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31st March 2005

Dr Basil Mathioudakis
Directorate D
Food Law and Biotechnology
The European Commission
DG SANCO, 200 rue de la loi
Brussels, B-1049, Belgium

Dear Basil,

I am offering some additional comments on this Directive. These are representative of the opinion of the Standing Committee on Nutrition of the Royal College of Paediatrics and Child Health, and reflect points that you may already have received from the Baby Feeding Law Group, of which the College is a Member.

The Articles relating to the promotion, claims relating to these products, and related dissemination of information concerning infant feeding are, in as much as they reflect the International Code, welcome.

Representations about the compositional criteria have already been made through other channels. No further comments on this are offered at this juncture, but the fact that other agencies have issues concerning these is worth comment. The evidence base for the current composition of breast milk substitutes is variable and certainly not necessarily functionally based, other than on short term (usually less than 6 months) anthropometric studies which may be accompanied by some haematological and biochemical screening. This continues to apply to new modifications.

The Committee feels that functionally relevant outcomes, ideally related to reference data derived from breast fed infants and their outcomes, would provide better yardsticks for the composition of breast milk substitutes, rather than comparisons with the composition of breast milk. It was also pointed out that even if breast milk composition was accepted as a baseline, the quality and variability of the compositional data on human breast milk left its use, as a criterion for the composition of formulas, open to selective use of data for new modifications.

The Committee considered that the evidence base for the composition and compositional changes of infant formulas and follow on formulas should be independently appraised and it endorsed the criteria for assessing innovations in Infant Formulae have been proposed by a COMA Working Group (Report on Health and Social Subjects 47: Guidelines on the Nutritional Assessment of Infant Formulas, and these have since been re-promulgated by an ESPGHAN Committee on Nutrition Commentary (Aggett PJ, Agostoni C, Goulet O, Hernell O, Koletzko B, Lafeber HL, Michaelsen KF, Rigo J, Weaver LT. 2001 The Nutritional and Safety Assessment of Breast Milk Substitutes
and other dietary products for infants: A commentary by the ESPGHAN Committee on Nutrition. Journal of Paediatric Gastroenterology and Nutrition. 32: 256-8). These guidelines offer an objective and transparent means of assessing amendment to Infant Formulas, that are highly relevant to improving the generalisability of this directive.

In this regard the Committee felt that the introduction of new Breast Milk Substitutes should be subject to regulatory review. There was concern that in the absence of such a process, opportunities remain for the introduction of new formulas, and this needs to be controlled by some competent

process. Furthermore this process should be independent of whether or not a claim was being made, and irrespective of any foreseeable process that may be introduced to review substantiating evidence for health claims.

The Committee supports measures to disallow functional claims concerning Breast Milk Substitutes. It was concerned about the use of nutrition and health claims
on a formula, as will be permitted by this Directive if such are within the terms of Annex IV.

It is appreciated that the definitions of claims are under review as are the bases on which these may be made. It was felt that a claim relating to allergenicity or safety may merit separate categorisation and consideration; legislation to allow such claims should be distinguished from any regulation relating to claims of purported functional benefits which should be considered separately.

It could be argued on ethical grounds that if there is independently verifiable scientific evidence that an ingredient benefits infant health, then it should be a legally required ingredient in all formulas. Parents should not have to work out what for themselves what a claim means by reading between the lines of labels. Most carers would find it challenging to differentiate between and prioritise claims on benefits. In such an important aspect of public health, it would seem impolitic and arguably negligent to leave such decisions to the carers of infants.

This raises the ethical issue relating to the non-uniform introduction and delivery, on the basis of commercial advantage and considerations, of beneficial improvements to breast milk substitutes. If these improvements have been shown to be similar to the observed outcomes in a reference group of breast fed babies, then it can be argued that such benefits should not be denied to other formula fed babies. Against the basic tenet that breast feeding is the preferred method of feeding, then to deny any formula fed infant a beneficial formula improvement would be contrary to elemental public health policy. This implies that the Commission currently would be willing to allow a significant cohort of its infant population, that is those who are not breast fed, to have varying grades of "second best".

My very best wishes.

Yours sincerely

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