REGULATION OF HEALTH AND NUTRITION CLAIMS IN THE EUROPEAN UNION

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SUMMARY
Nutrition and health claims made on food and food supplements are subject to European legislation which aims to protect the EU consumer from misleading or inaccurate claims used in labelling, marketing or advertising of food, but also to allow the food industry to use truthful and scientifically substantiated claims as a competitive marketing tool. This article provides historical background for the development of the EU Nutrition and Health Claims Regulation, describes the EU system of scientific assessment and authorisation of the claims, and also the on-going political debate with regard to health claims on plant substances, so called ‘botanicals’.

Key words: nutrition and health claims, food labelling, food supplements, EU food law, EFSA.

HISTORICAL BACKGROUND
At the end of the 90’s the EU rules on labelling\(^1\) and nutrition labelling\(^2\) of foods did not define conditions of use for nutrition claims, and in principle did not allow health claims. Consumers became more interested in nutrition issues and the relationship between diet and health, and the food industry had an interest to make claims about the beneficial effects of foods.

Although the EU labelling directives included a basic provision prohibiting the use of information that could mislead the purchaser, Member States and stakeholders viewed this general principle as not satisfactory for dealing with an increasing number of claims appearing on the labels. In the absence of specific provisions at the European level, some Member States adopted national legislations which resulted in different approaches to the use of these types of claims. These discrepancies among Member States were seen as barriers to consumer protection, the free movement of foodstuffs, and the proper functioning of the internal EU market\(^3\).

In light of this situation, there was movement to harmonise EU legislation with the objective of protecting consumers from misleading or inaccurate nutrition and health claims used in labelling, marketing or advertising of food, while also allowing the food industry to use such claims as are truthful and scientifically substantiated. The original rationale of the EU legislator was therefore not to prohibit all claims, but to allow certain claims which have supportive scientific evidence.
In January 2000 the European Commission published a 'White Paper on Food Safety' in which it considered introducing specific provisions to govern 'nutrition claims' and 'function claims'. In May 2001 the Commission published a discussion paper on claims which at that time included only 'nutrition' and 'functional' claims. The category of 'health claims', including 'disease risk reduction claims', was added in the Commission’s draft regulation presented in June 2002. The Commission put forward the proposal for the Nutrition and Health Claims Regulation in 2003, which was followed by intensive discussion in the European Parliament and at the Council. Ultimately, wide political agreement among the EU Institutions was reached in 2006, paving the way for final adoption and publication of the Regulation (EC) 1924/2006 on nutrition and health claims made on foods in December 2006. Food supplements, being part of food in the meaning of the EU General Food Law, were from the beginning fully integrated in the claims legislation.

**NUTRITION AND HEALTH CLAIMS**

The Regulation (EC) 1924/2006 (Claims Regulation) covers all claims on foods and food supplements made in commercial communication, i.e. labelling (including trade marks and brand names), advertising and promotion campaigns, as well as pictorial, graphic or symbolic representations.

Two types of claims are distinguished by the Claims Regulation: nutrition claims and health claims (Table 1).

**Table 1. EU definitions of nutrition and health claim made on foods and food supplements**

<table>
<thead>
<tr>
<th>NUTRITION CLAIM</th>
<th>HEALTH CLAIM</th>
</tr>
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<tbody>
<tr>
<td>A claim suggesting that a food has <strong>particular beneficial nutritional properties</strong> due to:</td>
<td>A claim suggesting that a <strong>relationship exists between a food and health</strong></td>
</tr>
<tr>
<td>- <strong>Energy</strong> it provides/ provides at a reduced or increased rate/ does not provide, e.g. ‘low energy’, ‘energy reduced’, ‘energy-free’</td>
<td>- <strong>General function claim - Article 13</strong></td>
</tr>
<tr>
<td>- <strong>Nutrients</strong> or other substances it contains/ contains in reduced or increased proportions/ or does not contain, e.g. ‘source of omega-3 fatty acids’, ‘low fat’, ‘sugar-free’</td>
<td>- A health claim referring to the role of a nutrient in growth, development and the <strong>functions of the body</strong>, psychological and behavioural functions, slimming or weight-control, e.g. ‘magnesium contributes to normal muscle function’</td>
</tr>
<tr>
<td></td>
<td>- Based either on generally accepted scientific evidence - Article 13(1) claim - or on newly developed scientific evidence - Article 13(5) claim</td>
</tr>
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<td>- <strong>Reduction of disease risk claim - Article 14(a)</strong></td>
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<td>- A health claim stating that the consumption of a food significantly reduces a risk factor in the development of a human disease, e.g. ‘plant sterols have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease’</td>
</tr>
<tr>
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<td>- <strong>Children claim - Article 14(b)</strong></td>
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<tr>
<td></td>
<td>- A health claim referring to children’s development and health, e.g. ‘calcium is needed for normal growth and development of bone in children’</td>
</tr>
</tbody>
</table>
Nutrition claims refer to energy or nutrient content of food (e.g. 'low energy', 'no added sugars', 'source of fibre'). At the time of this publication, the only permitted nutrition claims are thirty claims listed in the Annex to the Claims Regulation (Appendix I). The European Commission can propose additional nutrition claims if appropriate, e.g. a new nutrition claim 'no added sodium/salt' and additional conditions for a 'reduced saturated fat' claim have been added to the Annex in 2012.

Health claims suggest a relationship between food and health. Health claims are further divided into three more specific categories: general function claims (so called Article 13.1) referring to growth, development and the functions of the body and to psychological and behavioural functions, e.g. 'magnesium contributes to normal muscle function'; disease risk reduction claims (Article 14(a)), e.g. 'plant sterols have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease'; and children claims (Article 14(b)) referring to children's development and health, e.g. 'calcium is needed for normal growth and development of bone in children'.

The Claims Regulation requires that all health claims shall be truthful, clear, reliable and useful to the consumer in a sense that an average, reasonably well-informed consumer is expected to understand the beneficial effects expressed by a claim. False, misleading or ambiguous nutrition and health claims are not permitted and it is a food manufacturer's responsibility to scientifically justify a health claim.

CLAIMS AUTHORISATION PROCEDURE

In order to get an EU authorisation, all health claims must be submitted to the European Food Safety Authority (EFSA) to undergo scientific assessment carried out by the Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA).

The NDA Panel is comprised of 20 independent scientists from different EU Member States with expertise in various fields (e.g. human nutrition, toxicology, immunology, biochemistry, epidemiology and medicine).

Companies wishing to submit an individual application for authorisation of a health claim can apply to EFSA via national competent authority of a Member State which then sends the application file to EFSA (Figure 1).

Figure 1. Individual application procedure for authorisation of a health claim in the EU

Company prepares an individual health claim application (Art.13.5 or Art.14) and submits it the national competent authority

National competent authority verifies validity of the application and submits an application to EFSA

EFSA performs a scientific risk assessment and publishes a Scientific Opinion
A health claim dossier shall include information on characteristics of food for which the claim is made, a proposal for wording of a claim, and conditions of use and pertinent scientific data which form the basis for the substantiation of a claim\(^\text{18}\). The applicant may also request protection of confidential proprietary data included in the application. After a completeness check by EFSA Application Desk Unit, the NDA Panel verifies the quality of scientific evidence provided by the applicant (Figure 2).

**Figure 2. Scientific data which can be included in an application for a health claim\(^\text{18}\)**

- **HUMAN DATA**
  - Intervention studies (RCT prefered over non-controlled studies)
  - Observational studies (cohort, case-control, cross-sectional studies)
  - Meta-analyses
  - Systematic reviews
  - Text books

- **NON-HUMAN DATA**
  - In-vitro studies
  - Animal studies

Human studies in healthy populations are pivotal to assessments by the NDA Panel to conclude that a relationship between food and health is supported by credible evidence. In general terms, human studies should have appropriate design, should be carried out using the food/constituent for which a claim is made, should have appropriate outcome measures for the claimed effect and shall be performed on a study group which is representative for the target group of the claim (or on a group from which it is possible to extrapolate the study results to a target population). More specific requirements (e.g. type of study, biomarkers, endpoints, study population) are published in the form of EFSA guidelines documents divided into six specific categories of claims i.e., nervous system and psychological functions\(^\text{19}\); physical performance\(^\text{20}\); bone, joints, skin and oral health\(^\text{21}\); appetite ratings, weight management and blood glucose concentrations\(^\text{22}\); antioxidants, oxidative damage and cardiovascular health\(^\text{23}\); gut and immune system\(^\text{24}\).

Animal, in-vitro and other studies may be used to support the human studies, e.g. by explaining the mechanism of action of a food or food ingredient.

EFSA has a time limit of five months to publish a Scientific Opinion, however this time can be extended by a so called ‘stop-the-clock’ procedure if additional information is sought from the applicant. The main reasons for EFSA seeking additional information from the applicant are questions on the studies supporting the proposed claims, in particular on statistics\(^\text{25}\). The applicant has 15 days to formally reply to EFSA’s ‘stop-the-clock’ letter and provide the NDA Panel with requested clarifications.

Taking into account the totality of scientific evidence, the EFSA NDA Panel decides if a cause and effect relationship between consumption of a food/constituent and the health effect is established.
Once the Scientific Opinion of EFSA NDA Panel is published, the applicant or members of the public may make comments to the Commission within 30 days. In light of the comments received the NDA Panel decides if it is necessary to change its previous conclusions. EFSA response to the comments is made public.

**Figure 3. EFSA NDA Panel scientific assessment of health claims application**

Following a scientific assessment by EFSA, health claims are presented for authorisation through a ‘Committee Procedure’, i.e. by the Standing Committee on the Food Chain and Animal Health, where the European Commission is assisted by the EU Member States representatives. The Committee decision is then subject to a three-month scrutiny period of the European Parliament (EP) and the Council (Figure 4).

**Figure 4. EU decision-making process for claims authorisation**

**LIST OF PERMITTED ‘GENERAL FUNCTION’ HEALTH CLAIMS**

The Claims Regulation required the European Commission to create a Community list of permitted health claims on the basis of claims commonly used in the EU Member States and based on generally accepted scientific evidence e.g. ‘calcium is good for your bones’. The process started in 2008 with the submission of national lists from EU Member States covering over 44,000 proposed health claims based on generally accepted scientific evidence. Around 10,500 similar health claims were clustered by the European Commission into a single consolidated list of 4,637 claims which was then sent to EFSA for scientific assessment. Since 2008 EFSA NDA Panel has been systematically assessing the scientific evidence provided and has published several batches of scientific opinions, with a final publication issued in August 2012 (Figure 5).
On the basis on scientific opinions delivered by EFSA, the European Commission and the EU Member States agreed on a final list of permitted ‘general function’ claims which was published in the Official Journal of the European Union in May 2012\textsuperscript{26}. The final, long-awaited list included only 222 permitted health claims (i.e., less than 10% of those submitted) and the overwhelming majority of these were claims on vitamins and minerals relating to various functions of the body, for instance ‘vitamin C contributes to the normal function of the immune system’.

Following the publication of the list of permitted health claims, the remaining non-authorised claims have been listed in the on-line EU Register of Nutrition and Claims\textsuperscript{27} and are, as of 14 December 2012, no longer allowed. The list of permitted health claims has been amended in June 2013\textsuperscript{28} by a few additional claims. The remaining claims which did not get an EU authorisation have been inserted in the EU Register as ‘non authorised’ and the food and food supplements manufacturers were given six months, until 2 January 2014, to remove them from the EU market. These include for instance claims on a beneficial role of probiotic bacteria in the immune or digestive system and claims on glucosamine and joint health.

**BOTANICAL CLAIMS AND NUTRIENT PROFILES PENDING A DECISION**

Although the EU authorisation process for ‘general function’ health claims\textsuperscript{29} has been finalised, 2,078 health claims from the original consolidated list submitted to EFSA are still pending a decision on how EFSA shall assess them. These are health claims for herbal substances, or so called ‘botanicals’ or ‘botanical health claims’.

The Claims Regulation requires a scientific assessment ‘of a highest possible standard’ of all claims, including those on ‘various plants and herbal extracts’\textsuperscript{30}. EFSA has already assessed a number of
botanical claims, concluding that the evidence provided was not sufficient to substantiate these claims, noting lack of pertinent scientific studies in humans.

Following publication of negative EFSA Scientific Opinions on botanical claims, some concerns were raised that the approach of the Claims Regulation on the quality of scientific evidence supporting a claim is too strict and does not recognise the ‘peculiarity’ of botanical substances. In particular it was claimed that the ‘traditional use’ of botanicals in food supplements should be sufficient to substantiate a health claim, without submitting human studies showing a relationship between food and health. The European Commission decided that the issue required further reflection and asked EFSA to stop the scientific assessment of botanical claims in September 2010. Since then, the Commission and Member States have been reflecting on how to address this issue, leaving over 2,000 botanical claims still in use on the market.

In the EU, certain herbal substances can be present both in food (often in food supplements) and in herbal medicines. The EU Member States have a right to decide, on a case-by-case basis, whether a substance belongs to a food or a medicine category.

As a part of this process, at the end of July 2012, the European Commission circulated a discussion paper on health claims on botanicals used in foods. The paper suggests two possible scenarios for future assessment of botanicals claims. In ‘option 1’, EFSA would be asked to resume its assessment of health claims on botanicals with no changes to the approach. In ‘option 2’, botanicals would be considered as a particular case in the food area which would be addressed through a review of the legislation, recognising ‘traditional use’ as sufficient evidence to substantiate claims made on botanicals.

The proposal of a new legal measure for botanical claims has been controversial. Consumer organisations have called for equal standards of scientific assessment of all health claims made on foods, with no exceptions for botanicals. The EU Heads of Medicines Agencies (HMA) expressed concerns that making a special provision for botanical health claims on foods by accepting lower grade evidence, or relying on traditional use alone, might have important market implications in the area of herbal medicines. In the EU, foodstuffs do not undergo a safety assessment before being placed on the market. The food business operator holds a primary legal responsibility for ensuring food safety. The HMA concern is that if special provisions are made for botanical health claims, there would be no safety assessment in addition to assessment of health claims before they go on the market. In contrast, botanicals registered as traditional herbal medicinal products undergo safety assessments prior to being put on the market. As a result there could be the possibility that the marketing authorisation holder of herbal medicinal products would register products as food supplements in order to avoid scrutiny on safety and quality considerations.

At the time of this publication the European Commission has not taken a decision on the next steps. In the meantime, the botanical health claims remain ‘on hold’ and may continue to be used on the EU market under the responsibility of the food manufacturer, provided they comply with the Claims Regulation in general and existing national provisions applicable to them.

Another pending issue is setting the nutrient profiles for foods bearing nutrition and health claims.
According to the Claims Regulation, products bearing health claims shall fulfil certain nutritional criteria (so called ‘nutrient profiles’), in particular the content of fat, saturated fat, trans fatty acids, salt/sodium and sugars. So far, the establishment of nutrient profiles has not been finalised by the European Commission and the Members States although the Regulation had set a legal deadline of January 2009.

CONCLUSION

The adoption of the Nutrition and Health Claims Regulation in 2006 marked an important milestone by setting a general principle that health claims should only be authorised for use after a scientific assessment of the highest possible standard. The primary scope of the Regulation was to protect consumers from misleading or inaccurate claims and also to allow the food industry to use truthful and scientifically substantiated claims.

Although the implementation process of the Claims Regulation started over five years ago, the EU is still awaiting some important policy decisions such as on further scientific assessment of health claims on botanicals and on setting the nutrient profiles for foods. Nonetheless the Regulation has been partly implemented, resulting in EFSA assessment of thousands of health claims and the creation of an EU ‘positive’ list of more than 200 health claims. This list is systematically updated as the food manufacturers, following latest developments in food science, continue to send individual applications to EFSA, which regularly evaluates new health claims and publishes its Scientific Opinions.

However, the EU system for nutrition and health claims created a gap for thousands of ‘botanical’ health claims. These claims are still pending a EU decision on the best way to assess the quality of science supporting the beneficial claims of herbal substances used in food and food supplements.

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11. Recital (29) of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods
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28. Commission Regulation (EU) No 536/2013 amending Regulation (EU) No 432/2012 establishing a list of permitted health claims made on foods other than those referring to the reduction of disease risk and to children’s development and health
29. See definition of ‘general function health claims in Table 1.
30. Recital 9 of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods

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36. As listed in the Annex of Regulation (EU) No 432/2012 establishing a list of permitted health claims

APPENDIX

Appendix I. Examples of nutrition claims allowed on food and food supplements in the EU

HIGH FIBRE
- The product contains at least 6g of fibre per 100g or at least 3g of fibre per 100 kcal.

SOURCE OF PROTEIN
- Where at least 12% of the energy value of the food is provided by protein.

HIGH PROTEIN
- Where at least 20% of the energy value of the food is provided by protein.

SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S]
- The product contains at least 15% of recommended daily allowances (RDA) per 100g/ml or per package if a package contains a single portion (as defined in the Annex to Directive 90/496/EE)

HIGH [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S]
- The product contains at least 30% of recommended daily allowances (RDA) per 100g/ml or per package if a package contains a single portion (as defined in the Annex to Directive 90/496/EE)

CONTAINS [NAME OF THE NUTRIENT OR OTHER SUBSTANCE]
- The product complies with all the applicable provisions of this Regulation, and in particular Article 5. For vitamins and minerals the conditions of the claim ‘source of’ shall apply.

INCREASED [NAME OF THE NUTRIENT]
- The product meets the conditions for the claim ‘source of’ and the increase in content is at least 30% compared to a similar product.
Appendix I - continued

**REDUCED [NAME OF THE NUTRIENT]**

- The reduction in content is at least 30% compared to a similar product. For micronutrients a 10% difference in the reference values (as set in Directive 90/496/EEC) is acceptable; for sodium/salt a 25% difference is acceptable.

**LIGHT/LITE**

- The same conditions as those set for the term ‘reduced’; the claim shall also be accompanied by an indication of the characteristic(s) which make(s) the food ‘light’ or ‘lite’.

**NATURALLY/NATURAL**

- A food naturally meets the condition(s) for the use of a nutritional claim, the term ‘naturally/natural’ may be used as a prefix to the claim.

**SOURCE OF OMEGA-3 FATTY ACIDS**

- The product contains at least 0.3g alpha-linolenic acid per 100g and per 100kcal, or at least 40mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g and per 100kcal.

**HIGH OMEGA-3 FATTY ACIDS**

- The product contains at least 0.6g alpha-linolenic acid per 100g and per 100kcal, or at least 80mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g and per 100kcal.

**HIGH MONOUNSATURATED FAT**

- At least 45% of the fatty acids present in the product derive from monounsaturated fat under the condition that monounsaturated fat provides more than 20% of energy of the product.

**HIGH POLYUNSATURATED FAT**

- At least 45% of the fatty acids present in the product derive from polyunsaturated fat under the condition that polyunsaturated fat provides more than 20% of energy of the product.

**HIGH UNSATURATED FAT**

- At least 70% of the fatty acids present in the product derive from unsaturated fat under the condition that unsaturated fat provides more than 20% of energy of the product.
### Appendix II. Examples of Article 13.1 health claims allowed on food and food supplements in the EU

#### Calcium
- Calcium is needed for the maintenance of normal bones.
- The claim may be used only for food which is at least a source of calcium as referred to in the claim source of [Name of vitamin/s] and/or [Name of mineral/s].

#### Creatine
- Creatine increases physical performance in successive bursts of short-term, high intensity exercise.
- The claim may be used only for food which provides a daily intake of 3g of creatine.
- The claim may be used only for foods targeting adults performing high intensity exercise.

#### Dried Plums/Prunes
- Dried plums/prunes contribute to normal bowel function.
- The claim may be used only for food which provides a daily intake of 100g of dried plums (prunes).

#### Folate
- Folate contributes to maternal tissue growth during pregnancy.
- The claim may be used only for food which is at least a source of folate as referred to in the claim source of [Name of vitamin/s] and/or [Name of mineral/s].

#### Melatonin
- Melatonin contributes to the alleviation of subjective feelings of jet lag.
- In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a minimum intake of 0.5mg to be taken close to bedtime on the first day of travel and on the following few days after arrival at the destination.

#### Monascus Purpureous (Red Yeast Rice)
- Monacolin K from red yeast rice contributes to the maintenance of normal blood cholesterol levels
- The claim may be used only for food which provides a daily intake of 10mg of monacolin K from red yeast rice

#### Oat Grain Fibre
- Oat grain fibre contributes to an increase in faecal bulk.
- The claim may be used only for food which is high in that fibre as referred to in the claim HIGH FIBRE.

#### Olive Oil Polyphenols
- Olive oil polyphenols contribute to the protection of blood lipids from oxidative stress.
- The claim may be used only for olive oil which contains at least 5mg of hydroxytyrosol and its derivatives (e.g. oleuropein complex and tyrosol) per 20g of olive oil.

#### Pectins
- Pectins contribute to the maintenance of normal blood cholesterol levels.
- In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 6g of pectins.
- Warning of choking to be given for people with swallowing difficulties or when ingesting with inadequate fluid intake - advice on taking with plenty of water to ensure substance reaches stomach.
Appendix II - continued

### PLANT STEROLS AND STANOLS
- In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of at least 0.8g of plant sterols/stanols.

### PROTEIN
- Protein contributes to a growth in muscle mass.
- The claim may be used only for food which is at least a source of protein as referred to in the claim SOURCE OF PROTEIN.

### RIBOFLAVIN (VITAMIN B2)
- Riboflavin contributes to the maintenance of normal skin.
- The claim may be used only for food which is at least a source of riboflavin as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S].

### VITAMIN C
- Vitamin C contributes to the normal function of the immune system.
- The claim may be used only for food which is at least a source of vitamin C as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S].

### WATER
- Water contributes to the maintenance of normal physical and cognitive functions.
- In order to bear the claim, information shall be given to the consumer that in order to obtain the claimed effect, at least 2.0L of water, from all sources, should be consumed per day.
- The claim may be used only on water complying with Directives 2009/54/EC and/or 98/83/EC.