.

9.6.5.3 An additional prominent warning statement consisting of an explanatory statement shall appear on the label in bold letters in an area separated from other written, printed or graphic information if the ~~feed~~ **[infant formula]** for special medical purposes ~~[intended for infants]~~ poses a health hazard when consumed by infants who do not have the disease(s), disorder(s) or medical condition(s) for which the product is intended.

**9.6.5.6. This section can be deleted as the general recommendation remains still valid.**

f.ex.: physical activity is recommended as a general health promotion advice, no one worries about persons with disabilities coming to moral harm by this recommendation.

A recommendation for the single case of a special baby with a rare disease is taken by the health professional treating or supervising this infant and is explained to the parents or the care-takers together with the recommendations for feeding this baby according to his special needs.

#### **9.6.6 INFORMATION TO BE INCLUDED IN THE LABELLING OF FOODS [INFANT FORMULA] FOR SPECIAL MEDICAL PURPOSES ~~[INTENDED FOR INFANTS]~~**

~~9.6.5.4. This can be deleted as the product is only for infants: If the product has been formulated for infants only, it should carry a prominent statement to this effect.~~

#### **9.6.7 ADVERTISING OF FOODS [INFANT FORMULA] FOR SPECIAL MEDICAL PURPOSES ~~[INTENDED FOR INFANTS]~~**

~~The advertising of these products to the general public is prohibited~~

*The International Code includes much more extensive provisions which prohibit the advertising and promotion of all Breastmilk substitutes to the public and to health workers and a ban of free supplies and samples.. The inclusion of this limited ban on advertising to the general public is confusing and unnecessary. To underline this point, the text in section 1.4. applying to all products covered by this standard : “should take into account” should be replaced by ” shall take into account”*

*All IBFAN’s comments submitted in CRD 15 in 2002 still stay sustained*

### **Draft B**

IBFAN is not commenting on draft B. Our preference is stated in our comment on option A.