

EU Health claims: Important updates

Recently, a very significant development related to the implementation of the European Union Nutrition and Health Claims Regulation for foods has occurred.

As background, the EU Claims Regulation prescribes in Article 13.1 that the European Commission will develop a Community List of Permitted General Health Claims that are made on foods and food supplements, following their scientific validation by the European Food Safety Authority (EFSA).

Because of the very large number of claims requiring EFSA opinions and hence a lengthier than envisaged timescale, EFSA proposed to issue its evaluations in a series of batches. The European Commission at first objected, but later agreed to this. Consequently, EFSA issued a first batch of opinions on claims related to vitamins and minerals. However, no final decision has been taken yet on the adoption to the Community List this first batch.

Now, as a result of many concerns raised by a number of EU Member States and by stakeholders, which referred to potential distortion on the market between operators whose claims are rejected, and operators using claims for which assessment is still pending, the European Commission has issued a press release stating that it will wait to publish its Community List of Article 13 permitted general health claims until EFSA has delivered all of its opinions. This means that the Community List will be adopted in a single step, probably not before the end of June 2011.

In addition, the Commission also states that due to the divergence with how botanical ingredients are treated within the Claims Regulation and the Traditional Herbal Medicinal Products Directive (THMPD), claims for botanicals will be considered separately and their review will probably not be completed until after June 2011.

Industry has welcomed the new timeline resulting from this new approach because it now avoids the distortion of the market that would have followed a batch-wise approach, recognises the particular issues for botanical food supplements, and provides a significant amount of time for industry to continue the discussions with the European Commission and the Member States.

Calls for more dialogue on health claims

Following a conference hosted by the European Health Claims Alliance (EHCA) in Brussels at the end of September, industry representatives and leading scientists speaking at the conference called on the Commission to consider “other” and “more appropriate” scientific approaches to the evaluation of the Article 13.1 (‘generic’ health claims). In their view, the current scientific approach being applied to Article 13.1 health claims is

unsuitable for food products and threatens to wipe out the use of most of these claims.

It is now hoped that the discussions at the Conference will lead to an opening for dialogue with both the Commission and consumers so as to reach workable and sustainable solutions that facilitate appropriate implementation of the Nutrition and Health Claims on Foods Regulation, to the benefit of both industry and consumers.

Consensus conference on health claim substantiation

A successful scientific consensus Conference which debated methodologies for the scientific substantiation of health claims was recently held at the University of Hohenheim in Germany.

The conference was attended by 10 top international scientific experts. Following extensive discussions, its primary outcome was consensus that the current system used by the European Food Safety Agency (EFSA) for the assessment of health claims in the European Union was not appropriate. A paper based on this premise will now be prepared, for publication first in the scientific literature and from there to a wider audience, including regulators and government officials.

New guidance on gut and immune function health claims

The European Food Safety Authority (EFSA) has recently published for consultation a draft guidance document on the scientific requirements for health claims related to gut and immune function. The document is issued to inform the proceedings at the scientific meeting to discuss substantiation issues that EFSA is due to hold in December in Amsterdam.

The document has been drawn up from EFSA's scientific opinions on health claims related to the gastrointestinal tract and immune system and represents the views of EFSA's Scientific (NDA) Panel, based on experience gained to date from the evaluation of such health claims.

Further information can be found at: <http://www.efsa.europa.eu/en/consultations/call/nda100928.htm>

Source: EHPM, ERNA, EBF