



Health claims: results and experience from implementing the law in the EU

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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**
 - “Function” claims:
 - Art. 13 procedure → Union list
 - Additions: Art. 18 procedure - “new developed scientific evidence and/or based on proprietary data” (Art. 13.5)
 - Reduction of disease risk claims and claims referring to children’s development and health:
 - Art. 15, 16, 17 and 19 procedure → Individual authorisation → Union list

Nutrition claims

- The list of permitted nutrition claims is **fully applicable** since January 2010
- **First revision** finalised in February 2010 introducing 5 new nutrition claims on unsaturated fat, like omega-3 fatty acids
- **Second revision** currently under the scrutiny of the European Parliament and the Council
 - Introducing the claim 'with no added salt/sodium' and
 - Modifying conditions of use for the 'REDUCED' claim

Particular challenges in implementing the regulation/authorisation of claims

- Level of scientific substantiation
- Understanding of claims by the consumer
 - Average consumer/targeted consumer
- Wording of claims
 - Scientific → consumer perception
 - Linguistic/cultural aspects

Art. 13(5) / Art. 14 health claims (Individual applications)

- Commission has received **148 EFSA opinions**
- For the majority, the applicant/public made comments to the Commission – Article 16(6) of Regulation
- Scientific comments are transmitted to EFSA and a response is provided
- Comments and EFSA response to comments on SANCO's website:

http://ec.europa.eu/food/food/labellingnutrition/claims/comments_efsa_en.htm

Art. 13(5) / Art. 14 health claims (Individual applications)

- 19 authorised and 77 rejected claims (published in OJ)
- 52 claims under consideration and/or pending adoption of the measure
- Authorised and rejected claims on the European Union Register of nutrition and health claims made on food

<http://ec.europa.eu/nuhclaims/>

List of permitted Art. 13 health claims

- More than 44000 claims submitted by Member States
- Consolidated into a list of 4637 entries (IDs)
 - Some withdrawn
- **Regulation (EU) No 432/2012**
 - Adopted on 16 May and published on 25 May
 - Applies from 14 December 2012 (6 months deferral)
- 497 IDs (222 claims) authorised → EU Register
- 1554 IDs not authorised → EU Register

List of permitted Art. 13 health claims (497 IDs, 222 claims)

- **Many claims on vitamins and minerals**
- **Good number of claims on other substances, e.g.**
 - Fibre
 - Omega-3 fatty acids
 - Melatonin
 - Monascus Purpureus (Red yeast rice)
 - Polyphenols in olive oil
- **Claims on certain foods, e.g.**
 - Walnuts
 - Meat or fish
 - Carbohydrate-electrolyte solutions
 - Meal replacements
 - Water
- **Comparative claims / replacement claims, e.g.**
 - Foods with a low or reduced content of sodium
 - MUFA/PUFA in replacement of SFA
 - Sugar replacers

Art. 13 health claims on hold

- 2233 IDs **'on hold'**
 - 155 IDs under further assessment by EFSA or further consideration by risk managers
 - 2078 IDs on botanicals
- Claims on hold are:
 - Listed on SANCO website
 - Allowed to remain on the market

Intention to present a draft to SCOFCAH by the end of the year (except botanicals)

Further assessment

Art. 13(1) claims for which EFSA concluded that:

- **Characterisation** of micro-organisms is **insufficient**
- **Evidence** to substantiate the claim is **insufficient**

• Operators submitted additional data for **91 IDs**

- 17 IDs – Insufficient evidence
- 74 IDs – Insufficiently characterised micro-organisms

• EFSA's advice in two series

- 5 June 2012
- 7 August 2012



Two positive assessments

- Prunes / bowel function
- Alpha-cyclodextrine / glycaemic response

All claims on micro-organisms

- Negative assessment

Further consideration by risk manager

Positively assessed claims, such as

- Caffeine and performance / concentration / alertness
- DHA/EPA and blood pressure / triglycerides
- Glycaemic carbohydrates and brain function

Negatively assessed claims, such as

- Glucosamine and joint health
- 'Beauty' claims

Botanicals

- **Reflection on claims on 'botanicals' became inevitable**
 - Similar ingredients in Food Supplements and Traditional Herbal Medicinal Products
 - Different approach for allowing claims / therapeutic indications
 - Evidence of 'traditional use' carries different weight
- **This difference in legislation has been questioned**

EU Register

- **Interactive** database
- Useful **additional information** for operators and consumers on, for example:
 - Flexibility of wording
 - What should the claim be made on (substance vs. product)
- List of **permitted** claims
- List of **non-authorised** claims with **reasons**, such as:
 - Substance not characterised
 - Claimed effect too general to be assessed
 - Claim not substantiated

Summing up...

- **The Claims Regulation was necessary**
 - Thousands of submitted claims
 - Modest number of positive EFSA evaluations and subsequent approvals
- **Increasing support from**
 - Consumers
 - Companies with authorised claims
- **Legal challenges against the Regulation**
 - The water case
 - 3 challenges against the Art. 13 list



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