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WORKING DOCUMENT

FOR A PROPOSAL FOR A RECAST COMMISSION DIRECTIVE

ON INFANT FORMULAE AND FOLLOW-ON FORMULAE

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WORKING DOCUMENT FOR A PROPOSAL FOR A RECAST COMMISSION DIRECTIVE ON INFANT FORMULAE AND FOLLOW-ON FORMULAE

1. BACKGROUND

The Commission services have prepared a working document for a proposal for the amendment of Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae[1]. The document is based on a draft consolidated text of Commission Directive 91/321/EEC taking account of all the previous amendments i.e. a codified text of the Directive. The codified text is still in the process of being finalised so the text that will form the basis of the official working document could change but it is expected that any changes in the adopted codified Directive will not directly affect the proposed amendments highlighted in the attached working document.

The amendments proposed take into account ongoing discussions at the international level within the Codex Alimentarius forum, and the latest scientific advice on the essential composition of infant formulae and follow-on formulae.

2. AMENDMENT OF COMMISSION DIRECTIVE 91/321/EEC

Commission Directive 91/321/EEC on infant formulae and follow-on formulae sets out essential compositional requirements for infant formulae and follow-on formulae as well as certain other requirements such as specific labelling and maximum levels of pesticide residues.

Recent discussions in the Codex Committee on Nutrition and Foods for Special Dietary Uses mean that the definitions of infant formulae and follow-on formulae need to be reviewed to take account of these discussions.

The question of claims that may be made on the products needs to be considered. With respect to infant formulae, some permitted claims are no longer relevant or appropriate whilst claims on certain optional ingredients are not permitted.

In early 2003 the Scientific Committee on Food adopted a report on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae[2]. It is appropriate that the essential composition of the products should be revised to reflect this latest scientific advice.

The main amendments being proposed are as follows:

1. Definitions of "infant formulae" and "follow-on formulae"

> There have been extensive discussions in the Codex Committee on Nutrition and Foods for Special Dietary Uses on the definition of infant formulae. Therefore, it is appropriate to take into account the latest definition of "infant formula" in the proposed Draft Revised Codex Standard on Infant Formulae[3] when revising the

[1] OJ L 175, 4.7.1991, p35. Directive as last amended by Commission Directive 2003/14/EC (OJ L 41, 14.2.2003, p.37)

[2] Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae (adopted on 4 April 2003)

[3] Report of the 25th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses, ALINORM 03/27/26 Appendix V.

Community legislation. The definition of "follow-on formulae" should be revised to ensure that there is consistency between the definitions for infant formulae and for follow-on formulae.

2. Inclusion of new ingredients

The Directive indicates that the suitability of ingredients for the particular nutritional use of infants should have been established by generally accepted scientific data. The proposal elaborates further specific factors that manufacturers should take into account when considering the inclusion of new ingredients in infant formulae and follow-on formulae. The proposal indicates that the potential benefits and safety considerations should be evaluated by a review of the available data. As necessary preclinical and clinical studies should be conducted following published guidance on the conduct of such studies. The most recent guidance in this area was given in 2003 by the Scientific Committee on Food[4] although other bodies such as the UK Committee on Medical Aspects of Food and Nutrition Policy have published guidelines[5] which have been endorsed by the European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN).

It might be possible to include the provision that specific guidance on the level and type of evidence that companies should collect and evaluate before the commercialisation of a product containing a new ingredient could be developed by the European Food Safety Authority.

3. Labelling provisions and claims

The labelling provisions on the name and description should be updated to reflect the proposed changes in the definition of and the composition of infant formulae and follow-on formulae.

Directive 91/321/EC restricts claims on infant formula to those specified in Annex IV of the Directive. The recommendations of the SCF mean that it is appropriate to review the list of permitted claims and where appropriate extend the list to permit claims for certain optional ingredients for which conditions of use are specified in the Directive. In addition, it is appropriate to amend the Directive to permit statements on infant formula when ethical or religious considerations need to be taken into account.

Consideration should be given as to whether claims for follow-on formulae should be the subject of specific provisions.

[4] Chapter XI of the Report of the Scientific Committee on Food on the revision of Essential Requirements of Infant Formulae and Follow-on Formulae.

[5] Department of Health 1996. Report of the Working Group on the Nutritional Assessment of Infant Formulas of the Committee on Medical Aspects of Food and Nutrition Policy. Guidelines in the Nutritional Assessment of Infant Formulas. Report in Health and Social Subjects 47. London, The Stationery Office.

4. Essential composition of infant formulae and follow-on formulae

The Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae was adopted on 4 April 2003. Therefore the essential composition specified in Annexes I and II of Directive 91/321/EEC should be reviewed. The changes that would lead from the SCF report with respect to legislative requirements were initially considered by Member States and the Commission at a meeting on 13 October 2003. Below are details of the most important changes.

Energy

Based on the review of data that indicated that total daily energy expenditure and the energy content of breast milk are lower than previously assumed the SCF recommended that the maximum energy content of both infant formulae and follow-on formulae should be reduced to 295 kJ (70 kcal) per 100 ml.

Protein

Following an extensive review of the protein requirements of infants, the conversion factor for the calculation of protein content, and the amino acid profile of breast milk the SCF proposed several changes to composition of infant formulae and follow-on formulae with respect to protein.

The SCF proposed that the **crude protein content** of all formulae should be calculated by multiplying the nitrogen content by 6.25. In addition the SCF proposed that the non-protein nitrogen in formulae based on intact proteins should not be more than 15% of the total nitrogen.

The SCF did not propose any changes with respect to the **level of protein** in infant formulae but it considered that there was no need for a higher protein level in follow-on formulae and that the level of protein should be the same as infant formulae, including those for formula manufactured from protein hydrolysates. However, it is recognised that moderately higher levels of protein for follow-on formulae would not pose any risk to health of infants in the EU while they may be desirable for products intended for export to some third countries.

With regard to **protein quality** the SCF recommended that the protein source should be evaluated through appropriate studies to confirm that the formula satisfies the protein requirements of infants during the first months of life and in the case of formula manufactured from protein hydrolysates that they do have reduced allergenic potential. The SCF proposed that the requirements regarding protein efficiency ratio and net protein utilization were not necessary.

The protein quality is based on the indispensable and conditionally indispensable amino acid content of a formula matching the amino acid pattern of a reference protein on an energy basis. The SCF recommended that all formula should be compared to breast milk as the reference protein, rather than breast milk or casein, and recommended that all formula match 100% the amino acid profile of breast milk. With the chemical index of follow-on formulae being at least 80% of that of breast milk. In addition the SCF recommended that the indispensable and conditionally

indispensable amino acid profile of breast milk should be revised to reflect more recent data on breast milk composition.

Fat

The SCF proposed that the minimum **fat content** of infant formulae should remain unchanged at 4.4 g/100 kcal and the maximum level should be reduced to 6.0 g/100 mg and that the same requirements should apply to follow-on formulae.

The SCF proposed that instead of the maximum level of each of the **saturated fatty acids** lauric acid and myristic acids being not more than 15% of the total fats that the maximum level of the two fatty acids together should not be greater than 20% of total fatty acids.

With respect to **polyunsaturated fatty acids** the SCF propose that the minimum content of **linoleic acid** in infant formulae should be increased from 300 mg/100 kcal to 500 mg/100 kcal and that the maximum level should remain unchanged at 1200 mg/100 kcal. In addition they propose that a requirement for a minimum level of linoleic acid should apply to all follow-on formulae not just those containing vegetable oil and they proposed that the minimum and maximum levels should be the same as those for infant formula.

The SCF proposed that the minimum content of **α-linolenic acid** should depend on whether the formula contains long chain polyunsaturated fatty acids (LCPs). The SCF recommended that formula with added LCPs should contain a minimum of 50 mg α-linolenic acid/100 kcal whilst formula without added LCPs should contain a minimum of 100 mg/100 kcal. In addition the permitted ratio of linoleic acid to α-linolenic acid depends on whether or not LCPs are added.

The SCF did not propose any changes to the amounts of **LCPs** that may be added to infant formulae but they did propose the additional requirement that the decosahexaenoic acid content should not be greater than that of n-6 LCP. The SCF also proposed that the recommendations regarding added LCPs should also apply when these are added to follow-on formulae.

The SCF proposed that the maximum level of ***trans* fatty acids** in infant formulae and follow-on formulae should be reduced from 4% of total fatty acids to 3%.

Phospholipids

The SCF considered that until the safety of infant formulae containing phospholipids at substantially higher levels than those present in breast milk had been demonstrated the maximum level of phospholipids in infant formulae and follow-on formulae should be 1 g/litre.

Inositol

The SCF proposed that there should be a minimum level of myoinositol in infant formulae of 4 mg/100 kcal with a maximum level of 40 mg/100 kcal.

Carbohydrates

The SCF proposed that in addition to the sources of carbohydrates already permitted for use in infant formulae that **glucose** may be added to help camouflage the taste of formulae based on protein hydrolysates. In addition the use of **sucrose** should be restricted to the same purpose. The SCF proposed that the added amount of glucose or sucrose should not be more than 20% of the total carbohydrate content.

In the case of glucose added to follow-on formulae the SCF proposed that its use should be restricted to formulae based on protein hydrolysates and that maximum level should be 2 g/100 kcal.

Fructo-oligoasaccharides (FOS) and galacto-oligosaccharides (GOS)

The SCF had considered in 2001 the addition of fructo-oligoasaccharides (FOS) and galacto-oligosaccharides (GOS) to infant formula and follow-on formulae. At that time they had no major concerns on the inclusion of up to 0.8 g/100 ml of a combination of 90% oligogalactosyl-lactose and 10% high molecular weight oligofructosyl-saccharose. This conclusion was restated in the 2003 SCF report on the revision of the essential composition of infant formulae and follow-on formulae.

Vitamins and minerals

The SCF based its consideration of the requirements of vitamins and mineral elements on the recommended levels to prevent deficiency in infants over 6 months of age. The SCF made recommendations for the maximum levels based either on evidence of the safe maximum intakes or, if such evidence did not exist, a maximum level was proposed for guidance purposes. The SCF proposed that maximum levels on manganese and fluoride should be introduced. In addition the SCF recommended that with the exception of vitamin D and iron the minimum and maximum levels recommended for infant formulae should also apply to follow-on formulae.

5. Reference values for nutrition labelling

In March 2003 the SCF opinion on the revision of reference values for nutrition labelling[6] proposed labelling reference values for vitamins E and K, pantothenic acid, biotin, phosphorus, potassium, sodium, chloride, magnesium, manganese, chromium, molybdenum and fluoride. In addition new labelling reference values for certain vitamins and mineral elements were proposed taking into account recently published national recommended daily intakes. Therefore changes to the labelling reference values are proposed in accordance with the SCF opinion. The proposed labelling reference values include figures for chromium and molybdenum however the SCF Report on the revision of the essential composition of infant formulae and follow-on formulae noted that for both these substances there was no biological or nutritional data to define a minimum or maximum content in infant formulae and follow-on formulae. Therefore, the inclusion of labelling reference values for these elements may need to be considered.

The experts of Member States are asked to consider the amendments proposed in the attached preliminary draft in preparation for the meeting scheduled for 7 May 2004.

[6] Opinion of the Scientific Committee on Food on the revision of reference values for nutrition labelling (expressed on 5 March 2003).