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Study design in relation to documentation of health effects

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Do not forget food safety

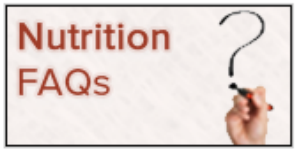
- You must document that your product is safe – unless will it never reach the market.

- And you must document that your product have the health effects you claim.

- Animal by-products
- Decontamination
- Feed additives
- Food contact materials
- Food ingredients
- Food processing
- GMO
- Nutrition
  - Applications workflow
  - FAQ
  - Guidance documents
- Pesticides
- About Applications helpdesk
- Ask a question

Nutrition and health claim applications

EFSA is responsible for verifying the scientific substantiation of health claims submitted for authorisation in the EU. This evaluation serves as a basis for the European Commission and Member States to decide whether to authorise the claims.



Short cuts for applicants

- Applications for health claims: guidance for applicants
- Submission to competent authority of a Member State
- Contact regarding scientific evaluation of regulated products: EFSA's Applications helpdesk
- Contact regarding authorisation: European Commission's Directorate-General for Health and Consumers

Guidance documents

EFSA engages regularly with stakeholders to explain the process followed by its Panel on Dietetic

See also

- Nutrition
- Dietary reference values and dietary guidelines homepage
- Nutrition and health claims homepage

Animal by-products
Decontamination
Feed additives
Food contact materials
Food ingredients
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GMO
Nutrition
▶ Applications workflow
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Ask a question

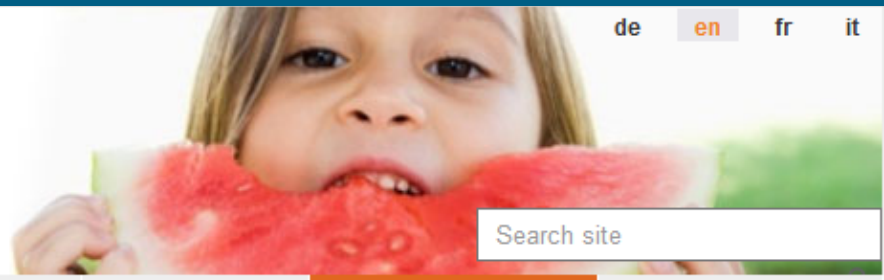
Nutrition applications - Applications workflow

Many food and feed related products require scientific risk assessment by EFSA before they can be authorised for use on the EU market. An application for these so-called 'regulated products' has to be submitted to EFSA to enable this risk assessment to be carried out. The procedures for submission of applications and the required information vary widely for each area depending on the specific legislation and applicable guidance. The information on this page will help to guide you through the administrative and legal requirements for the application process.

Applications workflow

Applicants who wish to submit an application for authorisation of a health claim under Articles 13.5 or 14 of Regulation EC 1924/2006 or for modification of an existing authorisation should consult the guidance documents and complete the relevant application forms . Applications should be submitted to the national competent authority of a Member State. The competent authority passes the application and any supplementary information supplied by the applicant to EFSA, which carries out the scientific evaluation.

- Health Claims application workflow (0.1 Mb)
- Novel foods application workflow (0.1 Mb)
- Infant formulae application workflow (0.1 Mb)
- Food allergies application workflow (0.1 Mb)
- How to prepare an application on health claims, novel foods, infant formulae, food allergies (0.1 Mb)



Regulated food ingredient applications

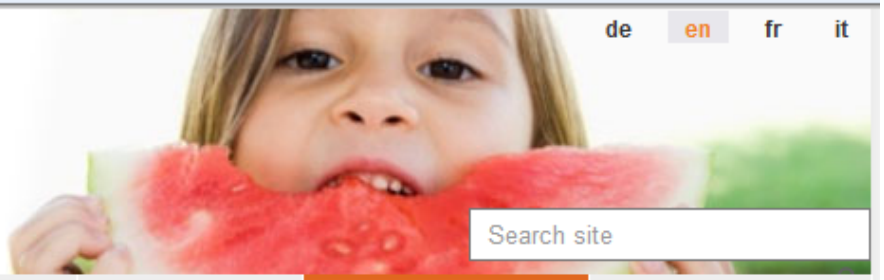
EFSA carries out the safety evaluation of regulated food ingredients (i.e. those which currently require market authorisation). These comprise chemical substances which are used as food additives, food enzymes, flavourings, smoke flavourings and sources of vitamins and minerals added to food (commonly called nutrient sources). This work includes (1) the evaluation of new substances and (2) the evaluation of new proposed uses for already authorised substances.

Short cuts for applicants

- Application procedure for:
  - Food additives, enzymes and flavourings: Regulation EC 1331/2008 and Regulation EU 234/2011
  - Smoke flavourings: Regulation EC 2065/2003 and Regulation EC 627/2006
  - Nutrient sources: Regulation EC 1925/2006

See also

- Food ingredients and packaging
- Aspartame homepage
- Food supplements homepage
- Food Colours homepage
- Food Additives homepage
- Flavourings homepage
- Smoke Flavourings homepage



Food ingredients applications - Applications workflow

Many food and feed related products require scientific risk assessment by EFSA before they can be authorised for use on the EU market. An application for these so-called 'regulated products' has to be submitted to EFSA to enable this risk assessment to be carried out. The procedures for submission of applications and the required information vary widely for each area depending on the specific legislation and applicable guidance. The information on this page will help to guide you through the administrative and legal requirements for the application process.

Applications workflow

The application procedures and technical requirements for regulated food ingredient authorisations vary under different EU legislation. You can find specific information related to each regulated food ingredient application type as follows:

Food additives, food enzymes and flavourings – the application procedure for food additives, food enzymes and flavourings is set down in Regulation EC 1331/2008. Further administrative and technical requirements for applications are explained in Regulation EC 234/2011. Applications should be submitted to the European Commission, which has provided a Practical guidance for applicants containing a check list and useful addresses, contact points and relevant documents. EFSA has published scientific guidance documents detailing the requirements for preparing the technical dossiers for applications.

- Food additives, flavourings, food enzyme application workflow (0.1 Mb)
- Re-evalution flavourings application workflow (0.1 Mb)

How to enter the European market?

- In order for a functional food/ ingredient/"food" to be approved by the European Food Safety Authority (EFSA), a dossier must be prepared with all the scientific data about the food.

- The dossiers must be prepared in accordance with Regulation (EC) No1924/2006 and its subsequent modifications (Regulation (EC) 107/2008 and 109/2008).

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, 2011.

- A guidance on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed has been made and complements the OECD Test Guide 408.

efsa
European Food Safety Authority
EFSA Journal 2011;9(12):2438

SCIENTIFIC OPINION

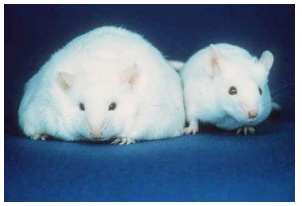
Guidance on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed [1]

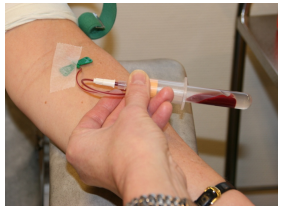
EFSA Scientific Committee[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

A dossier on health claims (effects) contains:

- Nutritional characterization
- Toxicity studies
- Pre intervention studies
  - In vitro (cell lines)
  - In vivo (animal models)
- Human intervention studies
  - Randomized Controlled Trials (RCT)
- Biostatistics
- Labelling





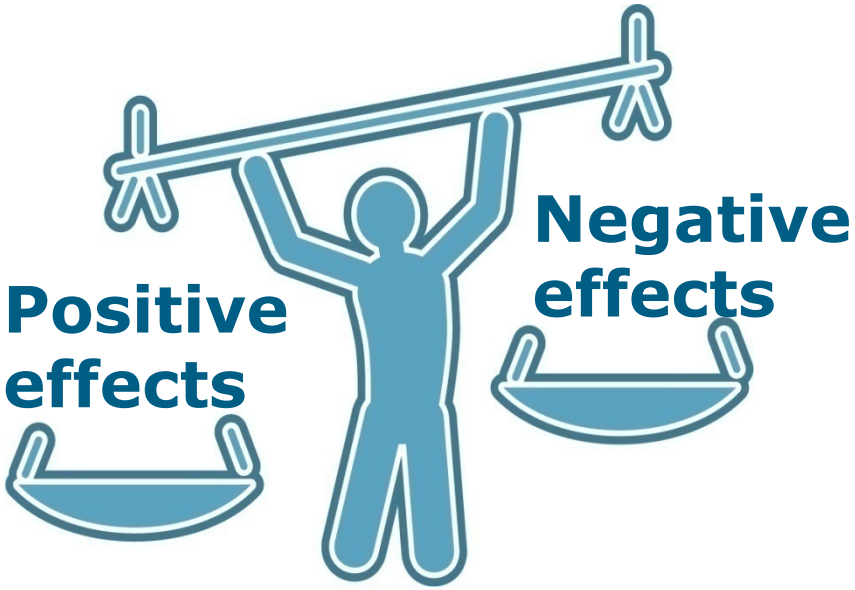
Human intervention trials to document health effects

- When performing experiments to document positive health effects, independent of model it is very important to look for adverse or negative effects.

- This should always be made clear in all scientific papers along with the outcome on the endpoints for positive health effects.

Human intervention trials

- This makes it possible to perform a “risk-benefit” assessment of the findings.



Human intervention trials

- There is a need to establish a cause and effect relationship and then we need human trials.
- Randomized double-blind placebo controlled trials, parallel or crossover.
  - Gold standard but not possible with food or complex matrices.
  - Patients versus healthy volunteers.
- We need dietary intervention trials with appropriate end points assessing both positive and negative outcomes.

Human intervention trials

- Although these trials will not reveal the underlying mechanisms they will add valuable information on cause and effect.
- Most of us eat several times a day and we also know that what we eat affects our health.
- Enjoy a nice and healthy lunch.

Photo Helge Skodvin

Thank you for your attention.