How do you get an approved health claim in Europe?

Experiences from within the system

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But not

efsa

European Food Safety Authority

Committed to ensuring that Europe's food is safe

Disclaimer

- **I have previously worked 6 years as an external expert on the panel for Nutrition, Dietetics and Allergies (NDA) responsible for scientific evaluations of health claims**

- **I do not represent EFSA and what I present here is my personal view on the subject and not necessarily the view of EFSA**

What is the role of EFSA in the approval of health claims?

- Important but with clear limitations
- Make scientific evaluations but are not risk managers
- Not about safety
- … but can evaluate safety if asked for
- Do not approve health claims
- There is no such thing as an "EFSA claim"

EU Regulation 1924/2006 on nutrition and health claim

18.1.2007 EN Official Journal of the European Union L 12/3

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)

Regulation (EC) No 1924/2006 should read as follows:

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

Food or medicine?

~~Medicine~~

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

~~Treat~~
~~Prevent~~

Foods
Food supplements

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Beneficial physiol. effect
Risk reduction
Nutritional claims

The European Commission

Health claims are interpreted broadly

It is mainly about how it can be perceived

– not the actual "statement" –

that determines if it should be considered a health claim or not

- **Goodbelly® orange juice?**
- **IQ – chocolate with DHA for kids**
- **Yoseff** (120 years old) **eats yoghurt every day?**
- **Heart shaped package or pictures?**
- **Gives you energy that lasts longer?**
- **Keeps you going?**
- **Gives you wings?**
- **Makes you strong?**

Why regulate this?

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

General principles for health claims

Claims must not:

- *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!*

Issues addressed by the NDA Panel

1) The claim falls under the legislation for health claims
   (not medicinal claim or the food not complying with the regulation)

2) The food is defined and characterised in the context of the claimed effect (ingredients/nutrients)

3) The claimed effect is defined and measurable

4) The claimed effect is a beneficial physiological effect

5) … or reduces a risk factor (Risk reduction claims - 14.1)

6) A cause and effect relationship is established between the consumption of the food/food constituent and the claimed effect *(for the target group under the proposed conditions of use)*

Issues addressed by the NDA Panel in the scientific assessment

- The totality of the available evidence
- Whether the studies are pertinent to the claim
- If the claimed effect is shown on a proper target group
- If the risk factor is relevant (14.1)
- Propose the conditions of use
- Propose wordings of health claims?

Scientific criteria for the evaluation of health claims

Health claims can be substantiated by:

- **"generally accepted scientific evidence"**
- "taking into account the **totality of the available scientific data**, and by **weighing the evidence"**
- **Mechanisms nice but not needed**

The NDA Panel makes a judgement on whether there is sufficient scientific evidence to support the claim

The burden is on the applicant to provide the evidence

Outcomes of a scientific assessment?

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

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

How is an application handled?

1. Submitted to a national authority
2. To EFSA for validation → type of claim, formalities 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 → Adopt and Publish a scientific opinion

   – or
7. Back to the WG for redrafting of the scientific opinion → Panel
8. To the commission (risk managers) for potential publication
9. Input from member states
10. If positive - Published on the list of approved claims

Until now

- **40.000 claims submitted for 13.1 !!!!!!**
- **Reduced to 4000 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**
- **Updating guidelines**

European Food Safety Authority

EFSA Journal 2014;12(10):3838

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to AlphaGOS® and a reduction of post-prandial glycaemic responses pursuant to Article 13(5) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Olygose, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to AlphaGOS® and a reduction of post-prandial glycaemic responses. Non-digestible carbohydrates, including α-galacto-oligosaccharides in AlphaGOS®, are resistant to hydrolysis and absorption in the small intestine and therefore do not contribute to post-prandial glycaemia. This opinion applies to non-digestible carbohydrates (e.g. non-starch polysaccharides, resistant oligosaccharides and resistant starch) which should replace sugars in foods or beverages in order to obtain the claimed effect. The Panel considers that the food constituent, non-digestible carbohydrates, which is the subject of the health claim, and the food constituent (i.e. sugars) that non-digestible carbohydrates should replace in foods or beverages are both sufficiently characterised in relation to the claimed effect. The Panel considers that a reduction of post-prandial glycaemic responses might be a beneficial physiological effect. A claim on non-digestible carbohydrates and reduction of post-prandial glycaemic responses has already been assessed by the Panel with a favourable outcome. The previous evaluation, including the proposed wording and the conditions of use, also applies to this application. The Panel concludes that a cause and effect relationship has been established between the consumption of foods/beverages containing non-digestible carbohydrates and a reduction of post-prandial glycaemic responses as compared with sugar-containing foods/beverages.

European Food Safety Authority

EFSA Journal 2014;12(11):3891

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to zinc and normal growth pursuant to Article 14 of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Specialised Nutrition Europe (formerly IDACE), submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to zinc and normal growth. The food constituent, zinc, which is the subject of the health claim, is sufficiently characterised. Normal growth is a beneficial physiological effect for infants and young children. The Panel considers that the role of zinc in normal growth is well established. Growth retardation is one of the clinical manifestations of severe zinc deficiency. Zinc supplementation has been reported to stimulate growth and development in zinc-deficient infants and young children. The Panel concludes that a cause and effect relationship has been established between the dietary intake of zinc and normal growth. The following wording reflects the scientific evidence: "zinc contributes to normal growth". The target population is infants and children up to three years of age.

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.

Is the system working well?

- Are the scientific requirements too high?
- Relevance of some claims questioned
- Botanicals etc not regulated
- Markets not following the rules

Some common pit-falls to avoid

- ✓ Do you really study the effect you want to claim?
- ✓ Is the study population relevant?
- ✓ Have you limited the risks of bias?
  - ✓ Are you using the right study design?
  - ✓ Do you have the right control?
  - ✓ Are you using the right statistical methods?
- ✓ Are you complying with "GCP-standards"?
- ✓ Are you meeting the required quality in reporting?
- ✓ Have you predefined your endpoints etc?
- ✓ Have you properly registered your study?
- ✓ Are you working with the right people?

Some final advice

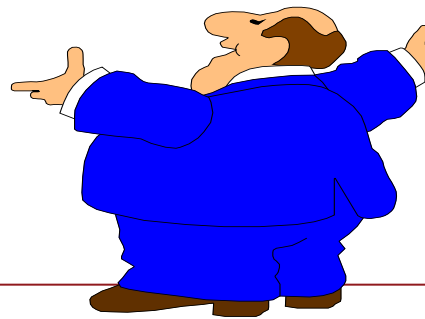
Define the effect you would like to claim and the food, in a collaboration between marketing/sales (commercial) and R&D (science)

What to you want to communicate?

Does the concept make sense to the consumer?

What are the chances of being able to substantiate the claimed effect?

Marketing pull and scientific push!



My second advise.....

Work with people who knows "the system"

From the design and implementation/execution, to the reporting of the study, as well as when writing the application.

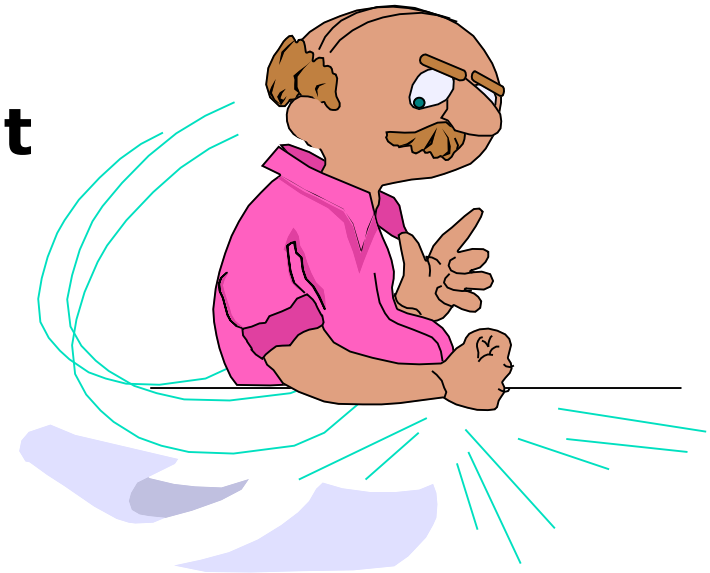
Most companies and scientists do not have the knowledge and experience that are needed for a successful application

Doing a scientifically interesting study of high quality is not necessarily the same as providing substantiation for a health claim

… my last advise - one that can save you a lot of money and time

Read the guidelines and learn from the mistakes of others to avoid making costly mistakes yourself

Very good investment



Questions?