

TECHNICAL REPORT OF EFSA

Response to comments on the Scientific Opinion on the substantiation of a health claim related to *Lactobacillus rhamnosus* GG and maintenance of defence against pathogenic gastro-intestinal microorganisms pursuant to Article 13(5) of Regulation (EC) No 1924/2006¹

European Food Safety Authority^{2,3}

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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 health claims related to *Lactobacillus rhamnosus* GG and maintenance of defence against pathogenic gastro-intestinal microorganisms pursuant to Article 13(5) of Regulation (EC) No 1924/2006.

Comments submitted to EFSA via the European Commission Services originated from the applicant (Valio Ltd.) and from Dr. Chan Yue Sun (consultant paediatrician).

EFSA has reviewed the comments and shared them with the chair of the NDA Panel and the chair of the NDA Working Group on Claims.

In its opinion adopted on 13 May 2011, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) concluded that a cause and effect relationship had not been established between the consumption of *Lactobacillus rhamnosus* GG and maintenance of defence against pathogenic gastro-intestinal microorganisms. The comments received do not change the conclusions of the NDA Panel.

KEY WORDS

Lactobacillus rhamnosus GG, gastrointestinal infections, pathogens, acute diarrhea, health claims, comments.

¹ On request from the European Commission, Question No EFSA-Q-2011-00933, issued on 27 September 2011.

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TABLE OF CONTENTS

Summary	1
Table of contents	2
Background as provided by the European Commission	3
Terms of reference as provided by the European Commission	3
Consideration	4
1. Introduction	4
2. Comments related to the study by Szajewska et al. (2001)	4
3. Comments related to the use of data obtained in subjects hospitalised for reasons not related to GI infections	4
4. Comments related to the Panel's evaluation of the application	5
Conclusions	5
Documentation provided to EFSA	5
References	5

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 Question under the mandate number M-2011-0063).

CONSIDERATION

1. Introduction

On 13 May 2011, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) adopted a scientific opinion on the scientific substantiation of health claims related to *Lactobacillus rhamnosus* GG and maintenance of defence against pathogenic gastro-intestinal microorganisms pursuant to Article 13(5) of Regulation (EC) No 1924/2006⁴ following an application for authorisation from Valio Ltd. submitted via the Competent Authority of Finland (Claims serial number: 0288_FI, EFSA-Q-2010-01028).

In accordance with Article 16 of Regulation (EC) No 1924/2006⁵, the applicants or members of the public may make comments to the European Commission on opinions published by the Authority pursuant to Article 16 and 18 of the Regulation. On 19 July 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 (Valio Ltd.) and from Dr. Chan Yue Sun (consultant paediatrician).

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 study by Szajewska et al. (2001)

The comments received by the applicant related to the presence of diarrhoea plus the rotavirus antigen (i.e. vs. the presence of the rotavirus antigen alone) as meaningful outcome measure to assess the effect of LGG on defence against gastro-intestinal (GI) pathogens, despite the absence of data on antibiotic use in the study population. It is noted in the Opinion that data on antibiotic use were not provided nor taken into account in data analysis, that asymptomatic rotavirus carriers were not excluded from the analysis, and that the number of subjects who tested positive for the rotavirus antigen did not differ between the placebo and LGG groups. Under these conditions, it is not possible to distinguish between diarrhoeal episodes of infectious and non-infectious (e.g. antibiotic-related) origin, and therefore the diarrhoeal episodes in this study, even in the presence of the rotavirus antigen, cannot be used as a surrogate marker for GI infections.

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

3. Comments related to the use of data obtained in subjects hospitalised for reasons not related to GI infections

The comments received from the applicant suggested that the Panel did not take into account the human data on the treatment of GI infections as supportive evidence for the scientific substantiation of the claim because data for an effect of LGG on the incidence and duration of GI infections were obtained in hospitalised children only (e.g. Hojsak et al., 2010) rather than in the general healthy population. As stated in the Opinion, the Panel considered as key studies for the scientific substantiation of the claim those which were conducted in subjects without GI infections at

⁴ EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. Scientific Opinion on the substantiation of a health claim related to *Lactobacillus rhamnosus* GG and maintenance of defence against pathogenic gastrointestinal microorganisms pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal, 9(6):2167, 19 pp.

⁵ 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.

recruitment (section 3.1. Development of gastro-intestinal infections). These studies included two related to traveller's diarrhoea, two conducted in free-living children and three on children hospitalised for reasons other than GI infections (among which was the study by Hojsak et al., 2010). After consideration of these seven studies, the Panel concluded that the evidence provided did not establish that consumption of LGG had an effect on the development of GI infections (i.e. in the general population that is the target of the health claim). With reference to the studies provided on the treatment of GI infections, the Panel considered that these studies could not be used as a source of data for the scientific substantiation of the claim in the absence of evidence for an effect of LGG consumption on the development of GI infections in the general population - the target population for the health claim (as described in section 3.1).

4. Comments related to the Panel's evaluation of the application

A second set of comments received was a detailed commentary on the Panel's evaluation of a number of scientific studies. EFSA considers that all of the substantive issues raised in these comments were already taken into account by the Panel in its evaluation of the claim and that the reasoning for the Panel's conclusions on the relevant studies is described in considerable detail in the Opinion.

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

CONCLUSIONS

In its opinion adopted on 13 May 2011, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) concluded that a cause and effect relationship has not been established between the consumption of *Lactobacillus rhamnosus* GG and maintenance of defence against pathogenic gastro-intestinal microorganisms. The comments received do not change the conclusions of the NDA Panel.

DOCUMENTATION PROVIDED TO EFSA

Comments submitted to EFSA via the European Commission Services originated from the applicant (Valio Ltd.) and from Dr. Chan Yue Sun (consultant paediatrician).

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