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Health & Consumer Protection Directorate-General
Food Law, nutrition and labelling
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**FINNISH OPINION ON ISSUES RELATED TO THE RECAST DIRECTIVE OF INFANT
FORMULAE AND FOLLOW-ON FORMULAE
(Recast version Sanco D4/HL/mm/D440180 Rev. 3 July 2005)**

To begin with the Ministry of Trade and Industry wants to express its apologies for the late delivery of comments requested by the Commission on September 12th 2005 at the meeting of the Dietetic Foods Expert Group (Infant Formulae and Follow on Formulae). The regrettable delay is due to personnel changes.

We would like to express our opinion concerning the following issues:

Article 4. Evaluation of new ingredients

As infants are among the most vulnerable consumer group, the protection of infant health and well-being should be the highest priority. The suitability and the safety of the new ingredients used in the production of both Infant and Follow-on Formulae, and of Infant or Follow-on Formulae with new or markedly modified composition must be carefully evaluated before they can safely be launched on the market.

Finland is of the firm opinion that a centralized assessment by EFSA covering both the safety and suitability would be the best way forward. The model proposed in the Article 4 in the recast version 3 July 2005, i.e. national evaluation and additional Member State network, might lead to overlapping work in the Member States but also result in different outcomes and therefore disturbances in the internal market. The Novel Food regulation is a practical example of problems, which might come along with a decentralized evaluation system.

The framework directive 89/398/EC concerning foodstuffs intended for particular nutritional uses is intended to ensure the effective functioning of the internal market whilst providing a high level of consumer protection. National systems e.g. safety evaluation can be problematic for the free movement of goods. The purpose of the directive 89/398/EC might not be reached with the proposed model.

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Assisting the Community in scientific issues is one of EFSA's main objectives. The use of EFSA's expertise in evaluating the safety and suitability of new ingredients in Infant and Follow-on Formulae is in line with EFSA's objectives and an effective and desirable way to ensure coherent assessment throughout the Community.

Article 9. Marketing

The WHO recommends exclusive breastfeeding of infants up to 6 months and partial breastfeeding up to two years old along complementary feeding in the population level. The corresponding Finnish recommendations, issued by The Ministry of Social Affairs and Health, are the following: exclusive BF 6 months and partial BF up to one year of age or even longer if mother wants. If breastfeeding is not enough or for one reason or another possible Infant Formulae are recommended up to one year of age. Infant Formula therefore complements or substitutes the breast milk. The purpose of Follow-on Formulae is the same as Infant Formulae: to complement or substitute breast milk. Therefore the marketing rules should be the same for both Infant Formulae and Follow-on Formulae.

As Member States are committed to the promotion of breastfeeding such sale or marketing practices should not be allowed which could reduce breastfeeding rates. In many Member States the Infant Formulae are indirectly marketed through the active marketing of Follow-on Formulae - consumers cannot necessarily discern IF from FOF. This has proven to be a real problem for food control authorities. Infant Formulae and Follow-on Formulae are often presented as product families with similar packages and names (e.g. the same brand name but numbers 1, 2 and 3 differentiate IF, FOF and toddlers milk).

Our conclusion is that the free marketing of Follow-on Formulae promotes the marketing of Infant Formulae as well. We fear that the provision in Article 8(9) "Infant formulae and follow-on formulae shall be labeled in such way as to avoid any risk of confusion between infant formulae and follow-on formulae" leaves too much room for interpretation and is not strong enough for enforcement purposes. Therefore we suggest that the marketing rules should be expanded to cover the Follow-on Formulae too.

We want to express our wish that the issues brought out above could be discussed at the next meeting of the working group on January 20th or alternatively at some other relevant meeting, in any case before the draft proposal for a directive is presented to the Standing Committee for approval. We would also like to receive information on the Commission plans to proceed with this directive.

With kind regards

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