Infant Feeding Action Coalition (INFACT) Canada
Comments on the Proposed Draft Revised Standard for Infant Formula Alinorm 03/26A Appendix II

Comments at step 3 of the Procedure

1.SCOPE

1.1 **Remove square brackets** from the second sentence **and add** the word ***compositional*** to read:

The provisions in this standard are also intended for infants with special nutritional requirements, except for certain ***compositional*** provisions that must be modified to meet those special requirements.

> ***An international standard must protect and meet the needs of all infants. Hence the compositional flexibility of the proposed draft standard can readily accommodate any adjustment in ingredients to meet the needs of infants requiring dietary modifications, while ensuring that the best possible overall protection of infants is retained.***

1.2 **Add** to read:

The standard contains compositional, quality and safety requirements to ensure ***as best possible*** a safe and nutritionally adequate product.

> ***Infant formulas cannot be declared to be 100% safe or nutritionally adequate as they are only a replacement for breast milk. To accurately describe these products, the phrase as best possible is needed to qualify the statement.***

Add the sentence from 2.1.1 to read:

Only products that comply with the criteria laid down in the provisions of this standard would be accepted for marketing as infant formula.

1.3 **Reword** to read:

The application of the Standard ***shall be in conformity with*** the recommendations given to countries under the International Code of Marketing of Breast-Milk Substitutes, World Health Assembly Resolution***s*** 54.2 (2001) ***and 55.25 (2002) and the Global Strategy for Infant and Young Child Feeding.***

2. DESCRIPTION

2.1.1 **Move** the second sentence to the Scope

> ***The 24th Session of the CCNFSDU determined that the sentence "only products that comply with the criteria laid down in the provisions of this standard would be accepted for marketing as infant formula" should stay in the proposed revised standard and be inserted into the scope to make it clear that there should be no non-standardized products marketed as infant formula.***

2.1.1 **Delete** the word [***normal***] as it is not clearly defined.

2.1.2 **Change** the sentence to read:

Infant formula shall be nutritionally adequate to ensure growth and development when used in accordance with its directions for use.

Delete the remainder of the sentence

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1.1 The description of the compositional sources for the manufacture of infant formulas should be kept as detailed as possible to have the fullest possible disclosure for parents and health care providers.

The current practice of extensive use of soy-based infant formulas is under considerable criticism and should be reviewed.
Both the report of the UK Committee on Toxicity (COT) and the report of the Scientific Advisory Committee on Nutrition (SACN) on Phytoestrogens and Health (http://www.food.gov.uk), regarding the potential risks of soy as a constituent of infant formula, questioned the safety of the use of soy formula. ***INFACT Canada requests that the Canadian delegate to the CCNFSDU support work by the CCNFSDU to review the use of soy as a protein source for routine non-cow's-milk-based infant formulae.***

The SACN report states:
"Conclusion
20. Based on the evidence cited in the report, SACN is in agreement that the use of soy-based infant formulae is of concern. Whilst there is clear evidence of potential risk, there is no evidence that these products confer any health benefit or therapeutic advantage over products based on cow's milk protein isolates….there are no substantive medical or clinical indications for the use of soy-based formulae and, secondly on grounds of potentially important sequelae, principally amongst young infants. If the use of soy-based formula is to continue on "clinical" grounds, responsibility is placed upon health professionals rather than the industry and consumers.

3.1.2(e) Fat and Fatty Acid

Add "***S***" to fatty acid, to read" ***Fat and Fatty Acids***"

Change to read:

the trans fatty acid level of liquid formula shall not exceed 2% and the trans fatty acid level of powdered formulas shall not exceed 1.5%.

Trans fatty acids have been implicated in impairing the metabolic conversion of linolenic and linoleic acids to DHA and AA. Essential fatty acids are important in the brain, neural and retinal development of infants especially during the first six months of life.

- No erucic acid should be added to infant formulas.
- No peanut oil should be added because they can still contain substances which may trigger a peanut allergy

- DHA and AA should be added to all infant formulas as a global standard.

(f) Carbohydrates

Lactose is the natural sugar found in breastmilk, therefore the lactose content in infant formula should be as optimal as possible. The addition of other sugars such as sucrose or starches should be restricted

The carbohydrate content should not be fixed in gram/100 kcal but related to their relative sweetness compared to lactose in breastmilk

3.2 Optional ingredients

3.2.3 **Add** to read:

Nutrition and health claims may not be made for optional ingredients.

3.6. **Add** the following to the end of the sentence to read:

The product and its components shall not have been treated by ionization radiation ***nor contain ingredients obtained through genetic modification.***

INFACTCanada supports the comments on GMOs from Brazil published in CX/NFSDU 03/6.

4. FOOD ADDITIVES

There is no need for thickening agents, emulsifiers and antioxidants in the preparation of infant formula with the exception of some special needs formulas where they may be necessary to enhance certain desired properties.

5. CONTAMINANTS

5.1 **Add** the following to the end of the sentence to read:

The product shall be prepared with special care under good manufacturing practices, so that residues of those plant protection substances which may be required in the production, storage and 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 is in accordance with the European legislation

5.2 **Delete** the current text and **reword** to read:

The product shall be free from residues of hormones, antibiotics, N-nitrosamines, nitrates, heavy metals, mycotoxins, as determined by agreed analysis, and free from other contaminants, especially pharmacologically active substances such as phytoestrogens.

Infant formula is the sole food for infants for the first six months of life and should be free from all contaminants, including residues of hormones and antibiotics. Since the impact of these substances is poorly understood either as single substances or their synergistic effects, the level of hazard they represent to the

developing infant is largely unknown. Thus the current text linkingthe inclusion of permissible substances and levels to known hazards is untenable and not possible. Ideally infant formula should be totally free from such contaminants.

6. HYGIENE

6.1 **Replace** "**it is recommended**" by: The product ***shall be prepared***….

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 **Reword** to read: "

The product **shall** 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; ***and shall be free from pathogenic microorganisms, parasites and any other poisonous or deleterious substances***"

6.3 **Add** a new section to read:

Consumers must be informed through full and adequate labelling that powdered infant formulas are not sterile products and that preparation instructions must be fully complied with to eliminate any risk of infection to the infant. The product must be prepared shortly before feeding and left-over prepared formula must be discarded.

(cf. recent Enterobacter sakazakki deaths in the US and in BELGIUM)

9. LABELLING

9.1 **Add** "**S**" to language **to read** " ***languages***" to reflect the multi-lingual situation in many countries

9.1.4 **Add** the following to the end of the sentence to read:

and must state the source of the protein content, i.e. Infant Formula Based on Cow's Milk.

Parents and health care providers must have full information regarding the animal or plant sources of the ingredients in infant formula.

9.1.5 **Remove** both sets of square brackets to **read**:

No nutrition and health claims shall be made regarding the dietary properties of the products.

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

Example: current claims for infant formula with LCPUFA made by manufacturers intend for health professionals and parents to believe that the inclusion enhances intellectual outcome similar to breastfed infants. Yet ISDI says in

CX/NFSDU 03/6 page 27 on LCPUFA "however it is not known if increases occur in neural tissues. Some studies do show a positive effect, where others were unable to measure such effects"

This example shows clearly how claims are based on inconclusive scientific evidence. Nutrition and health claims are prohibited for foods for infants and young children under the Scope of the Proposed Draft Guidelines for Use of Health and Nutrition Claims (at Step 8). The lack of scientific substantiation for claims made for infant formulas, the potential to mislead consumers and the marketing effect of competing with breastfeeding makes such claims unsuitable for these products.

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9.6.1 (b) **Remove** brackets from the first option and **retain** the text as proposed.

Delete the second option in 9.6.1(b).

The importance of breastfeeding for infants and young children is well documented by clinical and epidemiological research. As well the vitality of breastfeeding is supported by health professional bodies such as The American Academy of Pediatrics in their statement. Breastfeeding and the Use of Human Milk Pediatrics Vol 100 No 6 December 97

9.6.1. (f) **Add** the following sentence:

A warning that the product may not be sterile and can contain bacteria that may cause illness must be clearly stated on the label with directions that it is therefore critical that this product be prepared according to the instructions given on the label. All instructions for proper and safe preparation must be clearly legible; on the outside of the label; and in the languages of the country where the product is marketed.

9.6.2 **Change** to read:

The label shall have no pictures of infants and women nor any other picture or text which idealizes artificial feeding. The label must have graphics illustrating the method of preparation of the product and methods of feeding.

The label must have graphics so that mothers who cannot read are able to prepare the product for safe and proper use.

9.6.4 **Reword** to read:

Information shall appear on the label to the effect that infants should receive ***complementary*** food in addition to infant formula ***after the age of six months and onward as advised by an independent health worker to satisfy their specific growth and development needs.***

9.6.5 **Remove** brackets to **retain** the text.

Many brands currently show little difference between the labels of these two very different products. Young infants can become very ill if fed follow-up formula. These products are usually cheaper so mothers are tempted to buy them rather than routine formula.

This labelling requirement is already included in the European Council Directive on infant formulae and follow-on formulae intended for export to third countries (92/52/EEC) The Report of European Commission Scientific Committee on Food on the Revision of Essential Requirements of Infant formula (SCF/CS/NUT/IF/65 Final 18th May 2003) also recommends this safeguard for products marketed within the EC.

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