

# 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  - Some withdrawn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)

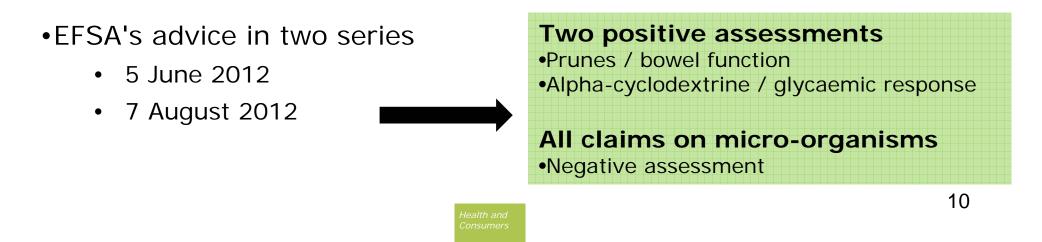




### **Further assessment**

#### 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

