Minutes' Statement of the Scientific Panel on Dietetic Products, Nutrition and Allergies replying to applicant's comment on the Panel's Opinion relating to the evaluation of goats' milk protein as a protein source for infant formulae and follow-on formulae

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(expressed on 6 December 2005 at its 12th plenary meeting, corresponding to item 8.1 of the agenda)

On 19 February 2004 the Panel adopted an Opinion on the evaluation of goats' milk protein as a protein source for infant formulae and follow-on formulae[1]. On 4 July 2005 the applicant submitted to the European Commission its comments and additional information in response to the Opinion. Following that, EFSA was asked by the European Commission to assess the submission and to consider whether there is a need to update the aforementioned Opinion of the Panel.

In its Opinion of 2004, the Panel concluded that the data submitted were insufficient to establish the suitability of goats' milk protein as a protein source for infant formula and that unmodified goats' milk protein is not suitable to be used as a protein source in infant formula.

The comments provided by the applicant refer, among other issues, to the following two main issues: 1) Amino acid pattern of the goats' milk protein-based formula; and 2) the clinical study of a goats' milk protein-based formula.

Comments on the amino acid pattern of the goats' milk protein-based formula

The conclusion of the Panel concerning this was that unmodified goats' milk protein, like unmodified cows' milk protein, is unsuitable as a protein source for infant formula within the permitted range (existing legislation) of protein concentration in infant formula. The Panel based its conclusion on the amino acid content levels of goats' milk protein compiled from the literature and submitted by the applicant (Darragh, 2003). This conclusion remains valid.

The Panel also concluded in 2004 that a formula based on unmodified goats' milk protein tested in the growth study does not provide per energy value the required amounts of both tryptophan and cysteine. This was based on the amino acid data provided in the original submission by the applicant. The applicant has now provided additional data on the average amino acid content of goats' milk formula over four seasons (1999 to 2003). Part of these data was already included in the original submission of 2003. According to this amino acid analysis, the goats' milk formula fulfils the requirements of Directive 91/321/EEC to provide per energy value at least the same amounts of indispensable and conditionally indispensable amino acids as the reference protein human milk according to Annex V of the Directive.

[1] Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission relating to the evaluation of goats' milk protein as a protein source for infant formulae and follow-on formulae. The EFSA Journal 30, 1-15. http://www.efsa.eu.int/science/nda/nda_opinions/catindex_en.html

Comments on the clinical study of a goats' milk protein-based formula

The Panel concluded in 2004 that the clinical study of a goats' milk protein-based formula submitted is insufficient to establish the nutritional adequacy and nutritional safety of goats' milk protein as a protein source in infant formula due to methodological flaws including insufficient sample size, restriction to anthropometric parameters only, absence of a breast-fed reference group and non-adherence to the study protocol.

The applicant has now provided additional growth data for a group of 34 exclusively breast-fed infants, which indicates, according to the applicant, that growth of infants fed goats' milk formula did not differ significantly from growth of exclusively breast-fed infants in New Zealand and from growth of infants receiving cows' milk protein-based infant formula. In its Opinion, the Panel already stated that body weights of the study infants from both formula groups were comparable to New Zealand reference growth data. However, the applicant acknowledges that the protocol was not fully observed with regard to exclusively formula feeding and that from 56 days an increasing variety of solid foods were introduced. While this may be representative of feeding patterns of infants in the region, it invalidates the comparison of the growth data of the non-exclusively formula-fed infants with that of exclusively breast-fed infants.

In its Opinion, the Panel concluded that the sample size was not sufficient to detect a weight increment difference of 0.5 of the actual measured standard deviation of daily weight increase and that a sample size of 63 infants per group would have been required. According to the applicant, a sample size of 40 infants per group would have been sufficient if the repeated measures analysis method was applied. However, the Panel considers that, even after taking into account the repeated measures analysis of the study, the actual sample size (enrolled 36 per study group with 30 and 32 infants finishing the study in the goats' and cows' milk formula group, respectively) was insufficient to detect statistical significant differences in growth between the two study groups.

Thus, the previous conclusion that the clinical study of a goats' milk protein-based formula submitted is insufficient to establish the nutritional adequacy and nutritional safety of goats' milk protein as a protein source in infant formula due to methodological flaws remains valid.

Conclusion

According to the amino acid analysis provided now, the goats' milk formula fulfils the requirements of Directive 91/321/EEC with respect to the amino acid pattern.

In agreement with the previous conclusion of the Panel the clinical study of a goats' milk protein-based formula submitted is insufficient due to methodological flaws. Therefore, on the basis of the data submitted, the previous overall conclusion of the Panel that there are insufficient data to establish the suitability of goats' milk protein as a protein source in infant formula remains valid.

Documentation provided to EFSA

Information submitted by Vitacare Ltd. to the European Commission in response to the Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on the evaluation of goats' milk protein as a protein source for infant formulae and follow-on formulae, July 2005.

Darragh A (2003). A review of literature on the protein, non-protein nitrogen, and amino acid composition of goats' milk, human milk and cows' milk. Institute of Food, Nutrition and Human Health. New Zealand. Unpublished report, August 2003.