

EU BIOTECH ACT II: Provisions on Regulatory Sandboxes

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This paper presents proposals regarding regulatory sandboxes with the aim of making the sandboxes a flexible and efficient tool helping simpler regulations and faster approvals, and this way contribute to better competitiveness, resilience and green transition. It consists of 3 parts:

1. WHY are regulatory sandboxes in biotechnology allowing the need for flexibility?
2. HOW can tailormade provisions in Biotech Act II allow such flexibility?
3. HOW can supplements in the recitals of the current Biotech Act I help flexibility?

1. THE WHY: Justification

In the following background and purposes of regulatory sandboxes are presented, the need for flexibility is stressed and the benefits for EU are underlined.

Background and purpose

The European Union is a global leader in safe, responsible, and innovation-friendly biotechnology. But, as demonstrated in the Draghi report, there is an urgent need for closing the innovation gap, simplification, addressing regulatory barriers and speeding up approval procedures. Frustrated companies are moving elsewhere, and the EU is left behind, while other parts of the world sprint off at high speed. Competitiveness is weakened, sustainability suffers and resilience is not considered – despite the EU's clear ability to create biotechnology, including biosolutions innovation. One of the major problems is regulatory barriers and very slow approval procedures, sometimes framed as “the double valley of death” for SMEs. Also, big companies suffer from the very complex and long approval procedures.

If this continues unchanged, the EU will continue falling behind, leaving the biosolutions market to other parts of the world. This is a huge problem for the EU. At the same time, it is crucial that the Union upholds EU values, food safety, the

precautionary principle, and the Single Market. It will take time to amend all the relevant regulations and practices – speed is needed and pathways are necessary. An omnibus regulation is helping but is not enough.

The purpose of introducing regulatory sandboxes in the Biotech Act II is to help ensure that EU regulation remains fit for purpose and fit for future technologies, while maintaining the EU's strong commitment to precaution, public trust, and scientific excellence. Sandboxes can enable evidence-building, mutual learning between innovators and regulators, and more efficient regulatory pathways, helping to reduce unnecessary delays without compromising safety. Regulatory sandboxes will, however, only become a gamechanger if they present a pathway which enables real changes – otherwise there is a risk that they are seen as too bureaucratic, toothless and time-consuming to create the changes needed.

If made in a future-oriented and innovation-friendly way regulatory sandboxes can become a very important experimental regulatory tool – a gamechanger. They can offer a structured and supervised environment in which innovative biotechnology solutions can be tested, evaluated, and better understood, while fully respecting the Union's high standards for safety, environmental protection, and the functioning of the Single Market. But it will only happen if some flexibility is built into the experimental, time-limited and monitored regulatory framework.

Need for flexibility

Law is static by nature, often representing former technology and frozen ethics, which calls for dynamic tools to ensure that regulation is fit for purpose. The regulatory landscape for biosolutions is complex and, in some areas, based on earlier scientific, technological, or societal assumptions. In some areas of biotechnology, the landscape is characterized by regulatory legacy, with complex, partly outdated regulations. EU regulation in biosolutions, food, plant protection etc. was drafted at a time when precision fermentation was not industrially viable, AI-designed proteins were not possible, non-animal testing methods were not scientifically mature, biopesticides were not developed, synthetic biology etc. did not exist. These circumstances have changed dramatically, creating a new situation, where regulations are not always fit-for-purpose and fit-for-future. In such cases of mismatch, it is important to allow flexibility to overcome barriers because of new research, knowledge, technologies and evidence and new innovative products, which are healthy, effective, and where the companies are eager to go to market, but experience regulatory, administrative barriers, slowing everything down. Sometimes they drown, also because the period with no income is too long, and often they take the product and the company to other parts of the world. This leads to company-drain. Regulatory sandboxes can create useful flexible steppingstones.

Flexibility is essential to change this situation and encourage innovation and startup companies to stay in Europe. Such flexibility can be achieved in different ways.

One efficient tool is for regulatory sandboxes to allow the supervisory authority in exceptional cases to test the innovative product on relevant regulations, but with no obligation to follow provisions which are outdated, and therefore irrelevant and instead test on experimental provisions, which are relevant for the new innovative product. It does not make sense to test new innovations on old, outdated and irrelevant rules. And testing experimental rules supports the learning between innovators and regulators.

Such temporary permitting (narrow and supervised flexibility elements is necessary to generate important evidence) can be helpful in breaking down regulatory barriers, where the regulation is outdated. Documentation for regulations being outdated can be based on significant changes in scientific or technological development. If current regulation was developed under scientific, technological or societal assumptions that have changed significantly this may lead to changes of the testing themes. This may be the case where fundamentally new knowledge, technologies or methods have replaced earlier approaches, and where solid research evidence based on independent research, supports that the new knowledge or technology has different characteristics, risks or innovation potential than those assumed when the regulation was originally designed. Flexibility can include special monitoring and reporting and can be revoked immediately if risks emerge. As flexibility is narrow, and fully supervised, it is a scientific tool, not a regulatory shortcut.

Another flexibility tool can be temporary national authorizations of innovative, important products. They may be considered only where it is necessary to generate essential evidence, and when supportive of the EU process. Member State-level temporary National market approvals include the potential in rare cases to give companies early market access, allow revenue generation, and possibility of investment in innovation, reduce pressure to relocate to the US, UK, Singapore etc. and strengthen local biotech ecosystems. For SME's it can be vital to start on a limited, national market, to start to earn money, avoid the "valley of death" and prefer Europe as their market and company base. This supports EU competitiveness, investment possibilities and strategic autonomy.

National approvals are temporary and supervised, monitored, transparent and notified to the EU. Based on national approvals the EU can use this as a strong basis for EU-wide approval, can create fast-track pathway, and can update regulation. This is faster and more politically feasible than top-down harmonization. National approvals are already used in other sectors, for example medical devices (national authorizations), chemicals (national derogation), digital regulation (national pilot schemes). National approvals may prevent innovation flight, generate evidence for EU-level rules, reduce long-term fragmentation and accelerate harmonization. They can function this way as a bridge, not a barrier.

When several Member States grant national approvals under comparable conditions, the resulting evidence provides a robust basis for EU-wide approval pathways and future regulatory alignment. The proposal ensures that regulation keeps pace with science, prevent company flight, accelerate innovation, reduce

fragmentation and create a pathway toward EU-wide harmonization – a mechanism to future-proof EU law. The approach is aligned with EU values, as the framework upholds the precautionary principle.

This step-by-step approach supports the EU procedure, where it is a challenge to have enough competent people in, for example, EFSA. The Member States will deliver scientific evidence and supervisory authorities' participation in the sandbox, and the EU will have a much more elaborated base to make their risk assessment, upholding independency as a condition for EU market approval. Member States can also prioritize regulatory sandboxes of great importance for resilience, competitiveness and the green transition, which will be beneficial for the EU priorities. This way a necessary mere holistic approach to the importance of innovation can be included in the step-by-step process.¹

The flexible approach seems compatible with EU values and the Single Market, as sandboxes operate under competent authorities, apply strict safeguards, and remain time-limited. They complement existing tools such as research projects, testbeds, pilot schemes, and experimental regulation, all of which help generate the knowledge needed to modernize regulatory frameworks while upholding EU values and safety. Member State sandboxes with flexibility and temporary national approvals must be seen as compatible with the Single Market, as they are legally permissible, experimental, time-limited, supervised by competent authorities and designed to generate evidence for future EU action, do not violate free movement principles, are proportionate and justified, and support EU-level harmonization.²

¹ The precautionary principle is extremely important, but a debate on how to include a more holistic approach and what the risk picture is, if the innovation-gap keeps widening, and how efficiency could play a role (“better than”) could be fruitful.

² Relevant treaty provisions are Article 5 TEU — Principle of Subsidiarity, allowing Member States to act when EU-level action is not strictly necessary; Article 114 TFEU — Internal Market Harmonisation, allowing derogations, transitional measures, national experimentation, when justified by innovation, safety, or scientific progress. The Court of Justice has repeatedly held that Article 114 does not require identical rules everywhere - only that differences must not create unjustified barriers; Article 168(4)(c) TFEU — High Level of Health Protection requiring that EU health-related regulation be based on scientific evidence; and Article 36 TFEU — Justified Restrictions. Temporary national approvals are justified when they protect health or the environment, they are proportionate, they are non-discriminatory and they are time-limited. Sandboxes seem to meet all 4 criteria. Relevant case law is i.e.. CJEU Case C-333/08 (Commission v France), where the Court confirmed that temporary national measures are permissible when they are proportionate, they are justified by scientific uncertainty, and they do not permanently restrict trade; and CJEU Case C-41/02 (Commission v Netherlands), where the Court accepted national derogations when they are limited in scope, limited in time, and subject to monitoring.

Benefits for EU

The benefits for EU accepting regulatory sandboxes with built-in flexibility, seem quite wide-ranging, helping company-drain from EU, supporting competitiveness, resilience and green transition, diminishing the innovation-gap, accelerating EU-level harmonization, and supporting SMEs to bridge the “valley-of-death”.

Regulatory sandboxes can help prevent company flights, if flexible and efficient

Europe is losing biotech companies to the US, UK, and Asia due to slow approvals. Member States are innovation ecosystems, being a strategic asset, needing local testing environment. If national regulatory sandboxes provide early market access, and support local ecosystems, they may reduce the innovation gap and help keep companies in Europe.

By allowing controlled experimentation and closer cooperation with competent authorities, regulatory sandboxes can support the EU's strategic objectives: strengthening competitiveness, improving resilience, contributing to the green transition, and ensuring that innovative companies choose to develop and scale their solutions within the EU.

Regulatory sandboxes can support competitiveness, resilience, and the green transition

Biotechnology is essential for sustainable materials, circular production, food security, and reducing dependence on third countries. Regulatory sandboxes can accelerate these transitions if they are used strategically, including a holistic assessment in national regulatory sandboxes.

National experimentation can reduce fragmentation and accelerate EU-level harmonization

Instead of waiting years for EU-wide agreement, Member States can test solutions, generate evidence, and demonstrate safety in practice. This bottom-up approach is faster and politically more feasible. It can benefit from the fact that biotechnology innovation clusters are geographically concentrated, examples being France (biomanufacturing), Germany (industrial biotech), Netherlands (agri-biotech) Finland/Sweden (biomaterials), and Denmark (biosolutions, precision fermentation).

Regulatory sandboxes can help identify and fix the lack of clarity with unclear scope of existing regulations and accelerate evidence generation. Parallel national sandboxes can produce more data, test more technologies, generate more regulatory insights, and reduce bottlenecks at EU level. They are thus a tool for reducing fragmentation and accelerating EU-harmonization. Regulatory sandboxes can provide testing, building up evidence and creating mutual learning between innovators and regulators. serve as a structured mechanism to generate scientific

evidence, reduce regulatory uncertainty, and accelerate the modernization of EU legislation.

Regulatory sandboxes can strengthen the Single Market by modernizing outdated rules and create evidence for future EU-wide harmonization. The purpose is to support long-term coherence and modernization of Union regulation by generating high-quality evidence on biotechnologies. This approach ensures that the Union remains at the forefront of safe, sustainable innovation, while maintaining its high standards of protection and the proper functioning of the Single Market.

Evidence generated through national and Union-level regulatory sandboxes, including any temporary national authorizations, can contribute to a broader evidence base for assessing whether Union regulation should be adopted or whether EU-wide authorization pathways should be explored.

Member States should be allowed some flexibility in their development of regulatory sandboxes, for example Member States may choose not to make regulatory sandboxes in a specific field (for example novel food);

National regulatory sandboxes can create step-by-step evidence and mutual learning

Regulatory sandboxes can provide testing, building up evidence and creating mutual learning between innovators and regulators. Evidence-based policymaking can ensure controlled, evidence-generating mechanism that ensures EU law remains scientifically valid, proportionate, and future-proof.

National regulatory sandboxes are time-limited, transparent, monitored by competent authorities, and notified to the EU. Member States have competent authorities with deep domain expertise, including scientific expertise, understanding of local industries, being able to supervise testing effectively and having the ability to act faster than the EU-level bodies.

Companies, including SMEs, are supported both to make startups and to scale

EU's ambition is to support SME' to help close the innovation gap. By enabling Member States to test innovative products and regulatory approaches under controlled conditions, these sandboxes can contribute to closing the innovation gap and support bottom-up harmonization.

For the support of the SME's to understand the complex regulations is crucial, and this can best be achieved by national regulatory sandboxes. If they are allowed to obtain national market approval based on the evidence from the regulatory sandbox, their possibility to obtain investment and revue to avoid the valley of death, increases.

Politically, accepting flexible regulatory sandboxes is a “win-win” compromise

- **Member States** retain flexibility.
- **The Commission** gains evidence for future harmonisation.
- **Industry** gains predictability and speed
- **Citizens** gain safer, greener innovations

2. THE HOW: TAILORMADE ARTICLES ON REGULATORY SANDBOXES IN BIOECHOLOGY

The most effective and purpose driven solution seems to be provisions on regulatory sandboxes specially tailored to biotechnology, other than health biotechnology, supplementing the provisions on health technology in Biotech Act I, article 49a-b, which in the proposal cover “all stages of the production, processing and distribution of food .. and also of the feed produced for, or fed to food-producing animals”. It also embraces GMO products.

OBJECTIVES

Regulatory sandboxes in Biotech Act II regarding biotechnology other than health technologies, pursue the following objectives:

- Support innovation and competitiveness: Create an innovation-friendly regulatory environment that encourages companies to develop and scale biotechnology solutions within the EU, addressing concerns about “company-drain” to jurisdictions with faster approvals.
- Maintain high safety and environmental standards: Ensure that all testing takes place under the supervision of competent authorities, with appropriate safeguards and monitoring, in line with EU values and the precautionary approach.
- Keep regulation up to date: Address situations where law is static by nature, often representing former technologies and frozen ethics, by generating evidence that can inform modern, science-based and proportionate regulation.
- Promote resilience and the green transition: Support biotechnological solutions that can enhance resilience, reduce environmental impacts, and contribute to the green transition, including biobased products that may replace more harmful alternatives.

CHAPTER I — PURPOSE AND PRINCIPLES

Article 1 — Purpose

This Regulation establishes regulatory sandboxes as carefully supervised frameworks that enable the responsible testing of innovative biotechnology products, processes, and methods. The aim is to support innovation and evidence-building in a manner that fully respects the Union’s high standards of safety, environmental protection, and the precautionary principle, while contributing to competitiveness, resilience, and the green transition. As part of this aim it is important

that the regulatory sandboxes can support a faster and simpler approval procedure - but still securing safety.

Article 2 — Evidence and Mutual Learning

Regulatory sandboxes shall facilitate structured, transparent, and closely monitored cooperation between innovators and regulators. Their purpose is to generate evidence that can inform future regulatory approaches and help ensure that Union legislation remains scientifically up-to-date, proportionate, and fit for purpose.

CHAPTER II — ESTABLISHMENT AND APPLICATION

Article 3 — Establishment

Member States, consortia of Member States, or the Union may establish regulatory sandboxes within the framework of this Regulation. All sandboxes shall operate under the supervision of one or more competent authorities and in coordination with the relevant EU bodies.

Article 4 — Application Requirements

Applications to establish a regulatory sandbox shall include:

- a description of the innovative product or method;
- a clear explanation of the regulatory challenges encountered;
- an assessment of expected societal benefits;
- a risk-mitigation plan;
- and, where relevant, a justification for any limited and exceptional flexibility needed to enable evidence generation.

CHAPTER III — FLEXIBILITY AND SAFEGUARDS

Article 5 — Limited and Exceptional Flexibility

1. Flexibility from existing national or EU rules may be considered only in exceptional, well-justified circumstances, where competent authorities determine that:
 - existing rules do not adequately reflect current scientific knowledge,
 - the absence of limited flexibility would prevent essential evidence generation, and
 - robust safeguards can ensure a high level of protection for health and the environment.

2. Any such flexibility shall be:
 - narrow in scope,
 - strictly time-limited,
 - subject to enhanced monitoring,
 - and notified the relevant EU authority.

3. Flexibility shall not prejudice Union-level decision-making processes nor undermine the functioning of the Single Market.

CHAPTER IV — NATIONAL AUTHORISATIONS UNDER CONTROLLED CONDITIONS

Article 6 — Temporary National Authorisations

1. In duly justified and exceptional cases, a Member State may consider granting a strictly time-limited national authorisation for a product tested within a regulatory sandbox, where this is necessary to generate real-world evidence under controlled conditions.
2. Such authorisations shall:
 - apply solely within the territory of the Member State concerned,
 - be subject to enhanced monitoring and reporting,
 - and be notified without delay to the relevant EU authority.
3. These authorisations shall **not** replace or pre-empt Union-level procedures.

Article 7 — Contribution to EU-Level Evidence

Evidence generated through national sandboxes, including any temporary national authorisations, may be considered by the relevant EU authorities as part of a broader evidence base when evaluating whether Union legislation should be adapted or whether an EU-wide authorisation pathway should be explored.

CHAPTER V — GOVERNANCE AND REPORTING

Article 8 — Duration

Regulatory sandboxes shall be time-limited, normally between two and four years, and shall not exceed five years.

Article 9 — Opt-Out

Member States may exclude specific sectors or product categories from participation in regulatory sandboxes.

Article 10 — Sandbox Plan and Exit Report

Each sandbox shall be governed by a sandbox plan specifying objectives, safeguards, supervision mechanisms, and reporting obligations.

Upon completion, an exit report shall summarise lessons learned, scientific insights, and potential implications for future Union legislation.

3. THE HOW: “RECITALS” ON REGULATORY SANDBOXES

RECITAL 113

Amendment

The food and feed sector is experiencing rapid technological advancements, including biotechnology, AI, smart farming techniques, development of new approach methodologies that could contribute to reduction of animal testing and circular economy practices promoting resource efficiency and waste reduction. It is therefore appropriate to provide Member States with the possibility of setting up regulatory sandboxes. **These sandboxes have the potential to help prevent “company-drain” and close the innovation gap, to support competitiveness, resilience and the green transition, and to make a step-by-step building of testing and evidence enabling faster approval processes going to market. To unleash the potential, it is crucial to allow some flexibility for the regulatory sandboxes. Their task is to test innovative products or processes under the supervision of a competent authority. Flexibility can be relevant, for example, where outdated regulation creates irrelevant barriers, and the competent authorities determine that the absence of flexibility would prevent essential evidence generation, and robust safeguards can ensure a high level of protection of health and the environment. Any such flexibility shall be subject to enhanced monitoring and notified to the relevant EU authority. An exit report shall summarize lessons learned, scientific insights, and potential implications for future EU legislation. In duly justified and exceptional cases, Member States may use the knowledge from the regulatory sandbox to grant strictly time-limited national authorizations for products tested, applicable solely within their territory and subject to enhanced monitoring and reporting, to generate real-world evidence without replacing or pre-empting Union-level authorization. Such a step-by-step process can help build up evidence, using relevant competencies in the Member States and make approval procedures faster. It can also help SMEs avoid the “valley of death” by creating revenue and enhance the chances for investment.**