How do you get a Health Claim approved?

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Disclaimer

Although I'm an external expert at EFSA (the Working Group on Claims and the Panel for Nutrition, Dietetics and Allergies) involved in scientific evaluations of health claim applications, the views presented here are my personal views and not necessarily the views of EFSA

How do you get a Health Claim approved?

That's easy

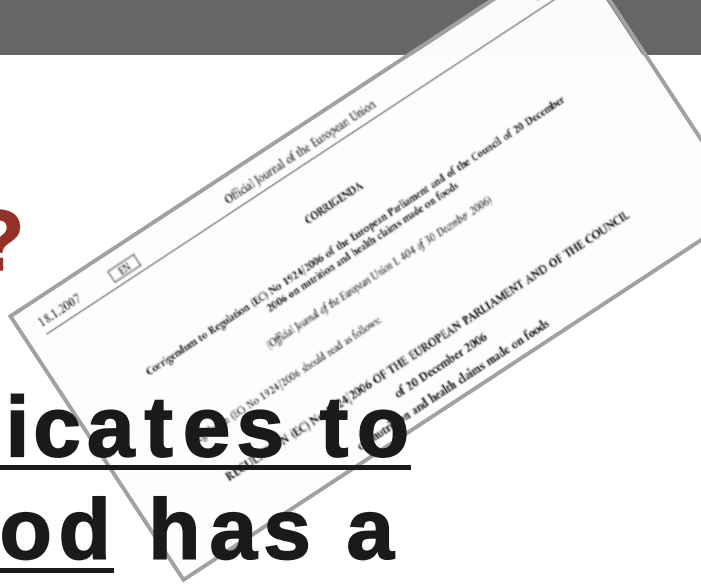
You write a good application based on good studies convincing the NDA-panel

that the claim should be substantiated

Why regulate health claims?

- **Protect the consumer**
- **Fair competition**
- **Facilitate trade**
- **Stimulate ”healthy” innovations**
- **Improve the health in EU**

What is a health claim?


Official Journal of the European Union

CORRIGENDA

Corrigendum to 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

(Official Journal of the European Union L 404 of 30 December 2006)

Anything that communicates to the consumer that a food has a beneficial effect related to health

The use of health claims is regulated by a regulation that is common for all EU-countries **(EC) No 1924/2006 about nutrition and health claims made on foods**

Claims are divided into claims on

- Function, development and health (article 13)
- Risk reduction (of disease) (article 14)
- Children's development and health (article 14)

Food or medicine?

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Medicine

Treat
Prevent
Alleviate

efsa European Food Safety Authority
Committed to ensuring that Europe's food is safe

Food
Food supplement

Beneficial physiol. effect
Risk reduction
Nutritional claims

efsa European Food Safety Authority
Committed to ensuring that Europe's food is safe

General principles for health claims

Claims must:

- be approved

Claims must <u>not:</u>

- *be false, ambiguous or misleading!*
- *give rise to doubt about the safety and/or the nutritional adequacy of other foods!*
- *encourage excess consumption!*
- *state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general!*

Who does what?

- **EFSA / NDA-panel – evaluate the science**
  - and answer questions from the commission
- **The Commission are risk managers**
  - together with national authorities
- **National authorities are responsible for checking the compliance with the regulation**
- **Courts interpret and decides weather or not a claim is OK**
  - National/regional and sometimes the EU-court

Issues addressed by the NDA Panel in the scientific assessment

The Panel considers the extent to which:

1) The food/constituent is defined and characterised
2) The claimed effect is defined and measurable
3) The claimed effect is a beneficial physiological effect ("beneficial to human health")
4) A cause and effect relationship is established between the consumption of the food/constituent and the claimed effect (for the target group under the proposed conditions of use)
5) Target population and amount of the food needed to achieve the effect (conditions of use)

Things that the NDA panel looks for in its scientific evaluation

- All relevant/pertinent documentation
- How is the effect shown/is it shown?
  - Validated methods
  - Study design
  - Relevant control
  - Statistical methods
- Target population
- Amount of food needed (“dose/dosing”)
- Wordings based on the findings in the studies

Outcomes of a scientific assessment?

1) A cause and effect relationship **has been established** between the consumption of the food/constituent and the claimed effect

2) The evidence provided is **insufficient to establish** a cause and effect relationship between the consumption of the food/constituent and the claimed effect

3) A cause and effect relationship **has not been established** between the consumption of the food/constituent and the claimed effect

European Food Safety Authority

EFSA Journal 2011;9(5):2170

SCIENTIFIC OPINION

Scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim (revision 1)[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The scientific and technical guidance of the EFSA Panel on Dietetic Products, Nutrition and Allergies for the preparation and presentation of an application for authorisation of a health claim presents a common format for the organisation of information for the preparation of a well-structured application for authorisation of health claims which fall under Article 14 (referring to children's development and health, and to disease risk reduction claims), or 13(5) (which are based on newly developed scientific evidence and/or which include a request for the protection of proprietary data), or for the modification of an existing authorisation in accordance with Article 19 of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. This guidance outlines: the information and scientific data which must be included in the application, the hierarchy of different types of data and study designs (reflecting the relative strength of evidence which may be obtained from different types of studies) and the key issues which should be addressed in the application to substantiate the health claim.

SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 10 December 2015

PUBLISHED: 18 January 2016

doi:10.2903/j.efsa.2016.4369

Guidance on the scientific requirements for health claims related to the immune system, the gastrointestinal tract and defence against pathogenic microorganisms

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

Abstract

The European Food Safety Authority (EFSA) has asked the Panel on Dietetic Products, Nutrition and Allergies (NDA) to update the guidance on the scientific requirements for health claims related to gut and immune function published in 2011. Since then, the NDA Panel has completed the evaluation of Article 13.1 claims except for claims put on hold by the European Commission, and has evaluated additional health claim applications submitted pursuant to Articles 13.5 and 14, which are in the area covered by this guidance. In addition, the NDA Panel has developed the general scientific guidance for stakeholders for health claims applications which addresses general issues that are common to all health claims. This guidance is intended to assist applicants in preparing applications for the authorisation of health claims related to the immune system, the gastrointestinal tract and defence against pathogenic microorganisms. Examples of claims evaluated favourably by the Panel will be used to provide guidance to applicants on the scientific requirements for the substantiation of health claims in specific areas, whereas examples of claims evaluated unfavourably by the Panel will be used to illustrate the shortcomings that prevented the substantiation of these claims. The general document represents the views of the NDA Panel based on the experience gained to date with the evaluation of health claims, and it may be further updated, as appropriate, in the light of experiences gained from the evaluation of additional health claim applications.

How is an application handled?

1. Submitted to a national authority by a company etc
2. To EFSA for validation → something missing / unclear etc
3. Scientific opinion drafted by a working group (external experts)
4. Questions to the applicant for clarification (optional)
5. Additional information from the applicant (optional)
6. Draft to the NDA panel → Publish a scientific opinion
7. To the commission (risk managers) for potential publication
8. Input / objections from member states
9. If positive - Published on the list of approved claims

Until now

- 40.000 claims submitted for 13.1 !!!!!!
- Reduced to 4.000 to be evaluated
- ”Botanicals” on hold (nobody knows what to do)
- Article 13.5 – beneficial physiological effects
- Article 14 – risk reduction
- Article 14 - children’s development and health
- Guidelines/updates

Is the system working well?

- Are the scientific requirements too high?
- Relevance of some claims questioned
- Botanicals not evaluated/regulated
- Rules are not followed

Questions?