

Food biotechnology regulatory sandboxes are an important enabler of EU innovation and competitiveness

To deliver ambitions to speed up the transition from lab to market for innovative technologies, EU policymakers should ensure innovative approaches to regulation, such as sandboxes for food biotechnology, are prioritised to boost European competitiveness and drive growth.

Paper summary

This paper sets out the case for the development of food biotechnology regulatory sandboxes in the EU at Member State level as a means of fostering business support, and thereby enabling innovative products with sustainability and economic benefits for the EU to come to market. Sandboxes enable policymakers and regulators to expand their knowledge of emerging products, ensuring they have the right regulatory resources and expertise to efficiently assess their safety.

The current EU regulatory framework for food biotechnology products is viewed as overly complex and costly, with evidence that this is discouraging innovative producers from coming to market and risking the EU losing out on the economic and sustainability benefits of these technologies.

Regulatory sandboxes are tools that allow businesses to test technologies under regulatory supervision. They do not involve weakening of safety standards, but instead allow regulators and producers to work together to explore mechanisms for assessing new technologies.

The benefits of sandboxes are broad. For regulators, they can support the understanding of innovative products which enables them to refine their risk assessment approaches and identify any resourcing and expertise gaps before they are asked to assess these products, supporting them to make timely, evidence-based decisions on authorisations.

For innovators, sandboxes enable the development of products which are regulation-compliant, whilst providing flexibility to experiment. This is essential for food biotechnology producers, where existing risk assessment approaches were not designed to account for innovation in product design. Sandboxes provide producers - particularly SMEs with limited regulatory expertise - with the tools to submit better applications and support the efficient operation of the regulatory system.

Finally, sandboxes also benefit consumers through helping to support new and innovative products in coming to market, broadening consumer choice whilst ensuring that representative feedback is taken into account so future products align with consumer needs.

The paper concludes with an annex of successful examples of regulatory sandboxes within the EU and globally, with the hope that these provide inspiration for EU regulators to prioritise the development of a food biotechnology sandbox within this Commission work programme.

The existing EU regulatory context

Governments across the world are recognising the role of food biotechnology, in [building a competitive, resilient food supply](#) as well as in addressing societal challenges such as [climate change](#). With evidence suggesting even a [modest diversification](#) of our protein system could dramatically boost domestic food production and reduce reliance on imports - as well as enabling the EU to capitalise on a sector that could create up to [9.8 million jobs globally by 2050](#) - there is a strong argument for policymakers to ensure these sectors can flourish within the EU. However, for this emerging industry to fulfil its economic and societal potential in Europe, food biotechnology must be able to reach the market efficiently and effectively. The EU has one of the most robust pre-market safety frameworks for food biotechnology in the world, which involves an evidence-based assessment of the safety and nutritional evidence of novel products and draws on world-leading experts from the European Food Safety Authority.

However, there is increasing evidence that the *implementation* of the EU's regulated products framework is causing producers to re-evaluate EU market entry. The regulatory framework is variously described as being [too inflexible](#) to enable consultation between companies and the regulator, [too slow](#) to provide approvals for food biotechnology products which have clearly demonstrated their safety credentials, and [too costly](#) to enable SMEs to enter the market. These bureaucratic inefficiencies and procedural complications - many of which are unrelated to food safety considerations - have led [some](#) to suggest that the EU runs the risk of being left behind as a product launch destination in favour of other global markets.

While not a silver bullet, one solution to a cumbersome regulatory path to market and poor industry-regulator collaboration could be found in regulatory sandboxes, which have so far only been trialled by the Commission for regulating blockchain technologies but provide exciting opportunities to bridge the gap between producers, consumers and regulators.

What is a regulatory sandbox?

Although there is no single definition of a regulatory sandbox, they generally refer to tools that allow businesses to test innovative technologies under the supervision of a regulatory authority. Sandboxes do not entail a weakening of safety standards - rather they enable regulators and producers to work together to explore appropriate mechanisms for assessing new technologies, whilst deepening the regulator's understanding of technologies and production methods. Sandboxes do not imply endorsement of a technology by a regulator, but rather the need for more information on risk assessment approaches for its regulation and feature safeguards to preserve overarching regulatory objectives, such as safety and consumer protection.

Sandboxes are time-limited, and often involve permitting companies to conduct limited engagement with 'real' consumers to enable feedback under robust regulator supervision. As the European Parliamentary Research Service [states](#), sandboxes have two roles:

- 1) They foster business learning through the testing of innovations in a real-world environment with regulator oversight; and

2) They support regulatory learning through the formulation of legal regimes to support businesses in their innovation activities under regulatory supervision. Sandboxes enable regulators to work with emerging products, and pre-emptively resource risk assessment functions and expertise gaps to minimise bureaucratic delays during authorisations.

What has the European Commission said about sandboxes?

The European Parliament Research Service [notes](#) that in recent years the sandbox approach has gained considerable traction across EU governments for regulating emerging technologies. Regulatory sandboxes operated by financial regulatory authorities such as the UK's [Financial Conduct Authority](#) are now widely used, while the Commission itself has supported the [European Blockchain Regulatory Sandbox](#), as well as setting out plans for sandboxes as part of the [Artificial Intelligence Act](#) and [Net Zero Industry Act](#).

In the 2024 [Communication on Boosting Biotechnology and Biomanufacturing in the EU](#), the Commission noted its desire to “...*further promote the establishment of regulatory sandboxes that allow to test novel solutions in a controlled environment for a limited amount of time under the supervision of regulators, as a way of bringing more of them quickly to the market.*” This was supported by ambitions in the new Commission's [Competitiveness Compass](#) to “...*promote the access of innovative companies to European research and technology infrastructures and regulatory sandboxes allowing innovators to develop and test new ideas.*”

Against this backdrop, the time is right for the European Commission to explore the application of regulatory sandboxes to a priority area of innovation: food biotechnology.

How could a sandbox for food biotechnology be established?

As noted in a recent [academic paper](#), under the existing regulatory framework it is unclear whether EFSA or the European Commission has the individual mandate to set up cross-EU regulatory sandboxes for food and feed. Instead, the initiative lies with Member States - many of whom have already [expressed strong interest](#) in exploring the concept of sandboxes for innovative food and feed technologies - to pursue the development of these testing and trialling structures.

However, to support Member States in doing this, it is necessary for the Commission to provide Member States with the legal and regulatory clarity to design national sandboxes within a common framework. This could be done by amending the General Food Law Regulation, and specifically Article 3 (8) to clarify that existing rules around ‘placing on the market’ can be loosened in situations which enable the pre-market, non-commercial testing and trialling of food and feed (as necessary) and more broadly providing explicit encouragement to Member States to pursue opportunities for sandbox development. To properly support the food biotech sector, these sandboxes should be equally applicable across all regulated food and feed product categories, including novel foods and products regulated

under the GM Food and Feed Regulation, ensuring that the full range of production technologies benefit from the opportunities that sandboxes provide.

What benefits could sandboxes bring to the food biotechnology sector?

Regulatory sandboxes established within Member States to support the implementation of the EU's regulated products framework present unique opportunities for European producers, regulators and consumers. Former Italian Prime Minister [Mario Draghi](#) highlighted the need to translate Europe's world-leading science into economic growth, and sandboxes provide opportunities to ensure Europe does not fall behind in an emerging technology field.

The benefits for regulators:

A food biotechnology sandbox could support EU and Member State food safety agencies and regulators in deepening their understanding of innovative products which would in turn enable them to refine their risk assessment approaches. In the dynamic food biotechnology sector, the pace of innovation means that regulators are consistently behind the curve of cutting edge technological developments which emerge within private companies and in research institutions. Sandboxes offer the opportunity to bridge this gap and develop a shared knowledge base, so that regulators including EFSA can proactively define proportionate risk assessment techniques.

At the same time, sandboxes offer an opportunity for EU and Member State regulators to identify any resourcing and expertise gaps with regards to food biotechnology technologies, in turn supporting regulators - particularly EFSA - to make timely and evidence-based decisions on new product authorisations without having to onboard new experts at short notice.

Supporting regulatory sandboxes would also signpost the EU's international standing as a pioneer in emerging food technology regulation, increasing the likelihood of future investment and onshoring of technological developments in food biotechnology. Demonstrating global leadership in regulatory approaches would also provide the EU with a leveraged position on international regulatory coordination for these technologies which can be expected in years to come via Codex Alimentarius and other multilateral fora.

The benefits for innovators:

Food biotechnology sandboxes would enable European innovators to develop their products in a manner which is regulation-compliant, but affords greater flexibility and room to experiment. This is particularly useful for food innovations where existing risk assessment approaches were not designed to account for the different production processes and innovation we currently see in product design, and can therefore be overly cumbersome or indeed almost impossible to reconcile with the design of new products seeking to enter the market.

Regulatory sandboxes would also provide food biotechnology producers with a better understanding of regulatory requirements for their products - ensuring applicants submit higher quality authorisation applications to regulators, as well as proactively introducing appropriate consumer protection safeguards into product design. Regulators can offer producers guidance

on how specific rules apply to the new products, upskilling the wider sector and maximising regulatory efficiency. This can be particularly beneficial for SMEs, who often lack in-house regulatory resources or expertise of more established competitors.

Reduced regulatory uncertainty and the ability to conduct testing can also help to facilitate financing for innovative firms, onshoring investment and job opportunities within the EU. In a recent [report](#), the United Kingdom Financial Conduct Authority found that 40% of firms that completed the inaugural programme of its financial services sandbox received investment during or following sandbox testing. As such, sandboxes also offer opportunities for economic growth and increased investment in the EU, boosting international competitiveness.

The benefits for consumers:

Consumers could also benefit from the introduction of food biotechnology sandboxes, as the proposal helps to foster innovation in food production within the EU - and therefore expand consumer choice - whilst ensuring that the same high levels of food safety in the EU are maintained for pioneering new products. Equally, by working with real consumers, producers can seek representative feedback and ensure future products align with EU consumer needs.

Regulatory sandboxes - an opportunity to lead in food innovation and support producers

The European Commission has placed competitiveness at the heart of its political agenda, with a [commitment](#) to ensuring that Europe is a place where growth and innovation can continue to be fostered. Perhaps nowhere is this more important than in the field of food biotechnology, which offers an opportunity to make the EU's food system more secure and resilient, more competitive and more sustainable in the face of ongoing environmental shocks.

Regulatory sandboxes for food biotechnology in the EU can help to deliver on these opportunities. They enable producers, consumers and regulators to come together in the spirit of co-design; robustly testing the appropriate regulatory and scientific mechanisms to assess these new food products whilst building a shared knowledge base which enables food products to come to market efficiently without compromising EU food safety standards.

The Commission has an unrivalled opportunity to secure the EU's position as a global leader in food innovation and ensure a sustainable and competitive future in the EU. Food biotechnology regulatory sandboxes should be a key element of this approach.

Annex - Case studies of operational sandbox programmes

The volume of existing precedents - both within the EU and internationally - for the successful implementation of the sandbox approach for innovative technologies is a strong exemplification of the potential opportunities they could provide in the context of food biotechnology in the EU.

The UK Cell-cultivated Products sandbox

In 2024, the UK Food Standards Agency (FSA) was awarded £1.6 million in funding to launch an innovative [sandbox programme for cell-cultivated products](#) (CCPs). The FSA recognised these products were unlike anything previously available in the UK, and so therefore that they needed to learn more about these products to evaluate their safety properly.

The sandbox will recruit a new team to work across the FSA to gather rigorous scientific evidence on CCPs in order to make well-informed and timely evidence-based recommendations about product safety, and will involve regular workshop-style collaborations between industry groups and the regulator. It will also allow the FSA to better produce guidance and support for all companies across the ecosystem on how to make products in a safe way and how to demonstrate this in authorisation applications, increasing regulatory efficiency and efficacy.

The Singapore Future Ready Food Safety Hub

Set up as a national research platform under the Singapore Food Story R&D agenda, the [Future Ready Food Safety Hub \(FRESH\)](#) provides expert counsel and food safety research services to public and private organisations working to bring food biotechnologies to Singapore. Leveraging Singapore's expertise in food toxicology and risk assessment science, FRESH drives collaboration between producers, regulators and academia to ensure that food biotechnologies can be properly assessed and evaluated before being brought to market.

FRESH aims to close the gap in scientific capabilities for food safety risk assessment and validation, supporting industry in new product development, to strengthen Singapore's food safety ecosystem by providing a neutral platform for collaboration between regulators, public research performers, and industry on food safety, and to enable regulatory responsiveness through early exposure of regulatory scientists to novel methodologies developed in the food industry, addressing emerging food safety issues and accelerating product time-to-market. FRESH focuses on integrating food safety assessment into R&D processes to ensure "safety by design" and accelerate the time-to-market of food biotechnologies and agri-food technologies.

The EU Blockchain Sandbox

The [pan-European Blockchain Regulatory Sandbox](#) for innovative Distributed Ledger Technologies establishes a pan-European framework for regulatory dialogues which aims to increase legal certainty for innovative blockchain technology solutions. The sandbox seeks to facilitate dialogue between regulators and innovators. Legal advice and regulatory guidance is

provided in a safe and confidential environment across industry sectors and geographic regions, which will help to identify best practices in the interest of the wider blockchain community.

Starting in 2023, the sandbox annually accepts cohorts of 20 blockchain use cases who are matched with relevant national and EU regulators for a safe and constructive dialogue on their most relevant regulatory issues. Use cases are selected on the basis of the maturity of the business case, legal and regulatory relevance and their contribution to EU policy priorities.

Sandboxes in the EU Artificial Intelligence Act

Within the [2024 AI Act](#), the Commission recognised that AI is a rapidly developing family of technologies that requires regulatory oversight and a safe and controlled space for experimentation, while ensuring responsible innovation and appropriate safeguards. The Act mandated that Member State national competent authorities establish at least one AI regulatory sandbox at national level to facilitate the testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service.

Objectives of the AI regulatory sandboxes are to foster innovation by establishing a controlled testing environment in the pre-marketing phase with a view to ensuring eventual compliance with EU law. Sandboxes aim to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities and impacts of AI use, to facilitate regulatory learning for authorities. Specifically, the sandboxes are envisaged as focusing on issues that currently raise legal uncertainty, with a view to future adaptations of the legal framework in cases where the existing framework is no longer appropriate or relevant, as well as to accelerate access to markets for SMEs.

The APPROVALS Project

The EU – via Horizon Europe – has already provided funding to apply the sandbox concept to emerging food technologies in the case of the [APPROVALS Project](#). Launched in September 2024 the project aims to facilitate the development of cellular agriculture techniques in food through the development and implementation of a testing space for stakeholders during the development process of their products. The APPROVALS project focuses on supporting producers during product development to enable their future market entry, with a sandbox component that will enable producers to work with other SMEs and experts. However, at this stage it will not primarily focus on questions of appropriate product assessment and the future regulatory or legislative amendments required to support the development of the sector with direct EU regulatory oversight.