



October 1, 2009

ISAPP responds to EFSA's ruling on probiotic claims

The European Food Safety Authority is the risk assessment body of the European Union for food and feed safety. Under this umbrella, it also provides scientific advice to risk managers. Although the efficacy and mechanisms of action of probiotics go beyond issues of risk, EFSA has been appointed to determine whether claims for probiotics are allowable. The process for this activity entails EFSA review of industry-submitted claims and the data offered as substantiation of those claims.

This week's rejection of a number of claims for probiotics follows previous similar decisions by EFSA. While each case must be assessed using the data provided to the panel, the International Scientific Association for Probiotics and Prebiotics (ISAPP: www.isapp.net) would like to make several comments on the issues at hand.

1. We agree with EFSA insisting that commercial use of the term "probiotic" has a meaning which is supported by human studies.
2. However, EFSA has not provided sufficiently clear guidelines for what types of studies they consider necessary to meet their standard of a substantiated claim.
3. ISAPP cannot comment on the validity of specific dossiers, but wants to emphasize that a standard of reasonable levels of evidence for health benefits of foods and supplements is needed, and it is not prudent to expect a level of substantiation of efficacy of these probiotic foods, equivalent to what is required for pharmaceutical agents.
4. The fact that some dossiers were rejected should not be interpreted to mean that there are no substantiated probiotics, nor that products containing rejected strains have not been shown to provide health benefits to humans, nor that probiotics have failed safety standards.
5. Of the claims that EFSA has permitted to date, such as 'probiotics help maintain a healthy gut flora' and probiotics 'balance your intestinal microflora', are of little help to consumers, who for the most part do not understand the organisms in the intestine. In addition, the claims are so general they do not take into account differences between probiotic strains and product formulations. This does not serve the public's interest.

It is difficult for any agency to have sufficient expertise to understand the many concepts of probiotics, and to weigh mechanistic *in vitro* and animal experiments with human studies on health and diseased cohorts. Moreover, the task is all the more challenging given that some probiotic foods provide benefits for people suffering from, or at risk of disease, as well as healthy subjects. ISAPP supports clearer communication from EFSA so that industry knows what is expected in the research it supports/conducts. This whole process must be for the overall public good. The precedent being set by EFSA has implications for population health given the millions of people taking probiotics around the world, and the economies of many communities who employ people working in this area.

Claims related to the benefits of probiotics have been approved in many countries. There is no reason to think that Europe will be any different in due course, especially given the volumes of data on benefits accrued from probiotic use. The sooner this can happen the better for all concerned.

Gregor Reid BSc Hons PhD MBA ARM CCM Dr HS FCAHS
President, ISAPP
Tel: 1-519-646-6100 x65256
gregor@uwo.ca

Glenn R. Gibson BSc Hons PhD
Vice-President, ISAPP
Tel: 44 (0)118 378 8715
g.r.gibson@reading.ac.uk