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**INTRODUCTORY PAPER TO THE
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 formulae¹. The document is based on a draft consolidated text of Commission Directive 91/321/EEC that takes 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 draft recast Directive 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. Changes to the existing text are shown by double strike through for deletions whilst new text is between the following special markers ☒ ☒.

Prior to drafting the attached version of the working document (SANCO D4/HL/mm/D440180.Rev2.) there have been discussions with expert representatives of Member States on the revision of Directive 91/321/EEC. The proposed amendments take into account these discussions with Member States, the latest scientific advice of the Scientific Committee on Food on the essential composition of infant formulae and follow-on formulae² and discussions at the international level within the Codex Alimentarius forum. The Commission services will continue to follow international developments which might need to be taken into consideration in the future development of a legislative proposal.

The Commission services are now seeking the views of representative European organisations who have an interest in the developments relating to the essential composition and labelling 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 provisions and maximum levels of pesticide residues.

The main amendments being proposed are:

1. Definitions of “infant formulae” and “follow-on formulae”

The 2003 Scientific Committee on Food report indicates that two of the general principles adopted by the Committee were that:

- infant formula must be safe and meet the normal nutritional requirements of infants born at term when used as the sole source of nutrition during the first months of life; and

¹ OJ L 175, 4.7.1991, p.35. 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)

- follow-on formula must be safe and meet the normal nutritional requirements of generally healthy infants and young children, when used as the principal liquid element in a progressively diversified diet after the timely introduction of complementary foods.

The World Health Organisation (WHO) Expert Consultation on the optimal duration of exclusive breastfeeding³ noted that available good scientific evidence on the optimal duration of exclusive breastfeeding is limited. After consideration of over 3000 references the review was based on two small controlled trials and 17 observational studies that varied in both quality and geographical provenance. The WHO Expert Consultation concluded that:

“...exclusive breastfeeding to six months confers several benefits on the infant and the mother. However, exclusive breastfeeding to six months can lead to iron deficiency in susceptible infants. In addition, the available data are insufficient to exclude several other potential risks associated with exclusive breastfeeding for six months, including growth faltering and other micronutrient deficiencies, in some infants”.

Based on its conclusions the Expert Consultation recommended exclusive breastfeeding for six months, with the introduction of complementary foods and continued breastfeeding thereafter, noting that this recommendation applies to populations. It was recognised that some mothers will be unable to, or choose not to, follow this recommendation and recommended that these mothers should be supported to optimise their infant’s nutrition. Therefore, it is important that the needs of individual infants are taken into consideration when advising on the timing of the introduction of complementary foods.

In the international context there have been extensive discussions in the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) on the revision of the Codex Standard for infant formulae. One of the main issues of discussion has been the definition of infant formulae. It is appropriate to take into account the latest definition of “infant formula” in the proposed Draft Revised Codex Standard for Infant Formulae⁴ when revising the Community legislation.

Infant formulae and follow-on formulae can be defined by their intended purpose so it is not necessary for the definitions to make reference to specific age ranges of infants. In addition, the product definitions in the Directive are intended solely for the differentiation of the products in legislative terms and will not be used by the general population. Also, it should be noted that the public health recommendation relates to the period of exclusive breastfeeding and not to feeding with infant formulae, therefore, the definition of infant formulae need not be linked to a specific time period.

The definition of “follow-on formulae” has been revised to ensure that there is consistency between the definitions of both infant formulae and follow-on formulae.

³ Expert Consultation on the optimal duration of exclusive breastfeeding conclusions and recommendations (Geneva, 28 to 30 March 2001), Annex to World health Assembly document A54/INF.DOC./4.

⁴ Report of the 26th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses, ALINORM 05-28 26 Appendix IV(A).

Information on the appropriate use of the products is given through the advice of the health care professionals and the labelling of the products (see point 3 below).

2. Inclusion of new ingredients

Under the existing Directive, following appropriate research and development, manufacturers may introduce new ingredients into infant formula and follow-on formula for the purpose of improving the products. Manufacturers can be asked by the Competent Authorities, if necessary, to demonstrate the safety and suitability of the ingredients for the particular nutritional requirements of infants.

During discussions with Member States four possible approaches to the inclusion of new ingredients in infant formulae were outlined:

1. The existing system – on request manufacturers make available the scientific dossier substantiating the suitability and safety of the new ingredient.
2. A notification system – Competent Authorities are notified by the manufacturer when an infant formula containing a new ingredient is placed on the market.
3. A temporary authorisation – the Commission obtains delegated power to authorise the use of a new ingredient following evaluation by European Food Safety Authority (EFSA) but prior to amendment of the specific Directive through the legislative procedure.
4. Approval of new ingredient through the Regulatory Committee procedure following evaluation by EFSA.

The Commission believes that the existing system has operated for the last 10 years without causing particular problems. There has been only one occasion when a new ingredient in infant formula has been referred to the Standing Committee. On this basis it would appear to be over restrictive to move from the current system to a system of prior approval. However, as in other areas, a system of notification of the placing on the market of ingredients that had not previously been included in infant formulae would make it easier for the Competent Authorities in Member States to monitor the market. Therefore, it would be appropriate that in order to efficiently monitor such product developments in infant formulae Member States should be notified when an infant formula containing a new ingredient is placed on the market. So that all Member States and the Commission are aware of the developments a system to exchange information on such notifications could be established.

To clarify the type of data that manufacturers may need to make available on request the working document indicates that the suitability of ingredients for the particular nutritional use of infants should have been established by generally accepted scientific data and elaborates certain factors that manufacturers should take into account when considering the inclusion of new ingredients in infant formulae and follow-on formulae.

3. Labelling provisions and claims

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

Article 8 (1) of the working document includes the product names in all the official Community languages. Certain product names will need to be revised but this will be done at a later stage in consultation with Member State experts.

It is proposed that the provisions on the labelling of follow-on formulae should be revised to take into account the WHO public health recommendation that exclusive breastfeeding should continue for the first six months of life. However, as already indicated above, the WHO Expert Consultation on the optimal duration of exclusive breastfeeding noted that the nutritional needs of individual infants should be taken into account.

The above WHO recommendation relates specifically to breastfeeding and some paediatric societies have argued that this recommendation might not apply to infants who are not breast fed. In such cases complementary food could be introduced at an earlier age. Therefore, it is important that the decision on how to feed the individual infant, including the age of introduction of appropriate complementary feeding, should take into account the advice of a health care professional.

The Commission believes that the labelling of follow-on formulae, which may be used as part of a mixed diet, should be in line with the promotion of exclusive breastfeeding for 6 months as a general measure. The working document indicates that the labelling of follow-on formulae should include a statement to the effect that the product is intended for infants over the age of 6 months. However, to provide some flexibility on the exact age of introduction, taking into account individual infant's needs and dependent on professional advice the working document proposes to include the following additional statement on the labelling which is based on the wording included in the Draft Revised Codex Standard for processed cereal based foods for infants and young children⁵ (section 8.6):

“... the decision to begin complementary feeding, including any exception to six months of age, should be made only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, based on the individual infant's specific growth and development needs.”

The additional labelling statement will ensure that advice of health professionals and the labelling do not result in contradictory and confusing messages for the mother or those responsible for the feeding of infants.

Directive 91/321/EC restricts claims concerning the special composition of an 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 clarify in the Directive that statements on infant formula regarding religious or other considerations that affect dietary choices are permitted.

⁵ Report of the 26th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses, ALINORM 05:28 26 Appendix V.

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

The Scientific Committee on Food in their report on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae proposed a number of changes to the essential composition of infant formula and follow-on formula. These proposals were taken into consideration when preparing the initial working document. Comments have been received from Member States and some stakeholders on some of the SCF proposals.

In addition, the SCF conclusions have been considered within the international context during discussions on the amendment of the Codex Standard for infant formula. It has proved difficult to reach consensus so at the last meeting of the CCNFSDU it was agreed that the recommendations for the essential composition that are under consideration should be reviewed by a small group of internationally representative scientific experts in infant feeding who would provide advice by the end June 2005. This advice will be considered by the CCNFSDU working group on the essential composition of infant formula who will report back to the CCNFSDU in November 2005.

It is anticipated that the future developments at the international level will need to be taken into consideration. It is for these reasons that some of the values in the Annex are in square brackets.

5. Reference values for nutrition labelling

In March 2003 the SCF opinion on the revision of reference values for nutrition labelling⁶ 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.

3. CONSULTATION OF INTERESTED PARTIES

The Commission services are now seeking the views of representative European organisation on the current working document. Comments of interested parties may be made available to the public. Please indicate if you do not want your comments, or certain parts of your comments to be made available.

The deadline for comments is: **4 March 2005**
(However, it will be possible to submit comments until 31st March).

Written comments should be sent to:
sanco.dietetic@cec.eu.int

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

or

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