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FAIRS Subject Report

Health Claims - EU Authorization Procedure

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Report Highlights:
This report describes how application dossiers for authorization of health claims should be prepared and presented.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
Brussels USEU [BE2]
[E4]

Health Claims – EU Authorization Procedure

Scope

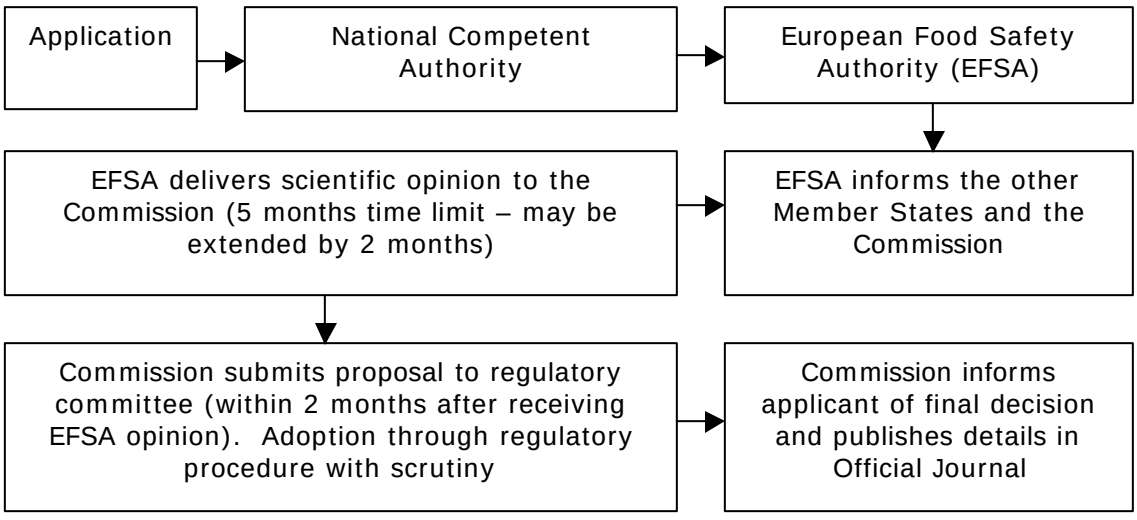
Regulation 1924/2006 establishes rules for the use of nutrition and health claims in the labeling, presentation and advertizing of foods. Regulation 353/2008 sets out implementing rules for applications for authorization of health claims as provided for in Article 15 of Regulation 1924/2006.

Application Procedure

Applications for the authorization of a health claim must be sent to the national competent authority of a Member State. Within 14 days, the national competent authority must acknowledge receipt of the application. The national competent authority then forwards the dossier to the European Food Safety Authority (EFSA) for scientific evaluation of the proposed health claim.

EFSA informs the other Member States and the European Commission and makes the application and any supplementary information available to them. EFSA will also make a summary of the application and make it available to the public. Within 5 months from the date of receipt of the application, EFSA must deliver its scientific opinion. If EFSA needs additional information from the applicant, the 5-month time limit will be extended by up to 2 months from the date of receipt of the requested information.

Within 2 months after receiving EFSA's opinion, the Commission will submit a proposal for the authorization of the health claim concerned to the Standing Committee on the Food Chain and Animal Health (regulatory committee). A final decision on the application will be adopted through the regulatory procedure with scrutiny. The Commission then informs the applicant of the decision taken and publishes the details in the Official Journal of the EU.



A simplified procedure exists for health claims that are based on newly developed scientific data (except claims referring to children's development and health). Under this simplified procedure (Article 18 of Regulation 1924/2006), if EFSA's opinion on the claim is positive, the Commission will take a decision after simple consultation with the Member States. If EFSA gives a negative opinion, the application will go through the full authorization procedure.

Preparation & Presentation of Applications

One claim per dossier

Each application for the authorization of a health claim may cover only one relationship between a nutrient or other substance, or food or food category, and a single claimed effect. However, an applicant may propose to use the same health claim on multiple formulations of a food if the accompanying scientific evidence is valid for all proposed formulations.

Type of health claim

Applicants must specify which type of health claim listed in Article 13 or Article 14 of Regulation 1924/2006 the dossier covers. Article 13 claims refer to growth, development and functions of the body, psychological and behavioral functions and slimming and weight control. Article 14 claims refer to the reduction of disease risk and to children's development and health.

Scientific evidence

Applications must demonstrate that the health claim is based on and substantiated by generally accepted scientific evidence. Studies and other materials that support the application should primarily consist of studies in humans and, where applicable, studies in children. Applications must also indicate whether the health claim concerned or a similar one has already been scientifically evaluated by a competent authority of either a Member State or a third country. If so, a copy of the scientific evaluation must be provided. The Annex to Regulation 353/2008 provides detailed technical guidance for the scientific substantiation of health claims.

Conditions for use

In addition to the proposed wording of the health claim, applications must include specific conditions for use:

- the target population for the intended health claims
- the quantity of the nutrient and pattern of consumption required to obtain the claimed beneficial effect
- where appropriate, indicate who should avoid using the nutrient
- a warning if excess consumption presents a health risk
- any other restrictions of use and directions for preparation and/or use

Proprietary Data

In order to benefit from data protection, applicants must indicate which information should be regarded as proprietary data. Requests for protection of proprietary data must be justified and all data must be included in a separate part of the application. If granted, the validaty will expire after five years.

Structure of the Application

Applications for the authorization of a health claim must be structured as follows:

Part 1 – Administrative & Technical Data

1.1 Table of contents
1.2 Application form
1.3 General information
1.4 Health claim particulars
1.5 Summary of the application
1.6 References

Part 2 – Food/Constituent Characteristics

2.1 Food constituent
2.2 Food or category of food
2.3 References

Part 3 – Overall Summary of Pertinent Scientific Data

3.1 Tabulated summary of all pertinent studies identified
3.2 Tabulated summary of data from pertinent human studies
3.3 Written summary of data from pertinent human studies
3.4 Written summary of data from pertinent non-human studies
3.5 Overall conclusions

Part 4 – Body of Pertinent Scientific Data Identified

4.1 Identification of pertinent scientific data
4.2 Pertinent data identified

Part 5 – Annexes to the Application

5.1 Glossary/abbreviations
5.2 Copies/reprints of pertinent published data
5.3 Full study report of pertinent unpublished data
5.4 Other

EFSA Guidance

EFSA has published a scientific and technical guidance document on the preparation and presentation of applications for authorization of health claims. Applications should follow the EFSA guidance in conjunction with the implementing rules established by Regulation 353/2008.

Visit our website: our website **http://useu.usmission.gov/agri/** provides a broad range of useful information on EU import rules and food laws and allows easy access to USEU reports, trade information and other practical information. More information on nutrition and health claims can be found at http://useu.usmission.gov/agri/claims.html. E-mail: AgUSEUBrussels@fas.usda.gov

Related reports from USEU Brussels:

Report Number	Title	Date Released
E47090	Nutrition & Health Claims - Update	October 2007
E36086	European Parliament passes new EU rules on nutrition and health claims	May 2006
E47043	Introduction to EU Institutions	June 2007
These reports can be accessed through our website http://useu.usmission.gov/agri or through the FAS website http://www.fas.usda.gov/scriptsw/attacherep/default.asp.		