FHI LFC24, a bovine milk-derived casein hydrolysate, and a reduction of post-prandial blood glucose responses: evaluation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006

Sjödin, Anders Mikael; EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

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FHI LFC24, a bovine milk-derived casein hydrolysate, and a reduction of post-prandial blood glucose responses: evaluation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

Abstract

Following an application from Food for Health Ireland (FHI), submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Ireland, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to FHI LFC24, a bovine milk-derived casein hydrolysate, and a reduction of post-prandial blood glucose responses. The food, FHI LFC24, which is the subject of the health claim, is sufficiently characterised. The claimed effect proposed by the applicant is that FHI LFC24, when co-ingested with carbohydrates, reduces post-prandial blood glucose responses. The target population proposed by the applicant is the healthy adult population. In view of the proposed mechanism by which the food would exert the claimed effect, i.e. 'by increased post-prandial insulin secretion', the applicant was requested to provide evidence that a reduction of post-prandial blood glucose responses achieved by an increase in insulin secretion is a beneficial physiological effect for the target population, i.e. the healthy adult population. The evidence provided by the applicant did not establish that a reduction in post-prandial glycaemic responses achieved by an increase in insulin secretion is a beneficial physiological effect for the target population. The Panel considers that a cause and effect relationship has not been established between the consumption of the food, FHI LFC24, and a beneficial physiological effect for the target population.

Keywords: FHI LFC24, post-prandial blood glucose, insulin, health claims

Requestor: Competent Authority of Ireland following an application by Food for Health Ireland (FHI)

Question number: EFSA-Q-2015-00755

Correspondence: nda@efsa.europa.eu

Panel members: Jean-Louis Bresson, Barbara Burlingame, Tara Dean, Susan Fairweather-Tait, Marina Heinonen, Karen Ildico Hirsch-Ernst, Inge Mangelsdorf, Harry McArdle, Androniki Naska, Monika Neuhäuser-Berthold, Grażyna Nowicka, Kristina Pentieva, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Daniel Tomé, Dominique Turck, Hendrik Van Loveren, Marco Vinceti and Peter Willatts

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Summary

Following an application from Food for Health Ireland (FHI), submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Ireland, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to FHI LFC24, a bovine milk-derived casein hydrolysate, and a reduction of post-prandial blood glucose responses.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The application included a request for the protection of proprietary data.

The approach of the NDA Panel for the evaluation of the health claim is outlined in the European Food Safety Authority (EFSA) general guidance for stakeholders on health claim applications and the guidance on the scientific requirements for health claims related to appetite ratings, weight management and blood glucose concentrations.

The food that is the subject of the health claim is FHI LFC24, which is a bovine milk-derived casein hydrolysate. The starting material for the hydrolysate is sodium caseinate, which is subjected to processing including enzymatic hydrolysis. The Panel considers that the food, FHI LFC24, is sufficiently characterised.

The claimed effect proposed by the applicant is that FHI LFC24, when co-ingested with carbohydrates, reduces post-prandial blood glucose responses. The target population proposed by the applicant is the healthy adult population.

The applicant indicated that the mechanism by which the food exerts the claimed effect is by 'increased post-prandial insulin secretion'. In view of the mechanism proposed, the applicant was requested to provide evidence that a reduction of post-prandial blood glucose responses achieved by an increase in insulin secretion is a beneficial physiological effect for the target population, i.e. the healthy adult population.

In reply, the applicant focussed on the safety of the food, i.e. elaborated on the differences between the food and antidiabetic drugs (such as sulfonylureas). The applicant stated that owing to distinct mechanisms of action, the risks (i.e. hypoglycaemia and β-cell exhaustion) associated with the use of sulfonylureas would not pertain to the milk-protein hydrolysate (i.e. FHI LFC24). However, the applicant did not provide evidence that a reduction of post-prandial blood glucose responses achieved by an increase in insulin secretion is beneficial for the healthy adult population, i.e. the target population for the claim.

The Panel notes that the evidence provided by the applicant does not establish that a reduction in post-prandial glycaemic responses achieved by an increase in insulin secretion is a beneficial physiological effect for the target population.

The Panel considers that a cause and effect relationship has not been established between the consumption of the food, FHI LFC24, and a beneficial physiological effect for the target population.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1924/2006[1] 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 this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction of disease risk and to children's development and health) which are based on newly developed scientific evidence, or which include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of this Regulation, an application for inclusion in the Community list of permitted claims referred to in Article 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

1.2. Interpretation of the Terms of Reference

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) 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: FHI LFC24, a bovine milk-derived casein hydrolysate, and a reduction of post-prandial blood glucose responses.

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of FHI LFC24, a positive assessment of its safety, nor a decision on whether FHI LFC24 is, 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.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

2. Data and methodologies

2.1. Data

2.1.1. Information provided by the applicant

Food/constituent as stated by the applicant:

- According to the applicant, the food which is the subject of the claim is a bovine milk-derived casein hydrolysate designated as FHI LFC24.

Health relationship as claimed by the applicant:

- According to the applicant, the co-ingestion of FHI LFC24 with carbohydrates results in a significant reduction in post-prandial plasma glucose concentrations. The applicant indicated that the mechanism through which this is achieved is by increased post-prandial insulin secretion.

Wording of the health claim as proposed by the applicant:

- 'FHI LFC24 helps to regulate blood glucose levels following food consumption'.

Specific conditions of use as proposed by the applicant:

- According to the applicant, 12 g of FHI LFC24 should be dissolved in 120 mL of mineral water. This beverage should then be consumed with a meal.
- The target population proposed by the applicant is the healthy adult population.

[1] 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.

2.1.2. Data provided by the applicant

Health claim application on FHI LFC24, a bovine milk-derived casein hydrolysate, and a reduction of post-prandial blood glucose responses pursuant to Article 13.5 of Regulation 1924/2006, presented in a common and structured format as outlined in the Scientific and technical guidance for the preparation and presentation of applications for authorisation of health claims (EFSA NDA Panel, 2011).

As outlined in the general guidance for stakeholders on health claim applications (EFSA NDA Panel, 2016), it is the responsibility of the applicant to provide the totality of the available evidence.

This health claim application includes a request for the protection of proprietary data (Food for Health Ireland, Studies 1–5, all five studies unpublished), in accordance with Article 21 of Regulation (EC) No 1924/2006.

2.2. Methodologies

The general approach of the NDA Panel for the evaluation of health claim applications is outlined in the EFSA general guidance for stakeholders on health claim applications (EFSA NDA Panel, 2016).

The scientific requirements for health claims related to appetite ratings, weight management and blood glucose concentrations are outlined in a specific EFSA guidance (EFSA NDA Panel, 2012).

3. Assessment

3.1. Characterisation of the food/constituent

The food that is the subject of the health claim is FHI LFC24, which is a bovine milk-derived casein hydrolysate.

The starting material for the hydrolysate is sodium caseinate, which is subjected to processing including enzymatic hydrolysis. An overview of the manufacturing process was provided.

The amino acid composition, proximate analysis, molecular mass distribution profile, molecular weight distribution of the peptides and degree of hydrolysis of FHI LFC24 were provided.

Information on the stability of the food and results of batch-to-batch analyses were provided.

The Panel considers that the food, FHI LFC24, a bovine milk-derived casein hydrolysate, which is the subject of the health claim, is sufficiently characterised.

3.2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is that FHI LFC24, when co-ingested with carbohydrates, reduces post-prandial blood glucose responses. The target population proposed by the applicant is the healthy adult population.

The applicant indicated that the mechanism by which the food exerts the claimed effect is by 'increased post-prandial insulin secretion'. In view of the mechanism proposed, the applicant was requested to provide evidence that a reduction of post-prandial blood glucose responses achieved by an increase in insulin secretion is a beneficial physiological effect for the target population, i.e. the healthy adult population.

In reply, the applicant focussed on the safety of the food, i.e. elaborated on the differences between the food and antidiabetic drugs (such as sulfonylureas). The applicant stated that owing to distinct mechanisms of action, the risks (i.e. hypoglycaemia and β-cell exhaustion) associated with the use of sulfonylureas would not pertain to the milk-protein hydrolysate (i.e. FHI LFC24). However, the applicant did not provide evidence that a reduction of post-prandial blood glucose responses achieved by an increase in insulin secretion is beneficial for the healthy adult population, i.e. the target population for the claim.

The Panel notes that the evidence provided by the applicant does not establish that a reduction in post-prandial glycaemic responses achieved by an increase in insulin secretion is a beneficial physiological effect for the target population.

The Panel considers that a cause and effect relationship has not been established between the consumption of the food, FHI LFC24, and a beneficial physiological effect for the target population.

4. Conclusions

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

- The food, FHI LFC24, a bovine milk-derived casein hydrolysate, is sufficiently characterised.
- The claimed effect proposed by the applicant is that FHI LFC24, when co-ingested with carbohydrates, reduces post-prandial blood glucose responses. The target population proposed by the applicant is the healthy adult population. The applicant indicated that the mechanism by which the food exerts the claimed effect is by 'increased post-prandial insulin secretion'. No evidence was provided that a reduction in post-prandial glycaemic responses achieved by an increase in insulin secretion is a beneficial physiological effect for the target population.
- A cause and effect relationship has not been established between the consumption of the food, FHI LFC24, and a beneficial physiological effect for the target population.

Steps taken by EFSA

1) Health claim application on FHI LFC24, a bovine milk-derived casein hydrolysate, and a reduction of post-prandial blood glucose responses pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0444_IE). Submitted by Food for Health Ireland (FHI), University College Dublin, Belfield, Dublin 4, Ireland.
2) The application was received by EFSA on 1 December 2015.
3) The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The application included a request for the protection of proprietary data.
4) The scientific evaluation procedure started on 11 January 2016.
5) On 17 March 2016, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application and the scientific evaluation was suspended on 7 April 2016, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
6) On 22 April 2016, EFSA received the applicant's reply and the scientific evaluation was restarted, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
7) During its meeting on 28 June 2016, the NDA Panel, having evaluated the data, adopted an opinion on the scientific substantiation of a health claim related to FHI LFC24, a bovine milk-derived casein hydrolysate, and a reduction of post-prandial blood glucose responses.

References

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2011. Scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim (revision 1). EFSA Journal 2011;9(5):2170, 36 pp. doi:10.2903/j.efsa.2011.2170

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2012. Guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations. EFSA Journal 2012;10(3):2604, 11 pp. doi:10.2903/j.efsa.2012.2604

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2016. General scientific guidance for stakeholders on health claim applications. EFSA Journal 2016;14(1):4367, 38 pp. doi:10.2903/j.efsa.2016.4367

Food for Health Ireland (unpublished, claimed as proprietary by the applicant). Study 1: Intervention study in a healthy overweight population.

Food for Health Ireland (unpublished, claimed as proprietary by the applicant). Study 2: The effects of FHI LFC24 in ob/ob mice in an acute study.

Food for Health Ireland (unpublished, claimed as proprietary by the applicant). Study 3: The effects of chronic administration of FHI LFC24 in DIO mice.

Food for Health Ireland (unpublished, claimed as proprietary by the applicant). Study 4: The effects of chronic administration of FHI LFC24 in ob/ob mice on islet function.

Food for Health Ireland (unpublished, claimed as proprietary by the applicant). Study 5: *In vitro* study experiments.

Abbreviations

FHI Food for Health Ireland
NDA EFSA Panel on Dietetic Products, Nutrition and Allergies