EuropaBio Position on the Food and Feed Safety Omnibus (May 2026)

Biotechnology plays an essential role in the delivery of EU goals for competitive, healthy, resilient and sustainable economies and societies, specifically in the food and feed sectors, as recognized by the European Commission in its Communication "*Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU*"[1]. The Communication states that biotechnology can help reduce the EU's external dependencies including in the agri-food sector, contribute to food and feed with improved environmental and health traits, and reduce the overall environmental footprint of agri-food production systems, making them more resilient and supportive to reach the EU's climate neutrality goal.

However, innovative biotechnologies and products still encounter regulatory obstacles when entering the EU market, which may delay the launch of new products, increase the costs involved in the regulatory approval of such products or expose them to potential legal uncertainty, when they have already been authorized.

EuropaBio welcomes the European Commission's proposal on a Food and Feed Safety Omnibus as a positive step to address some of these issues, simplifying the regulatory framework without compromising the safety of the products placed on the market and the protection of consumers.

Legal clarification of the status of fermentation products made with genetically modified microorganisms (GMMs)

Precision Fermentation

Precision fermentation enables the production of biologically active and structurally complex molecules that conventional chemistry cannot generally manufacture or produce efficiently. It relies on the use of microorganisms such as bacteria, fungi, microalgae or yeast, whose performance can be improved and optimized through genetic engineering to produce - through fermentation - specific compounds, such as vitamins, enzymes, proteins, amino acids or lipids, minimizing the resources used in the process and the amount of waste produced by it.

Thanks to scientific and technological developments, increasingly impactful and innovative solutions are being launched by small and large companies to produce ingredients intended for mainstream food and feed applications. Precision fermentation has emerged as one of the most dynamic

[1] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU", Brussels, 20.3.2024, COM (2024) 137 final

innovation areas in Europe and globally, with hundreds of startups developing new products for a growing range of applications, and larger companies seizing strategic investment opportunities.

Unfortunately, due to diverging interpretations of Regulation (EC) No. 1829/2003[2] by Member States, the legal status of these products as not falling under the scope of the Genetically Modified Food and Feed Regulation in the EU has been challenged by some national authorities. Companies have been facing legal uncertainty and have been exposed to the risk of product recalls, while also coping with a lack of harmonized application of the Regulation across the EU internal market.

The European Commission's Proposal

The European Commission Food and Feed Safety Omnibus proposal contains positive and timely elements towards clarifying and harmonizing the implementation of the regulatory framework for food and feed made with the help of Genetically Modified Microorganisms (GMMs), unlocking their full market potential and their benefits for customers and consumers.

The proposed amendment clarifies that these products should not be considered genetically modified food or feed, when they do not contain the viable production microorganism (i.e. its complete and alive cells capable of reproduction). It also offers guidance on residue presence, thereby providing a path forward to overcome the market fragmentation resulting from diverging interpretations among Member States of the currently unclear Regulation (EC) No. 1829/2003.

By streamlining processes and providing companies with greater legal certainty, the proposal strengthens the competitiveness of the European biotechnology sector, in line with the broader objectives of the Biotech Act, and it enables companies to reliably deliver sustainably manufactured food and feed products to customers and consumers.

While the clarification proposed in the Omnibus is an essential step forward, it will however be critical to ensure an agreed harmonised and consistent implementation at Member State level to prevent diverging national approaches from re-emerging. Towards that end, we call on the Commission to take all necessary and appropriate accompanying actions, including the provision of a clear and authoritative guidance. In this context, it should be ensured that the presence of viable cells of the production microorganism remains the sole criterion for determining the legal status of food and feed products made with GMMs and establish whether they are genetically modified food or feed products which require authorization as such under Regulation (EC) No. 1829/2003.

The presence of residues shall not be used as a regulatory criterion and shall continue to be addressed during the safety assessment required under product-specific legislation[3] carried out by the European Food Safety Authority (EFSA).

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[2] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed

[3] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ; Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition; Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97; Regulation (EC) No 1331/2008 of the European Parliament and of the

The authorization of fermentation products made with GMMs

Microorganisms can be genetically modified to optimise the production of specific substances, such as vitamins, proteins, amino acids, lipids and enzymes for food and feed use, through fermentation. Following fermentation and production of the target substance (e.g., vitamin) in a closed fermenter under strictly controlled conditions[4], the microorganism is separated from the target product.

The target substance is then purified before being incorporated into other products and/or placed on the market under sectoral legislation such as the Regulations on food additives, feed additives or food enzymes. Under the current procedure, the safety of the microorganism's residues which may be present in the target product is evaluated by the EFSA as part of the product-specific risk assessment. As an example, a food enzyme produced by fermentation with GMMs will undergo the risk assessment that food enzymes are subject to under Regulations (EC) No. 1331/2008 and 1332/2008, in order to be authorised as such.

To this end, a company must submit a full scientific and administrative dossier under the Common Authorisation Procedure laid down in Regulation (EC) No. 1331/2008, with specific requirements set out in Regulation (EC) No. 1332/2008 on food enzymes. To complete the dossier, companies are required to commission scientific studies whose completion may require multiple years.

Thanks to this process, fermentation products made with GMMs have been safely placed on the EU market for decades. Today, food and feed products and their value chains are highly dependent on biotech and the use of GMMs, which often represents the sole viable method for production:

- **100% of vitamin B2** used in food is currently produced with GMMs.
- **All poultry and pig feed** incorporate **one or more GMM derived ingredients** (e.g., enzyme).
- A regulatory re-classification of fermentation products would lead to the withdrawal of approx. **300-500 fermentation products** from the EU market, with no suitable alternatives available.
- GMM-fermentation-derived enzymes are used in approx. **2,500 commercial formulations**.

This widespread use is sustained by the efficiency and sustainability benefits that the use of GMMs in precision fermentation bring:

- higher **yields**,
- improved **performance**,
- better **nutrient usage**,
- reduction of **environmental footprint**.

Moving away from viable cells as sole regulatory criterion would hamper industry from producing and marketing such GMM-derived products in Europe. Such a shift would trigger the need for already

Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings

[4] Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms

authorised commercial products (under e.g. the Food Enzymes Regulation) to be authorized also under Regulation (EC) No. 1829/2003, thereby creating major legal and regulatory uncertainty resulting in significant delays for products used in the EU market.

This would undermine the economic viability and attractiveness of the EU internal market, given the substantial additional time, effort, and costs associated with GM food and feed authorisation. Such an approach would also negatively affect the resilience of value chains, leading to product withdrawals from the market and supply disruptions during lengthy reauthorisation processes, with approval processes for GM products currently taking on average five years.

Regulatory streamlining for feed additives

Feed additives are an important application of industrial biotechnology. EuropaBio welcomes the removal of the mandatory 10-year renewal requirement for most feed additives. This change fosters coherence with other sectoral frameworks such as Regulation (EC) No. 1333/2008 on food additives, which do not require periodic renewal of authorised products. It also reduces unnecessary administrative burden for companies and for EFSA alike while providing the same safety safeguards.

Closing remaining regulatory gaps through the Biotech Act II

While the Omnibus lays a foundation for clearer, more coherent and enabling regulatory pathways for biotech-derived food and feed products, it must be complemented in the Biotech Acts I and II to fully address remaining gaps. Building on the clarifications and streamlining already introduced, Biotech Act II offers a unique opportunity to deliver more ambitious, competitive and innovation-friendly pathways for industrial biotechnology applications.

Within this broader objective of establishing clearer and more enabling regulatory pathways, several unresolved issues continue to illustrate where additional clarification would be particularly impactful in food and feed applications. These include the regulatory treatment of feed additives intended exclusively for export, as well as the legal status of certain uses of food cultures, where long-standing divergences in interpretation persist across Member States. From a broader perspective, the Biotech Act II should also offer next steps to move towards a product-centric approval system for biotechnology products, focusing on the characteristics of the products rather than on the methods used to obtain them.

Addressing such issues would contribute to more coherent, predictable pathways, reduce fragmentation, and better support innovation and investment in sustainable fermentation and biotechnology-based products.