

BERBERINE SAFETY PROJECT

A coordinated scientific initiative led by the Botanical Research Foundation (FBR)

Executive Summary

The Botanical Research Foundation (FBR) is launching a coordinated scientific programme to generate robust data supporting the safety assessment of berberine, a widely used botanical ingredient in food supplements currently under evaluation by the European Food Safety Authority (EFSA).

This initiative aims to fill critical data gaps identified by EFSA and to ensure continued, evidence-based use of berberine within the European market.

Why This Project Matters

- Regulatory urgency
- EFSA has identified significant data gaps regarding berberine safety
- Market impact
- Potential regulatory restrictions may affect:
 - product availability
 - supply chains
 - commercial sustainability
- Sector-wide relevance
- This is not a single-company issue — it affects the entire botanical and supplement industry

Scientific Approach

The project follows internationally recognised risk assessment methodologies:

FBR – Fondazione Botanica per la Ricerca

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Integrated Weight of Evidence (WoE) Strategy

Combining:

- In vivo studies (OECD, GLP compliant)
- In vitro assays (validated biological models, including ToxTracker & ReproTracker)
- In silico modelling (QSAR, PBK, read-across)

Scope of Investigation

- Berberine (pure extract, 95–97%)
- Whole-plant preparations (*Berberis spp.*)

Project Objectives

1. Generate robust toxicological evidence
2. Address EFSA data requirements
3. Support risk assessment dossiers
4. Enable long-term regulatory compliance
5. Facilitate scientific publication in peer-reviewed journals

Investment & Structure

- Estimated total budget: ~ €550,000
- Minimum contribution per participant: ~ €10,000

Key characteristics:

- Shared cost model
- Centralised scientific coordination (FBR)
- EFSA-aligned methodology
- Use of accredited testing laboratories

Timeline & Feasibility

The expected regulatory timeline allows:

- execution of studies
- analysis and interpretation
- publication in high-impact journals

This provides a realistic window to influence the regulatory outcome.

Why Participate

By joining the initiative, stakeholders will:

-  Protect business continuity
 -  Share costs across the industry
 -  Influence scientific evidence generation
 -  Gain early access to study results
 -  Strengthen credibility with regulators
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Call to Action

Companies and associations are invited to actively participate in the project and contribute to the fundraising effort.

 Contact: segreteria@fondazionefbr.eu

 Deadline: May 11, 2026

About FBR

Botanical Research Foundation (FBR) Piazza VI Febbraio 16 – Milan, Italy