

EU Health Claims Update

- Adoption of the list of permitted health claims

On 5th December, the Standing Committee adopted a list of 222 permitted health claims as a proposed Regulation. It will now go through the 'scrutiny' process by the European Parliament and the Council before becoming law, probably in Spring 2012. At the time of its publication in the Official Journal of the European Community, a list of disallowed health claims will also be published in the Union Register at:

http://ec.europa.eu/food/food/labellingnutrition/claims/community_register/index_en.htm

A 6-month transition period is set for claims that are not in accordance with the Regulation.

Claims not included in the permitted list but whose evaluation by the Authority or whose consideration by the Commission has not yet been completed (e.g. botanicals, probiotics still under review) will be published on the website of the Commission and may continue until a decision is taken.

- Botanical Claims

The review of health claims for botanicals remains pended while European Commission and EFSA reflect on how best to achieve a consistent and coherent treatment of this category of claim, taking into account the criteria for both food and medicines law.

Claims on substances that can be regarded as medicinal ingredients in some countries:

At its recent meeting, the Standing Committee proposed that, given that the intention of the Nutrition and Health Claims Regulation is not to harmonise ingredients, the following recital be added: *"Addition of substances to or the use of substances in foodstuffs is governed by specific Union and national legislation, as is the classification of products as foodstuffs or medicinal products. Any decision on a health claim in accordance with Regulation (EC) No 1924/2006 such as inclusion in the list of permitted claims referred to in Article 13(3) thereof does not constitute an authorisation to the marketing of the substance on which the claim is made, a decision on whether the substance can be used in foodstuffs, or a classification of a certain product as a foodstuff".*

- EFSA Guidance

The European Food Safety Authority (EFSA) has published draft guidance on making neurological and psychological health claims submissions which focuses on:

Claimed effects which are considered to be beneficial physiological effects;
Studies/outcome measures which are considered to be appropriate for the substantiation of health claims.

The guidance is cautious towards making claims related to neurological or psychological health. With the exception of some well-known nutrients, the Dietetic Products, Nutrition and Allergies (NDA) Panel noted that "for other food constituents, maintenance or improvement of 'neurological function', 'brain function' or 'psychological functions' (the latter encompass both cognitive and affective domains) per se are not sufficiently defined for a scientific evaluation".

EFSA has also published its final Guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health. Unfortunately, the final version has been

published without any chance to discuss its content in dedicated technical workshops and insufficient changes have been made to provide greater clarity.

- *Ombudsman complaint admissible*

The European Ombudsman has confirmed the admissibility of the complaint submitted by EHPM last September concerning the maladministration of the implementation of the article 13.1 of the Nutrition and Health Claims Regulation, which calls for a different type of assessment for article 13.1 claims.

The Ombudsman has now opened an investigation and the European Commission has until the end of February to submit an opinion on the allegation. EHPM then has a further month to make observations on the Commission's response.

The Ombudsman is an elected body of the European Parliament and, while the result of the investigation is not yet known, the admissibility of the complain is an important element in the industry's campaign to seek a review of the Nutrition and Health Claims regulation, and in particular to reconsider the adoption of a negative list of article 13.1 claims.

- *A Review of the Consequences of Implementation of the Nutrition and Health Claims Regulation*

EHPM has provided a four page executive summary of this lengthy report prepared by ERNA, which details all the issues and problems arising from the regulation and its implementation. In particular, the summary explains why a fundamental review of the Nutrition and Health Claims Regulation is essential and why it fails to achieve its basic aims of consumer protection, fair competition and innovation.

The ERNA report has been sent to the EU Commissioners of DG SANCO, DG Enterprise, DG Trade, DG Internal Market and DG Research and to the EFSA Executive Director.

For the full report see: <http://www.erna.org/ERNA-Report-on-Claims.aspx>

Source: EBF, EHPM, ERNA