European Food Safety Authority

Considerations for Preparing a Dossier

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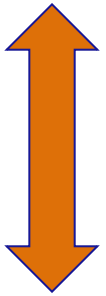
Outline

I. Regulatory considerations

II. Technical considerations

III. Scientific considerations



I. Regulatory Considerations

EU Regulation on nutrition and health claims

- **Scope (nutrition or health claim, medical, cosmetic, other…)**
- **Which type of claim (function, disease risk, children)?**
  - *Claimed effect ? Target population ?*
- **Limited time for Art 13.5 and Art. 14 procedures for both, EFSA and applicants**
  - *Ensure completeness before submitting to a Member State*

II. Technical Considerations

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- Advisory Forum & scientific cooperation
- Animal health & welfare
- Biological hazards
- Biological monitoring
- Contaminants
- Dietary & chemical monitoring
- Emerging risks
- Feed
- Food ingredients and packaging
- GMO
- Nutrition
  - About us
  - Topics A-Z
  - Panel members
  - Events
  - Working groups
  - Publications
  - Requests & mandates
  - Guidance for applicants
  - **Health claim applications**

Health claim applications

Health claims made in relation to food products require authorisation under Regulation EC 1924/2006 before they can be used in the labelling and marketing of these products in the EU. Within the context of this authorisation procedure, EFSA's Panel on Dietetic Products, Nutrition and Allergies (NDA) is responsible for verifying the scientific substantiation of the health claims.

- Topic: Nutrition and health claims

Detailed information on the application procedure, including how to check the status, question number and deadlines, is available on the nutrition pages of the Applications helpdesk section of this website. Guidance documents published by the NDA Panel are also essential reading for the preparation of health claim applications.

- Helpdesk: Health claim applications
- Guidance documents of the NDA Panel

1. Introduction

2. Regulatory Q & A

3. Guidance

http://www.efsa.europa.eu/en/nda/ndaclaims.htm

1. Introduction to Health Claims

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Nutrition and health claims

2. FAQ – Regulatory & Technical

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1. I have submitted a health claim for evaluation by EFSA. How can I check the status of my application?
2. I am not sure if my claim requires authorisation. Who should I contact?
3. Is there an official list of all authorised health claims?
4. I am a new applicant. How do I prepare an application?
5. Are the requirements the same for all health claim evaluations?
6. What happens to my application when EFSA has received it?
7. How long does EFSA's evaluation take?
8. Do I need to pay?
9. Does EFSA authorise health claims?
10. Short cuts for applicants

…add FAQ, Question 1

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1. I have submitted a health claim for evaluation by EFSA. How can I check the status of my application?

All applications received by EFSA are given an Application Number and an EFSA Question Number (e.g. EFSA-Q-2009-12345) and are listed in the EFSA Register of Questions (ROQ), which describes the status and progress of EFSA's scientific work. To find an application, click on the Question option in the top menu of the ROQ, then in the Question type field select 'Application' and select the relevant Food sector area (e.g. 'Health claim Art. 14'). You can then search using key words or a Question Number if you know it. After…

…add FAQ, Question 2

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2. I am not sure if my claim requires authorisation. Who should I contact?

If you have any questions related to whether a health claim requires authorisation or whether a specific claim is authorised for use, please contact the national competent authority of a Member State. If you have any further questions related to the authorisation of health claim, please contact: Unit E4 – Nutrition, Food Composition and Information, Directorate-General for Health and Consumers (DG SANCO), European Commission.

…add FAQ, Question 4

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4. I am a new applicant. How do I prepare an application?

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.

3. EFSA Guidance - General

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Guidance for applicants on health claims

- Scientific and technical guidance
- Parts 1-4 of the application (0.2 Mb)
- Appendix A – Application form (0.1 Mb)
- Appendix B – Overall summary of the application (0.1 Mb)
- FAQ - Pre-submission guidance (0.2 Mb)

3. Pre-submission Guidance

1 - 3. Is my application for authorisation of a health claim **eligible for scientific evaluation by EFSA, under Art 14 or 18 procedure?**

4. How should my "**Summary of the Application" look like?**
5. Can I submit **multiple health claims in the same application?**
6. What is the **procedure for the submission of applications for authorisation of health claims?** ***Rev.***
7. How shall I submit an application based on **proprietary data?**
8. How shall I submit an application containing **confidential data?**
9. If my application cites references, and encloses copies/reprints of published or unpublished data, how shall I address their **Intellectual Property Rights?**
10. In which **language shall I submit my application?**
11. **How and to whom shall I submit my application?**
12. How many **paper copies?**
13. Can I submit **electronic copies of my dossier?**
14. Where can I find the **List of National Competent Authorities within the framework of the Regulation?**
15. **When shall I submit my application?**
16. How shall my application be **validated?**

III. Scientific Considerations

1. **General & specific EFSA Guidance**
2. **EFSA review of the evidence**
3. **Published opinions**

   Favourable *(What is in there?)* and unfavourable *(Described limitations)*

1. General & specific EFSA Guidance

(General) Scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim (EFSA Journal 2011;9(5):2170 [36 pp.].)

Specific scientific requirements for health claims related to

1. **Gut & immune function**
2. **Antioxidants, oxidative damage & cardiovascular health**
3. **Bone, joints & oral health**
4. **Appetite ratings, weight management & blood glucose**
5. **Neurological & psychological function**
6. **Physical performance**

2. EFSA Review of the Evidence

1. Characterisation of food/substance
2. Beneficial to human health
3. Cause and effect relationship
4. Food quantity required for claimed effect
5. Representativeness of data for target population

3. Published Opinions - Favourable

Food/constituent	Health relationship
Vitamins, minerals	Cardiovascular, brain, gut, immune, bone, dental, antioxidant, metabolism
Protein, carbohydrate	Muscle, bone, energy,
Fatty acids	Brain, cardiovascular, vision
Fibre(s)	Gut, cardiovascular, post prandial blood glucose
Other substances - phytosterols/stanols, chewing gum, meal replacements, tomato extract	Cardiovascular, dental, weight management,

Add 3. Unfavourable Opinions

Main reasons

- Lack of suitable human studies to substantiate the claim for the intended population group
  - No human studies
  - Studies in patients only and not relevant to the intended population group
  - Studies relevant to the intended population group but of poor quality, unsuitable measurements, inappropriate study design, statistical analyses, etc.
- Claimed effect not defined or not considered a beneficial physiological effect
- Food/substance not sufficiently described

EFSA guidance and dialogue with stakeholders

- **EFSA guidance:**
  - preparation and presentation of applications (2007)
  - general principles for substantiation of claims (2009, 2010)
  - scientific requirements for substantiation of specific types of health claims (2010-2012)
- **EFSA dialogue with applicants** before acceptance and during evaluation, clock stops, EFSA's response to comments after publication
- **Stakeholder meetings** to discuss general principles and specific topics, Scientific colloquium
- **Presentations at conferences**

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THANK YOU

efsa anniversary 10 efsa anniversary

Committed *since 2002*
to ensuring that Europe's food is safe