



European
Dietetic
Food Industry
Association

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11/352 Annex 1

TO:

Head of Unit E4
General Food Law, Nutrition and Labelling
Directorate General for Health and Consumers
B-1049 Brussels BELGIUM

Brussels, 25 August 2011

IDACE comments to

EFSA Scientific Opinion on the substantiation of a health claim related to beta-palmitate and increased calcium absorption pursuant to Article 14 of Regulation (EC) No 1924/2006, of 28 July 2011

Dear Mr Mathioudakis,

By means of this document, IDACE would like to provide its comments on the EFSA opinion issued following question n. EFSA-Q-2008-172. This Opinion was adopted on June 30th 2011 and published on July 28th 2011.

This opinion relates to the application by IDACE for the authorization of the health claim "beta palmitate enrichment contributes to increase calcium absorption". The target population proposed by IDACE is infants from birth to 12 months of age, including healthy infants consuming follow-on formula, preterm infants and infants needing foods for particular nutritional uses including foods for special medical purposes.

The Panel has concluded that, although Beta-palmitate is sufficiently characterized and an increase in calcium absorption might be considered as a beneficial physiological effect, the evidence provided is insufficient to establish a cause and effect relationship between the consumption of beta-palmitate and an increase in calcium absorption.

IDACE appreciates EFSA opinion regarding the characterization of Beta-Pamitate and the benefits of calcium absorption.

Nevertheless IDACE regrets that EFSA did not adopt a holistic approach for the assessment of the cause and effect relationship and as such did not base its conclusion on the totality of evidence submitted in the application..

Detailed IDACE comments are listed below as follows:

1. IDACE acknowledges the comments EFSA gave on the different clinical trials. Nevertheless IDACE would like to emphasize that if the whole body of evidence had been evaluated it would have been shown that many clinical trials provided within the application proved an effect, notably the decrease in faecal calcium excretion through increased absorption (Lucas 1997, Carnielli 1995, Carnielli 1996, Kennedy 1999, Lopez 2001).
2. IDACE believes that Bone Mineral Density and/or Bone Mineral Content could be recognized as an indicator of calcium absorption.

Furthermore, publications have shown that, as almost all calcium is used for bone mineralization, Bone Mineral Density can be used as a long term marker of Ca bioavailability (Fairweather-Tait SJ et al 2002, Heaney RP 2006, Schuette SA et al 1988).

Given the above and considering the totality of the evidence and the clear understanding of the working mechanism, the evidence provided by the Kennedy study should also be considered in the overall evaluation of the application.

3. The study of Carnielli et al. (1995), addressed in the IDACE application, showed statistically significant effects on faecal calcium excretion between a high beta-palmitic group and a control group while the calcium intake was similar. Both parameters were used to calculate the percentage of absorbed calcium.

As the faecal calcium excretion was significantly lower in the beta-palmitate group, a concordant effect of beta-palmitate on calcium absorption was expected but was not statistically demonstrated.

There was a statistically significant increase observed in urinary calcium excretion, which EFSA acknowledges as evidence for a physiologically significant increase in calcium absorption. **It should be recognized that this study gives relevant insight into the working mechanism and the effect on calcium absorption of beta-palmitate.**

4. The study of Lucas et al. (1997) included, according to EFSA, an inadequate control group. Beta-palmitate level in the formula of the control group was lower versus the high beta-palmitate group. This control formula was chosen by the investigators as composition reflects the strategy manufacturers might use to decrease palmitic oil in their formula. A significant increase in calcium absorption was demonstrated in the study comparing high beta-palmitate formulas with low beta-palmitate formulas. **Although, the control may not have been chosen well, it would be fair to recognize that this study also gives relevant insight in the working mechanism of beta-palmitate and the effects on increased calcium absorption.**

IDACE CONCLUSION:

- IDACE believes that EFSA did not base its conclusion on the totality of evidence submitted including both direct evidence and indirect indicators.
- IDACE believes that measuring Bone Mineral Density, Bone Mineral Content and decreased calcium faecal excretion are indicators for improved calcium absorption.
- IDACE requests EFSA to reconsider its overall conclusion that the scientific evidence provided is insufficient to establish a cause and effect relationship between the consumption of beta-palmitate and the increase of calcium.

Additional references not included in the IDACE dossier:

Fairweather-Tait SJ, Teucher B. Calcium bioavailability in relation to bone health. Int J Vitam Nutr Res 2002;72(1):13-8

Heaney RP. Absorbability and utility of calcium in mineral waters. Am J Clin Nutr 2006;84:371-4

Schuette SA, Knowles JB. Intestinal absorption of Ca(H₂PO₄) and Ca citrate compared by two methods. Am J Clin Nutr 1988;47(5):884-8

