

The new EC Regulation on nutrition and health claims on foods

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Abstract

The area of health claims has been unregulated in Europe until recently. A new regulation on nutrition and health claims made on foods came into force on 19 January 2007. The Regulation has been eagerly awaited by all parties involved. The Regulation includes 37 whereas clauses, 29 Articles and an annex for nutrition claims and conditions applying to them. In practice, three main types of health claim are included in the Regulation, as referred to in Articles 13 and 14. The type of the scientific evidence is described slightly differently for Article 13.1 and Article 13.5: "generally accepted scientific evidence" and "newly developed scientific evidence", respectively, although the scientific status of evidence shall be the same for all kinds of claims. So far, there are four types of guidance for applying the Regulation. The wording of health claims is an essential issue in the Regulation, as well as the concept of nutrient profiles. In the Regulation there are three issues of special interest, when compared to the Swedish Food Sector's Code of Practice, i.e. concerns about "other substances", "food supplements" and "the average consumer". The Regulation will be evaluated in 2013, reporting the impact of this Regulation on dietary choices and the potential impact on obesity and non-communicable diseases.

Introduction

The new 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 has been applied since 1 July 2007. It came into force on 19 January 2007 (1).

Although nutrition claims were regulated to some extent in 1990, within the directive on nutrition value declaration (2), the area of health claims has been unregulated in Europe until now. On 18 July 2003, the Commission presented the proposal for the Regulation (3) which is now under application (1). The Regulation has been eagerly awaited by all parties involved, i.e. by consumer organizations, e.g. the European Consumers' Organization (BEUC) (4), the food industry and the retailers, as well as by national authorities and the European Food Safety Authority (EFSA).

Scope

The Regulation includes 37 whereas clauses, 29 Articles (Table 1) and an annex for nutrition claims and conditions applying to them (Table 2). The whereas clauses are considerations of all the aspects regulated in the Articles in general terms. Some of the most important areas considered are consumer

aspects, the need for scientific evidence for making nutrition and health claims, and the need for protection of innovative data developed by the food industry. The scope is described in Article 1; it is "to harmonize the provisions laid down by law, regulation or administrative action in Member States by ensure the effective functioning of the internal market whilst providing a high level of consumer protection." The Regulation shall "apply to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer", and "shall also apply in respect of foods intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers."

Definitions of claims

In Article 2 there are definitions of the following concepts: "claim", "nutrient", "other substance", "nutrition claim", "health claim" and "reduction of disease risk claim".

The definition of a claim is: "any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any

Table 1. The 29 articles in 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

Chapter I. Subject matter, scope, definitions	
Article 1	Subject matter and scope
Article 2	Definitions
Chapter II. General principles	
Article 3	General principles of all claims
Article 4	Conditions for the use of nutrition and health claims
Article 5	General conditions
Article 6	Scientific substantiation for claims
Article 7	Nutrition information
Chapter III. Nutrition claims	
Article 8	Specific conditions
Article 9	Comparative claims
Chapter IV. Health claims	
Article 10	Specific conditions
Article 11	National associations of medical, nutrition or dietetic professionals and health-related charities
Article 12	Restrictions on the use of certain health claims
Article 13	Health claims other than those referring to the reduction of disease risk and to children's development and health
Article 14	Reduction of disease risk claims and claims referring to children's development and health
Article 15	Application for authorization
Article 16	Opinion of the Authority
Article 17	Community authorization
Article 18	Claims referred to in Article 13(5)
Article 19	Modification, suspension and revocation of authorizations
Chapter V. General and final provisions	
Article 20	Community register
Article 21	Data protection
Article 22	National provisions
Article 23	Notification procedure
Article 24	Sageguard measures
Article 25	Committee procedure
Article 26	Monitoring
Article 27	Evaluation
Article 28	Transitional measures
Article 29	Entry into force

form, which states, suggests or implies that a food has particular characteristics". Thus, brands and trade marks are also covered in the rules.

"Nutrition claim means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to:

- the energy (calorific value) it (i) provides; (ii) provides at a reduced or increased rate; or (iii) does not provide; and/or
- the nutrients or other substances it (i) contains; (ii) contains in reduced or increased proportions; or (iii) does not contain."

Table 2. List of the nutrition claims found in the annex of 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

Energy	Low, -reduced, -free
Fat	Low, fat-free
Saturated fat	Low, -free
Sugars	Low, -free, with no added
Sodium/salt	Low, very low, -free
Fibre	Source of, high
Protein	Source of, high
Vitamins, minerals ^a	Source of, high
Contains ^b	
Increased ^c	
Reduced	Reduced ^c
Light/lite	
Naturally/natural	

^a Name; ^b name of nutrient or other substance; ^c name of nutrient.

It should be noted that the word "beneficial" has been added into this definition, compared to the definition in the Guidelines of Codex Alimentarius (5) and in the Directive of nutrition labelling of foodstuffs (2).

A health claim is 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." The specific health claim, dealing with "reduction of disease risk claim", is defined as "any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease".

In practice, three main types of health claims are included in the Regulation, as referred to in Articles 13 and 14. For Article 13.1 there are three sub-groups (a–c). Furthermore there is one group of claims, referred to as Article 13.5.

The health claims are:

- reduction of disease risk claim (Article 14 claim)
- health claims referring to children's development and health (Article 14 claim)
- other health claims (Article 13 claim).

Article 13.1

- the role of a nutrient or other substance in growth, development and the functions of the body; or
- psychological and behavioural functions; or

- c) without prejudice to Directive 96/8/EC, slimming or weight control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet, which are indicated in the list.

Article 13.5

Claims based on newly developed scientific evidence and/or which include protection of proprietary data.

The classification of health claims is done partly depending on the market situation, and partly on earlier legal aspects on health claims. Article 14 claims are now allowed “notwithstanding Article 2(1)(b) of Directive 2000/13/EC”, i.e. “the labelling must not attribute to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties” (6).

The type of scientific evidence is described slightly differently for Articles 13.1 and 13.5: “generally accepted scientific evidence” and “newly developed scientific evidence”, respectively, although the scientific status of evidence shall be the same for all kinds of claims, expressed as follows in the Regulation. “Scientific substantiation should be the main aspect to be taken into account for the use of nutrition and health claims and the food business operators using claims’ should justify them. A claim should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence” (whereas clause 17).

Register for permitted claims

According to Article 20, the Commission shall establish and maintain a Community Register of nutrition and health claims made on food, including the following:

- a) the nutrition claims and the conditions applying to them as set out in the Annex (Table 2)
- b) restrictions adopted in accordance with Article 4(5) (nutrient profiles)
- c) the authorized health claims and the conditions applying to them provided for in Articles 13 and 14
- d) a list of rejected health claims and the reasons for their rejection.

The register should be regularly updated in order to take into account scientific and technological developments. According to Article 17.5, “health claims included in the lists provided for in Articles 13 and 14 may be used, in conformity with the conditions applying to them, by any food business operator, if they are not restricted for use in accordance with the provisions of Article 21.”

Nutrition claims

Table 2 shows the different kinds of nutrition claim that are permitted so far. The wording used in the annex could in practice be different from those listed, i.e. “any claim considered to have the same meaning for consumers as a nutrition claim included in the above-mentioned list should be subject to the same conditions of use indicated therein. For example, claims related to the addition of vitamins and minerals such as ‘with...’, ‘restored...’, ‘added...’, or ‘enriched...’ should be subject to the conditions set for the claim ‘source of...’” (whereas clause 21). A discussion is ongoing with regard to amending the annex to include nutrition claims for, for example, “source of” and “high” omega-3 fatty acids, as proposed in a report by EFSA (7), but including minimum conditions for both α -linolenic acid and very long-chain omega-3 fatty acids (8).

Article 13 and 14 claims

Member States shall provide the Commission with lists of claims as referred to in paragraph 13.1 by 31 January 2008 at the latest accompanied by the conditions applying to them and by references to the relevant scientific justification. The Commission shall, after consulting EFSA, in accordance with the procedure referred to in Article 25.2, adopt the list of permitted claims by 31 January 2010 at the latest.

The register of Article 13.1 claims will be based on proposals sent to the Commission by the 27 European Member States. In Sweden, the National Food Administration (NFA) is the authority responsible for this procedure. The Commission will then forward a list to EFSA, who will scrutinize the references from a scientific point of view. The Panel on Dietetic Products, Nutrition and Allergies (NDA) of EFSA will be assisted by international experts in this task. EFSA is now setting up a database of experts with experience in scientific substantiation of health claims.

In Sweden, the list including proposals for Article 13.1 claims, which will be sent to the Commission, will be based on lists proposed by the food industry itself. Work on these lists began in 2006. The NFA has invited two organizations to coordinate this task. The Swedish food supplement producer's association (Svensk Egenvärd) is the co-operating organization for the health food industry (e.g. food supplements) and the SNF Swedish Nutrition Foundation deals with claims for ordinary foods. Since 1990, SNF has had a co-ordinating role in the Food Sector's Code of Practice for "Health claims in the labelling and marketing of food products" (9, 10). NFA will also deal with proposals for Article 13.1 claims as sent directly to NFA by the food business operators. The deadline for proposals sent to NFA was 30 September 2007. NFA will have discussions concerning borderline questions with the Swedish Medical Products Agency.

Reduction of disease risk claims, according to Article 14, will only be listed in the Community Register after an application. This will be sent to the national competent authority of Member States, in Sweden to NFA. The procedure for the inclusion of these kinds of claims is described in Articles 15, 16, 17 and 19, and also in an EFSA guidance (11). The time schedule in this process is quite tight, and Article 14 claims can in principle appear on the Community list after a maximum of approximately 12 months, i.e. in principle before the year 2010, when the Article 13.1 list will be published, at the latest.

Guidance

For applying the Regulation there is a need for a guidance. So far, there are four types of guidance.

The NDA Panel of EFSA published "Scientific and technical guidance for the preparation and presentation of the application for the authorization of a health claim" on 26 July 2007 (11):

The purpose of the guidance is to assist applicants in preparing and presenting their applications for authorization of health claims which fall under Article 14 of the Regulation, i.e. reduction of disease risk claims and claims referring to children's development and health. The guidance will be updated at a later stage to cover applications for authorization of the health claims which fall under Article 18 of the Regulation, i.e. applications for inclusion of

health claims in the Community list of permitted claims provided for in Article 13.3 which are based on newly developed scientific evidence and/or which include a request for the protection of proprietary data. It is intended that the guidance will be kept under review and will be amended and updated as appropriate in the light of experience gained from evaluation of health claim applications.

Guide to compile an Article 13.1 list

In May 2007 a document was published, based on the explanatory notes made by CIAA, EHPM, ERNA for assisting Member States to compile a list of health claims according to Article 13.2 (12). During spring 2007, this document was discussed during the meetings of the Commission's experts group on nutrition and health claims. Contributions to the final text of the document have been made by delegations from the UK, Denmark, Ireland, Finland, France and the Netherlands. This document has been used in most Member States for the guidance of the list of health claims in Article 13.1. In Sweden the document was published on the NFA website on 29 June 2007.

Commission guidance

The Commission's expert group on nutrition and health claims has met several times since 11 July 2006. During these meetings Member States have had the chance to discuss interpretation issues with the Commission, and a guidance on the implementation has been on the agenda. During the meeting of 11 September 2007, it was stated that the Standing Committee on the Food Chain and Animal Health will, at their meeting in October 2007, deal with a proposal for this guidance. The topics for the guidance include interaction with other legislation, comparative claims and classification of claims.

National guidance

When new EU regulations and directives are published, it is common for authorities to publish a national guidance. Denmark, for example, published a proposal for a national guidance to the new Regulation in June 2007 (13). Since the Commission probably will publish its guidance late in 2007, Sweden is waiting for this publication.

Importance of wording

The wording of health claims is an essential issue in the Regulation. “In order to ensure that health claims are truthful, clear, reliable and useful to the consumer in choosing a healthy diet, the wording and the presentation of health claims should be taken into account in the opinion of the European Food Safety Authority and in subsequent procedures” (whereas clause 29).

Wording is mentioned in the EFSA guidance (11) as follows:

- a proposal for the wording of the health claim for which authorization is sought including, as the case may be, specific conditions for use (Article 15.3f)
- “that the wording of the health claim complies with the criteria laid down in this Regulation” (Article 16.2b)
- a proposal for the wording of the health claim, including, as the case may be, the specific conditions of use (Article 16.4c).

This is further elaborated in the EFSA guidance (11):

The application must contain a proposal for the wording of the health claim, including, as appropriate, the specific conditions of use. The following should be specified, with a rationale: the target population for the intended health claim; the quantity of the food/constituent and pattern of consumption required to obtain the claimed effect, and whether this quantity could reasonably be consumed as part of a balanced diet; and where appropriate, a statement addressed to persons who should avoid using the food/constituent for which the health claim is made; a warning for a food/constituent that is likely to present a health risk if consumed to excess; any other restrictions of use; directions for preparation and/or use.

Nutrient profiles

The concept of nutrient profiles is an important issue, which is dealt with in whereas clauses 11 and 12:

The application of nutrient profiles as a criterion would aim to avoid a situation where nutrition or health claims mask the overall nutritional status of a food product, which could mislead consumers when trying to make healthy choices in the context of a balanced diet.

The establishment of nutrient profiles should take into account the content of different nutrients and substances with a nutritional or physiological effect, in particular those such as fat, saturated fat, *trans*-fatty acids, salt/sodium and sugars, excessive intakes of which in the overall diet are not recommended, as well as poly- and monounsaturated fats, available carbohydrates other than sugars, vitamins, minerals, protein and fibre. When setting the nutrient profiles, the different categories of foods and the place and role of these foods in the overall diet should be taken into account and due regard should be given to the various dietary habits and consumption patterns existing in the Member States. Exemptions from the requirement to respect established nutrient profiles may be necessary for certain foods or categories of foods depending on their role and importance in the diet of the population. These would be complex technical tasks and the adoption of the relevant measures should be entrusted to the Commission, taking into account the advice of the EFSA.

According to Article 4, the Commission shall, by 19 January 2009, establish specific nutrient profiles.

Other issues of special interest

In the Regulation there are three issues of special interest, compared to the Swedish Food Sector's Code of Practice (14): concerns about “other substances”, “food supplements” and “the average consumer”.

Functional foods have been a topic since the mid-1980s. Over the years a significant amount of scientific evidence showing physiological effects of other substances, i.e. non-nutrients, has been published. Two groups of “other substances” are plant sterols/stanols and their esters and probiotics. The regulation is now opening up for the food business operators to use generic claims for such substances, which was possible within the Swedish Code of Practice only as “product specific physiological claims”, subject to scientific substantiation of specific products (14). In the Regulation this issue is mentioned in whereas clause 9:

There is a wide range of nutrients and other substances including, but not limited to, vitamins, minerals including trace elements, amino acids, essential fatty acids, fibre, various plants and herbal extracts with a nutritional or physiological effect that might be present in a food and be the subject of a claim. Therefore, general

principles applicable to all claims made on foods should be established in order to ensure a high level of consumer protection, give the consumer the necessary information to make choices in full knowledge of the facts, as well as creating equal conditions of competition for the food industry.

The annex includes a nutrition claim for “contain” an “other substance”.

The Regulation deals with health claims made for “food category, a food or one of its constituents”, thus including food supplements. In the Swedish Code of Practice “pharmaceutical-like forms, such as tablets or capsules, even if these are made from food raw materials” have not been included (14). The definition of “food supplement” set out in Directive 2002/46/EC shall apply (15).

Since providing a high level of consumer protection is one of aims of the Regulation, there are some aspects to be considered when applying the rules. A new concept is introduced in the Regulation, i.e. the “average consumer”. The following is said in whereas clause 16:

It is important that claims on foods can be understood by the consumer and it is appropriate to protect all consumers from misleading claims. However, since the enactment of Council Directive 84/450/EEC of 10 September 1984 concerning misleading and comparative advertising (1), the Court of Justice of the European Communities has found it necessary in adjudicating on advertising cases to examine the effect on a notional, typical consumer. In line with the principle of proportionality, and to enable the effective application of the protective measures contained in it, this Regulation takes as a benchmark the average consumer, who is reasonably well-informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors, as interpreted by the Court of Justice, but makes provision to prevent the exploitation of consumers whose characteristics make them particularly vulnerable to misleading claims. Where a claim is specifically aimed at a particular group of consumers, such as children, it is desirable that the impact of the claim be assessed from the perspective of the average member of that group. The average consumer test is not a statistical test. National courts and authorities will have to exercise their own faculty of judgment, having regard to the case-law of the Court of Justice, to determine the typical

reaction of the average consumer in a given case.

In Article 3 it is stated that the use of nutrition and health claims shall not be false, ambiguous or misleading. In Article 4.2 it is stated that “The use of nutrition and health claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim”. However, this aspect is not focused on in the EFSA guidance (11).

Restrictions on the use of certain health claims

Article 12 deals with restrictions on the use of certain health claims. The following health claims “shall not be allowed:

- a) claims which suggest that health could be affected by not consuming the food;
- b) claims which make reference to the rate or amount of weight loss;
- c) claims which make reference to recommendations of individual doctors or health professionals and other associations not referred to in Article 11.”

Transitional measures

In Article 28 there are six different paragraphs considering the transitional measures. Article 28.1 is the main paragraph:

Foods placed on the market or labelled prior to the date of application [i.e. 1 July 2007] of this Regulation which do not comply with this Regulation may be marketed until their expiry date, but not later than 31 July 2009. With regard to the provisions in Article 4.1., foods may be marketed until 24 months following adoption of the relevant nutrient profiles and their conditions of use.

The following paragraphs deal with trade marks and brand names (Article 28.2), nutrition claims which have been used in a Member State before 1 January 2006 (Article 28.3), nutrition claims in the form of pictorial, graphic or symbolic representation (Article 28.4), health claims as referred to in Article 13.1(a) (Article 28.5), and health claims other than those referred to in Articles 13.1(a) and 14 (Article 28.5).

Since Article 14 claims were not allowed earlier in the European Union, although applied in some

country Code of Practice, e.g. Sweden, transitional measures are thus missing for these types of claim, and they must comply with the Regulation from 1 July 2007.

Evaluation by 2013

In Article 27 it is stated:

By 19 January 2013 at the latest, the Commission shall submit to the European Parliament and to the Council a report on the application of this Regulation, in particular on the evolution of the market in foods in respect of which nutrition or health claims are made and on the consumers' understanding of claims, together with a proposal for amendments if necessary. The report shall also include an evaluation of the impact of this Regulation on dietary choices and the potential impact on obesity and non-communicable diseases.

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