

# Food Fermentation Europe (FFE) position paper Biotech Act (Part I) and the Food & Feed Simplification Omnibus February 2026

## About FFE

Food Fermentation Europe ([FFE](#)) is the industry association representing companies active in biomass and precision fermentation for food and feed. FFE promotes science-based regulation, predictable and efficient market pathways, and European scale-up of safe fermentation-enabled products and ingredients, in complementarity with farming and wider EU bioeconomy objectives.

## What we welcome – recognition of advanced fermentation in Europe

- The Commission's recognition that advanced fermentation can contribute to EU competitiveness, bio-manufacturing scale-up and supply resilience, and that authorisation pathways must be more predictable and innovation-friendly.
- The pragmatic focus on operational delivery alongside targeted legal adjustments where specific bottlenecks are evidenced.
- The wider simplification agenda to reduce administrative burden and improve Single Market functioning – an important enabler, provided it results in workable, harmonised implementation for advanced fermentation across Member States.

## Executive summary

- **EU potential and resilience in uncertain times**
  - Europe's advanced fermentation sector is a practical lever that sits at the junction of three EU priorities: industrial competitiveness and biomanufacturing scale-up; credible, science-based food/feed safety; and resilient protein and ingredient supply through diversification.
  - With a "[Moderate Policy Support](#)" pathway, complimentary proteins (including biomass and precision fermentation) can become a meaningful EU industrial opportunity: up to €53bn domestic market by 2040 (up to €79bn incl. full value chain), ~€60bn annual trade potential, 0.5 million jobs, and €111bn added value when indirect effects are included.
  - In a more volatile geopolitical context, this is also about reducing dependency risks in inputs and ingredients and keeping first-of-a-kind capacity, know-how, and value creation in Europe.
- **What doesn't work and who is affected**
  - The EU does not lack legal routes to market (Novel Foods, food enzymes/additives, feed additives). The constraint is predictability in practice: unclear evidence expectations, uneven interpretation, long time-to-decision, and avoidable administrative burden.
  - This uncertainty hits innovators and scale-up investors first (cost of capital, siting decisions, timelines), but it also affects downstream food companies

(ingredient availability and pricing) and ultimately EU consumers and farmers through slower diversification and weaker industrial spillovers.

- OECD ([2026](#)) characterises this as a competitiveness gap driven by fragmentation, limited effective pre-submission engagement, and lengthy processes that invite iterative additional-data requests and inflate costs.
- **The solution**
  - Use Biotech Act I and the Food & Feed Simplification Omnibus as the near-term, implementable delivery vehicle to make approvals and compliance more predictable without lowering safety standards. Three operational fixes are necessary:
    - (1) Make “innovation testing spaces / regulatory sandboxes” usable for Novel Foods (under strict, risk-based conditions) so evidence can be generated earlier and more efficiently.
    - (2) Establish time-bound, structured pre-submission dialogue to clarify data requirements early across Novel Foods, additives/enzymes, and feed additives; this reduces avoidable iteration and improves legal certainty.
    - (3) Ensure the Omnibus delivers workable, harmonised implementation for contained-use fermentation with GMMs and avoids compliance approaches that function as de facto zero-tolerance where it is not scientifically or legally warranted.

The European Commission, European Parliament and Council must define a clear, risk-based sandbox model that can cover Novel Foods (scope, safeguards, time limits, data outputs aligned to EFSA needs) and strengthen pre-submission interactions so study design and evidence expectations are clearer earlier. These fixes are operational in nature and can be delivered without reopening the EU’s food and feed safety framework.

### Core asks for Biotech I and the Food and Feed Simplification Omnibus

- **Make predictability the default:** introduce a structured, time-bound pre-submission track across Novel Foods, enzymes/additives and feed additives, including clear study and dossier expectations, and service standards that reduce iteration – while fully preserving EFSA’s independent risk assessment.
- **Correct the exclusion of Novel Foods from regulatory sandboxes:** enable controlled, risk proportionate participation of Novel Foods cases to generate regulatory learning for the main food biotech pathway, under transparent governance and without any derogation from safety requirements.
- **Ensure implementable rules for contained use fermentation outputs:** clarify, for enforcement and operators, the distinction between viable production organisms and other residuals (including DNA) and avoid compliance approaches that are non-operational in practice.
- **Rationale:** These are operational fixes that can be delivered quickly within Biotech Act I and the Omnibus, reducing uncertainty, fragmentation and administrative burden that currently drives time-to-decision and deters EU scale-up, without reopening the substance of the EU food/feed safety framework or lowering standards.

## Who is affected and how

- Today, time-to-decision and evidentiary expectations remain insufficiently predictable to support investment grade scaleup in Europe, despite robust underlying safety rules.
- Operators and investors in Europe face higher financing costs and weaker EU deployment incentives when timelines are long and unpredictable, compared with jurisdictions offering clearer case-by-case early guidance and faster decision-making processes.
- Uncertainty at EU level also increases the risk of divergent Member State interpretation and enforcement, further raising compliance costs and deployment risk.
- Farming-linked value chains are indirectly affected. Indicative modelling from [Systemiq](#) points to measurable upstream demand for EU arable outputs (incl. sugar and starch crops used in advanced fermentation), with ~16% of supported jobs in arable farming and potential income upside through differentiated pricing for food-grade crops (15–20% in the model; up to ~€5bn/year by 2040). It also suggests resilience benefits through reduced reliance on imported protein feed inputs (incl. ~2.6 MMT less soy meal) and ~23 MMT lower overall feed demand.

## Policy recommendations

The immediate objective is not to rewrite EU risk governance, but to make existing pathways more predictable and operational, support investment in EU scale-up while fully maintaining the EU's high safety standards.

### Short-term fixes (Biotech Act Part I + Simplification Omnibus)

- **Novel Foods sandboxes:** enable regulatory sandboxes for Novel Foods under strict risk-based conditions (scope limits, time limits, transparency, and governance safeguards). The purpose is to generate EFSA-relevant evidence earlier and build regulatory learning for the EU's main food biotech route, without any derogation from safety requirements or any shortcut around EFSA's independent risk assessment.
- **Pre-submission as default:** establish a structured, time-bound pre-submission track across Novel Foods, additives/enzymes and feed additives, with clear study-design and dossier expectations and service standards. This directly reduces fragmentation and iterative "additional data" cycles that prolong time-to-decision and raise costs, while preserving EFSA's independence ([OECD 2026](#)).
- **Contained-use GMM outputs:** ensure the Omnibus delivers harmonised, workable implementation for food-grade contained-use fermentation across Member States. Clarify for operators and enforcement the distinction between viable production organisms and other residuals (including DNA), and avoid compliance approaches that are non-operational in practice, including outcomes that amount to de facto zero tolerance.

## Medium-term structural changes (Biotech Act Part II + related follow-up instruments)

- Build a coherent delivery chain across biotech, food/feed safety, and industrial policy instruments, with coordinated guidance and capacity measures to avoid fragmented implementation.
- Align innovation support with the scale-up gap (e.g., first-of-a-kind support (FOAK), pilot and demonstration infrastructure, clusters, and de-risking finance) to anchor biomanufacturing investment in Europe.
- Anchor public messaging in diversification and complementarity with farming, underpinned by transparency and verifiable information, including on feedstock sourcing and supply chain benefits.

## Conclusion

FFE asks the European Commission, the European Parliament and Member States to treat Biotech Act Part I, its follow-through into Part II, and the Food & Feed Simplification Omnibus as a single delivery chain focused on predictability and implementation. Europe already has market-entry routes for advanced fermentation products; what is holding back EU scale-up is uncertainty in evidence expectations, fragmented execution, and avoidable administrative iteration that extends time-to-decision and deters investment. The near-term priority is therefore a set of operational fixes that can be delivered without reopening the EU food and feed safety framework: make structured, time-bound pre-submission dialogue the default across Novel Foods, enzymes/additives and feed additives; correct the exclusion of Novel Foods from sandboxes through a controlled, risk-proportionate model that generates EFSA-relevant evidence and regulatory learning under transparent governance; and ensure the Omnibus results in workable, harmonised rules for contained-use GMM fermentation outputs, including clear distinctions between viable production organisms and other residuals (including DNA) and avoiding non-operational compliance approaches.

If implemented, these measures preserve EFSA's independent risk assessment and the EU's high safety standards, while turning policy ambition into competitiveness, investment, and real-world availability for European food and ingredient value chains.