



16 August 2010

**GUIDELINES ON FORMULATED SUPPLEMENTARY FOODS FOR OLDER  
INFANTS AND YOUNG CHILDREN (CAC/GL 08-1991)**

**ELECTRONIC WORKING GROUP, CONVENED BY GHANA**

**ISDI COMMENTS ON THE SECOND DRAFT**

The International Special Dietary Foods Industries (ISDI) represents at Codex Alimentarius the manufacturers of special dietary foods and has been actively involved in the development of relevant Codex standards and guidelines. ISDI is especially interested in contributing to work that is related to nutrition products for infants and young children.

ISDI wishes to thank Ghana for chairing this electronic working group and preparing the consultation document on the new work to revise the “Codex Guidelines on Formulated Supplementary Foods for Older Infants and Young Children”.

Having the opportunity to review the second draft, ISDI is happy to provide the following comments.

**GENERAL COMMENTS**

ISDI considers that one essential element is a good definition of the categories of products considered, and of the infant and young children to whom these products are intended, in order to avoid overlaps and confusion with current standards.

On a general basis, ISDI considers that the revision of the guideline should be an opportunity to clarify it, reviewing if necessary the structure of the text. It is essential for this Guideline, as opposed to Standards, to be as general as possible and cover the whole category, i.e. foods and foods fortificant.

ISDI considers that the Guidelines should better define the different categories of products being considered.



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### GUIDELINES ON SPECIFICALLY FORMULATED SUPPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN (CAC/GL 08-1991)

*a. Several suggestions were received from the EWG regarding title. This is up for comments.*

ISDI considers like New Zealand and EU “that confusion exists around complementary feeding”, and “would support guidance which clearly identifies the target group and which differentiates food standards which include compositional criteria for complementary foods intended for older infants and young children whom are well nourished compared with those whom are malnourished”.

ISDI is also supporting Germany and “finds still unclear what the target groups of the products are.

Regarding that section, ISDI considers that:

- The word “complementary” should not appear in the title
- The word “supplementary” should stay in the title
- The word “specifically” should be added in the title to clarify that these foods are formulated under a specific national context (malnourished young children)
- Definition of “specifically” and “supplementary” should be given under the paragraph “3. Description”
- In the version 2 proposed by Ghana, some inputs of countries were not fully taken into account.
- Purpose should be further amended to include malnutrition situation
- Scope should be further amended to differentiate from existing standards on complementary foods for well-nourished infants/young children

ISDI amendments:

- Title: “Guidelines on ***specifically*** formulated supplementary foods for older infants and young children”
- Purpose: “To provide guidance on nutritional and technical aspects of the production of ***specifically*** formulated supplementary foods for older infants and young children ***at risk of malnutrition*** (...)”
- Scope: “The provisions of these Guidelines apply to Specifically Formulated Supplementary Foods for Older Infants and Young Children as defined in Section 3.1 below. ***The existing Codex standards and Guidelines, including the standards that apply to infant and follow-on formulae, processed cereal based foods and canned baby-foods foods designed for infants and young children, are out of scope of these guidelines***”



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### 3. DESCRIPTION

*3. a) Please comment on the proposed modifications (highlighted in green and blue) suggested for section 3 under description below.*

ISDI is supporting USA to give amended definition of “food fortificant” and Germany for the re-wording of the paragraph. ISDI is supporting the WHO definition of supplementary foods given by Ghana in its answers to countries questions.

- A definition of “specifically” and “supplementary” should be given under this paragraph.
- This paragraph should give additional definitions to clarify (i) the scope (ii) the target population and (iii) to reinforce the reference to local context
- As these guidelines apply to a wide variety of foods, it has to remain as generic as possible to be broadly implemented. As a consequence, ISDI is not in favour of mentioning examples of foods in this paragraph such as porridges, pastes, bars. In the version 2 proposed by Ghana for point 3.1, some inputs of countries were not fully taken into account.
- ISDI is supporting version 2 proposed by Ghana for point 3.4

ISDI amendments:

- 3.1: “Specifically Formulated Supplementary Foods for Older Infants and Young Children means foods used as supplement of daily diet to rehabilitate moderately malnourished older infants and young children, to prevent a deterioration of nutritional status of those at risk by meeting their additional needs. The formulation is specifically providing the nutrients, which either are lacking or are present in insufficient quantities in local daily diet. They are not suitable for use by infant under six months of age”.
- 3.5: “The term food-based home fortificant is a category of 3.1 and means a food fortificant that could be used to enrich homemade food either with macro nutrient or with micronutrients which are lacking in the diet. These products are used for fortification of foods available in the country where the fortificant is sold. They are added at the time of preparation to provide specified amounts of nutrients. Non-food supplements such as micronutrients powders should be addressed separately”



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### 4. SUITABLE RAW MATERIALS AND INGREDIENTS

4. a) Please comment on the proposed modifications (highlighted in green) and deletions suggested for section 4 under below.

ISDI considers that the word “Specifically Formulated Supplementary” should stay and not be replaced by “complementary”

ISDI amendments:

4.1. “The following raw materials, most of which are locally available, are suitable ingredients for the production of *specifically* formulated *supplementary* foods for older infants and young children under the specified conditions given below”

ISDI is supporting Germany amendment regarding 4.1.1.2

4.1.1.2. “Besides carbohydrates (mainly consisting of starch) cereals contain a significant quantity of protein (8-12%). Whereas rice has a satisfactory essential amino-acid composition, all other cereals are as a rule limited in lysine. *Combining cereals with other plant foods (e.g. pulses) can compensate for limiting amino acids.*”

ISDI supports Mexico statement on 4.1.2.1 that “other pulses can be used when they are appropriate”. Addition of the words “soya” and “etc” is supported: 4.1.2.1. “Pulses, including chick peas, lentils, peas, cow peas, mungo beans, green gram, kidney beans, *soya, etc*, are good source of protein (20-35%).

On 4.1.4.1, ISDI questions the fact to have the specific request for this particular ingredient. The quality of ingredients should be addressed in the chapter 5.

On 4.1.5: Regarding Fats in general, ISDI would oppose the general setting of a minimum limit for fat, as this should be justified on the basis of the local diet and decided at national level according to local context.

ISDI would like to stress that PAHO/WHO recommendation is for the diet and not for a specific product. ISDI wonders if this criteria is a relevant one in that perspective, especially since they are products requiring addition of oil at the point of use (as foreseen in point 9.2.4.4 and 9.2.4.6) that would not comply.

On 4.1.5.3, ISDI is supporting EU statement that there is “no evidence that Trans fatty acids from hydrogenated fats is different to that of naturally occurring Trans fatty acids in milk or meat fat. There is therefore a need for consideration for the proposed prohibition”.

ISDI proposes the following amendment: *“Fats and oils have to be appropriately processed to reduce, as far as possible, the Trans fatty acids content”*



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On 4.1.6.1, ISDI recommends using the terms “Milk and Milk products” (instead of “dairy products”) and adding text to allow for other milk ingredients at the end of the paragraph. There are much more dairy ingredients that can be added than the three currently mentioned.

The text would then read:

**“Milk and milk products** are considered beneficial to growth and can be added to Complementary food. Dairy products can be added as dried skimmed milk, full fat milk, Semi-skimmed milk solids **or other dairy ingredients”**

4.1.6.2. ISDI agrees with the content of the paragraph on whey protein concentrates. However, one could question the level of details included here. Other protein sources of equivalent quality could be considered as well.

4.2.1. ISDI supports addition of animal source food. However, the wording “nutrient dense food” is unclear and should be revised.

4.2.2: ISDI shares USA comment that “The recommendation in the reference cited (WHO TRS 916) was made in the context of the total diet and was not intended to pertain to individual foods. We question why this recommendation is applied to individual foods in this Consultation Document”

ISDI supports that the formulation is done on a case-by-case basis in line with the scope of the Guidelines “The formulation is specifically providing the nutrients which either are lacking or are present in insufficient quantities in local daily diet”

ISDI would therefore delete the wording: ~~“provide less than 10% of the total energy of the product.”~~

4.2.3. ISDI would thank Ghana to better define “traditional flavours”. ISDI also proposes to broaden the list to other flavours than the currently proposed ones (i.e. vegetable extracts).

## 5. TECHNOLOGIES FOR AND EFFECTS OF PROCESSING

ISDI considers that the word “Specifically Formulated Supplementary” should stay and not be replaced by “complementary”.

5. a) Please comment on the proposed modifications (highlighted in yellow) and deletions suggested for section 5 below.  
b) Are there any other additions or modifications needed?

5.1.1: In order to secure quality of the end products, ISDI supports Mexico and suggests introducing destoning and metal detection as such:

“Cleaning or washing: to eliminate dirt, **all type of stones or foreign bodies (e.g. metal pieces)**, damaged grains and noxious seeds, insects and insect excreta and any adhering material”



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### 5.5.1.2: ISDI supports Mexico and its amendment “

“The effects of this technology are:

- Gelatinization of the starchy portion of the mixture with minimal quantities of water;
- Inactivation of lectins and simultaneous reduction of trypsin inhibitor activity;
- A reduction in the quantities of water needed for preparation of the food.
- ***Flavour development***

5.5.2.2. ISDI supports Mexico and its amendment: pre-digestion is also used to get a better consistency of the product to allow a higher nutrient density.

ISDI proposes to add at the end of the sentence “The predigested product has improved organoleptic characteristics, higher digestibility, good solubility and requires less water for the preparation of the feed (***higher nutrient density***)”.

## 6. FORMULATION

6. a) Please comment on the proposed modifications (highlighted in green) and deletions suggested for section 6 below.

6.1.1. The word “Specifically Formulated Supplementary” should stay and not be replaced by “complementary”

6.1.2: ISDI supports Argentina, New-Zealand and Germany comments. ISDI agrees to delete this paragraph.

6.1.3: ISDI supports Germany amendment and would further amends as such:

6.1.3 “The selection of ingredients for the formulation of ***Specifically*** Formulated Supplementary Foods ***to supplement the local diet of*** Older Infants and Young Children should be made having regard to the provisions in Sections 4 though 6.1.2 above and taking into account the following aspects:

- Nutrient content of the local diet (***including processed cereal based foods and canned baby foods when relevant***)

6.1.5: ISDI would like to stress that the recommended values are for children not at risk of malnutrition. According to local diet and contexts, it could be necessary to authorise higher amounts of vitamins and minerals to compensate for deficiency and/or favour micronutrients reserves in the body. The addition of paragraph 6.1.5 should not prevent having the flexibility necessary in specific or local contexts.

6.2.2: ISDI supports Mexico amendment:

“The energy density of the food can be increased by:

- (a) The addition of fats and oils, and/or digestible carbohydrates including, in moderation, sugars; and/or,
- (b) Processing the basic ingredients as indicated in Section 5.



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### *(c) Enzymatic hydrolysis of flours"*

6.3.2: ISDI shares its concerns with USA regarding the scientific basis for selection of the protein digestibility corrected amino acid score as the indicator of protein quality and thanks Ghana to provide more information, among others on the selection of the method and the cut-off value of 70%, including references.

6.3.3: ISDI could agree with that point if 6.3.2 is clarified.

6.3.5. ISDI supports USA statements in line as well with 4.2.2.

ISDI proposes the deletion of this paragraph:

~~**6.3.5 Taking into account the preceding considerations, the energy from protein content should not be less than 10% of the total energy from the product. be in the order of 15-g per 100-g of the food on a dry-matter basis.**~~

6.4.1. ISDI supports USA statements in line as well with 6.3.5.

ISDI proposes the deletion of "At least 30% of energy derived from fat would be desirable"

6.4.1 Incorporation of adequate quantities of fats and/or oils, as technologically feasible, is recommended in order to increase the energy density, the amount of essential fatty acids and reduce total volume of the product. ~~**At least 30% of energy derived from fat would be desirable.**~~

6.4.2. ISDI supports Mexico statement and amendment:

6.4.2. ~~**"When adequate for the product (or "when relevant for the aim of the product in the diet"), the level of linoleic acid (in the form of glycerides) should not be less than 300 mg per 100 kcal or 1.4 g per 100 g of dry product and the ratio between linoleic acid and alpha-linolenic acid should be between 5:1 and 15:1**~~

6.5.2. ISDI proposes deletion of "The dietary fibre content of the formulated food should therefore be reduced to a level not exceeding 5 g per 100 g"

6.5.2. Increasing the intake of dietary fibres increases stool bulk, may cause flatulence and decrease appetite. Fibre load also can affect the efficiency of absorption of important nutrients from diets with a marginal nutrient contents. ~~**The dietary fibre content of the formulated food should therefore be reduced to a level not exceeding 5-g per 100-g.**~~

6.6.4: ISDI suggests that the Nutrient Reference Values for older infants and young children are not in the scope of this guidelines but discussed as part of the "Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the Codex Guidelines on Nutrition Labelling" (ALINORM10/33/26 - Appendix IV), which is currently discussed at CCNFSDU.

ISDI considers that in having NRV detailed in specific guidelines, revision of the guidelines occurs when revision of the NRVs occur, which is not an adequate process.



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ISDI would therefore favour the deletion of section 6.6.4 and of the table of RNIs in the Annex, considering that those elements shall be developed in relation with NRVs by a specific working group in Codex, and that this table would be detrimental to the flexibility that is needed by national authorities to face specific contexts in relation with the formulated supplementary foods for older infants and young children.

ISDI would suggest replacing the text in 6.6.4 by the following text:

*“The addition of vitamin and minerals and the nutrients to be considered in the development of a complementary and supplementary food for older infants and young children should also take into account the WHO/FAO Guidelines on food fortification with micronutrients (2006), the Codex guidelines on nutrition labeling and the future Codex principles in the development of NRVs.”*

Two options to consider with regard to the inclusion of a Table in the Annex:

1. Again ISDI reiterates that the specific values in the Table be based on new work on the Nutrient Reference Values for older infants and young children that is anticipated to be discussed as part of the “Proposed Draft Additional or Revised Nutrient Reference Values for Labeling Purposes in the Codex Guidelines on Nutrition Labelling (Alinorm 10/33/26-Appendix IV) which is currently under discussion at CCNSFDU.

OR

2. Alternatively, ISDI could concur with US and Mexico, with support of the use general principles for establishing nutrient levels to be added to the FCF instead of prescriptive values based on RNI or EAR. Reference could be made to Committee on Nutrition and Foods for Special Dietary Uses’ proposed general principles for establishing Nutrient Reference Values of Vitamins and Minerals for the General Population as a draft annex to the Codex Guidelines on Nutrition Labelling. (See Appendix III of ALINORM 10/33/26).

In any case, ISDI recommends that the text be revised so that it is clear that the Table in the Annex provides the reference nutrient intakes for those vitamins and minerals for which levels have been established, and not only those most frequently deficient.



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### 7. HYGIENE

*7. a) Please comment on the proposed modifications and deletions suggested for section 7 below.*

7.3. ISDI is not in favour of reference to the Code of Hygienic practice for foods for infants and children (CAC/RCP 21-1979) because it refers now to formulae only.

Reference to microbiological criteria for foods (CAC/GL 21-1997) as well as Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004) need to be assessed in depth, as they are partially appropriate to the product and/or to the target group.

Developing specific and adequate hygienic criteria for supplementary foods used for infants and young children will be supported by ISDI.

ISDI considers that there could be a need for the definition of specific microbiological criteria for foods for infants and older children. In the meantime the products should comply with the appropriate sections of the Recommended International Code of Practice – General Principle of Hygiene (CAC/RCP 1 1969), and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.

The products should also 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).

### 8. PACKAGING

The word “Specifically Formulated Supplementary” should stay and not be replaced by “complementary”

### 9. LABELLING

*Question 8. a) Please comment on the proposed modifications*

The word “Specifically Formulated Supplementary” should stay and not be replaced by “complementary”

9.1. ISDI would support the inclusion of additional text to section 9.1, in line with other guidelines and standards, to allow communication on the aim of the products intended for specific nutritional purpose, based on scientifically supported nutrition and health claims.

9.2.1.2. If the scope has been clarified as above, the wording as proposed by Switzerland and incorporated in Ghana 2nd draft is in line with ISDI position.



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In order to answer to EU concerns, ISDI believes that a footnote such as “ *\* locally available food includes homemade food as well as processed cereal-based foods (STAN 47-1981 rev 1-2006) and canned baby foods (STAN 73-1981)*” will clarify.

9.2.4 [should currently read 9.2.3]:

ISDI agrees with EU comments however, when relevant (specific need on fat), alpha-linoleic and linolenic acid could be labelled.

ISDI proposes:

9.2.4 (b) “the amounts of protein, carbohydrates and fat, and the amount of linoleic and alpha-linolenic acid *when relevant*, expressed in grams”.

Otherwise ISDI agrees with the modifications as proposed by Ghana.

9.2.4.6. ISDI is not sure to understand the aim of the sentence and would thank Ghana to provide the rationale behind this new proposal in the second version of the draft from Ghana. Products covered by these guidelines are supplemented food and their use needs to be fully understood/labelled

### ANNEX

#### 9. a) Please comment on the proposed modifications (highlighted in green)

ISDI underlines the need to assess the Annex regarding WHO work, which is on-going (cf. comment made in 6.6.4).

ISDI, as requested by Mexico, Bolivia and USA, would favour reference to national nutritional references.

ISDI endorses the US comment about providing general principles for establishing nutrient levels to be added to the FCF instead of prescriptive values based on RNI or EAR.

ISDI does not support a single reference value of 50% for the amount of nutrients that should be contained in a daily ration. The amount should be scientifically based considering local conditions including the nutrient contribution to the diet from local food and the nutritional status of the target population as well as nutrient contribution of breast milk and national legislation.

ISDI also questions the wording in the last sentence as it implies that an enriched/fortified complementary food should be enriched/fortified with all nutrients listed in the table. Text needs to be revised .

ISDI would therefore favour the deletion of the table of RNIs in the Annex. In any case, we would suggest the text to be amended as follows:

The vitamins and minerals listed in the Table include those for which nutrient levels have been established for older infants and young children and should be considered in the

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formulation of a supplementary food. *Alternatively nutrient reference values may be developed according to the proposed general principles for establishing Nutrient Reference Values of Vitamins and Minerals for the General Population as a draft annex to the Codex Guidelines on Nutrition Labelling under development by CCNFSDU. (See Appendix III of ALINORM 10/33/26).*

Local conditions including the nutrient contribution to the diet from local foods and the nutritional status of the target population as well as national legislation should be taken into account in determining the nutrients to be added. When a food is enriched [fortified] with one or more of these vitamins and minerals, the total quantity of each of these added vitamin(s) and/or mineral(s) contained in a daily ration of the food should be *scientifically determined taking into account the nutrient contribution of breastmilk as well as local conditions including the nutrient contribution to the diet from local food and the nutritional status of the target*