EFSA and Probiotics: Gut Response

By Paul Tenning [5]

Editor’s Note: On December 2, the European Food Safety Authority (EFSA; Parma, Italy) held a meeting in Amsterdam with the intention of clarifying its process of reviewing Article 13 and Article 14 health claims, specifically those concerning gut and immune health. The probiotics community was well represented at the meeting, which was led by members of EFSA’s Dietetic Products, Nutrition, and Allergies (NDA) panel. Below are reflections from the meeting from representatives of probiotics specialist Danisco A/S (Denmark).

Thus far, all health claims regarding probiotic microorganisms have been rejected by EFSA. EFSA’s reasons for rejection have been that strains have either been insufficiently characterized or that cause-and-effect links have been poorly substantiated.

The high rejection rate of health claims related to probiotics currently used in the marketplace has led to a significant reduction in companies’ willingness to invest in the introduction of new probiotic products. Simply put, the probiotics industry will be hesitant to innovate until the situation with EFSA is resolved. So, how can we improve the rate of successful claims?

Consider the Entire Body of Evidence
At the recent meeting between EFSA and stakeholders in Amsterdam, EFSA was challenged on its strict review of health claims dossiers. EFSA’s primary response was to recite the European Commission’s Regulation: “Health claims should only be authorized...after a scientific assessment of the highest possible standard.” This regulation, however, does not allow EFSA to consider emerging science in its assessment of claims.
Adhering to the mandate handed down to it by the European Commission, EFSA is doing an outstanding assessment of the claims applications. However, we would argue that in requiring “the highest possible standard,” the mandate does not allow EFSA to consider the totality of the evidence. We suggest that all of the science indicating that a food ingredient has a health benefit should play a role in the overall assessment. That is, the totality of the evidence may be stronger than the sum of its parts. EFSA’s interpretation of “assessment to the highest possible standard” should be widened to also encompass studies that indicate a health benefit, even if those study results may not prove with the most stringent statistical significance that an effect is found in every subject.

Improve Communication
EFSA should also be given resources to meet with applicants before submissions take place, when needed. An informal meeting between the applicant and an EFSA representative may result in a better understanding of which studies should be included in the dossier. As it stands, EFSA has provided very little information regarding the data required for these applications—which may account for why, of the 1,764 Article 13.1 claims EFSA has so far published opinions on, about 90% have been rejected.
By June of this year, EFSA intends to finalize the review of the remainder of the 13.1 claims related to
non-botanical ingredients. Claims on botanical ingredients will be addressed thereafter. The European Commission has indicated that a regulation with the approved 13.1 claims can be expected by late this year, or alternatively by early 2012. Open communication with applicants would improve the quality of the dossiers, which would in turn benefit EFSA, as it would mean better use of its resources.

Align Scientific Standards
It was also evident from the meeting in Amsterdam that EFSA and the scientific community are evaluating the science differently. Typically, industry liaises with academia to conduct and conclude on scientific studies. The legislation, however, forces EFSA to assess claims according to criteria that are different from the general scientific criteria, which may give more weight to clinical outcome data versus effects on disease-risk factors. This disparity with the scientific community highlights and confirms the need for a dialogue between applicants and EFSA before submission of the dossiers. This was also outlined in a recent appeal from independent scientists (www.gut-health.eu).

Where Do We Go from Here?
We feel that the unfavorable Opinions of the probiotic claims have led to unnecessary damage to the industry’s credibility. Note one statement made by a consumer organization at the recent annual conference held by CIAA (Confederation of the Food and Drink Industries of the EU): “[It] is high time something happened about the lots of false and misleading information circulated by the food industry.”

Numerous studies on the benefits of probiotics show that many probiotics can make a difference to health. The effects are strain specific and are limited to certain outcomes. Health benefits are not as immediate as taking an aspirin is to a headache, but instead, the effects are demonstrated after regular consumption and as part of a nutritious diet.

As a result of EFSA’s claims rejections, the risk we see is that consumers will lose out, as the opportunity to make informed choices disappears. The high rejection rate triggers concern in the marketplace that is negative for both consumers and industry. Slight modifications in the mandate given to EFSA, and a more open attitude towards an innovative food industry, could easily change this, to the benefit of EFSA, the consumers, and industry.

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