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E-ALERT | Food & Drug

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EUROPEAN COMMISSION ADOPTS LIST OF GENERAL HEALTH CLAIMS

On 16 May 2012, the European Commission adopted the much delayed list of permitted general health claims (Permitted List) for foods after scrutiny of the list by the European Parliament and the Council ended on 27 April 2012. The Permitted List contains just 222 health claims and their associated conditions of use. The vast majority of health claims submitted to the Commission for review were rejected. Food operators can use health claims on the Permitted List provided the conditions of use and other requirements of Regulation (EC) No 1924/2006[1] (the "Claims Regulation") are met. The Permitted List of general health claims does not cover claims authorized following individual applications under Article 13(5) (so-called innovative claims) and Article 14 (disease risk reduction claims and claims relating to children) of the Claims Regulation.

The regulation adopting the Permitted List is expected to be published in the Official Journal of the European Union shortly. It will come into effect on the 20th day after publication and start applying six months later. The six-month period is intended to allow food companies sufficient time to comply with the list for products they place on the market, but the exact effect remains unclear as the Claims Regulation itself also contains complex transitional rules. This issue applies specifically to claims relating to the role of a nutrient or other substance in growth, development and the functions of the body (Article 13(1)(a) of the Claims Regulation).

Claims not on the permitted list – other than botanical-based claims and other claims categorized by the Commission as "on-hold" – will therefore likely be prohibited in the EU from December 2012. EU member state competent authorities will be responsible for enforcing the legislation.

Linguistic or cultural differences in the wording of the claim will be taken into account, provided that the phrase has the same meaning as that of a permitted health claim. The Permitted List can be accessed *via* the EU Register of health claims.[2] A list of claims not on the Permitted List, including rejected and "on-hold" claims, can also be found on the Register.

John Dalli, Commissioner in charge of Health and Consumer Policy, said that the "*[D]ecision is the culmination of years of work and marks a major milestone in regulating health claims on food. The EU-wide list of permitted health claims will be available on-line and will allow consumers everywhere in the EU to make an informed choice. Non-scientifically backed claims will have to be removed from the market after a short transition period. Some work remains to be done and the Commission – with the needed scientific background - will now focus on concluding its work by tackling those claims which are still under consideration.*"

Background

In 2008, EU Member States submitted around 44,000 general health claims after input from food manufacturers. The European Commission consolidated these claims into a list of 4,600 claims. The Commission asked the European Food Safety Authority (EFSA) to review the claims on the list and determine whether they are supported by scientific evidence. However, in 2010,

[1] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.
[2] The Union Register can be found at: http://ec.europa.eu/nuhclaims/

the Commission announced that it was restructuring the review process so that the Permitted List of health claims would be adopted in two steps. The Commission said that the list of health claims for all substances other than so-called "botanicals" would be adopted in a single step. The Commission said that it would "reflect" on how to assess claims for botanicals. In addition, a number of claims were later added to the "on-hold" list pending further assessment, including (i) micro-organisms that were insufficiently characterized; and (ii) health claims where there was insufficient evidence of "cause and effect".

Of the remaining 2,758 non-botanical health claims reviewed by EFSA, only one in five claims (mostly for vitamins and minerals) were approved. EFSA rejected claims for a number of reasons, including insufficient characterization of the food and/or insufficient evidence demonstrating a "cause and effect" relationship between the food and the claim.

Around 2,200 entries, many of which concern botanical substances, are still awaiting assessment. The Commission has placed such claims "on-hold", however, the legal basis for putting such claims on-hold and the associated transitional periods are unclear. Nevertheless, the Commission has said that on-hold claims may continue to be used provided they comply with the Claims Regulation and applicable member state rules.

Implications for Manufacturers

Food manufacturers should act now to determine whether their commercial communications bearing health claims, including labeling and advertising, comply with the new arrangements. In particular, companies should assess whether all of their health claims benefit from the six month transitional period referred to above. Food manufacturers should therefore:

- Review all EU commercial communications that contain any health claims, including marketing materials, websites and food labeling, to ensure health claims comply with the Permitted List or otherwise fall under the "on-hold" list;

- Manage existing stock to accommodate the new rules, including relabeling/repackaging to remove/amend health claims where necessary. In particular, companies will need to consider whether foods bearing health claims that have already been placed on the market and that have a shelf life of more than six months need to be withdrawn from the market. Much will depend on enforcement attitudes and practices in individual member states. This issue is particularly important for food supplements, which typically have a shelf-life of 2 to 3 years; and

- Continue monitoring developments regarding claims on the "on-hold" list.

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