codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/NFSDU 03/6-Add. 3**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-fifth Session
Bonn, Germany, 3- 7 November 2003

PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA

- Comments at Step 3 of the Procedure -

Comments from:

JAPAN
EUROPEAN COMMUNITY

AOECS – ASSOCIATION OF EUROPEAN COELIAC SOCIETIES
ENCA – EUROPEAN NETWORK OF CHILDBIRTH ASSOCIATIONS
IBFAN – INTERNATIONAL BABY FOOD ACTION NETWORK

Japan

1.1 Scope

We are of the opinion Draft Revised Standard for Infant Formula (ALINORM03/26A APPENDIX Ⅱ) shall apply only to products intended for general or normal population and shall not apply to infants with special medical requirements. We believe that there needs to be another standard developed for infants with special medical requirements.

Therefore, we support the development of Draft Standard B contained in CX/NFSDU 03/6-ADD.1

2.1 Product Definition

2.1.1

We propose to remove the square brackets for the same reason as described above.

3. Essential Composition and quality factors

The description of substances is inconsistent in this section as well as in Section 10 on methods of analysis. We propose to have a consistent description such as vitamin name followed by chemical name in parentheses or chemical name followed by vitamin name in parentheses.

In addition, we wish to propose that the order of provisions in Section 10 should be the same as in this section.

3.1.2

(a) Vitamins

Niacin, niacin equivalents

We agree with the use of preformed niacin. However, according to the report by Itoda T et al. (Jpn. J. Ped. Gastroenterol. Nutr., 10, 11 (1996)), the minimum level “0.8mg/100kcal” is too high. We propose to be established the minimum level with taking into account the variability in region.

(b) Minerals

Calcium

We propose to remove square brackets of the Ca:P ratio in the footnote. The Ca and P content of infant formula is much higher than that of breast milk. Since P places a high metabolic load on infants, significant effort has been made to reduce the load. Furthermore, since Ca delay the digestion and absorption of fat, increasing the Ca content to an unnecessarily high level may reduce the amount of available energy taken in. Therefore, both P and Ca should be reduced with optimizing the balance.

Selenium

We agree with introduce of minimum level of selenium. However, according to reports by Nui S *et al.* (Bulletin of the Faculty of Agriculture, Tamagawa Univ., 37, 1 (1997)) and Higashi A *et al.* (*Acta Paedeatr. Scand.*, 72, 433 (1983)), the minimum level “7μg/100kcal” is too high. We propose to be established the minimum level with taking into account the variability in region. Moreover, introduce of high minimum level for selenium could induce imbalance among essential compositions.

(e) Fat and Fatty Acid

Linoleic acid

We agree to establish a maximum level for linoleic acid, however, the establishment should be done on the basis of clear scientific evaluation.

Trans fatty acid

We propose that the trans fatty acid content should be established from the result with the international method, AOAC methods, because the proposal value “4%” is referred to references using capillary gas chromatography which is not standardized worldwide concerning to separation methods for each isomer and regulation of standard materials.

9.1 The Name of The Food

9.1.6

We propose to delete the clause:

> 9.1.6 [Products containing not less than 0.5 mg Iron (Fe)/ 100 kilocalories shall be labelled "Infant Formula with added Iron"].
> or
> [Products containing less than 0.5 mg Iron (Fe)/ 100 kcal 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 other additional sources.]

Because minimum and maximum amounts per 100 kcal of Iron (Fe) has be established at “3.1 Essential Composition” of the standard as 0.5mg and 1.5mg respectively, no additional labelling is necessary.

9.6 Additional Labelling Requirements

9.6.1 b)

Because there is not enough scientific evidence that the breast milk protects against diarrhea, we propose to delete the clause:

> b) [a statement of the superiority of breastfeeding or breastmilk, for example the statement: Breastmilk is the best food for your baby, it protects against diarrhea and other illnesses].

And because the superiority of breast milk is already adequately expressed by “Breast milk is the best food for your baby”, we propose to amend the clause “The statement "Breastfeeding is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breastmilk.” to “The statement "Breastfeeding is the best food for your baby"”.

ANNEX 1 Essential and semi-essential amino acids in breast milk

We propose to examine, first of all, which secretion period of breast milk should be referred to in determining the amino acid composition as NRV by taking into account of Table 1, which shows the differences among ALINORM 99/26, CX/NFSDU 98/7 ANNEX 1, Report by Yonekubo et al. and Report by Idota et al. Thereafter, the amino acid composition of the breast milk of the specified period should be reviewed.

There are large differences in the amino acid composition of breast milk, which is referred to as NRV to be used for evaluating nutritional values of products.

The protein content is the highest in colostrums, and it thereafter decreases even after 1 month after delivery. The expression of protein content per energy shows the same pattern. The amino acid content also varies in parallel. Therefore, with regard to the secretion period, it should be discussed which breast milk should be referred to for the evaluation of amino acid composition as NRV.

Differences in several data sources to be considered: interpretation of Table 1

The previously proposed Codex values show no data source, as pointed out by various countries, and no ground for the proposed Codex values.

The values proposed by Canada are based on the amino acid patterns reported by Sarwar *et al.* (1996) and FAO/WHO/UNU (1985). The values of His, Ile, Leu, Lys, Thr, Trp and Val were the values of breast milk reported by Sarwar *et al.*, while the values of Cys, Met, Phe, Tyr and Arg are based on the amino acid pattern reported by the FAO/WHO/UNU (1985).

The FAO/WHO/UNU (1985) data use the average of the data from four references, all of which are old data reported in 1954-1985, and were obtained from small samples. The values of breast milk reported by Sarwar *et al.* are based on the transitional milk on the 5th to 10th days of delivery from 12 mothers who had full-term delivery at an institution in Toronto. These specific data should not be used as a reference for NRV. Moreover, the use of transitional milk is in itself a problem.

Yonekubo *et al.*and Idota *et al.* determined the amino acid composition of the breast milk of several thousand mothers throughout Japan, taking into account of the limiting factors such as mothers' health, babies' developmental conditions, secretion period, and regional and seasonal variations.

Table 1 Comparison of amino acid composition among several data sources.

(mg/100kcal)

	Alinorm 99/26	CX/NFSDU 98/7 ANNEX 1	Yonekubo *et al.* 21 days–less than 3 months	Idota *et al.* 16–60 days
Arginine	107	69	65.3	66.2
Cystine	44	24	34.8	45.1
Histidine	47	45	43.5	46.8
Isoleucine	83	72	110.3	96.3
Leucine	167	156	195.9	183.4
Lysine	119	122	123.4	125.6
Methionine	23	29	27.6	26.2
Phenylalanine	75	62	71.1	71.4
Threonine	77	80	78.4	88.1
Tryptophan	31	30	36.3	29.4
Tyrosine	85	59	72.6	75.5
Valine	99	80	107.4	88.0

Notes: lower values of breast milk analysis by Yonekubo *et al.* and Idota *et al.*

Yonekubo *et al.* (21 days to less than 3 months): *J. Jap. Soc. Nutr. Food Sci*,. 42, 194 (1989）.

Idota *et al*. (16 to 60 days on average): *Jap. J. Pediatric Gastroenterol. Nutr.*, 5, 209 (1991).

The following comments are corresponded with CRD1 titled "Report on the Meeting of the Working Group on Essential Composition of Infant Formula, 2 November 2002, at Berlin".

Revised General Principles for Establishing Minimum and Maximum Values for the Essential Composition of Infant Formula

4. and 7.

Minimum levels of constituents in breast milk should be discussed by taking into account the average levels of the constituents, their regional variation, variations by lactating period and dietary habitat, and nutritional requirements of the constituents. In the case of nutrients for which deficiency is not reported in infants fed with breast milk, the minimum level should be below the mean value of that in breast milk. Maximum levels should be introduced only when high dose is proved to have an adverse health effect.

In regard to discussing minimum and maximum levels of ingredients we propose to introduce the following conditions:

- Age of target infant: 0 – 5 months and 6 – 11 months (proposed by Japan)
- average daily intake of nursery infant formula: 750ml/day (based on breast milk intake; proposed by Japan)
- energy intake: 67kcal / 100ml (proposed by the U.S.A.)

6. d)

Because it could be impractical to take into account the variability in ingredients [and in water] after the infant formula product is purchased in advance, we propose to amend the clause "d) the inherent variability in ingredients [and in water] that may be added to the infant formula product before or after it is purchased." to "d) the inherent variability in ingredients [and in water] that may be added to the infant formula product before it is purchased".

EUROPEAN COMMUNITY

SECTION 1.1 "SCOPE"

The second sentence of this section causes concern for the reasons outlined in the discussion paper (CX/NFSDU 01/5-Add 1) prepared in 2001 by the German delegation. The options for dealing with the issue were discussed at the last session of the CCNFSDU but no conclusion was reached. The European Community would prefer foods for special medical purposes for infants to be eliminated from the Scope of the standard. The European Community will carefully consider the paper prepared by the electronic Drafting Group on the Scope and Text of the Proposed Draft Revised Standard for Infant Formula.

The European Community made the comment to the last session that the last sentence of paragraph 2.1.2, as was, should be revised and moved to the Scope. Alinorm 03/26A Appendix II has deleted the sentence at the end of 2.1.1 with a note that it should be moved to the Scope although the sentence has not been placed in the Scope.

If it is agreed that the sentence should be placed in the Scope then the European Community considers that the wording of the sentence needs to be revised. The reason is that the current wording of the sentence protects the use of the description "infant formula" rather than preventing the presentation of other products as suitable for satisfying by themselves the nutritional requirements of infants. Therefore, the following revised sentence could be incorporated in the Scope of the Standard as paragraph 1.2 a:

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

SECTION 3.1 "ESSENTIAL COMPOSITION" AND "ANNEX 1"

The European Community's Scientific Committee on Food adopted, on 4 April 2003, a Report on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae (available at http://europa.eu.int/comm/food/fs/sc/scf/out199_en.pdf). The report is under consideration with a view to amending the existing legal requirements on the essential composition of infant formulae in the European Union.

SECTION 3.2 OPTIONAL INGREDIENTS

Section 3.2.1

With respect to the wording in square brackets the European Community considers that in the context of the proposed standard the terms "ingredients" and "substances" would be technically more correct than the term "nutrients". This would be in line with the wording of section 9.3 (b) which refers to "ingredient".

Section 3.2.2

The Committee is considering which wording "usefulness", "suitability" or "beneficial effect" should be included in the section. In the opinion of the European Community the phase "suitability for the particular nutritional uses of infants" implies that the substance has a nutritional effect in the infant. Of those proposed in square brackets the European Community supports retaining the term "suitability".

In addition, if the Committee agrees to the proposed change of wording in section 3.2.1 then the mention of "nutrients" in 3.2.2 should be changed to "substances".

Section 3.2.3

Again, if the Committee agrees that in section 3.2.1 the second occurrence of the term "nutrients" should be changed to "substances" then the wording of this section should be revised in accordance with the agreed wording for 3.2.1.

SECTION 4 FOOD ADDITIVES

No comments are made at this stage as this issue is under consideration by the electronic Working Group co-ordinated by Switzerland.

SECTION 9.1.5 THE NAME OF THE FOOD

The inclusion of the section 9.1.5 will depend on the outcome of the Committee's consideration of the paper prepared by the electronic Drafting Group on the Scope and Text of the Proposed Draft Revised Standard for Infant Formula.

The European Community considers that the last sentence of 9.1.5 is independent of the first sentence. In the absence of a definition of "health claims" within Codex, it is suggested that the proposed sentence "No health claims shall be made regarding the dietary properties of the product" should remain in square brackets, and discussions deferred until "health claims" have been defined.

SECTION 9.1.6 "THE NAME OF THE FOOD" (IRON)

Consideration of this section will depend on the outcome of discussions on Section 3.1.

SECTION 9.3 DECLARATION OF NUTRITIVE VALUE

The Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985 (Rev. 1 – 1993) indicate that information on energy value should be expressed in kJ and kcal. Therefore it is proposed that the energy declaration should be in both kJ and kcal and the first part of section 9.3 (a) should be changed to:

"the amount of energy, expressed in kilocalories (kcal) <u>and</u> kilojoules (kJ)…".

In addition the Codex Guidelines on Nutrition Labelling suggest that the values used in nutrient declaration should be weighted average values. Therefore, it is proposed that in section 9.3 (b) "total" should be changed to "average".

SECTION 9.6 "ADDITIONAL LABELLING REQUIREMENTS"
Section 9.6.1 b)
As noted in the comments submitted to the last Committee meeting there is an error in the proposal made by the European Commission at the 23rd Session of the Committee. The alternative wording for 9.6.1.b) should refer to "breastmilk" rather than "breastfeeding". Thus it is proposed that the sentence should be corrected to the following:

> "*b) The statement "Breastmilk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breastmilk.*"

The European Community supports the inclusion of the above revised sentence in the standard and the first option for wording under section 9.6.1.b should be deleted.

"Independent health worker"
Sections 9.6.1 c) and 9.6.4 refer to "independent health worker", during discussions on the proposed draft revised standard for processed cereal-based foods for infants and young children concerns were raised about this proposed wording. For the Committee's information the European Community legislation refers to "independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care".

AOECS – ASSOCIATION OF EUROPEAN COELIAC SOCIETIES

According to the criteria of ESPGHAN (European Society for Paediatric Gastroenterology, Hepatology and Nutrition) the Infant Formula has to be gluten-free, because gluten cannot be tolerated by any baby in the first months of their life.

The European Commission Directive on Infant formulae and follow-on formulae (91/321/EEC) meets these requirements, precising only milk- and soy-protein and starches gluten-free by nature being permitted for these foodstuffs.

AOECS strongly requests to consider this also in the Codex Standard for Infant Formula.

ENCA – EUROPEAN NETWORK OF CHILDBIRTH ASSOCIATIONS

Draft A in 9.9.5 (right column)

Labels should not discourage breastfeeding and have the same text as in 9.8.1. a + b (left column) unless breastfeeding is medically totally contraindicated

and after 9.9.10, right column, add chapters containing the same text as 9.8.1.e., 9.8.2. and 9.8.3. in left column

Draft B chapter 8.4.6.

labels should not discourage breastfeeding and apply point 9.8.1 a + b of the proposed Draft Revised Standard for Infant formula, unless breastfeeding is medically totally contraindicated

and add a further para

8.4.8 - 8.4.10 which will have the same wording as 9.8.1e 9.8.2 and 9.8.3 in the Proposed Draft Revised Standard for Infant Formula

The same suggestion applies to **draft D**

IBFAN – INTERNATIONAL BABY FOOD ACTION NETWORK

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. ***IBFAN requests that the CCNFSDU initiate a critical review 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.***

IBFAN 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.