European Food Safety Authority; Response to comments on the Scientific Opinion of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) on the scientific substantiation of a health claim related to beta-palmitate and increased calcium absorption pursuant to Article 14 of Regulation (EC) No 1924/2006

EFSA Publication; Tetens, Inge

Publication date:
2011

Document Version
Publisher's PDF, also known as Version of record

European Food Safety Authority

Supporting Publications 2011:209

TECHNICAL REPORT OF EFSA

Response to comments on the Scientific Opinion of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) on the scientific substantiation of a health claim related to beta-palmitate and increased calcium absorption pursuant to Article 14 of Regulation (EC) No 1924/2006[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, EFSA was asked to review the scientific comments received on the Scientific Opinion of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) on the scientific substantiation of a health claim related to beta-palmitate and increased calcium absorption pursuant to Article 14 of Regulation (EC) No 1924/2006.

Comments submitted to EFSA via the European Commission Services originated from the applicant (IDACE).

EFSA has reviewed the comments and shared them with the chair of the NDA Panel, Prof. Albert Flynn, and the chair of the NDA Working Group on Claims, Prof. Sean (J.J.) Strain.

In its opinion adopted on 30 June 2011, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) concluded that the evidence provided was insufficient to establish a cause and effect relationship between the consumption of beta-palmitate and an increase in calcium absorption. The comments received do not change the conclusions of the NDA Panel.

KEY WORDS

Beta-palmitate, calcium absorption, infants, health claims, comments.

[1] On request from the European Commission, Question No EFSA-Q-2011-01081, issued on 30 November 2011.

[2] Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: EFSA wishes to thank Albert Flynn, Sean Strain and EFSA staff member Juliane Kleiner for the support provided to this technical report.

Suggested citation: European Food Safety Authority; Response to comments on the Scientific Opinion of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) on the scientific substantiation of a health claim related to beta-palmitate and increased calcium absorption pursuant to Article 14 of Regulation (EC) No 1924/2006. Supporting Publications 2011:209. [7 pp.]. Available online: www.efsa.europa.eu

TABLE OF CONTENTS

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Article 16(6) of Regulation (EC) No 1924/2006 on nutrition and health claims states that: "The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public. The applicant or members of the public may make comments to the Commission within 30 days from such publication."

The Regulation does not foresee a consultation on the EFSA opinion. It does, however, allow for the applicant or members of the public to make comments to the Commission relating to the EFSA opinion. The Commission's services have established a practice for handling the comments provided by applicants and members of the public in order to allow their full consideration by the regulators in the health claims' authorisation process. More particularly, whenever the comments relate to the scientific assessment, they are transmitted to EFSA for consideration. The Commission and the Member States await the EFSA response to the comments before proceeding with the final discussion and the vote in the Standing Committee on the Food Chain and Animal Health on the draft measure authorising or rejecting the health claims for which comments were made.

The procedure briefly outlined above is in line with the procedure foreseen in Article 31 of Regulation (EC) No 178/2002, whereby the Authority may be requested by the Commission to provide scientific or technical assistance in any field within its mission, and when the matter does not require scientific evaluation by a Scientific Committee or a Scientific Panel.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Commission requests EFSA, within the framework of scientific and technical assistance to the Commission foreseen in Article 31 of Regulation (EC) No 178/2002, to evaluate the comments of a scientific nature received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006 and to provide the Commission with a response.

Relevant actions performed under this mandate will be carried out in good cooperation between the Commission and EFSA in accordance with the procedure set out in the Annex to the Mandate (to be found in the EFSA Register of Questions under the mandate number M-2011-0063).

CONSIDERATION

1. Introduction

On 30 June 2011, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) adopted a scientific opinion on the scientific substantiation of a health claim related to beta-palmitate and increased calcium absorption pursuant to Article 14 of Regulation (EC) No 1924/2006[4] following an application for authorisation from IDACE submitted via the Competent Authority of France (Claims serial number: 0092_FR, EFSA-Q-2008-172).

In accordance with Article 16 of Regulation (EC) 1924/2006, the applicants or members of the public may make comments to the European Commission on opinions published by the Authority pursuant to Articles 16 and 18 of the Regulation. On 14 September 2011, the European Commission requested EFSA to respond to the scientific comments received during the commenting period specified in Article 16 of the Regulation. Comments submitted to EFSA via the European Commission Services originated from the applicant (IDACE).

EFSA has reviewed the comments and shared them with the chair of the NDA Panel, Prof. Albert Flynn, and the chair of the NDA Working Group on Claims, Prof. Sean (J.J.) Strain.

2. Comments related to the use of faecal calcium excretion as a proxy for calcium absorption

The claimed effect identified in the application and evaluated by the Panel, and which might be a beneficial physiological effect for the target population for which the claim is intended (i.e. infants from birth to 12 months of age), was an increase in calcium absorption.

The comments received relate to the use of faecal calcium excretion as a proxy for calcium absorption in five of the studies provided by the applicant (Carnielli et al., 1995, 1996; Kennedy et al., 1999; Lopez-Lopez et al., 2001; Lucas et al., 1997).

Of these, three (Carnielli et al., 1995, 1996; Lucas et al., 1997) were balance studies which addressed the effects of beta-palmitate on calcium absorption. Two of them (Carnielli et al., 1995, 1996) also assessed faecal calcium excretion, whereas one (Lucas et al., 1997) investigated faecal excretion of fatty acid soaps relative to fat intake. The fourth study (Lopez-Lopez et al., 2001) investigated the effect of beta-palmitate on calcium content in faeces but did not address calcium absorption and did not report on calcium intake. The study by Kennedy et al. (1999) did not address calcium absorption or faecal calcium excretion.

One small study (nine subjects per group, Carnielli et al., 1996) showed a statistically significant effect of beta-palmitate on calcium absorption which was associated with a statistically significant decrease in faecal fat excretion and faecal calcium excretion. However, a significant effect of beta-palmitate on calcium absorption was not observed in two studies (Carnielli et al., 1995; Lucas et al., 1997) compared to the control formula, despite a significant decrease in faecal excretion of calcium (Carnielli et al., 1995) or of fat (Lucas et al., 1997). The Panel considered that while there was evidence to support the biological plausibility of a proposed mechanism by which beta-palmitate could exert the claimed effect, two out of three studies did not find an effect of beta palmitate on calcium absorption.

The comments received did not provide further evidence which would warrant a re-evaluation of these studies.

[4] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

3. Comments related to the use of bone mineral density (BMD) and bone mineral content (BMC) in infants as a proxy for calcium absorption

The comments received also related to the use of bone mineral density (BMD) and bone mineral content (BMC) in infants as a proxy for calcium absorption in relation to one study (Kennedy et al., 1999) provided for the scientific substantiation of the claim.

The Panel notes in the Opinion that owing to limitations in the study design it could not be established that a higher BMC and BMD at three months of age in a sub-sample of the beta-palmitate group could be attributed to better calcium absorption. The Panel also notes that the evidence provided does not establish that a single measurement of BMC and BMD at the age of three months can be generally used as a proxy for the estimation of overall calcium absorption from birth as no baseline measurement was taken. The additional references quoted by the applicant address the effects of calcium from different sources on calcium absorption and bone mineral density in adults, or in post-menopausal or elderly women (Heaney, 2006; Schuette and Knowles, 1988), or whether calcium deposition in bone and its subsequent metabolism could be used as an indirect long-term assessment of calcium utilization or bioavailability (Fairweather-Tait and Teucher, 2002), but do not provide additional information about the use of a single BMC and BMD measurement at the age of three months as a proxy for calcium absorption.

The comments received did not provide further evidence which would warrant a re-evaluation of the study.

CONCLUSIONS

In its opinion adopted on 30 June 2011, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) concluded that the evidence provided was insufficient to establish a cause and effect relationship between the consumption of beta-palmitate and an increase in calcium absorption. The comments received do not change the conclusions of the NDA Panel.

DOCUMENTATION PROVIDED TO EFSA

Comments submitted to the European Commission by IDACE.

REFERENCES

Carnielli VP, Luijendijk IH, van Goudoever JB, Sulkers EJ, Boerlage AA, Degenhart HJ and Sauer PJ, 1995. Feeding premature newborn infants palmitic acid in amounts and stereoisomeric position similar to that of human milk: effects on fat and mineral balance. American Journal of Clinical Nutrition, 61, 1037-1042.

Carnielli VP, Luijendijk IH, Van Goudoever JB, Sulkers EJ, Boerlage AA, Degenhart HJ and Sauer PJ, 1996. Structural position and amount of palmitic acid in infant formulas: effects on fat, fatty acid, and mineral balance. Journal of Pediatric Gastroenterology and Nutrition, 23, 553-560.

Fairweather-Tait SJ and Teucher B, 2002. Calcium bioavailability in relation to bone health. International Journal for Vitamin and Nutrition Research, 72, 13-18.

Heaney RP, 2006. Absorbability and utility of calcium in mineral waters. American Journal of Clinical Nutrition, 84, 371-374.

Kennedy K, Fewtrell MS, Morley R, Abbott R, Quinlan PT, Wells JC, Bindels JG and Lucas A, 1999. Double-blind, randomized trial of a synthetic triacylglycerol in formula-fed term infants: effects on stool biochemistry, stool characteristics, and bone mineralization. American Journal of Clinical Nutrition, 70, 920-927.

Lopez-Lopez A, Castellote-Bargallo AI, Campoy-Folgoso C, Rivero-Urgel M, Tormo-Carnice R, Infante-Pina D and Lopez-Sabater MC, 2001. The influence of dietary palmitic acid

triacylglyceride position on the fatty acid, calcium and magnesium contents of at term newborn faeces. Early Human Development, 65 Suppl, S83-94.

Lucas A, Quinlan P, Abrams S, Ryan S, Meah S and Lucas PJ, 1997. Randomised controlled trial of a synthetic triglyceride milk formula for preterm infants. Archives of Disease in Childhood. Fetal and Neonatal Edition, 77, F178-184.

Schuette SA and Knowles JB, 1988. Intestinal absorption of Ca(H2PO4)2 and Ca citrate compared by two methods. American Journal of Clinical Nutrition, 47, 884-888.

GLOSSARY/ABBREVIATIONS

BMC	Bone mineral content
BMD	Bone mineral density