European Community Comments for the

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-eighth Session
Chiang Mai, Thailand 30 October – 3 November 2006

AGENDA ITEM 4a

DRAFT REVISED STANDARD FOR INFANT FORMULA [AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS] (SECTION A) – (CX/NFSDU 06/28/4-ADD.3)
- Comments at Step 6 of the Procedure –

European Community Competence
European Community Vote

The European Community (EC) appreciates the work of the electronic Working Group, in particular the efforts of the Chair of the group in highlighting the areas where there is or is not consensus on the essential composition of infant formulae.

The EC has the following comments on the proposals for the essential composition of infant formulae.

Section a) Protein

Footnote 2 – Traditionally different appropriate conversion factors have been used for the calculation of the protein content from the nitrogen content of different protein sources. Recent scientific advice is that for the specific purposes of calculating the protein content of infant formulae it is appropriate to use a single conversion factor adapted to these products. The calculation of the protein requirements proposed by the ad hoc International Expert Group was based on the nitrogen conversion factor (NCF) of 6.25 for all protein sources. Infant formula is a sophisticated product that is specially developed to satisfy the nutritional requirements of infants and the NCF is applied to the final product prepared ready for consumption and not to the individual protein or nitrogen sources. Therefore, the EC believes that the approach proposed by the scientific advisory groups is acceptable.

The EC believes that footnote 2 should be revised to clarify the specific considerations that concern infant formulae in relation to the calculation of protein content and proposes that it should be redrafted as follows:

“Infant formula is a complex product that is specially developed to satisfy the nutritional requirements of infants. For the purpose of this standard, the calculation of the protein content of the final product prepared ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular nitrogen
source. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25.”

Second part of 3.1.4 – Based on the scientific advice the EC supports that for calculation purposes the concentration of methionine and cysteine and of phenylalanine and tyrosine can be added together. However, the EC believes that the ratios should be reviewed and proposes that the conditions should be that the ratio of methionine:cysteine and phenylalanine:tyrosine are less than 2. However, in the case of methionine:cysteine, the ratio may be greater than 2 and less than 3 if the suitability of the formula has been demonstrated.

Section b) Lipids
Footnote 5 - The EC believes that the reference to the different fatty acids should be expressed in terms of “total fat content” rather than “total fatty acids”. On this basis the EC supports the following maxima:

- Lauric and myristic acids shall not exceed 20% of total fat content;
- Trans fatty acids shall not exceed 3% of total fat content; and,
- Erucic acid shall not exceed 1% of total fat content.

The EC notes that in footnote 5 the wording related to the maximum amount of the fatty acids varies: “should not exceed”, “not higher than” and “shall be less than”. The EC believes that potentially this could be confusing and therefore proposes that for consistency the wording “shall not exceed …” should be used when expressing a maximum level.

Linoleic acid
The EC notes that the proposed maximum is 1.2 g/100 kcal or 0.3 g/100 kJ. The EC supports the figure of 1.2 g/100 kcal and notes that this is roughly equivalent to 0.285 g/100 kJ. The EC proposes that the requirements for linoleic acid should be expressed, as is the case in the existing Codex Standard, in terms of “milligrammes in the form of glycerides”. In which case the EC proposes that the following figures should be used: minimum 300 mg/100 kcal (70 mg/100 kJ); and, maximum 1200 mg/100 kcal (285 mg/100 kJ).

Section c) Carbohydrates
Footnote 6 – The EC believes that the provisions on the addition of precooked and/or gelatinised starches in terms of percentage of total carbohydrate and grams per 100 ml are jointly applicable and are not alternatives, therefore the “or” should be changed to “and” and would read as follows: “Only precooked and/or gelatinised starches may be added to infant formulae up to 30 % of total carbohydrate and up to 2 g/100 ml”.

Vitamins and minerals
The EC believes that proposed upper levels of vitamins and minerals should be based on both safety considerations and on the principle that these products are intended to satisfy the particular nutritional requirements of the intended users. Therefore, the addition of vitamins and minerals should be aimed at ensuring that the product meets the range of nutritional requirements of infants during the first months of life. However, the inclusion of excessive amounts of components may put a burden on metabolic and other physiologic functions of the infant. Those components taken in the diet which are not utilised or stored by the body have to be excreted, often as solutes in the urine. Since water available to form urine is limited and the infant’s ability to concentrate urine is immature during the first months of life, the need to excrete any additional solutes will reduce the margin of safety of a product, especially under conditions of stress, such as fever, diarrhoea or during weight loss. Therefore, the EC
believes that it is important that methods of manufacture of the products should aim to avoid excessive levels of vitamins and minerals in the product.

The EC supports the majority of the proposed minimum and maximum or guidance levels that were included in ALIMORM 06/29/26 Appendix IVA. The EC has the following comments on the summary presented in CX/NFSDU 06/28/4-Add.3.

**Section d) Vitamins**

**Pantothenic Acid**

The IEG report has included 2 figures for the range of pantothenic acid in infant formula: in the text 60-300 μg/100 kcal whilst in the summary table 400-2000 μg/100 kcal is quoted.

Based on the advice of the Scientific Committee on Food the EC believes that the figures in the table of the IEG report are the appropriate basis for the level of pantothenic acid in infant formula. The SCF recommended that the level of pantothenic acid in infant formula should be between 400-2000 μg/100 kcal. The conclusions of the SCF are based on the recommendations of the US Food and Nutrition Board that, for infants 0-6 months, an adequate intake of pantothenic acid was 1.7 mg/day. Based on the usual assumption of a 5 kg infant consuming 500 kcal/day an AI of 1.7 μg/day is equivalent to 340 μg/100 kcal, therefore the EC believes that the minimum level of pantothenic acid should be 400 μg/100 kcal (95 μg/100 kJ) and the maximum should be 2000 μg/100 kcal (475 μg/100 kJ).

**Section e) Minerals and Trace Elements**

**Iodine**

The maximum level for iodine in CX/NFSDU 06/28/4-Add.3 is 75 μg/100 kcal and the summary indicates that there is consensus. However, Annex IV(A) of ALINORM 06/29/26 proposed a maximum level of 50 μg/100 kcal. Based on the scientific advice the EC supports the maximum level of 50 μg/100 kcal proposed in the ALINORM.

**Copper**

Based on the advice of the SCF the EC believes that the maximum level of copper of 100 μg/100 kcal (25 μg/100 kJ) would be appropriate. This level is around three times the proposed minimum level of 35 μg/100 kcal.

**EDITORIAL COMMENT**

The EC notes that in certain cases the figures for the levels expressed per 100 kJ are different to those that have been calculated by the EC.