Factsheet: EFSA Health Claim Registration (EU)

The Role of Clinical Research in your Dossier

What is a Health Claim?

A health claim is any statement or visual representation that states, suggests, or implies a relationship exists between a food, one of its constituents, or a nutrient, and health.

All claims on packaging, in advertising, and in marketing within the EU must be scientifically substantiated and approved by the European Commission, following a scientific assessment by the European Food Safety Authority (EFSA).

Types of Health Claims (Regulation (EC) No 1924/2006)

There are two main categories of claims that require a specific application and authorisation:

Claim Type	Article	Description
Function Claims (New Evidence)	Art. 13(5)	Claims based on newly developed scientific evidence and/or including a request for the protection of proprietary data.
Disease Risk Reduction & Child Health	Art. 14	Claims referring to the reduction of a disease risk factor (e.g., "Plant sterols have been shown to reduce cholesterol levels...") and claims concerning children's development and health.

The Critical Role of Clinical Research

EFSA places published and unpublished human intervention studies (clinical trials) at the top of the evidence hierarchy for demonstrating a cause-and-effect relationship between the consumption of a food/ingredient and the claimed health benefit.

Key Requirements for Clinical Studies

A successful EFSA dossier relies on the quality of the research, not the quantity. Your clinical study should incorporate the following elements:

Requirement	Description
Study Design	Preferably randomised, double-blind, placebo-controlled trials (RCTs). This design provides the strongest scientific substantiation.
Participants	The study must be conducted in a target population representative of the healthy general population for whom the claim is intended. Claims must not refer to the treatment, diagnosis, or cure of a disease.
Intervention	The specific food or constituent for which the claim is made must be well-characterised. The dose and consumption pattern in the study must be relevant to the consumer's daily use.
Health Effect	The demonstrated effect must be statistically significant and relevant to human health, measured using validated markers and validated methods.
Consistency	Results must be consistent across the different studies in the dossier. EFSA assesses the totality and balance of the evidence.

The Registration Process: Step-by-Step

Submitting an application for a new health claim (Art. 13(5) or Art. 14) is a meticulous process:

- Preliminary research and dossier preparation (the most time-consuming step): conducting extensive research, including designing and executing high-quality clinical studies, and preparing a detailed scientific and technical dossier in line with EFSA's latest guidance.
- Submission to the national competent authority: the dossier is submitted to the national competent authority of an EU Member State (e.g., the NVWA in the Netherlands), which performs an initial check.
- Validation by EFSA: EFSA validates the dossier and checks that all required administrative and scientific information is present.
- Scientific review by EFSA's NDA Panel: the Panel on Nutrition, Novel Foods and Food Allergens (NDA Panel) assesses the scientific substantiation of the claim. EFSA is required to deliver its opinion within five months of the completeness check, extendable by a further two months if supplementary information is requested from the applicant.
- EFSA opinion: EFSA publishes its scientific opinion (favourable or unfavourable).
- European Commission decision: the European Commission and the EU Member States take a final decision on the authorisation of the claim and its conditions of use.
- Inclusion in the EU Register: once approved, the claim is added to the EU Register of Nutrition and Health Claims and may be used across the EU.

Protection of Proprietary Data

Authorised claims based on new, proprietary scientific data (Art. 13(5) and Art. 14) may qualify for five years of exclusivity, during which competitors are prohibited from using that evidence to support their own claims, under the conditions set out in Article 21 of Regulation (EC) No 1924/2006.
