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EUROPEAN UNION

REVIEW OF HEALTH CLAIMS MADE ON FOOD

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REVIEW OF HEALTH CLAIMS MADE ON FOOD

Executive Summary

Health claims made on food in the European Union are governed by Regulation No. 1924/2006 and its implementing regulations. Health claims are prohibited unless they meet certain key requirements, are assessed by the European Food Safety Authority (EFSA) based on scientific data, are authorized by the Commission, and are included in the EU lists of approved health claims.

Regulation No. 1924/2006 differentiates between “general function” health claims under article 13 and health claims that refer to the reduction of a disease under article 14. Both claims are subject to different authorization procedures. The EFSA plays an important role in providing scientific advice, upon assessing the scientific documentation provided for “general function” claims and claims regarding disease risk reduction. The European Commission makes the final decision on approved claims and on any conditions thereof, or rejected claims and reasons for rejection.

I. Legal Framework for Health Claims

Regulation (EC) No. 1924/2006 on Nutrition and Health Claims Made on Foods is the basic legal instrument that governs the requirements and approval process for nutrition and health claims in the European Union.¹ As a Regulation, it is binding and directly applicable in its entirety on all EU Members and needs no further legislative action by EU members. Regulation No. 1924/2006 imposes strict restrictions on health claims. Health claims are defined as “any claim that states, suggests, or implies that a relationship exists between a food category, a food or one of its constituents and health.”² Another pertinent definition relates to “reduction of disease risk claim” and it means “any health claim that states, suggests or implies that the

¹ Regulation (EC) No. 1924/2006 of the European Parliament and of the Council of December 20, 2006, on Nutrition and Health Claims Made on Foods, 2006 OFFICIAL JOURNAL OF THE EUROPEAN UNION [O.J.] (L 404) 9, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:404:0009:0025:EN:PDF>. Regulation No. 1924/2006 has been supplemented by implementing regulations. See Commission Regulation (EC) No. 353/2008 Establishing Implementing Rules for Applications for Authorisation of Health Claims, 2008 O.J. (L 109) 11, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008R0353:EN:NOT>; and Commission Regulation No. 1169/2009 amending Regulation No. 353/2008, 2009 O.J. (L 314) 34, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:314:0034:0035:EN:PDF>.

² Reg. (EC) No. 1924/2006, art. 2, para. 5.

consumption of a food category, or a food or one of its constituents significantly reduces a risk factor in the development of a human disease.³

The scope of Regulation No. 1924/2006 applies to health claims made during commercial communications and that appear in the labeling, presentation, or advertising of foods intended to be delivered to the final consumer. It also applies to foods sold unpacked or in bulk, and to foods intended for restaurants, hospitals, schools, canteens, and mass caterers.⁴ Claims such as “lactose-free” or “gluten free” that target a specific group of consumers are dealt with by Council Directive 89/398/1989 on the Approximation of the Laws of the Member States Relating to Foodstuffs Intended for Particular Nutritional Uses.⁵

A. Restricted Health Claims

Regulation No. 1924/2006 contains a category of certain health claims that are not allowed under any circumstances. These include (a) claims that indicate that general health could be affected by not consuming the particular food; (b) claims that refer to the rate or amount of weight loss; and (c) claims that refer to recommendations of individual doctors or medical associations not approved by the EU Members.⁶

B. Permitted Health Claims

As a rule, health claims are prohibited. They may be allowed, however, provided that they adhere to certain requirements.

There are two types of health claims:

- (1) “General function” health claims under article 13 of Regulation No. 1924/2006. Such claims may relate to the growth, development, and functions of the body; psychological and behavioral functions; or slimming or weight control.
- (2) Health claims that refer to the reduction of disease as provided in article 14 of the regulation. The second category is subdivided into (a) risk reduction claims of article 14, paragraph (1)(a) in reducing a risk factor in the development of a

³ *Id.* art. 2, para. 6.

⁴ *Id.* art. 1, para. 2.

⁵ Council Directive 89/398/EEC on the Approximation of the Laws of the Member States Relating to Foodstuffs Intended for Particular Nutritional Uses, 1989 O.J. (L 186) 27, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0398:EN:HTML>, as amended by Directive 2003/120/EC, 2003 O.J. (L 333) 51, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:333:0051:0051:EN:PDF>.

⁶ Reg. (EC) No. 1924/2006, *supra* note 1, art. 12.

disease;⁷ and (b) health claims referring to children's development under article 14(1)(b).⁸

Permitted health claims must comply with the following: (a) meet general and specific requirements; (b) be authorized; and (c) be included in the list of authorized claims.

C. General and Specific Conditions

Under the general requirements, health claims *inter alia* must not be false, ambiguous, or misleading; create doubts as to the safety and/or nutritional adequacy of other foods; encourage or condone excess consumption of food; or state changes to functions of the body that could raise or exploit fear in the consumer.⁹

Health claims are permitted if they meet certain key conditions as prescribed in articles 5 and 6 of Regulation No. 1924/2006. Some of these conditions are as follows:

- The presence, absence, or reduced content of a nutrient or other substance in a food on the basis of which the claim is made, “has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific data”;¹⁰
- The average consumer can be expected to understand the beneficial effects as contained in the claim;¹¹ and
- Health claims are based on and substantiated by generally accepted scientific data.¹²

Health claims that meet general requirements are permitted, provided that they adhere to the following specific conditions:

- Contain language in the labeling, or in the presentation and advertising indicating the significance of a balanced diet and healthy lifestyle; the quantity of the food and frequency of consumption required to obtain the claimed beneficial effects; a warning in case of excess consumption; and individuals who should avoid the specific food; and

⁷ The Commission cites as an example the following claim: “Plant stanol esters have been shown to reduce blood cholesterol. Blood cholesterol is a risk factor in the development of coronary heart disease.” European Commission Directorate General on Health and Consumers, *Health Claims: Type of Health Claims*, EUROPA, http://ec.europa.eu/food/food/labellingnutrition/claims/health_claims_en.htm (last updated July 12, 2011).

⁸ The Commission cites the following as an example of a health claim referring to children's development: “Vitamin D is needed for the normal growth and development of bone in children.” *Id.*

⁹ Reg. (EC) No. 1924/2006, *supra* note 1, art. 3.

¹⁰ *Id.* art. 5, para. 1(a).

¹¹ *Id.* art. 5, para. 2.

¹² *Id.* art. 6.

- Reference to general benefits of the specific food for the general well-being of people may be made if accompanied by a specific health claim included in the list of approved claims.¹³

II. Authorization Process

Health claims must be authorized through an application for an authorization to the national competent authorities of a Member State. The application must include the nutrient or other substance on the basis of which the claim is made, a copy of studies, and where available peer review studies pertaining to the health claim, as well as a copy of other studies relevant to the claim.¹⁴ There is a distinct authorization procedure for general function health claims under article 13 and those under article 14(1)(a) and (b).

A. Authorization Procedure for Health Claims Under Article 13

To be included in the list of authorized claims, “general function” health claims must meet two criteria: (a) be based on generally accepted scientific data; and (b) be well understood by the average consumer.¹⁵

The European Commission was given the authority to compile an EU list of allowed health claims other than those claims that refer to the reduction of disease risk and to children’s development and health. The twenty-seven EU Members provided the Commission with close to 44,000 health claims, which were subsequently consolidated into a list of 4,637 claims.¹⁶ The list is adopted through the Regulatory Committee procedure and after a consultation with the European Food Safety Authority (EFSA). EFSA is an independent European Agency, funded by the EU budget and established in 1992, that functions independently from the Commission, the European Parliament, and the EU Members.¹⁷ The EFSA publishes its opinions in series.

The European Food Safety Authority is authorized to evaluate the scientific evidence provided to substantiate general function health claims. During the period of July 2008 to March 2010, the Commission submitted to the EFSA a list of 4,637 claims. In order to protect European Union consumers from unsubstantiated health claims related to food placed on the

¹³ *Id.* art 10, paras. 2–3.

¹⁴ *Id.* art. 15.

¹⁵ *Id.* art. 13, para. 1.

¹⁶ European Commission, Directorate General on Health and Consumers, *Health Claims: Authorizing Procedures*, EUROPA, http://ec.europa.eu/food/food/labellingnutrition/claims/health_claims_en.htm (last updated July 12, 2011).

¹⁷ EFSA was established on the basis of Regulation No. 178/2002 Laying Down the General Principles and Requirements of Food Law and Establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety, 2002 O.J. (L 31) 1, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002R0178:EN:NOT>.

market, the Commission ordered the progressive adoption of a list of permitted health claims for all substances other than botanicals after which the claims on botanicals would be processed.¹⁸

Consequently, the EFSA evaluated the general function health claims, as were prioritized by the European Commission by the end of June 2011 and has published 341 opinions on 2,758 general function health claims.¹⁹ In May 2010, the EFSA published the complete list in the Access Database.²⁰ EFSA anticipates that it will complete its work on evaluating all health claims by December 31, 2011, contained in the consolidated list of article 13, which have not been adopted by EFSA.²¹

B. Authorization Procedure for Applications Under Article 14(1)(a) and (b)

Reduction of disease risk claims are authorized following the procedure described in articles 15–18 of Regulation No. 1924/2006 and are included in the list of permitted claims with all conditions that apply to them.²² Individual applications are sent to the national competent authorities, which must acknowledge receipt within fourteen days and inform the EFSA.²³ National authorities must also forward to the EFSA the application and any appended documentation.²⁴ The EFSA is responsible for informing the other EU Members and the Commission, and making a summary of the application available to the public.²⁵ The Commission, upon consulting the EFSA and the Regulatory Committee provided for in article 24, paragraph 2 of Regulation No. 1924/2006, was required to establish implementation rules for the application of article 15 and related to the preparation and presentation of the application.²⁶ To this effect, in 2008, the Commission adopted Regulation No. 353/2008 on Establishing Implementing Rules for Applications for Authorization of Health Claims as Provided for in Article 15 of Regulation (EC) No. 1924/2006.²⁷ Its Annex contains Technical Rules for the preparation and presentation of the application for health claims. Finally, the Commission in cooperation with the EFSA was also required to provide technical guidance to assist food business operators in the preparation and presentation of the application in order to be assessed

¹⁸ Press Release, European Union, Food: Commission Reviews the Progressive Adoption of the List of Permitted Health Claims, IP/10/1176 (Sept. 27, 2010), <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/1176&type=HTML>.

¹⁹ ‘General Function’ Health Claims Under Article 13, EUROPEAN FOOD SAFETY AUTHORITY (EFSA), <http://www.efsa.europa.eu/en/ndaclaims/ndaclaims13.htm> (last visited Oct. 26, 2011).

²⁰ *Id.* (click on “EFSA’s Register of Questions”).

²¹ EFSA’s Modus Operandi for Article 13(3) Health Claims of Regulation (EC) No. 1924/2006 (May 7, 2010), <http://www.efsa.europa.eu/en/ndaclaims13/docs/art13modusoperandi.pdf>.

²² Reg. No. 1924/2006, *supra* note 1, art. 14, para. 1.

²³ *Id.* art. 15, para. 2(a).

²⁴ *Id.*

²⁵ *Id.*, para. 2(b).

²⁶ *Id.*, para. 4.

²⁷ Reg. No. 353/2008, *supra* note 1.

scientifically.²⁸ Such guidance documents were adopted in 2007 and are available on the EFSA's website.²⁹

C. Role of the EFSA

The EFSA has a time limit of six months from the date of application to give its opinion. Such a deadline can be extended if the EFSA needs additional information.³⁰ The EFSA has the duty to confirm that the language of the health claim is supported by scientific data; assess whether the health claim adheres to the provisions of Regulation No. 1924/2006; and advise as to whether the proposed language of the health claim is understandable by the average consumer.³¹

In the case of a favorable opinion authorizing the health claim, the EFSA must forward its opinion to the Commission, the Member States, and the applicant; it will also prepare a report analyzing its assessment of the health claim and substantiate its decision.³² The EFSA is required to make its opinion publicly available.³³

D. Role of the Commission

The Commission, within three months of receiving the opinion of the EFSA, will submit to the Standing Committee on the Food Chain and Animal Health³⁴ a draft decision on the lists of permitted health claims after taking into account the opinion of the EFSA. If the Commission's decision differs from the opinion of the EFSA, the Commission must explain the reasons.³⁵ The Commission will adopt its final decision, inform the applicant, and publish details of the decision in the Official Journal of the European Union.³⁶

²⁸ Reg. No. 1924/2006, *supra* note 1, art. 15, para. 5.

²⁹ *Guidance for Applicants on Health Claims*, EFSA, <http://www.efsa.europa.eu/en/ndaclaims/ndaguidelines.htm> (last visited Oct. 27, 2011).

³⁰ Reg. No. 1924/2006, *supra* note 1, art. 16, para. 1.

³¹ *Id.*, para. 2 (see Appendix for a chart describing the procedural steps and citing a five-month period for the EFSA to assess claims and provide an opinion).

³² *Id.*, para. 5.

³³ *Id.*, para. 6.

³⁴ The Standing Committee on the Food Chain and Animal Health was established by article 58 of Regulation (EC) No. 178/2002, 2002 O.J. (L 31) 1, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF>.

³⁵ Reg. No. 1924/2006, *supra* note 1, art. 17, para. 1.

³⁶ *Id.*, paras. 3–4.

E. European Union Register

The European Union Register on Nutrition and Health Claims Made on Food³⁷ was established based on Regulation No. 1924/2006³⁸ and is often updated to provide information to the public on nutrition claims; authorized health claims and the conditions applying to them; rejected health claims and the grounds thereof; and health claims that have been approved based on proprietary data, which are kept in a separate Annex to the Register.³⁹

F. Safeguard Measures

Regulation No. 1924/2006 gives the EU Members the authority to temporarily suspend the use of a health claim within its territory, if that Member has serious grounds to conclude that the health claim is not well substantiated.⁴⁰

III. Case of Health Claims Related to Yogurt

In January 2011, the EFSA published its Scientific Opinion on the Substantiation of Health Claims Related to Live Yogurt Cultures and Improved Lactose Digestion.⁴¹ The opinion deemed that live yogurt cultures, which were the subject of the health claim, are sufficiently characterized in relation to the claimed effect. The claimed effect is “lactose digestion.” In examining the evidence, the opinion considered that thirteen out of fourteen human studies showed enhanced digestion of lactose in yogurt in those who suffer from lactose indigestion. The opinion concluded that a cause and effect relationship was established between the consumption of live yogurt cultures and improved digestion in those individuals who suffer from lactose intolerance. In order to bear the claim, however, the yogurt should contain at least 10⁸ CFU (colony forming units) live starter microorganisms per gram.⁴²

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³⁷ *European Union Register of Nutrition and Health Claims Made on Food—Introduction*, EUROPA, http://ec.europa.eu/food/food/labellingnutrition/claims/community_register/index_en.htm (last updated Aug. 16, 2010).

³⁸ Reg. No. 1924/2006, *supra* note 1, art. 19.

³⁹ *Id.*, para. 2.

⁴⁰ *Id.* art. 23.

⁴¹ EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), Scientific Opinion on the Substantiation of Health Claims Related to Live Yoghurt Cultures and Improved Lactose Digestion (ID 1143, 2976) Pursuant to Article 13(1) of Regulation (EC) No. 1924/2006, EFSA JOURNAL 2010:8(10) 1763, <http://www.efsa.europa.eu/en/efsajournal/doc/1763.pdf>.

⁴² *Id.*