

9 June 2025

EFFCA Contribution to the Call for Evidence on the European Biotech Act

EFFCA welcomes the Commission's initiative to establish a European Biotech Act to support the EU biotechnology sector's competitiveness, resilience, and sustainability. We fully support the goal of enhancing the translation of innovation into market-ready solutions, particularly in the food sector, where fermentation and microbial technologies are critical.

The Biotech Act presents an opportunity to create a future-proof framework that embraces both traditional practices like fermentation and modern biotechnology. We urge the Commission to fully recognise fermentation as a key tool in sustainable food systems and the EU bioeconomy.

1. Regulatory Barriers to Food Culture with bioprotective effect

EFFCA shares the Commission's view that the current regulatory landscape is fragmented and not well-suited to biotechnology. One major challenge in our sector is the lack of legal clarity for certain food cultures with bioprotective effects. Around 8000 years ago, humans began using fermentation primarily to protect and preserve foods such as dairy products, wine, and beer. Today, however, factors like appearance, taste, and texture have become equally important. These uses are food ingredients under the General Food Law (Reg. (EC) No 178/2002), but some Member States classify them as food additives. This inconsistency leads to legal uncertainty, uneven implementation, and unnecessary burdens for the industry.

The additive classification would trigger pre-market authorisation and EFSA evaluation, which is disproportionate and inappropriate for microbial cultures with a long record of safe use. This would create delays, financial strain, and loss of EU competitiveness. It may also discourage the use of cultures with bioprotective effect, a key asset in food waste reduction.

EFFCA supports maintaining food cultures as ingredients under General Food Law. To ensure consumer transparency, a voluntary label could be introduced via delegated act under Regulation (EU) No 1169/2011. In parallel, self-regulatory industry guidelines that ensure safety and quality should be officially recognised. These measures would support legal certainty, innovation, and sustainability, while reducing regulatory fragmentation.

2. Innovation and NGTs in Food Microorganisms

EFFCA supports the Commission's goal to enable products developed with modern biotechnology. A key gap is the absence of a framework for New Genomic Techniques (NGTs) applied to food microorganisms.

We urge the Commission to include a roadmap enabling the use of microorganisms improved through targeted mutagenesis and cisgenesis. The current GMO rules are outdated and poorly suited to the precision and safety of microbial NGTs. This creates uncertainty, delays, and investment loss for EU actors.

NGTs allow targeted, minimal changes that improve food safety, nutrition, and shelf life. EFFCA advocates a science-based and proportionate approach, supported by whole genome sequencing and risk assessment. Alignment with trade partners is also key to avoid compliance gaps and maintain global competitiveness.

3. Alignment with EU Objectives

EFFCA's proposals contribute directly to the Commission's five priorities:

1. Speed & Streamlining: Legal clarity on food cultures and NGTs reduces time-to-market;
2. Financing & Scale: Regulatory certainty attracts investment and supports scale-up;
3. Skills: A clear framework boosts biotech expertise in fermentation;
4. Data & AI: Genomic tools and predictive analytics drive microbial innovation;
5. Environmental & Societal Impact: Food cultures reduce waste and support health and biodiversity.

Conclusion

EFFCA urges the Commission to:

- Fully recognise fermentation as a core biotechnology;
- Ensure that all food cultures applications are classified as ingredients;
- Develop a fit-for-purpose framework for microbial NGTs;
- Apply streamlined, science-based regulation across biotech sectors.