



## Joint statement on regulatory sandboxes under the Biotech Act I and the exclusion of novel foods

Brussels, 30 March 2026

The Commission proposal for a European Biotech Act, adopted on 16 December 2025 introduces regulatory sandboxes under the General Food Law (Regulation (EC) No 178/2002) to create controlled environments where regulators and applicants can test innovative products, processes, data requirements and methodologies, including New Approach Methodologies (NAMs) and AI-driven tools. The undersigned associations strongly welcome this initiative as an important step toward strengthening regulatory learning, improving study design, and ensuring that EU food law remains responsive to rapid scientific and technological developments.

Recital 113 of the proposal explicitly recognises that the food and feed sector is undergoing rapid technological development. These advances are expected to support sustainability objectives, reduce animal testing and improve resource efficiency. In this context, it should be noted that the novel food framework is the primary EU regulatory pathway through which innovative foods and food ingredients are authorised. Excluding any innovative sector, for instance novel foods, from regulatory sandboxes therefore removes the possibility for the EU food sector to test and refine many of the very innovations that the Biotech Act seeks to promote.

In areas characterised by fast-moving innovation, regulatory sandboxes have the potential to:

- provide a structured and transparent framework for early dialogue between applicants and authorities,
- support clarity on data requirements and facilitating high-quality, science-based risk assessment before formal authorisation procedures begin.
- reduce uncertainty, avoid unnecessary costs and prevent avoidable failures in development.

However, Article 56(7) of the proposed Biotech Act, which introduces Article 49a(2)(a) into Regulation (EC) No 178/2002, explicitly excludes novel foods from the scope of regulatory sandboxes. This exclusion is further justified in Recital (115) on the grounds that certain novel foods may raise “ethical or cultural concerns” and that these are best addressed within the framework of Regulation (EU) 2015/2283.

Regulation (EU) 2015/2283 is straightforward regarding the basis for authorisations:

- Article 7 provides that a novel food may only be authorised if, “on the basis of the scientific evidence available, (it) does not pose a safety risk to human health.”
- Article 6 of Regulation (EC) No 178/2002 establishes that risk assessment must be based exclusively on scientific evidence and carried out in an independent, objective and transparent manner.

Under EU food law, safety is assessed exclusively on the basis of scientific evidence. EFSA's mandate is strictly limited to independent, objective and transparent scientific risk assessment. We would like to stress that while ethical or cultural considerations may be relevant at political level, they do not form part of EFSA's evaluation and are not criteria for authorisation under the Novel Foods Regulation (EU) 2015/2283.

We consider that:

- the exclusion of all novel foods from any EU sandbox on the basis that certain products may raise ethical or cultural concerns in certain countries is disproportionate.
- the vast majority of novel foods authorised under Regulation (EU) 2015/2283 do not trigger such considerations.
- even where broader societal questions arise, regulatory sandboxes could provide a structured setting in which such aspects are discussed early in the development process, without affecting the science-based safety assessment carried out by EFSA.

**The introduction of regulatory sandboxes concerns the scientific and technical preparation of risk assessment, not market authorisation and not broader societal debates. Including novel foods within a sandbox would not modify the legal basis for authorisation, nor would it bypass the safety assessment required under Regulation (EU) 2015/2283.**

### **Deliberate introduction of incoherence in the adopted proposal**

The proposal allows sandboxes to apply to food enzymes, food additives, flavourings, processing aids, feed, food contact materials, food production processes, and AI- or data-driven testing methodologies, provided these do not qualify as novel foods. In practice, this means that biotechnology-driven processes, fermentation techniques, data generation methods, testing strategies and digital tools may be tested in a sandbox environment when they relate to these categories. However, it is inconsistent that when the very same processes and methodologies lead to a product that falls under the Novel Foods Regulation, the general sandbox principles that are valid for the other categories cease to apply.

This distinction is not based on scientific risk, nor on the nature or complexity of the technology involved, but solely on the regulatory classification of the final product. The same biotechnological process, data generation method or AI-supported testing strategy may benefit from a sandbox when applied to enzymes, additives or processing aids, yet be excluded when leading to a product classified as a novel food.

**This exclusion weakens the coherence of the regulatory framework and introduces avoidable fragmentation in the treatment of biotechnology-derived innovations.**

### **The innovation ambition of the Biotech Act I is weakened by this exclusion.**

A growing proportion of novel foods are developed through advanced biotechnological approaches, including precision- and biomass-fermentation, microbial production systems, cell-based techniques and other innovative manufacturing methods. These products are often first-of-their-kind and require new types of data, new testing strategies and new assessment approaches. They are precisely the cases where early dialogue with regulators and EFSA on

study design, data requirements and methodological approaches would bring the greatest value, both for applicants and for regulators.

For first-of-their-kind products, such as foods derived from precision- and biomass-fermentation, cell-based production or other advanced biotechnologies, early engagement with regulators on study design, data generation strategies and testing methodologies is critical. Where scientific experience is limited, a structured “safe space” to clarify expectations would enhance the robustness of safety assessment while reducing unnecessary duplication of studies, avoidable costs and development failures, thereby streamlining the process and reducing time to market.

Excluding novel foods from this framework does not provide additional consumer protection. Instead, it removes the possibility for regulators and applicants to learn, in a controlled setting, how to assess the most innovative and scientifically complex food products emerging from biotechnology and biomanufacturing, and moves this learning to the time when the novel food is submitted for safety assessment, with consequences on process, predictability and timelines.

This exclusion also sits uneasily with the broader objectives of the Biotech Act. The proposal emphasises the need to strengthen EU biotechnology, biomanufacturing, digitalisation and the use of AI, and it amends the General Food Law to broaden the scope of EFSA pre-submission advice to study design. Yet the category of foods most directly resulting from these biotechnological advances is excluded from the very instrument designed to support regulatory adaptation to them.

**Policymakers should be clear that regulatory sandboxes do not grant automatic market access and do not bypass Regulation (EU) 2015/2283.**

Under the proposed framework, it requires the establishment of a dedicated ‘sandbox plan’ specifying scope, objectives, duration and safeguards, in accordance with the criteria laid down in Article 49b. These plans must be communicated to the Commission and EFSA, ensuring transparency and appropriate oversight of sandbox activities. Their purpose is to improve how safety assessments are prepared and conducted.

Under this proposal, regulatory sandboxes in the food and feed area can only be established by Member States, whereas in other regulatory domains covered by the Biotech Act the Commission may also establish such sandboxes. This asymmetry merits further consideration, as it may affect the coherence and scalability of sandbox initiatives across the EU.

Recital 168 of the proposal foresees that regulatory sandboxes in the health sector may be established at EU level by the Commission, potentially following input from the European Medicines Agency, based on an analysis of benefits, risks and regulatory challenges. In contrast, in the food and feed area, regulatory sandboxes are established at Member State level. In this context, a similar mechanism could be explored, whereby EFSA could play a supporting role, for instance by identifying emerging scientific or methodological challenges relevant to risk assessment and facilitate coordination among Member States.

## Conclusion

The undersigned associations consider that the exclusion of any innovative sector, like novel foods from regulatory sandboxes is not justified on legal, scientific or innovation grounds and creates an internal inconsistency within the Biotech Act framework.

Including novel foods under the sandbox scheme would not alter the safety standard or the requirements of Regulation (EU) 2015/2283. It would instead enhance the quality, predictability and efficiency of scientific risk assessment for the most innovative and technologically advanced food products.

Including novel foods within this framework would strengthen the quality of safety assessments, improve EFSA pre-submission dialogue, support the validation of innovative methodologies, and ensure that the regulatory system evolves in step with scientific and technological progress in the EU food sector.

We therefore invite the Commission and co-legislators to ensure that novel foods can benefit from regulatory sandboxes under the same science-based conditions applicable to other regulated food categories.

## Key messages

- Regulatory sandboxes are structured frameworks that allow companies and authorities to test innovative approaches, products or methodologies in a controlled environment, under regulatory supervision, with the objective of improving understanding of regulatory requirements while maintaining safety standards.
- Regulatory sandboxes are designed to strengthen scientific risk assessment, improve study design and clarify data requirements, while fully maintaining the integrity of existing authorisation procedures.
- The justification for excluding novel foods based on “ethical or cultural concerns” does not align with the legal framework of EU food law, where authorisation is based on scientific safety assessment, nor does it align with the reason for sandboxes as mentioned above.
- The sandbox can apply to biotechnological processes, data generation, AI tools and food production stages, but not when the output qualifies as a novel food, creating an internal inconsistency in the framework.
- Novel foods are often first-of-their-kind biotechnological products, precisely where regulatory learning and early dialogue with EFSA would bring the greatest value.
- Excluding novel foods does not enhance consumer protection. Instead, it limits the ability of regulators and applicants to improve the scientific robustness and predictability of safety assessments for innovative products.
- This exclusion contradicts the research, innovation and biotechnology objectives of the Biotech Act and creates an unjustified difference compared to other regulated food categories.
- Including novel foods in regulatory sandboxes would strengthen the quality, efficiency and predictability of safety assessments while maintaining full application of Regulation (EU) 2015/2283.