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Mr. Basil Mathioudakis
European Commission
Head of Unit
DG Health & Consumers
Directorate E4
Rue de la Loi 200
1049 Brussels

Subject: Response to additional 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 1924/2006 (Claims serial number: 0288_FI, EFSA-Q-2010-01028)

Dear Mr. Mathioudakis,

Thank you for informing EFSA about the additional comments the European Commission received from Prof. Lorenzo Morelli related to the EFSA opinion on *Lactobacillus rhamnosus* GG and maintenance of defence against pathogenic gastro-intestinal microorganisms (EFSA-Q-2010-01028).

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. EFSA wishes to clarify the issues raised by the additional comments not covered yet in the EFSA Technical Report on a 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 (Supporting Publications 2011:194).

1. General considerations on the EFSA evaluation

In relation to the comment raised on EFSA's approach towards communication with applicants, I would like to point out that an appropriate dialogue with applicants is a crucial aspect of EFSA's work and that EFSA has already a system in place which foresees a dialogue with individual applicants during the EFSA completeness check of an application during the evaluation process. Regulation (EC) No 1924/2006 on nutrition and health claims specifically foresees that EFSA can seek supplementary information from applicants during the evaluation process through a list of questions agreed by the NDA Panel or the Working Group of Claims of the NDA Panel. This procedure is regularly used by EFSA to give the applicants the possibility to provide missing information, to clarify specific issues in the application and to comment on the

points raised by the NDA Panel during the assessment phase. In addition applicants have also the possibility to seek further clarification from the Secretariat of the NDA Panel (Nutrition Unit) on the list of questions agreed by the NDA Panel. In this context I would also like to highlight that during the evaluation process resulting in the opinion in question, the applicant had the opportunity to comment on how the studies on diarrhoea during antibiotic use should be considered for the substantiation of the claim, as well on as other issues.

2. Studies on diarrhoea during antibiotic use

The comment questioned why studies of effects of *Lactobacillus rhamnosus* GG in preventing antibiotic-induced diarrhoea in subjects under antibiotic treatment were not taken into account for substantiating the claim. As stated in the Opinion, antibiotic treatment may induce diarrhoea by mechanisms unrelated to gastro-intestinal infections. Thus, any effect of *Lactobacillus rhamnosus* GG on antibiotic-induced diarrhoea may not be predictive of an effect on infection-induced diarrhoea. Accordingly, the Panel considered that studies on diarrhoea during antibiotic use (or meta-analyses including these studies) cannot be used as a source of data for the scientific substantiation of a claimed effect related to the maintenance of defence against pathogenic gastro-intestinal microorganisms.

3. Hojsak (2009) study

The comment refers to the statement in the opinion ‘The Panel notes that microbiological confirmation of the infectious nature of the vomiting and diarrhoea episodes was not obtained’ and questions whether this is a requirement. While this would be helpful in confirming the infectious nature of vomiting and diarrhoea, the opinion makes it clear that this is not a requirement for diagnosis of a gastrointestinal infection: ‘The Panel considers that gastrointestinal infections clinically diagnosed by the primary care physician following well defined criteria can be used as an appropriate outcome measure for the scientific substantiation of the claim, provided that adequate exclusion criteria for the most common non-infectious causes of diarrhoea have been applied, as was done in this study’.

4. Conclusion

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.

Yours sincerely,



Dr. Juliane Kleiner
Head of Nutrition Unit
European Food Safety Authority

Cc: Sabine Osaer, Christina Antoniou, Noel Griffin, Francesco Felice Carlucci (EC)