

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

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Health and Consumers



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 \rightarrow 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 - Some withdrawn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)

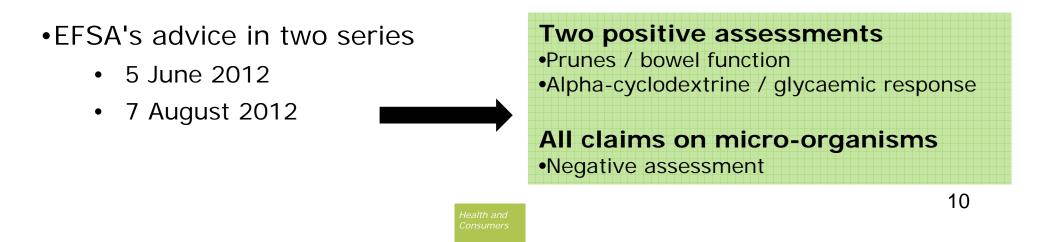




Further assessment

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





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 <u>necessary</u>

- 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



European Commission

