Clinical trials for substantiation of Health Claims

Anders Sjödin

Professor, MD, DMSc

NEXS, Copenhagen University

External expert on the NDA panel and WG on Claims at EFSA

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 make an EFSA-study

How do you make a clinical study that can support an application for a health claim?

Start from the end!

- ✓ What do you want to be able to communicate?
- ✓ Is that a beneficial physiological effect/health claim?
- ✓ Is it measurable/quantifiable?

How do you perform a clinical study that can support an application for a health claim?

- The right methods
- The right food and comparator/placebo
- Subjects relevant for the target population
- Study design – "unbiased"
- Statistical methods to show an effect
- Transparency – what was really done – what was planned?
- Collaborate with the right experts/CRO's
- **Read guidelines and previous opinions!**

Where do you find useful information?

http://www.efsa.europa.eu/en/topics/topic/nutrition-and-health-claims

Scientific guidelines

- General scientific guidance for stakeholders on health claim applications
- Guidance on the scientific requirements for health claims related to functions of the nervous system, including psychological functions
- Guidance on the scientific requirements for health claims related to physical performance
- Guidance on the scientific requirements for health claims related to bone, joints, skin and oral health
- Guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations
- Guidance for health claims related to the immune system, the gastrointestinal tract and defence against pathogenic microorganisms
- Guidance on health claims related to antioxidants, oxidative damage and cardiovascular health

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.

European Food Safety Authority

EFSA Journal 2014;12(12):3908

GUIDANCE OF EFSA

Guidance on Statistical Reporting[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Statistical analyses are an essential part of risk assessments. Statistical reporting varies considerably amongst the documents that EFSA receives and produces, which can lead to lack of transparency and reproducibility of results. This guidance aims to improve quality, openness and transparency of EFSA's work and information/analyses received by EFSA (including dossiers). It is not intended to provide guidance on which statistical methodology should be applied and how statistical analysis should be performed. A template is proposed, that covers in the broadest possible way, the reporting of relevant aspects of a statistical analysis including: objectives, sources of information (data), study design, data quality, analysis methods, results and interpretation. The guidance and template serve to harmonise and standardise transparent statistical reporting to facilitate reproducibility of the analysis, interpretation and use of the statistical results, and independent peer

Scientific guidelines

- General scientific guidance for stakeholders on health claim applications
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- Guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations
- Guidance for health claims related to the immune system, the gastrointestinal tract and defence against pathogenic microorganisms
- Guidance on health claims related to antioxidants, oxidative damage and cardiovascular health

SCIENTIFIC OPINION

EFSA Journal

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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.

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.

More questions?