

IDACE

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ASSOCIATION OF THE FOOD INDUSTRIES FOR PARTICULAR NUTRITIONAL USES OF THE EUROPEAN UNION

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IDACE POSITION ON CLAIMS FOR INFANT FORMULAE

Article 8.7 and Annex IV of

Draft Commission Directive 91/321/EEC on infant formulae and follow-on formulae
SANCO D4/HL/mm/D440180 Rev.2, dated February 2005

1. INTRODUCTION

The Infant Formula Industry fully recognises that breast milk is the ideal food for infants from birth onwards. However, when a mother cannot breastfeed her baby or chooses not to do so, infant formulae are the only products specifically formulated to fulfil the nutritional needs of healthy infants.

Since the early 1900's, the challenge for the Infant Formula Industry has been to modify cows' milk into a safe alternative for infants who are unable to be breastfed for whatever reason. Through research and innovation, (for example, the addition of long-chain polyunsaturated fatty acids (LCPs), nucleotides, probiotics and prebiotics), products are being constantly improved, which is to the benefit of the infant. These improvements, which in legislation remain on a voluntary basis, have led to a greater differentiation between products. Whilst there is a compositional standard for infant formulae¹, no two formulae are the same.

Healthcare professionals and purchasers need to have information about the exact nature and characteristics of the product in order to make an informed choice. Directive 91/321/EEC only allows this information in a very restrictive way.

Therefore, IDACE believes that Article 7.6 and the related Annex IV of Directive 91/321/EEC (Art 8.7 in the draft recast Directive) should be amended to allow the communication of these improvements.

In light of this, IDACE proposes the following amendments to Directive 91/321/EEC:

- **Adaptation of the current Article 7.6 (Art 8.7 in the draft recast Directive rev 2)**
- **Revision of Annex IV in line with the general principles defined in Chapter IV of the draft Proposal for a Regulation of the European Parliament and of the Council on Nutrition and Health Claims Made on Foods (further referred to as the proposed claims Regulation).**

¹ Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae, as amended

This IDACE position paper relates only to infant formulae. These products are unique due to the fact that their claims are regulated by Annex IV of Directive 91/321/EEC. Only a very limited number of compositional claims are allowed.

This position paper does not cover follow-on formulae, processed cereal based food, baby food and other foods for particular nutritional uses for infants and young children.

2. LABELLING INFORMATION ON INFANT FORMULAE

Manufacturers are required to ensure that the products they provide pose no risk to health, in line with the general principles of liability² and safety³. Labelling⁴ is also required to give the exact nature and characteristics of the product, enabling the consumer to make his or her choice in full knowledge of the facts. Directive 91/321/EEC only allows for this information in a very restrictive way, therefore IDACE wishes to make the following proposals for the labelling of infant formulae with regards to claims.

Nutrition and health claims on infant formulae are currently regulated by Article 7.6 of Directive 91/321/EEC(Art 8.7 in the draft recast Directive rev 2)⁵.

IDACE would like to consider three categories of information for infant formulae:

- 1) Labelling information not considered as nutrition or health claims,**
- 2) Nutrition claims and other statements that provide for simple descriptions related to the composition of infant formulae,**
- 3) Claims related to health effects.**

2.1. Labelling information not considered as nutrition or health claims

Article 7 of Directive 91/321/EEC lays down certain specific labelling requirements for infant formula. It does not include the provisions laid down by Article 5.3 of General Labelling Directive 2000/13/EC which also apply. Article 5.3 requires information regarding the physical condition of the infant formula (e.g. granulated, instantised, liquid, ready to use, thickened), or the specific treatment which it has undergone (e.g. acidified, hydrolysed, fermented, UHT) to accompany the name under which it is sold in all cases where omission of such information could create confusion in the mind of the purchaser.

Article 8.8 of the draft the recast Directive rev2 provides for statements concerning the suitability of the product for use in a diet where choice is influenced by religious or other considerations. IDACE believes this would also include statements on organic production if the formula complies with Council Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs.

² Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products

³ Council Directive 92/59/EEC of 29 June 1992 on general product safety and Regulation 178/2002 of the European Parliament and Council of 28 January 2002 laying down the general principles of food law, establishing the European Food safety Authority and laying down procedures in matters of food safety.

⁴ Directive 2000/13/EC of 20 March 2000 on the approximation of the laws relating to the labelling, presentation and advertising for foodstuffs

⁵ *This Article 7.6 reads:* "The labelling may bear claims concerning the special composition of an infant formula only in the cases listed in Annex IV and in accordance with the conditions laid down therein.

2.2. Nutrition claims and other statements that provide for simple descriptions related to the composition of infant formulae

A “Nutrition claim” is defined in Art. 2.4 of the proposed claims Regulation as “*any claim which states, suggests or implies that a food has particular nutrition properties due to the energy (calorific value) it provides, provides at a reduced or increased rate, or does not provide, and/or due to the nutrients or other substances it contains, contains in reduced or increased proportions, or does not contain*”.

IDACE would like to stress the need to communicate the presence or absence of certain nutrients, other substances or ingredients. At the same time, IDACE acknowledges that it may not be appropriate for infant formula to indicate reduced or increased content on certain nutrients, other substances or ingredients.

This communication would consist of simple and informative statements such as:

- **Information on the presence of non-compulsory nutrients, ingredients, or other substances, which are therefore not present in every formula** such as, carnitine, choline, cows’ milk protein, LCPs, medium-chain triglycerides (MCTs), nucleotides, prebiotics (e.g. oligosaccharides, inulin, resistant starch), probiotics (e.g. non-pathogenic L(+)lactic acid producing bacteria), pro-vitamin A carotenoids, soy protein, taurine, vegetable oil, and information on the calcium to phosphorus ratio and/or iron to vitamin C ratio.
- **Information on the presence or absence of a given ingredient that is relevant for certain infants** such as those related to the type of vegetable oil, soy protein, peanuts, cows’ milk protein.

2.3. Claims related to health effects

A “Health claim” is defined in Art. 2.5 of the proposed claims Regulation as: “*any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health*”.

IDACE is of the opinion that for infant formulae, such claims must demonstrate a benefit for infant's health or positive physiological effects. The presence of a nutrient or other substance in breast milk is not sufficient to justify a health claim, as its presence might not provide *ipso facto* an improved product.

The manufacturer who places an infant formula on the market is responsible for justifying any health claim on the basis of sound scientific evidence. **Evidence should be based on the criteria proposed by IDACE as given in section 4 of this document.**

The evaluation by the European Food Safety Authority (EFSA), of a dossier prepared by a manufacturer to support a health claim, as described in Chapter IV of the proposed claims Regulation, should be a transparent process involving independent scientific authorities and an appeal procedure. This process must respect confidentiality where requested by the applicant.

3. RATIONAL WHY NUTRITION AND HEALTH CLAIMS SHOULD BE AUTHORISED FOR INFANT FORMULAE

3.1. Claims have a useful function

Nutrition and health claims offer health care professional and parents relevant information about the composition and properties of the formula that is specifically developed to satisfy, by itself, the nutritional requirements of infants for the first 4-6 months.

It has been manufacturers' experience that parents need information because they choose products for their infant with great care.

Leading academic paediatricians at the Second World Congress on Paediatric Gastroenterology and Nutrition in July 2004 in Paris have emphasized the need for manufacturers to provide meaningful information to both parents and health care professionals on the nutrition of infants and young children. The European Scientific Committee on Food also expressed this in its *Report on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae*⁶

3.2 There are no grounds for a ban on claims for infant formulae

IDACE is not aware of any study showing that parents of infants are more readily persuaded by nutrition or health claims than other adults or that claims on infant formulae have a negative impact on breastfeeding. IDACE is also not aware of any nutrition-based rationale for such restrictions. Claims that are scientifically substantiated, appropriate and expressed in a manner that is clear and not misleading to the parent or caregiver should be allowed on infant formulae, with the substantiation validated through independent scientific review.

3.3 Claims assure appropriate nutritional use

Prohibiting communication on the nutritional and health benefits of foods that are specifically formulated to meet the nutritional needs of infants could lead parents to purchase other foods bearing a nutrition or health claim that are not adapted to the specific nutritional needs of these infants, thereby leading to possible negative health effects.

3.4 Claims are consistent with the WHO International Code of Marketing of Breast-milk Substitutes, and the Global Strategy for Infant and Young Child Feeding

There is no reason to prohibit claims on infant formula if they are scientifically substantiated and as long as they are in line with national practices and the WHO International Code on the Marketing of Breast-milk Substitutes whose goal is to "*contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding, and by ensuring the proper use of breast milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution*"

Furthermore, Article 7.2 of the WHO Code states that information provided by manufacturers to health care professionals regarding breast milk substitutes: "should be restricted to scientific and factual matters". This is exactly the type of information represented by nutrition and substantiated health claims.

⁶ SCF/CS/NUT/IF/65 Final 18th May 2003

“The global strategy for infant and young child feeding is based on respect, protection, facilitation and fulfilment of accepted human rights principles. (...) Women, in turn, have the right to proper nutrition, to decide how to feed their children, and to full information and appropriate conditions that will enable them to carry out their decisions.”(See Section 2.3, p.5, 2003 edition). Nutrition and health claims on formulae encourage optimised nutrition for infants who are not breast-fed.

3.5 A ban on claims would impede innovation

The allowance of factual, science-based nutrition information in labelling provides an incentive for research to add health benefits to infants fed infant formulae.

Claims support research - over 2000 papers supported or conducted by infant formula manufacturers have been published during the last 5 years in this field. Many of the lines of research have led to improvements in public health of infants and in some cases of the broader population.

4. CONCLUSIONS AND IDACE PROPOSAL

In conclusion, IDACE believes that the positioning of the two categories of claims or statements as mentioned above in sections 2.2 and 2.3 requires adaptation of:

- Article 7.6 of Directive 91/321/EEC (Art 8.7 of the draft recast Directive) in which a procedure similar to the one described in the Claims Regulation could be included, and of
- Annex IV. In order for a claim to be included in Annex IV, an application shall be forwarded to the EFSA. Such application shall demonstrate a benefit for infant's health or positive physiological effects based on generally accepted scientific data. The applicable conditions as to what constitutes generally accepted scientific data in relation to infant formula are listed in the Annex to this proposal⁷. IDACE would suggest restructuring the table of Annex IV as follows:

⁷The claims concerned can be:

- (1) Health claims describing a generally accepted role of a nutrient or other substance as indicated in Article 12 of Chapter IV of the claims proposal, or
- (2) All other health claims as defined in the same Regulation.

*ANNEX IV***“CRITERIA FOR INFANT FORMULAE,
WARRANTING A CORRESPONDING CLAIM RELATED TO A HEALTH EFFECT”**

Claim related to	Conditions warranting the claim
Reduction of risk to allergy to milk proteins. This claim may include terms referring to reduced allergen or reduced antigen properties.	<p>(a) The formulae shall satisfy the provisions laid down in Section 2.2 of Annex I and the amount of immunoreactive protein measured with methods generally acceptable as appropriate shall be less than 1% of nitrogen containing substances in the formulae;</p> <p>(b) The label shall indicate that the product must not be consumed by infants allergic to the intact proteins from which it is made unless generally accepted clinical tests provide proof of the formulae's tolerance in more than 90% of infants (confidence interval 95%) hypersensitivity to proteins from which the hydrolysate is made;</p> <p>(c) The formulae administered orally should not induce sensitization, in animals, to the intact proteins from which the formulae are derived;</p> <p>(d) Objective and scientifically verified data as proof to the claimed properties must be available.</p>
[A generally accepted role of a nutrient or a substance ⁸]	[Conditions for the claim that is specifically recognised for use in the labelling and presentation of infant formulae, which may follow from an approval procedure similar to the one foreseen in the future Regulation on Nutrition and Health Claims made on Foods]
[Other health effects] ⁸	[Conditions for the claim that is specifically recognised for use in the labelling and presentation of infant formulae, which may follow from an approval procedure similar to the one foreseen in the future Regulation on Nutrition and Health Claims made on Foods]

⁸ Specific examples including, as the case may be, the proposed wording will be included here in the future after approval of the specific health claims according to the general principles defined in Chapter IV of the claims proposal.

ANNEX

Claims related to health effects⁹

The responsible manufacturer should make a request for an *a priori* authorisation through the EFSA / European Commission. For each request for a health claim the following conditions shall apply where appropriate:

1. A minimum of two independent clinical trials or a multi-centre equivalent supporting the claim should have been conducted.
2. These clinical trials should have been founded on a systematic review of relevant existing information.
3. Appropriate pre-clinical studies should have been performed for previously untested components of infant formulae.
4. An appropriate human research ethics committee should have approved all studies of infant formulae.
5. All studies should be interpreted in the light of outcomes of healthy infants exclusively breastfed for at least three months.
6. The statistical power of the studies should be stated and the confidence limits of differences observed should be presented.
7. If the composition or manufacturing processes have changed substantially, or if new scientific developments have occurred, additional checks to justify the continued validity of the claim may be necessary.
8. If a new ingredient, assessed in a specified product, is found to be beneficial to the infant, other products also including the new ingredient but with a different composition, cannot be assumed to be nutritionally or physiologically equivalent without further consideration and assessment as appropriate.

⁹ IDACE is aware of the 2001 ESPGHAN Medical Position Paper (J Pediatr Gastroenterol Nutr 2001; 32: 256-8) and has made comments and suggestions (IDACE Ref 02/252). Also the expected SCF guidance on Article 3 of Directive 91/231/EEC could be taken into consideration.