



14 April 2006

**ISDI COMMENTS ON
Draft Revised Standard for Infant Formula and Formula for Special Medical Purposes
Intended for Infants (A)**

(EXCEPT ESSENTIAL COMPOSITION)
Alinorm 06/29/26 Appendix IV (A) – At Step 6

Answer to Circular letter CL 2005/53 - NFSDU

ISDI PROPOSAL	JUSTIFICATION
<p>4. FOOD ADDITIVES</p> <p>The following additives are permitted in the preparation of Infant Formula, as described in Section 1 of this Standard, and with the restrictions stated below:</p> <p>Only the food additives listed in this Section or the Codex Advisory List of Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979) may be present in the foods described in Section 2.1 of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to following conditions:</p> <p>a) The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and</p> <p>b) The food into which the food additive is carried-over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (CAC/STAN 192-1995, Rev. 5 (2004)).</p> <p>The following additives are acceptable for use in the preparation of Infant Formula, as described in Section 2.1 of this Standard (in 100 mL of product, ready for consumption prepared following manufacturer's instructions, unless otherwise indicated).</p>	<p><u>Replace</u> the current text by the text in bold.</p> <p><u>Rational:</u> adds clarity and allows consistency with the wording agreed in 2005 for the Draft Revised Standard for Processed Cereal-based Foods for Infants and Young Children.</p>

<p>INS 410: Carob bean gum (locust bean gum) 0.1g 0.5g in all type of formula</p>	<p><u>Change</u> the level of INS 410</p> <p><u>Rational</u>: Non caloric thickening agent. Emulsion stabiliser, adjustment of viscosity. Used in some anti regurgitating formulas. If a lower level is used, the solution separates very quickly in phases. Carob bean floats to the upper level of the solution very quickly, so a minimum viscosity is needed to prevent this phenomenon.</p>
<p>4.6 Carry-over of Food Additives No food additives shall be present as a result of carry-over from raw materials and other ingredients with the exception: (a) of the food additives listed under Sections 4.1 to 4.4 of this standard within the limits of the maximum levels stipulated in this standard; and (b) {of the carrier substances mentioned in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children within the limits of the maximum levels stipulated in that List.}</p>	<p><u>Delete</u> []</p> <p><u>Rational</u>: while acknowledging that CCFAC is currently considering establishing a new additive functional class for nutrient carriers, ISDI believes that the list of nutrient carriers should remain where it is currently i.e. at the end of the advisory list of mineral salts and vitamin compounds for the use in foods for infants and young children currently under revision by CCNFSDU. ISDI believes that this list of nutrient carriers should also be reviewed.</p>
<p>9.1.6 {Products containing not less than 0.5 mg Iron (Fe) /100 kilocalories shall be labelled “Infant formula with added iron”}</p> <p>Or</p> <p>{Products containing less than 0.5 mg Iron (Fe) /100 kilocalories shall be labelled with a statement to the effect that when the product is given to infants over the age of four months, their total iron requirements must be met from additional sources.}</p>	<p><u>Retain</u> option 2</p> <p><u>Rational</u>: the wording in option 2 is more relevant for caregivers.</p>
<p>9.5. Information for use {Products in liquid form may be used either directly or prepared with safe water and previously boiled water before feeding according to directions for use. Products in powder form also require safe and previously boiled water for preparation [...] hazards of inappropriate preparation.}</p> <p>All products should be used according to instructions for use. Products in powder form and concentrated liquids should be prepared with safe and previously boiled water before feeding. Ready for consumption liquid formula may be used directly according to instructions for use.</p>	<p><u>Reword</u> and change the order of the sentence.</p> <p><u>Rational</u>: adds clarity and powdered formula are the most commonly used type of formula around the world.</p>

<p>9.5.1 Adequate directions for the appropriate preparation and use of the product to minimize microbiological risks, including its storage and disposal after preparation, i.e. e.g. that powdered formula should be fed immediately after its reconstitution, and that formula remaining in the bottle after feeding should be discarded, shall appear on the label [or in the accompanying leaflet] and in the accompanying leaflet if available.</p>	<p><u>Amend</u> the square brackets to “[and in the accompanying leaflet if available.]”</p> <p><u>Rational:</u> this information should appear on the label as there is a risk that the mother/carer may lose an accompanying leaflet if this is the only source of this information.</p>
<p>9.5.2 Adequate directions regarding the storage of the product after the container has been opened shall appear on the label [or in the accompanying leaflet] and in the accompanying leaflet if available.</p>	<p><u>Amend</u> the square brackets to “[and in the accompanying leaflet if available.]”</p> <p><u>Rational:</u> this information should appear on the label as there is a risk that the mother/carer may lose an accompanying leaflet if this is the only source of this information.</p>
<p>9.5.4 The directions should be accompanied by a warning about the health hazards of inappropriate preparation.]</p>	<p><u>Delete</u> the bracket</p>
<p>9.6.6 [No [nutrition and] health claims shall be made regarding the dietary properties of the product]</p> <p>Nutrition and health claims shall be permitted for foods for infants where they have been demonstrated in rigorous studies with adequate scientific standards.</p> <p>Taking into account paragraph 1.4 of the Guidelines for Use of Nutrition and Health Claims, nutrition and health claims may be permitted under national legislation for the foods that are the subject of the standard provided that they have been demonstrated in rigorous studies with adequate scientific standards.</p>	<p><u>Reword</u> into a positive statement</p> <p><u>Rational:</u> ISDI proposed wording is in support of the wording proposed by Switzerland (Alinorm 05/28/26 para 83). It is of the utmost importance that information on the dietary properties of infant formula can be communicated as:</p> <ul style="list-style-type: none"> • Claims explain the specific nutritional characteristics of the different formula • Claims do not interfere with a mother’s decision to breast feed. Prohibiting claims on these products cannot be justified by public health grounds. • Providing factual, science-based nutrition information on labelling protects the health of the formula-fed infants by differentiating the composition of formula from less nutritious alternatives. • Some countries already allow certain health and nutrition claims on infant formula. • Provisions ensuring that claims for foods for special dietary uses are appropriately used, have already been detailed in Section 3.1 of Codex STAN 146-1985. <p>Finally, there is no reason to prohibit the communication of relevant information through labelling and literature if it complies with the above mentioned criteria and as long as this communication remains in line with national practices and the WHO International Code on the Marketing of Breast-milk Substitutes.</p> <p>For the <u>detailed justification</u>, see the Annex.</p>

Annex

Justification to support the permission of Nutrition and Health Claims for Infant Formulae

Given the importance that the communication of health claims have in terms of providing information to parents and health care professionals on the proper use of breast milk substitutes, and also to provide an incentive for scientific research around infant and child nutrition, it is very important that specific provisions are discussed and included in the Codex Standard for Infant Formula.

As currently worded, the prohibition is in conflict with 3.2.1 and 3.2.2 regarding optional ingredients, because the mere statement of inclusion of an optimal ingredient, except within the ingredients declaration panel, or its amount would be prohibited.

Notably the definition of health claims in the Codex Food Labelling Guidelines includes 2.2.1 *Nutrient Function Claims* – a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body. Statements about the role of nutrients in growth and development in the context of feeding of infants provide point-of-use nutrition education for mothers. Similarly, 2.1.2 *Nutrient Comparative claims* help mothers to understand the nutritional limitations of other milks, such as cows' or goats' milk, and educate mothers to the nutritional shortcomings of other milks and to differentiate among various formulas.

If 9.6.6 were accepted, as is, any description of a role of nutrient in infant development would be banned regardless of the level of scientific evidence behind the statement. Infant formula labelling is an important source of nutrition information and education to consumers. Manufacturers rely on labelling statements to identify recent science-based changes in composition – changes supported by clinical evidence.

The proposed wording has the advantage that product labels are reviewed on a country by country basis already, and thus, the scrutiny of claims is at the appropriate level.

It is troublesome that CCFL accepted guidelines prohibiting all types of health claims without consideration of type of claim or extent of supportive information. (prohibition of health claims is under discussion in the EU, current Australian regulation prevents nutrition and health claims). It also is troublesome that the prohibition of nutrition and health claims was decided without input from the users of the information namely, mothers who purchase formula, and health care professionals who advise mothers on the use of formula. The United States, which has the most experience with and most comprehensive regulations on health claims, does not prohibit health claims on infant formula (and in the U.S. health claims refer only to the subset of Codex health claims that relate nutrients to disease risk).

Importantly, health claims (of the type typically appearing in the labelling of infant formula) are consistent with WHO and are important to support scientific innovation. Article 4 of the WHO Code for the Marketing of Breast milk Substitutes states, "Governments should have the responsibility to ensure that objective and consistent information is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition." Nutrition and health claims are science-based objective, consistent information.

Article 7.2 states, "Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code should be restricted to scientific and factual matters," exactly the type of information represented by health claims.

Article 9.4 of the Code states, "The label of the food products within the scope of this Code should also state all of the following points: (a) the ingredients used; (b) the composition/analysis of

the product.” As written, clause 9.1.5 would prohibit factual information about the composition of the product.

WHA resolution 54.2 does not resolve to prohibit health claims, but does ask that the Code be taken into consideration in dealing with health claims. It calls on all sectors of society, including commercial enterprises, to “contribute to improved nutrition for infants and young children by every possible means at their disposal.” “Every possible means” clearly must include the description of nutritional components in infant formula, especially components that have been shown clinically to contribute to improved nutrition of infants.

“The WHO Report of an Expert Consultation, The Optimal Duration of Exclusive Breastfeeding, March 28-30, 2001 states, “The expert consultation recognized that some mothers will be unable to, or choose not to, follow this recommendation (to breastfeed); they should be supported to optimize their infants’ nutrition.” Health claims encourage optimized nutrition for babies not breastfed.

Understanding the Codex Alimentarius states, “In the best traditions of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO), as part of its persistent endeavors to develop the Codex Alimentarius the Commission has encouraged food-related scientific and technological research as well as discussion.” Health claims foster scientific research.

The Scientific Committee of Food (2003) recommended, “modifications to an infant formula or a follow-on formula beyond the established standards should be based on and justified by defining an expected benefit (nutritional, functional, technological, or others).” Thus, the medical and scientific communities expect manufacturers to demonstrate and communicate benefits related to innovations, precisely the type of information that the prohibition of health claims would prevent.

Finally, it must be remembered that the purpose of Codex is to protect the health of consumers and ensure fair practices in the food trade (Annex 1). Fair practices in food trade should include nutrition and health claims to allow manufacturers of foods to describe their products fully and allow consumers to be protected from inferior products. Fair practices, for infants who are not breastfed for whatever reason, should ensure that formulas that have been designed and shown through scientific studies to have special attributes can be identified for those attributes.

As stated in 1.2 of the scope of the Standard, “No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal health infants during the first months of life.” Only infant formula can meet the nutritional needs of infants who are not breastfed. There are many organizations committed to protecting breastfeeding; only the Codex standard exists to protect the health of formula fed infants. The standard is not intended to assist in public health campaigns to promote breastfeeding; it is designed to protect the nutritional status and health of infants who are not breastfed.