

**International Association of Consumer Food Organisations
(IACFO)**

**Draft Revised Standard for Infant Formula and Formulas for Special
Medical Purposes Intended for Infants**

Alinorm 05/28/26 Appendix 1V

Comment
(At step 3 of the procedure)

**SECTION B: FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED
FOR INFANTS**

IACFO supports all the comments by IBFAN on this standard

1.Scope

1.1 REWORD to read:

*This section of the standard applies to Formulas for Special Medical Purposes Intended for Infants, in liquid or powdered form, intended, where necessary, and only when human milk is unavailable or cannot be utilized, **in meeting the nutritional requirements of infants when medically indicated and to be used only under continuing medical care.***

Rationale:

The terms **disorder, disease or medical condition** are vague and undefined. The term **when medically indicated** is simpler and helps to protect against needless use of these products. Special needs infants have the most to gain from breastmilk and this must be protected wherever this is feasible.

The term **when medically indicated** is also in conformity with the WHO/UNICEF Baby-Friendly Hospital Initiative.

1.2 REWORD to read:

*This section **of the standard** contains compositional, quality, labelling and safety requirements for Formulas for Special Medical Purposes Intended for Infants.*

1.3 DELETE normal healthy to read:

No product other than infant formula may be marketed to or otherwise represented as suitable for satisfying by itself the nutritional requirements of infants during the first months of life.

1.4 ADD as in SECTION A and CHANGE 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 (1981) the Global Strategy for Infant and Young Child Feeding and World Health Assembly Resolution 54.2 (2001), WHA Resolution 55.25 (2002) and subsequent relevant resolutions of the WHA.*

Rationale:

It is of critical importance that infants with special medical needs are not needlessly formula fed. The necessity for compliance with the International Code and relevant resolutions of the WHA is even more important for this high needs population than for full term healthy infants.

2. DESCRIPTION

2.1 Product Definition

2.1.1 REWORD to read:

*Formula for Special Medical Purposes Intended for Infants means a breastmilk substitute that complies with section 2, Description, of the Codex Standard for the Labelling of and Claims for Special Medical Purposes (CODEX STAN 180-1991) and is specially manufactured to satisfy, by itself, the **special** nutritional requirements of infants **when medically indicated with specific disorders, diseases or medical conditions** during the first **six** months of life up to the introduction of complementary feeding.*

2.1.2 See 2.1.2 of Section A and change to read:

*Infant formula **must be processed** and packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.*

Rationale:

The safety and hygienic properties of formulas for infants with special medical needs are vital, especially since high needs infants who are formula fed infants are immunologically compromised.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

3.1.1 DELETE the phrase synthetic compounds suitable for human consumption and ADD through independently funded and systematically reviewed research to be suitable for infant feeding to read:

*Formula for Special Medical Purposes Intended for Infants 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 proven, through independent research to be suitable for infant feeding. All ingredients and food additives used shall be gluten-free*

Rationale:

Synthetic compounds increases the risk for allergies, inflammatory disease or autoimmune responses. Infants medically and/or immunologically compromised will be more vulnerable to these potential side effects.

The wording in the previous draft noting all possible ingredient sources should be retained. This is more informative for consumers. To omit this information could be deceptive for consumers.

The use of soy as a core ingredient should be reviewed. SEE APPENDIX A.

3.1.2 REWORD to read:

*The formulation of Formula for Special Medical Purposes Intended for Infants should be based on sound medical and nutritional principles. Their use should have been demonstrated **by independently-funded and systematically-reviewed scientific research**, to be safe and beneficial in meeting the nutritional needs of infants for whom they are intended.*

3.1.3 DELETE the phrase deriving from disease(s), disorder(s) or medical condition(s) for whose dietary management the product is specially formulated, labelled and presented.

REWORD to read:

*The energy content and nutrient composition of Formula for Special Medical Purposes Intended for Infants shall be based on the requirements for infant formula as given in Sections A 3.1.2 and A 3.1.3 except for the compositional provisions which must be modified to meet special nutritional requirements **when medically indicated.***

3.2 Optional Ingredients

3.2.1 CHANGE text to read:

*In addition to the compositional requirements listed under 3.1.3, ingredients may be added **only if demonstrated by independently-funded and verifiable research to be safe and essential for infant health and when medically indicated.** ~~in order to provide substances ordinarily found in human milk and to ensure the formulation is suitable as the sole source of nutrition for the infant.~~ **No nutrition or health claims or comparative claims may be made for these infant formulas.***

Rationale:

Additional/Optional ingredients should be kept to a minimum. Ingredients should be permitted for use in breastmilk substitutes only when shown by independently-funded research to be safe, essential and efficacious for infant health. Conversely, if an ingredient is essential for health and has been shown to be safe through independently-funded and systematically-reviewed research, it should be a legally required ingredient available to all infants. The standard should be revised at the earliest opportunity to list all ingredients added.

Section A seems to permit the presence of numerous optional ingredients. This calls into question the need for a separate SECTION B of the standard. If any and all ingredients are to be allowed any modifications required for medically indicated uses could be made within the range of ingredients permitted.

All infants who are artificially fed should be assured the safest and most nutritious substitute possible. Optional ingredients also increase the likelihood of manufacturers using claims to promote different types of formulae in competition with breastmilk.

3.2.2 REWORD the text to read:

*The suitability **of ingredients that may be added** for the particular nutritional use of infants **as medically indicated, must be demonstrated through independently-funded and systematically reviewed research to be bio-available, safe, to have no unintended side effects and to have the ability to achieve the intended effect, taking into account the levels present in human milk as appropriate.***

3.5 Purity Requirements

SEE IBFAN COMMENTS ON 3.5 SECTION A.

3.6. Specific Prohibition

DELETE brackets and retain text with ADDITIONS to read:

*The product and its components shall not contain commercially **produced** hydrogenated oils and fats, shall not have been treated by ionizing **radiation and** **shall not contain ingredients modified through genetic engineering.***

4. FOOD ADDITIVES

CHANGE to READ:

Food additives for infants with special medical needs should be kept to a minimum.

Rationale:

Thickening agents, emulsifiers and antioxidants are not needed in infant formulas. These non-nutritive chemicals expose infants to further needless risks in addition to the large number of foreign substances known to be present in infant formulas. As well formula fed infants are in an immunologically deprived status and less able to handle unnecessary foreign chemicals. Additional additives - often added for cosmetic purposes - may be even more harmful to infants who have special medical needs than to healthy infants. Cosmetic ingredients are frequently used to please the parents rather than providing for the infant's needs.

No ingredient should be added unless it has been demonstrated to be safe, by means of independently funded scientific research.

5. CONTAMINANTS

5.1 Pesticide Residues

REWORD 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.***

Rationale:

This is in accordance with the European legislation.

5.2 Other Contaminants

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.

Rationale:

Infant formula for medical purposes may be 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.

The use of soy-based infant formulas needs to be reviewed. SEE APPENDIX A.

6. HYGIENE

6.1 DELETE **it is recommended that** and INSERT **shall** to read:

*The product covered by the provisions of this standard **shall** be prepared and handled in accordance with....*

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 hazardous or deleterious substances***

6.3 ADD this new paragraph

The consumers should be informed through labelling of the product in the form of a warning that powdered infant formula is not a sterile product.

Labels must carry on the outside of the panel, a clear, conspicuous, easy to read and understandable warning of possible contamination, stressing preparation instructions to minimize the risk of harm related to the lack of sterility.

Labels must highlight the need to prepare correctly just before feeding; have explicit preparation instructions both in text and graphic and in local languages; and instruct on the need to discard left-over feed to prevent multiplication of microbial contaminants present in the product (cf. Joint FAO/WHO workshop on Enterobacter sakazakii and other microorganism in powdered infant formula).

The report of the FAO/WHO Workshop on Enterobacter sakazakii and other microorganisms in powdered infant formulas recommends: "In situations where the mother cannot breastfeed, or chooses not to breastfeed for any reason, caregivers should use, whenever possible and feasible, commercially sterile liquid formula."

9. LABELLING

9.1 The Name of the Food

9.1.1 INSERT the following text:

*The text of the label and all other information accompanying the product shall be written in the appropriate languages **of the countries where the product is sold.***

9.1.2 Add the sentence:

The name of the product should not be, or contain, anything which indicates or may be understood by the purchaser to be a claim of any kind or to imply a health advantage. The name should not imply that the product is like human milk.

Rationale:

For example: **HA** or **Hypo-allergenic** (indicating possible reduction of allergy risk), **AR, Staydown**, (indicating anti-reflux properties), **Organic, Prebiotic, Probiotic** or **Humana**. All these descriptive terms indicate claims that promote the product as having certain properties. These should be considered health and nutritional function claims and therefore should not be permitted. Particular properties of products are more safely conveyed through clear nutrition labelling, or independent certification stamps, alongside clear instructions that indicate the intended use of the product. No claim implying a health advantage or regarding the efficacy of the product should be made or implied. (See Appendix B: Allergenicity Claims)

9.1.3 INSERT the following text:

Formulas for Special Medical Purposes Intended for Infants shall indicate the nature of the protein, fat, carbohydrate and other ingredients for the purpose of compositional modification, including food additives and optional ingredients. This information must be presented in a clear, factual and scientific manner that is not in any way promotional or idealizing.

9.5 Information for use.

This section must have been inadvertently omitted and should be reinserted. Insert the text to be the same as Section A with the following change:

9.5.1 Remove the text in brackets **or in the accompanying leaflet** and the ADD the following paragraphs

*Adequate directions for the appropriate preparation and use of the product, including its storage and disposal after preparation, **including the following statement: “Formula remaining after feeding must be discarded” must appear on the label.***

When in powdered form, a clear, conspicuous, easy to read and understandable warning must appear on the outside panel of the label that POWDERED INFANT FORMULA IS NOT A STERILE PRODUCT and that the product may have been contaminated during manufacture. Labels must clearly alert the user of the need to prepare the product according to instructions to minimize the risk of harm related to the lack of sterility and that preparation must be just before feeding. Explicit preparation instructions must appear both in text and graphics in local languages (cf. Joint FAO/WHO workshop on Enterobacter sakazakii and other microorganism in powdered infant formula)

Rationale:

The above information MUST appear on labels, to ensure that all caregivers, including occasional care-givers, have adequate notice that powdered infant formulas are not sterile and full information on use and preparation each time the product is used.

Leaflets are unacceptable and add risk of misuse as they are easily lost or discarded.

This information is of vital importance to parents of infants with medical needs.

The Risk Profiles of *Enterobacter sakazakii* in Powdered Infant Formulas, tabled at the 35th and 36th sessions of the CCFH as well as the FAO/ WHO expert consultation report of the Workshop on *Enterobacter Sakazakii* and other microorganisms in powdered infant formula (February 2004), make it very clear that special concern should be given to minimize the health risks associated with the contamination of powdered infant formulas.

The revision process of the Proposed Draft Revised Recommended International Code of Hygienic Practices for Foods for Infants and Children is inadequate to address the immediate urgency of this serious health concern.

9.6 Additional Labelling Requirements**9.6.1 Delete and REPLACE with the following text:**

Labels (except where specifically medically indicated such as for PKU, where the need for breastmilk is carefully monitored, or Galactosemia, where breastfeeding is contraindicated) shall 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) **the statement “Breastfeeding provides the best food for your baby” or a similar statement as to the superiority of breastfeeding and breastmilk;**
- c) **a prominent statement that the products should only be used on the advice of a health worker, independent of commercial interest, as to the need for its use and the proper method of use, such as, “Use only when medically indicated and only under medical supervision”;**
- d) **instructions for appropriate preparation;**
a warning against the health hazards of appropriate preparation
a warning that powdered infant formulas may be contaminated with harmful microorganisms during manufacturing, or they may become contaminated during preparation, therefore in order to reduce the risk of potential infection it is necessary to discard any unused formula immediately after every feed.
- e) **product labels must clearly distinguish the product as suitable for infants with medical needs where breastmilk needs to be limited or is contraindicated.**
- f) **A statement that the product must be ONLY be used when medically indicated and under continuing medical**

supervision for the feeding of infants with... who cannot be breastfed.

Rationale:

The statement should not make a health or disease risk reduction claim. The product simply needs to say what it contains, its purpose and how it can be used safely. Since these products are to be administered only under medical supervision there is no need to provide a rationale for their use.

9.6.2 INSERT the following text to READ:

The label shall have no pictures of infants and women nor any other picture or text which idealizes the use of infant formula. The terms “humanized”, “maternalized” or similar terms shall not be used;

9.6.3 DELETE the references to 4.5.3 and 4.5.5 of the Codex Standard 180-1991 and retain 4.5.2 to read:

A complete statement concerning adequate precautions, known side effects, contraindications, and product-drug interactions, as applicable.

9.6.4 RE-INSERT the following text with changes as in Section A to read:

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

9.6.5 Retain as is

9.6.6 RE-INSERT the following text:

The label shall have no nutrition, health or comparative claims, nor any symbols, pictures of infants and women or other pictures or text, which idealizes artificial feeding or implies a health advantage. The term “humanized”, “maternalized”, or other similar terms shall not be used.

Statements or claims that reflect ethical or religious considerations and which influence dietary choices should not be permitted. However it is essential that manufacturers label products clearly so that all ingredients, especially those which are relevant to ethical or religious considerations are fully disclosed using nutrition labelling. The products must not carry any symbols or logos which imply special health advantages.

Rationale:

Given the nature of breastmilk substitutes there is a potential for any claim to suggest superiority over breastfeeding. (Product promotions and labels are using graphics on foods – for example a brain or a battery – to symbolize intelligence, energy etc.) The market for specialized infant formulae has expanded in recent years, fueled by unsubstantiated health claims and various promotional devices. The claims are invariably supported by industry-funded research and exploit parental concerns by suggesting that certain infant behaviours or normal feeding occurrences which are

classified as “ill health” or ‘symptoms of illness’ (regurgitation, colic, sleep disorders, intolerance, etc) can be addressed by these products¹. Specialized formulae are often presented as the first option for care in these cases. There is evidence from the USA, where restrictions on marketing are minimal, that 40% of mothers switch to specialized formulas even though published evidence indicates that only 2-7% should need them. This increases the proportion of babies fed soy formula (in the USA 26% of babies are fed on soy formulas) and encourage parents to believe that their babies are allergic or otherwise abnormal².

Religious symbols also imply a special use. The German baby food company Humana Milchunion, has agreed to an out of court settlement with parents of two Israeli infants who died from, and dozens more who were harmed by, a soy baby formula that it sent to Israel without the vital vitamin B-1 missing (thiamine) that was marked on the label. All these babies would be alive or unharmed today has they been breastfed.

APPENDIX A

COUNTRY WARNINGS ISSUED REGARDING THE USE OF SOY-BASED INFANT FORMULAS

To date a number of countries have reviewed and issued statements of concern about the routine use of soy formulas.

UK, January 2004

Earlier this year the UK Medical Officer of Health¹ reiterated that soy formulas should not be used as the first choice for the management of infants with proven cow’s milk sensitivity, lactose intolerance, galactokinase deficiency and galactosemia. The warning, based on a report by the Committee on Toxicity, notes the long-term risk posed for reproductive health linked to the high levels of phytoestrogens found in these products. The MOH also advises there are “no health benefits associated with the consumption of soy-based infant formulas”.

British Dietetic Association, 2003

In an announcement published in the Journal of Family Health Care², the Association notes that “***Dietitians should discourage the use of soy protein in children with atopy or cow’s milk allergy in the first six months of life to avoid sensitization to soya protein and exposure to phytoestrogens while organ systems remain at their most vulnerable. This would include the use of soy infant formula...When a soy based infant formula is used parents should be informed of current findings relating to phytoestrogens and health and on the clinical need for soy formula.***”

This notification follows a category of others.

¹ SMA High Energy is a food for special medical purposes not suitable for normal healthy babies. A promotion for this infant formula to health visitors in Wales, contained 20 health claims, no breastfeeding is best notice and an offer of winning £39 worth of play equipment. April 2004.

² Polack FP et al. *Changing partners : the dance of infant formula changes*. Clinical Pediatrics, Vol 38, no 12, December 1999, pp 703-708

Australia, March 1999

The Australian and New Zealand Food Authority³ warn that infants fed soy formulas are exposed to 47mg of isoflavone per day and that this level is at least 240 times greater than consumed by breastfed infants. The report notes concerns about the potential to adversely affect subsequent sexual development and fertility.

New Zealand, December 1998

New Zealand's Ministry of Health recommends⁴ that soy-based infant formulas should only be used under the direction of health professionals for specific medical indications. Other options should be considered first. As well clinicians are urged to be aware of the use of soy formulas and thyroid function and to consider assessment of thyroid function when satisfactory growth and development is not achieved.

Switzerland, 1997

The Swiss Commission on Food, also issues an information sheet to all paediatricians based on a review report⁵. This report too warns that very restrictive use should be made of soy formulas because of the potential harm from isoflavones.

References:

1. Department of Health CMO's Update. **Advice issued on soy-based infant formulas**. January 2004, page 2
2. The British Dietetic Association **Paediatric group position statement on the use of soya protein for infants**. J Fam Health Care 13: 93, 2003
3. ANZFA **Phytoestrogens: An assessment of the potential risks to infants associated with exposure to soy-based infant formula**. March 1999
4. Tuohy, P. **Soy-based infant formula**. Ministry of Health, Wellington, New Zealand, December 1998
5. Zimmerli B. et al. **Existence and development of isoflavones daidzein and genistien in baby food**. Communication regarding food stuffs in Hyg. 88:19-232, 1997

Appendix B:

Allergenicity Claims

Allergenicity claims such as HA are particularly problematic and would be more safely handled with a nutrition statement such as, ***contains hydrolysed proteins*** alongside generic product descriptions and warnings that the product should be used only on the advice and under the guidance of an independent health professional.

When *Nan HA* was first launched in the UK in 2002, eleven leading health and consumer organisations, wrote to the Minister for Public Health, Hazel Blears to challenge the legality of HA claim. Nestlé eventually launched the product with a warning stuck on the top of the tin, stating that the product ***may cause an allergic reaction if given to an***

infant with diagnosed allergy to cow's milk. This strategy is not only inadequate, but completely contradicts the thrust of the message contained in the HA claim³.

Since the launch the company has been reported to the UK Advertising Standards Authority (ASA) for using ***misleading and dangerous*** claims for ***hypoallergenic*** infant formula. Advertisements to health workers made claims that the product is ***the starter infant formula of choice that significantly reduces the risk of allergy*** and that the ***exclusive use of a hydrolysed formula is recommended to reduce the risk of developing an allergy***⁴. The adverts imply that 'partially hydrolysed' formulae have the same properties as fully 'hydrolysed' formulae. The UK Food Standards Authority has warned against using partially hydrolysed formula with allergic infants because of the risk of a reaction.

HA or Hypoallergenic claims are not permitted in North America following Nestlé/Carnation's launch of Good Start HA in the US in 1988, when several allergic babies suffered from anaphylactic shock. Nine US States and the Food and Drug Administration investigated and forced Nestlé to stop using 'hypoallergenic' claims which they said were: "Misleading and deceptive...Those babies who had severe reactions to Carnation Good Start have paid a high price for the company's irresponsible conduct."

The claims for hydrolysed proteins and the development of the market for infant formulae containing partially hydrolysed proteins was underpinned by the work of Dr R.K.Chandra, a Canadian researcher who has in recent years been discredited and whose entire body of work is now under investigation.⁵

Leading Swedish allergy specialist, Prof Bengt Björkstén, questioned the European ESPGHAN support for hypoallergenic milks in 1993: "The conclusions drawn by the Committee [ESPGHAN]...differ substantially from what most American and European researchers suggest, and they are almost identical to those suggested by the company marketing the partially hydrolysed product direct to the public... Why did the Committee not properly address this important controversy but merely uncritically quote a review published in a company sponsored book by an employee of the company?" (Acta Paediatrica, 1993)

The Scientific Committee for Food *Report on the Revisions of Essential requirements of Infant formulae and Follow-on Formulae* also expressed concern about the validity of the claims and on Page 48 states:

³ <http://www.babymilkaction.org/press/press28july04.html>

⁴ [British Journal of Midwifery, July 2004](#)

⁵ **Canadian medical journals such as Nutrition, have called for an investigation into Chandra's entire body of research on the basis that his research on vitamins and dementia is fundamentally flawed. The British Medical Journal refused to print Chandra's work saying the paper had: "All the hall marks of being entirely invented." An editorial in Nutrition said Chandra failed to provide raw data so that experts could check his statistics: "As a journal, we regret that our peer-review process failed to identify these problems before publication," acknowledging that the incident reflected badly on the peer-review process: "Sometimes the peer reviewers...just [take] the data for face value. They aren't statisticians."**
www.cbc.ca/stories/2004/06/10/sci-tech/chandra040610,
www.biomedcentral.com/news/20040511/02,
<http://bmj.bmjjournals.com/cgi/eletters/328/7431/67#48196>,

“it has been shown for some products that they were nutritionally inadequate. It is unknown if such products were removed from the market. The inherent claim that hydrolysates result in less allergic diseases cannot be deduced from technical data alone and needs substantiation in clinical trials. Surprising is the total lack of clinical studies published on follow-on formulae based on partially hydrolysed proteins.”

and on pages 50 & 51: *“To our knowledge there are no systematic studies to assess growth and biological parameters of infant formulae with partially hydrolysed protein to determine the minimal safe protein content.”*

and Page 161: *“The Committee concludes that there is no scientific foundation to base a claim that a formula induces ‘reduction of risk of allergy to milk proteins’ or is ‘hypoallergenic’ on a content of immuno-reactive protein of less than 1% of nitrogen-containing substances, as is presently the case.”*

The properties of the product – for example, that it contains hydrolysed proteins, can be conveyed through clear nutrition labelling alongside clear instructions which indicate its intended use. No claim regarding the efficacy of the product should be made or implied.