



Helsinki, June 30th 2011

Basil Mathioudakis
DG Sanco
E4 Food Law, nutrition and labelling
European Commission
Rue de la Loi 200
1049 Brussels
Belgium

REF: EFSA 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

Dear Mr Mathioudakis,

The NDA Panel of EFSA published on 1st June an opinion on the above health claim application with the conclusion that a cause and effect relationship has not been established between the consumption of L. GG and maintenance of defence against pathogenic gastrointestinal microorganisms.

We were disappointed by the opinion, but encouraged that it showed some opportunities with which to proceed with future health claim applications. We do lament that the current regulation does not foresee consultation on the EFSA opinion. Such consultation would provide valuable feedback to applicants and facilitate improvements in research and the quality of future applications.

Like several other applicants, we also strongly express our wish to have informative discussion between the Panel and applicants for health claims during the evaluation procedure. Through a pre-submission dialogue it would be possible for applicants to have guidance on complying with the criteria set by the Panel for scientific substantiation of a health claim, given that the specifics of these criteria are set case-by-case. We believe that such an approach would again, in the long run, save time and resources of both the applicant and EFSA and lead to better quality research and submissions.

We also want to draw the attention of the Commission to very short time frames of the clock stop and the extension of the evaluation process given in the art. 13.5 procedure. When considering amendments to the regulation, these time frames need to be addressed, as well as the need for two different evaluation procedures (art. 13.5 and art. 14).

We have carefully considered the Panel's response to our health claim application and while we have a number of questions, our priority is to seek clarification on the following points. This will assist us in the preparation of future applications.

1. In the study of Szajewska et al. (2001), the Panel stated that the incidence of rotavirus infections was not significantly different between the L.GG and the placebo groups. This result actually refers to the presence of antigen alone, but for an important clinical outcome (diarrhoea associated with the rotavirus antigen) there *was* a significant difference. The absence of data on antibiotic use should not

vitate this finding, as clinical symptoms and the presence of rotavirus antigen together are sufficient for the diagnosis of rotavirus infection. We therefore request clarification as to whether this study should be viewed as a positive finding for reduction in the incidence of diarrhoea by administration of L.GG.

2. A common criticism of the Panel is the nature of the study methodologies and statistical analyses that have been applied in published randomised controlled trials over the last 20 years. It is important for applicants and scientists designing new clinical trials to understand the detailed methodological and statistical requirements that the Panel is applying above and beyond current practices in high quality peer review scientific journals using. In addition, it would be helpful to understand how statistical re-treatment of raw data in well-designed historical trials could be validly applied to avoid enforcing a wasteful redundancy in much scientific investment to date, including much work funded by the European Union. Will EFSA release such guidance documents in the near future?
3. We understood from the opinion that human treatment data could have been used as supportive data if there had been evidence obtained from human studies in the target population. The Panel admitted the evidence in hospitalised children (Hojsak et al 2010), which is not the target population. However, the difficulty of demonstrating an effect in the body's defense in free-living, fully healthy people is broadly acknowledged. Demonstration of the effect is much more feasible in a hospital setting where the incidence of infections is higher. We would therefore like to further discuss the Panel's view that conclusions can not be drawn for the general population from results obtained in hospitalised subjects (for reasons not related to GI infections). This is especially pertinent when the Panel has acknowledged that studies on IBS can be used as primary data for claims on gastrointestinal comfort, although there is a functional disturbance of the intestine in IBS patients with an unknown etiology. Can the Panel provide us with clear guidance on this matter?

We would like to emphasize that there is ample scientific research available on micro-organisms with beneficial effects on health, accepted already by scientific communities around the world. It is important to find ways to exploit this research for communication to the benefit of European consumers. Without such opportunity, the European food industry is losing significant commercial potential.

Finally, we want to conclude by saying that we categorically support EFSA's goal in protecting consumers from spurious health claims on foods by requiring that the scientific evidence for health claims be rigorously evaluated. Our main wish is that the system be efficient in achieving this shared goal.

Yours sincerely,



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VP, R&D Valio Ltd.



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