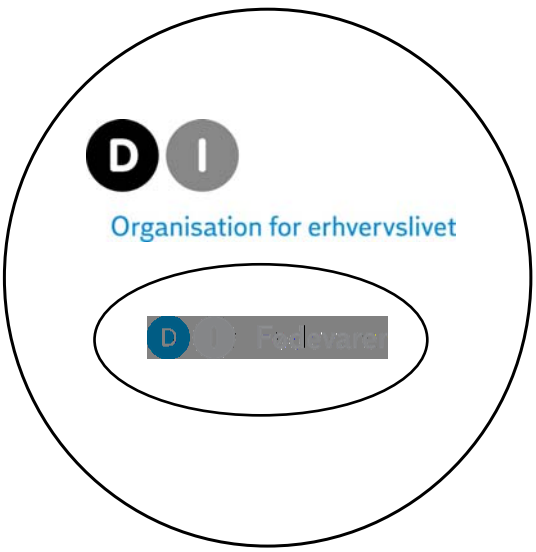
Bioactive Food ingredients

Danish and European legislation on documentation

Danish Food and Drink Federation



Danish Food and Drink Federation

Organisation:
Chairman: Jørn Dirksen
Board: 15 members
CEO: Ole Linnet Juul
Sekretariate 12 employees

251 members:

Fish, bread, cakes, chocolate and confectionery, marmelade, juice, flour og breakfast cereals, meat, poultry, ingredients, crisps, beer, soft drinks, ice cream, sugar, oils, margarines.....

Branches and sektors:
-Meat industry
- Danish Bakery and Confectionery Industry
-Juice og marmelade
-Danish Millers
-Danish Nutraceutical Industry
-Ingredient industry

Why is legislation important?

- Sets the frames for what products can be launched
- Drives innovation and product development
- Drives research
- Gives level field of competition

Background for legislation

- Food safety
- Non-misleading labelling for end-consumers
- Promoting healthy food choices
- Common market

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Regulating Bioactive Ingredients in Foods

- Regulation (EC) No 1924/2006 on **nutrition and health claims** made on foods
- Regulation (EC) No 1925/2006 on the **addition of vitamins and minerals** and of certain other substances to foods
- Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning **novel foods** and novel food ingredients
- Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
- National laws on **other substances** added to foods (danish law underway)
- 1180 af 12/12 2005. Law of **medicinal** products

To be found at: //retsinfo.dk and //eur-lex.europa.eu

Ruling Bioactive Ingredients in Foods

- EFSA - scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim (*www.efsa.europa.eu*)
- EFSA - Guidance on Safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements
- Drogelisten- advisory list of botanicals and extracts (*www.fvst.dk*)
- NETTOX-list (*www.eurofir.net)*
- Novel Food catalogue (*http://ec.europa.eu/)*
- ESCOP monographs (*www.escop.com)*

  - and others

Nutrition and health claims regulation 1924/2006

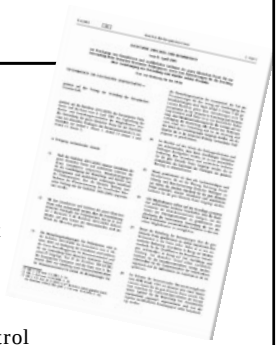
Regulation is in force -

Nutritional claims:
Information about nutritional content
e.g. low content of saturated fat

Health claims:
Information about the products positive effect on health
e.g. Fibers increases healthy digestion

- but many elements to be implemented before, the regulation is fully functional

Nutrition and health claims regulation
- health claims



Article 13 : Health claims other than those referring to the reduction of disease risk

1. Health claims describing or referring to:
(a) the role of a nutrient or other substance in growth, development and the functions of the body, or

(b) psychological and behavioural functions; or

(c) without prejudice to Directive 96/8/EC, slimming or weightcontrol or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet,

Article 14 : Reduction of disease risk claims

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EFSA´s guidance for documenting health claims

the claimed effect of the food/constituent is **relevant for human health**,

a cause and effect relationship is established between the consumption of the food/constituent and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),

the quantity of the food/constituent and pattern of consumption required to obtain **the claimed effect could reasonably be achieved** as part of a balanced diet,

the specific study group(s) in which the evidence was obtained is **representative of the target population** for which the claim is intended.

The Art 13 list, and Art. 14 claims

EFSA has published the first batch of evaluations of art. 13.1 claims 1 October 2009

http://www.efsa.europa.eu/EFSA/ScientificPanels/efsa_locale-1178620753812_NDA.htm

Article 13.5 and 14 claims are being evaluated and published in the EU Official Journal

http://eur-lex.europa.eu/JOIndex.do?ihmlang=en

Regulation 1924/2006

- addition of vitamins and minerals and of certain other substances to foods

European regulation in force from 1 July 2007

Stating that foods can be added

vitamins, minerals and certain other substances with a physiological or nutritional effect

Content of regulation 1925/2006

What vitamins and minerals - Annex 1

What sources for vitamins and minerals- Annex 2

Forbidden or limited uses of substances - Annex 3

Maximum limits and minimum limits, and certain restrictions.

The regulation also contains:

National requirements for compulsory additions

Other ingredients with a generel permission

EFSA guidance for assesment of botanical preparations intended for use in food supplements

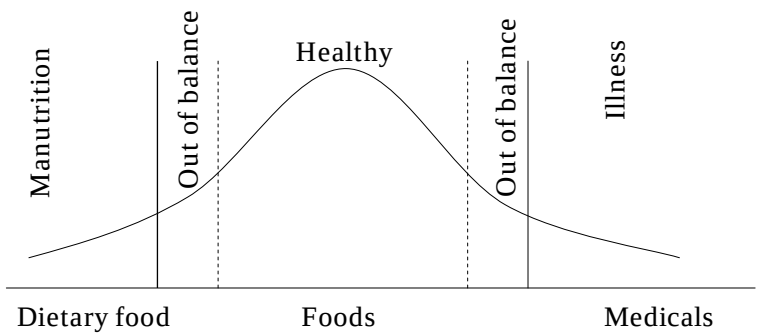
- **toxic compounds**
- **Level of use**
- **Assesment of existing data giving**
  - No Safety concern
  - Need for further data
  - Safety concern

Other regulations

- Novel food
  - A safety assesment

- Medicinal law
  - Setting the limits between medicins and foods

How to document an effect ?



Conclusions

- Bioactive ingredients are regulated by EU Regulation in combination with EFSA guidelines and national laws
- These include demands with regard to safety and effect
- More detailed regulation of bioactive ingredients can be expected in the near future.
- Regulation will be the driver of product development and research