European Food Safety Authority

The EFSA Journal (2009) 940, 1-8

SCIENTIFIC OPINION

Kinder Chocolate® and growth

Scientific substantiation of a health claim related to Kinder Chocolate® and growth pursuant to Article 14 of Regulation (EC) No 1924/2006[1]

Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies

(Question No EFSA-Q-2008-283)

Adopted on 22 January 2009

PANEL MEMBERS

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SUMMARY

Following an application from Soremartec Italia S.r.l. Gruppo Ferrero submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of Italy, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of Kinder Chocolate®, a milk chocolate filled with anhydrous milk filling, and growth.

The scope of the application was proposed to fall under claims referring to children's development and health.

The product for which the claim is made is a chocolate bar delivering 40 mg of calcium in one 'satiating' portion size, with a 'limited amount' of energy (70 kcal), intended for consumption between meals. The Panel considers that the product for which the claim is made is sufficiently characterised.

The claimed effect is that the chocolate product 'helps to grow'. The target population for the products bearing this health claim is children and young adults aged 4 to 21 years old. The Panel considers that normal growth is beneficial to children's health.

A total of 39 publications were considered by the applicant to be pertinent to the claim, including 13 human intervention studies, 12 human observational studies and 14 review

[1] For citation purposes: Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies on a request from Soremartec Italia S.r.l. Gruppo Ferrero on Kinder Chocolate®. *The EFSA Journal* (2009) 940, 1-8.

articles. These studies focussed on the occurrence of abdominal symptoms of milk consumption in lactose intolerant subjects, on calcium absorption and calcium balance in lactose intolerant subjects, on ghrelin secretion, energy balance and regulation of food intake, and the interaction of magnesium, vitamin B6 and vitamin C on calcium absorption and balance. These were mainly studies in adults. The Panel considers these studies as having limited relevance for the claim on the product.

In addition, the applicant presented two unpublished short term intervention studies with the product (for which the claim is proposed) in a young adult study population (24-30 yr). The objectives of these two studies focussed on endpoints such as effects on glucose metabolism, ghrelin levels, plasma lipid profile, inflammatory markers, blood pressure, body weight, body mass index and waist circumference.

The Panel considers that both studies with the product for which the claim is made, were not performed in the target population of children and used various biomarkers/endpoints that were not directly related to growth.

The Panel concludes that a cause and effect relationship has not been established between the consumption of Kinder Chocolate and the claimed effect of “helps to grow” in children and young adults.

Key words: Kinder Chocolate, a milk chocolate filled with anhydrous milk filling, and growth.

TABLE OF CONTENT

BACKGROUND

Regulation (EC) No 1924/2006[2] harmonises the provisions that relate to nutrition and health claims and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of that Regulation and are authorised in accordance with this Regulation and included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Articles 14 to 17 of that Regulation lay down provisions for the authorisation and subsequent inclusion of reduction of disease risk claims and claims referring to children's development and health in a Community list of permitted claims

According to Article 15 of that Regulation, an application for authorisation shall be submitted by the applicant to the national competent authority of a Member State, who will make the application and any supplementary information supplied by the applicant available to European Food Safety Authority (EFSA).

Steps taken by EFSA:

- The application was received on 08/04/2008.
- During the check for completeness[3] of the application, the applicant was requested to provide missing information on 20/06/2008.
- The applicant provided the missing information on 05/09/2008.
- The application was considered valid by EFSA and the scientific evaluation procedure started on 15/09/2008.
- During the meeting on 22 January 2009, the NDA Panel, after having evaluated the overall data submitted adopted an opinion on Kinder Chocolate, a milk chocolate filled with anhydrous milk filling, and growth.

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16 of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: Kinder Chocolate® and growth.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of Kinder Chocolate, a milk chocolate filled with anhydrous milk filling Kinder Chocolate, a milk chocolate filled with anhydrous milk filling, a positive assessment of its safety, nor a decision on whether Kinder Chocolate, a milk chocolate filled with anhydrous milk filling, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

[2] European Parliament and Council (2006). 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. Official Journal of the European Union OJ L 404, 30.12.2006. Corrigendum OJ L 12, 18.1.2007, p. 3–18.

[3] In accordance with EFSA "Scientific and Technical guidance for the Preparation and Presentation of the Application for Authorisation of a Health Claim"

It should also be highlighted that the scope, the proposed wording of the claim and the conditions for use as proposed by the applicant may be subject to changes pending the scientific evaluation by EFSA, and pending the outcome of the authorization procedure foreseen in Articles 16 and 17 Regulation (EC) No 1924/2006.

ACKNOWLEDGEMENTS

The European Food Safety Authority wishes to thank the members of the Working Group for the preparation of this opinion: Jean-Louis Bresson, Albert Flynn, Marina Heinonen, Hannu Korhonen, Ambroise Martin, Andreu Palou, Hildegard Przyrembel, Seppo Salminen, Sean (J.J.) Strain, Inge Tetens, Henk van den Berg, Hendrik van Loveren and Hans Verhagen.

1. Information provided by the applicant

Applicant's name and address: Soremartec Italia S.r.l. Gruppo Ferrero, Italy

The application includes proprietary data. The applicant claimed proprietorship of data related to the product composition and of data obtained from studies with the product.

1.1. Food/constituent as stated by the applicant

Kinder Chocolate, a milk chocolate filled with anhydrous milk filling,

1.2. Health relationship as claimed by the applicant

According to the applicant, the consumption of Kinder Chocolate can be helpful to reach the nutrient requirements, especially for some groups of the population, such as children and young adults aged 4-21 years.

Kinder Chocolate is portioned in bars of 12.5 g, each of them having a caloric content of 70 kcal (293 kJ) between 2 % and 4 % of the daily energy requirement of children and adults aged 4-21 years. Moreover one portion of Kinder Chocolate (12.5 g) delivers 40 mg of calcium. With respect to calcium delivery, Kinder Chocolate can claim that it is the chocolate that helps to grow because of the changing behaviour in food preference in the young generation and to achieve a positive calcium balance according to food choice and taste evolution.

1.3. Proposed wording of the health claim

"Kinder Chocolate, the chocolate that helps to grow."

1.4. Specific conditions for use as proposed by the applicant

The target population for the intended health claim is children and young adults aged between 4-21 years.

The consumption of Kinder Chocolate is positioned as between meal eating occasion.

According to the applicant, "eating between meals can be helpful in meeting calorie and nutrient requirements, especially for some groups of population, such as children". According to the data submitted, one portion of Kinder Chocolate (12.5 g) delivers 40 mg of calcium amounting to 5 % of calcium RDA (7 % for 100 Kcal). The daily consumption should be related to the physical activity of the child and the choice of the parents.

2. Assessment

2.1. Characterisation of the food/constituent

The food that is the subject of the health claim is Kinder Chocolate® a chocolate bar with an anhydrous milk filling (60 % by weight; milk chocolate covering 40 %) which contains energy and delivers macronutrients (protein, carbohydrates, and fat), as well as micronutrients, especially calcium and phosphorus, low levels of magnesium and some vitamins specified in the application. The product contains 40 mg of calcium corresponding to 4 – 8.9 % of the Population Reference Intake (PRI) for children (SCF, 2003) in one portion size of 12.5 g, with an energy value of 70 kcal, intended for consumption between meals. These are all recognised nutrients and are measurable in foods by established methods.

The Panel considers that the food that is the subject of the health claim (i.e. Kinder Chocolate, a milk chocolate bar filled with anhydrous milk filling) is sufficiently characterised.

2.2. Relevance of the claimed effect to human health

The claimed effect is that the chocolate product 'helps to grow'. The target population is children and young adults aged between 4-21 years.

The Panel considers that normal growth is beneficial to children's health.

2.3. Scientific substantiation of the claimed effect

The applicant performed a literature search in Pubmed, without specifying the search terms used, and refers to the Italian nutrient recommendations (Livelli di Assunzione Raccommandati Nazionali) and to European Legislation. Thirty nine publications were considered by the applicant to be pertinent to the claim, including 13 human intervention studies, 12 human observational studies and 14 review articles (indicated by the applicant as systematic reviews).

The human intervention and observational studies, as well as the review articles, selected by the applicant focus on various effects, such as abdominal symptoms of milk consumption in lactose intolerant subjects, on calcium absorption and calcium balance in lactose intolerant subjects, on ghrelin secretion, energy balance and regulation of food intake, and the interaction of magnesium, vitamin B6 and vitamin C on calcium absorption and balance. Groups/subjects in these studies appear to be mainly adults, except for one intervention study on combined intake of calcium and lactose in African American adolescent girls (Pribila et al., 2000), an observational study on spontaneous fracture risk and bone density in young girls (Goulding et al., 1998), one study on secular trends in energy and fat intakes in young children (2-19 yr; Troiano et al., 2000) and on calcium requirements and bone mineral content in children (Martin et al., 1997). The Panel considers these studies as having limited relevance for the claimed effect as they relate either to specific groups not representative of the general population of children, e.g. lactose intolerant subjects, or to biomarkers and clinical endpoints that are not relevant to the claimed effect.

In addition, the applicant presented two unpublished short term intervention studies with the product (for which the claim is proposed) in a young adult study population (24-30 yr) (Marangoni 2008a, 2008b). The objectives of these two studies focussed on endpoints, such as effects on glucose metabolism, ghrelin levels, plasma lipid profile, inflammatory markers, blood pressure, body weight, body mass index and waist circumference.

The Panel considers that both studies with the product for which the claim is made were not performed in the target population of children and used various biomarkers/endpoints that were not directly related to growth.

The Panel concludes that a cause and effect relationship has not been established between the consumption of Kinder Chocolate and the claimed effect of "helps to grow" in children and young adults".

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- Kinder Chocolate® (a milk chocolate bar filled with anhydrous milk filling) that is the subject of the health claim is sufficiently characterised.

- The claimed effect is that the chocolate product 'helps to grow'. The target population is children and young adults aged between 4-21 years. Normal growth is beneficial to children's health.
- A cause and effect relationship has not been established between the consumption of Kinder Chocolate® and the claimed effect in children and young adults, aged 4-21 years.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on Kinder Chocolate and growth pursuant to Article 14 of Regulation (EC) No 1924/2006 (claim serial No: 0153_IT). July 2008. Submitted by Soremartec Italia S.r.l. Gruppo Ferrero.

REFERENCES

Goulding A, Cannan R, Williams SM, Gold EJ, Taylor RW, Lewis-Barned NJ (1998). Bone mineral density in girls with forearm fractures. *J. Bone Min. Res.* 13:143-148.

Martin AD, Bailey DA, McKay HA (1997). Whiting S. Bone mineral and calcium accretion during puberty. *Am. J. Clin. Nutr.* 1997; 66: 611-615.

Marangoni F. (2008a). Main results of a study on the functional effects of Kinder Chocolate. Unpublished proprietary data. Unpublished proprietary data.

Marangoni F. (2008b). Assessment of the glycaemic index and insulin and ghrelin response to Kinder Chocolate consumption. Unpublished proprietary data.

Pribila BA, Hertzler SR, Martin BR, Weaver CM, Savaiano DA (2000). Improved lactose digestion and intolerance among African-American adolescent girls fed a dairy-rich diet. *J. Am. Diet. Ass.* 100:524-528.

SCF (Scientific Committee for Food), 2003. Nutrient and energy intakes for the European Community, Reports of the Scientific Committee for Food 31st series, Office for Official Publication of the European Communities, Luxembourg, 1993.

Troiano RP, Briefel RR, Carroll MD, Bialostosky K (2000). Energy and fat intakes of children and adolescents in the United States: data from the National Health and Nutrition Examination Surveys. *Am. J. Clin. Nutr.* 72S:1343S-1353S.