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EU-27 FAIRS Subject Report Nutrition & Health Claims - Update 2007

Approved by:

Kurt Seifarth U.S. Mission to the EU

Prepared by:

Hilde Brans

Report Highlights:

Regulation 1924/2006 on nutrition and health claims entered into force on January 19, 2007. Some of the provisions became applicable on July 1, 2007 but many still have to be established. This report provides an update on the implementation of Regulation 1924/2006.

Includes PSD Changes: No Includes Trade Matrix: No Annual Report Brussels USEU [BE2]

Nutrition & Health Claims - Update

Scope

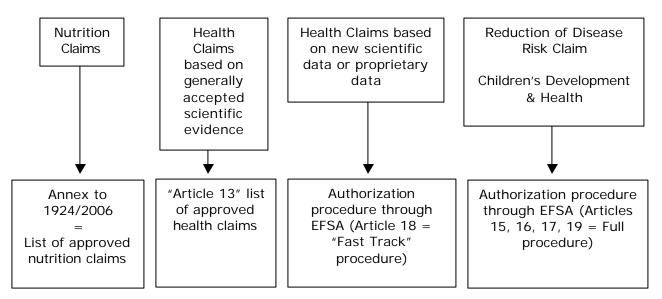
Regulation 1924/2006 on nutrition and health claims was published on January 18, 2007 and became applicable on July 1, 2007. It is important to know that the new rules apply to all commercial activities (label, websites, advertising, press) and not just to the label on the actual food product. Claims may only be used if a food product meets a certain "nutrient profile". Some of the provisions apply since July 1, 2007 but many still have to be established.

Provisions of the regulation began being applied on 7/1/2007 starting with:

- o Conditions for the use of nutrition claims (Annex to Reg. 1924/2006)
- o Nutrition labeling
- o Specific labeling requirements
- o Requirements for comparative claims
- o Claims that are not authorized
- o Possibility of a notification procedure for Member States

Aspects of the regulation that still have to be established include: nutrient profiles (by 2009), an EU positive list of health claims - the so-called "article 13" list (by 2010), a Commission Decision on authorized pictograms for nutrition claims.

Overview of authorization procedures for different types of claims



An EU positive list of allowed nutrition claims has already been established in the Annex to Regulation 1924/2006. Claims referring to the absence of an ingredient or component (other than nutrients) such as "lactose free" and to the absence of allergens such as "gluten free" are not considered to be nutrition claims in the context of this regulation.

The "article 13" list of generally accepted health claims will be established by 2010, based on Member States' national lists of authorized health claims which will be assessed by EFSA¹. A

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¹ EFSA = European Food Safety Authority

major concern for the food industry is the timetable for approving new claims. According to the Commission, companies cannot apply for the authorization of new claims based on new scientific evidence and proprietary data protection until the "article 13" list has been adopted. This would imply that companies could start submitting applications only in 2010. Another concern is whether EFSA will have the necessary resources to carry out its legally mandated work.

Approval of new health claims with proprietary data protection would expire after five years. If the claim still complies with the regulation after the five-year period, the Commission would submit a proposal for approval under the new Comitology procedure². If approved, the claim would have indefinite approval but the applicant would lose the proprietary data protection which means that other companies could use the scientific data and other information used to support the claim.

Regulation 1924/2006 classifies the different types of health claims a follows:

- o Function, growth & development claims (Article 13.1a)
- o Psychological and behavioral functions claims (Article 13.1b)
- Claims referring to slimming, weight-control, reduction in the sense of hunger, increase in the sense of satiety, reduction of the available energy from the diet (Article 13.1c)
- New claims based on newly developed scientific evidence and/or which include a request for the protection of proprietary data (Article 13.5)
- Disease risk reduction claims (Article 14)
- o Children's health and development claims (Article 14)

Nutrient profiles

Nutrient profiling is a food categorization model based on nutrient content (levels of fat, sugar, salt). EFSA has until January 2008 to provide scientific advice on this issue. The Commission has another year, until January 2009, to establish nutrient profiles through the new Comitology 2 procedure.

EFSA is organizing a scientific colloquium on nutrient profiles in October 2007.

Commission interpretation guidelines

The Commission is working on guidelines for the interpretation of Regulation 1924/2006 (publication is expected this fall). These guidelines will also clarify the interaction with the Directives relating to foodstuffs for particular nutritional uses and the Novel Food Regulation.

Transition periods

 Foods placed on the market or labeled prior to 7/1/2007: until expiry date or until 7/31/2009.

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² When EU legislative acts are adopted under the co-decision procedure, implementing powers are often delegated to the Commission. It is in this implementation phase that "Comitology" comes into play. Comitology refers to the committees composed of Member States experts which adopt measures needed for the implementation of EU laws. Under the "old" Comitology procedure, only the Council could block a Commission proposal. The "new" Comitology procedure gives the European Parliament the same blocking powers putting them on equal footing with the Council.

- Nutrition claims used in a Member State before 1/1/2006 which are not included in the Annex: until 1/19/2010.
- o Trade marks or brand names that can be interpreted as a nutrition or health claim that were on the EU market before 1/1/2005: until 10/19/2022.
- o Health claims referring to the role of a nutrient or other substance in growth, development and functions of the body and complying with national legislation: until the adoption of the article 13 list (1/31/2010 at the latest). In the meantime, national provisions continue to apply.
- o Reduction of disease risk claims and claims referring to children's development and health: no transition period. In June 2007, the Commission proposed an <u>amendment</u> to Regulation 1924/2006 to introduce a three-year transitional period for children's development and health claims. This should allow industry to adapt to the new rules, either by phasing out products which do not meet the new criteria or by applying for claim authorization. The proposal has to be adopted under the co-decision procedure.

Commercial Impact

At this point it is difficult to assess how Regulation 1924/2006 will impact the food industry. The following factors will play an important role in the commercial impact:

- o EU positive list of nutrition claims: how difficult will it be to extend the list?
- o Nutrient profiles: will certain food categories be excluded?
- o "Article 13" list: which health claims will be allowed?
- o New claims: will companies be able to submit an application for the authorization of a new claim before the "Article 13" list is adopted?
- o New Comitology² procedure: will it slow down authorizations?

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