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Piacenza June 29th, 2001

To: Mr. Basil Mathioudakis
European Commission
Head of Unit
DG SANCO Directorate E4
Rue de la Loi 200
B-1049 Brussels

Re: 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 2011;9(6):2167)

Dear Mr Masthioudakis

I write concerning this recently published EFSA opinion relating to a claim for *Lactobacillus rhamnosus* ATCC 53103(LGG). The applicant, Valio Ltd, have asked me to give an independent assessment of the outcome of this opinion.

As already done for other applicant I accepted this commitment, in order to provide my own contribution to the debate on the process of assessing health claims for probiotics in EU.

General comments.

I have to point out that, at the moment, the published opinions seem to support only "traditional" health claims (vitamins, minerals, charcoal...) while the "innovation" is facing serious difficulties. This is striking, if we take in consideration the amounts of money that EU have used to support research in this area (I was the coordinator of the first EU funded project in the field of probiotics in 1991). This efforts has led Europe to gain a leading position not only in the scientific arena but also in the world-wide markets. The Opinions provided by the NDA panel are providing a kind of excommunication to the European science and companies.

As already mentioned in a previous letter of mine, the real problem seems the lack of communication between applicant and the Panel, a problem which could be easily solved by introduction a pre-submission step in the evaluation process. A further evidence of this need is provided, as regards the to *Lactobacillus rhamnosus* GG, in the following section.

Specific comments.

In evaluating (EFSA Journal 2011;9(6):2167) the efficacy of *L. rhamnosus* GG strain the Panel states:

"Six studies in healthy adults and children under antibiotic treatment and two meta-analyses which included studies on the prevention of antibiotic-induced diarrhoea were presented. The Panel notes that these studies did not provide adequate information about the aetiology of diarrhoeal episodes, and that antibiotic treatment may induce diarrhoea by mechanisms unrelated to GI infections."

It means that, while meta-analysis score "positive" the clinical action of this strain, the Panel discard this evaluation and ask for the aetiology of the pathological condition.

This is surprising; this request seems more appropriate for drugs and not for a food or a food supplement. Moreover, aetiology of diarrhoea is definitely hard and sometimes impossible to be defined, even when drugs are evaluated.

In addition, during the meeting with stakeholders (Amsterdam, Dec. 2, 2010) it was clarified to stakeholders that evaluation of application under art. 14 are based on the following provisions of Reg. CE 1924/2006:

•Article 2 (6): "reduction of disease risk claim means any health claim that states, suggests or implies that the consumption of a food....significantly reduces a **risk factor** in the development of human disease."

No reference was made to the identification of the "origination" (aetiology) of the disease (diarrhoea), while in the application dealing with *L. rhamnosus* GG and gastro-intestinal infections the risk factor was clearly identified.

For this comment it could be concluded that a deep gap does exist between the scientific and the Panel assessment and that the guidelines provided by the Panel are not really followed by the Panel itself, with a very extensive use of the case-by-case approached.

More specifically: in the evaluation of data reported by Hojsak et al. (2009) *The Panel notes that microbiological confirmation of the infectious nature of the vomiting and diarrhoea episodes was not obtained.*

Is this really required by Reg. 1924/2006?

If yes, it would be extremely relevant to know this position before submitting an application or designing a clinical protocol; otherwise the final result is a serious damage to European research and industrial framework.

It is my opinion that the evaluation process is to be changed, allowing the NDSA to use a more open approach with applicants.

My Very Best Regards



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