Nutrition and Health Claims in the EU: Key provisions

Directorate General for Health and Food Safety

These slides accompany the explanation of the acquis to Albania and North Macedonia and can only be used for that purpose. Their content is subject to further development of the acquis and interpretation by the Court of Justice of the European Union

Unit E.1, Food information and composition, food waste

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Nutrition and Health Claims in the EU

- 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 (HNC Regulation)

Entered into force on 19 January 2007

Applicable from 1 July 2007

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1924-20121129&rid=4

Scope of the Regulation

- Claims made in commercial communications including:
  - Generic advertising
  - Promotional campaigns

- Does not apply to claims made in non-commercial communications
  - Dietary guidelines or advice by public authorities
  - Information in the press or scientific publications

Claims

Claim: '*any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics" (Art. 2.1)*

Nutrition Claim: *"any claim which states, suggests or implies that a food has particular beneficial nutritional properties…" (Art. 2.4)*
e.g. "High in Vitamin C"

Health Claim: *"any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health"* (Art. 2.5)

Art. 13
- Growth, development, function of the body
- Psychological, behavioural functions
- Slimming/weight control, hunger, satiety, reduction of available energy

e.g. "Vitamin C contributes to the normal function of the immune system"

Art. 14
- Reduction of disease risk claims

e.g. "Plant stanol esters have been shown to reduce blood cholesterol. Blood cholesterol is a risk factor in the development of coronary heart disease"

- Claims referring to children's growth and development

e.g. "Calcium is needed for normal growth and development of bone in children"

General principles and conditions

- **Nutrition and health claims shall not (Art. 3):**
  - *"be false, ambiguous or misleading"*
  - *"give rise to doubt about the safety and/or the nutritional adequacy of other foods"*
  - *"encourage or condone excess consumption of a food"*
  - *"state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general"*
  - *"exploit fear in the consumer"*

General principles and conditions

Nutrition and health claims shall (Art. 5)

- Refer to a beneficial nutritional/physiological effect
- Refer to the food ready for consumption in accordance with the manufacturer's instructions
- Be accompanied by nutrition information (Art. 7)

The nutrient/substance on which the claim is made shall (Art. 5)

- Be present in the final product in a quantity to produce the claimed effect
- Where applicable, be readily available to be used by the body

Reasonable consumption of the product shall provide a significant quantity of nutrient/substance to produce the claimed effect (Art. 5)

General principles and conditions

Health claims shall not refer to prevention, treatment or cure of a disease

Health claims shall be accompanied by information on (Art. 10)

- Importance of balanced diet / healthy lifestyle
- Quantity of the food / pattern of consumption required to obtain the claimed effect
- Where appropriate, persons who should avoid using the food
- Appropriate warning related to excess consumption of the food

Health claims shall not (Art. 12)

- Suggest that health could be affected by not consuming the food
- Make reference to rate or amount of weight loss
- Make reference to recommendations of individual doctors or health professionals

General well-being claims ➔ link to a specific health claim complying with the Regulation (Art. 10.3)

General principles and conditions

- Nutrition and Health claims shall be based on and substantiated by **generally accepted scientific evidence (Art. 6.1)**
  - Recital 17 "*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*"
  - Recital 23 "*Health claims should only be authorized for use in the Community after a scientific assessment of the highest possible standard*"
- **Health claims shall be understandable for the average consumer**

Other legitimate factors

However…

Authorisation of scientifically substantiated health claims may also be refused due to other ***legitimate factors****. (Article 17.1)*

Criteria for substantiation

Regulation – health claims should be substantiated by:

- "*Generally accepted scientific evidence*"
- "*Taking into account the totality of the available scientific data*"
- "*Weighing the evidence*"

EFSA criteria for scientific substantiation:

- Relevance to human health
- Causality of the relationship
- Food quantity required for claimed effect
- Representativeness of data for target population

Main issues addressed by the NDA Panel

Defining the claim

1. Is the food/constituent defined and characterised ?
2. Is the claimed effect defined and is it a beneficial physiological effect ?

Substantiation

3. Is a cause and effect relationship established between consumption of the food/constituent and the claimed effect ?
   - for the target group and under the proposed conditions of use
   - Human data are central

➢ Scientific substantiation requires a favourable outcome to ALL three questions

Use of permitted claims

For all claims:

- Only authorised claims may be made
- If in compliance, all operators may use authorised claims, subject to principles and conditions:
  - Limited flexibility allowed for wording
  - Compliance with specific conditions of use of the claim AND
  - Compliance with other general principles and conditions

- Subject to compliance with nutrient profiles (not yet adopted)

- Possibility to protect data for 5 years

Union lists of claims

- **Nutrition claims - List of permitted claims in Annex of Regulation (EC) No 1924/2006**
  - Amendments to the Annex (Art. 8)

- **Health claims – Lists of permitted claims to be adopted**

  - 'Function' Article 13 health claims
  - Reduction of disease risk claims and claims referring to children's development and health

Nutrition claims

- The list of permitted nutrition claims is fully applicable since January 2010 and now contains 30 permitted claims

- First revision introduced 5 new nutrition claims on unsaturated fat, like omega-3 fatty acids (2010)

- Second revision introducing the new claim 'with no added sodium/salt' and modifications to the conditions of use of the 'reduced [name of the nutrient]' claim (2012)

Health Claims: Where do we stand today?

267 permitted health claims

2145 health claims under consideration

2059 non-authorised health claims

* Function claims: **229**, Art.13(5): **5**, Proprietary data: **3**, Disease risk reduction: **14**, Children claims: **11**

http://ec.europa.eu/nuhclaims/?event=register.home

'Function' Article 13(1) claims remaining 'on hold'

Where we stand today:

- **2095 IDs remaining 'on hold'**

  2078 IDs on botanicals

  17 IDs were put on hold in June 2013 either for further assessment by EFSA or for further consideration by risk managers (e.g. caffeine, foods with reduced lactose)

- **Claims 'on hold' are:**

  Listed on SANCO website

  Allowed to remain on the market until finalisation of their consideration

EU Register

http://ec.europa.eu/nuhclaims

- **Interactive** database

- Useful **additional information** for operators and consumers such as:

  - List of **permitted** claims with wording, condition of use, restrictions
  - List of **non-authorised** claims with **reasons**, such as:
    - Substance not characterised
    - Claimed effect too general to be assessed
    - Claim not substantiated
  - List of claims **"on hold"**

Guidance for the application of the rules

Member States are responsible for the enforcement of EU rules

- **Guidance of 2007**
- **EU guidelines for the implementation of specific conditions in Article 10 of Regulation (EC) No 1924/2006 (Decision 2013/63/EU)**
- **Member States' guidance document on flexibility of wording**

Evaluation of Regulation (EC) No 1924/2006 on nutrition and health claims

It focusses on:

- **nutrient profiles;**

- **health claims on botanicals in food,** including the **more general regulatory framework** for their use in food

REFIT Evaluation - Nutrient profiles

- **Foods can bear claims if they comply with nutrient profiles**
- **Derogations** foreseen for nutrition claims
- EFSA opinion adopted in 2008
- Strong **opposition** from many food sectors / Some support from certain sectors
- Strong **support** for the concept from consumer and health NGOs
- Not a condition for food to bear claims at this stage, as not adopted

REFIT evaluation on health claims on Botanicals

Reflection on 'botanicals' became inevitable:

- Suspension of the risk assessment and risk management on botanicals in 2010: on-hold list
- Similar ingredients in Food Supplements and Traditional Herbal Medicinal Products (THMP)
- Evidence of 'traditional use' accepted for therapeutic indications on THMP and not for claims on foods
- Stricter requirements for the placing on the market of THMP

REFIT evaluation on the use of Botanicals

- Whether the current legislative framework applicable to botanicals is sufficient in terms of safety of the use of botanicals and the smooth functioning of the internal market?

Timeframe of the REFIT evaluation

- Publication of the Roadmap - October 2015;
- Launching of the External Study - May 2016;
- Workshops with Member States and Stakeholders – June 2016;
- Draft final report submitted – End September 2017;
- Second workshops with Member States and Stakeholders – 26 and 27 October 2017;
- Finalisation of external study – June 2018;
- Results of the evaluation (Commission Staff Working document) expected for end of June 2019.

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