Reimagining Regulation for Accelerated Progress:

Five case studies

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Developed with the expert contributions of, and endorsed by, the Task Force on

Sustainable Food Systems and Innovation

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Executive Summary

The year 2026 marks a pivotal moment to advance meaningful change in global food and agricultural policy, trade, and development. With the European Commission's Vision for Agriculture and Food now setting the strategic direction, and negotiations on the next Common Agricultural Policy (CAP) and the Multiannual Financial Framework (MFF) progressing, Europe has a critical opportunity to translate ambition into action. This period is decisive for reshaping food systems to strengthen resilience, sustainability, and long-term competitiveness. In this context, biotechnology and the bioeconomy stand out as essential enablers, driving innovation across agriculture and food systems while supporting the broader transition toward a more sustainable and circular economy.

This report examines five cases where targeted regulatory streamlining could strengthen the competitiveness of biotechnology while supporting economic resilience and innovation in sectors such as sustainable agriculture, food security, and climate resilience:

- The use of existing information in risk assessment for Genetically Modified Organisms (GMOs) utilising OECD instruments (case A).
- The regulatory process for stacked GM events (case B).
- The regulatory framework for biopesticides (case C).
- A 90-day whole food feeding study in rodents (case D).
- The regulatory framework for precision fermentation (case E).

Across all five cases, the analysis demonstrates that regulatory streamlining can be achieved without compromising high standards of safety and environmental protection. More proportionate, science-based regulatory approaches can improve efficiency, reduce unnecessary administrative burdens, and accelerate market access for innovative technologies. In addition, each of these cases could be implemented through relatively simple adjustments to relevant EU law or no changes at all thus avoiding the opening up of major regulatory instruments and avoiding laborious negotiations.

The report concludes that meaningful progress will depend on structured dialogue between institutions, societal stakeholders and policymakers. Such dialogue is essential to identify institutional and procedural bottlenecks, improve transparency and coordination in biotech regulation, and foster public trust in regulation. Beyond the specific cases analysed, there is a clear need for a shared EU-level vision and narrative for biotechnology, one that clearly articulates how innovation can contribute to the EU's strategic objectives in competitiveness, sustainability, climate resilience, and food security.

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1. Introduction

The year 2026 will be a defining year in global food and agricultural policy, trade and development. As economic, environmental, and political dynamics evolve, food systems are increasingly at the heart of broader geopolitical and socio-economic transformations. Challenges, ranging from climate change and food insecurity to economic instability, trade uncertainty, and geopolitical uncertainty, are reshaping the global landscape, necessitating a fundamental shift in how we approach them. With the European Commission's *Vision for Agriculture and Food* unveiled and negotiations on the next Common Agricultural Policy (CAP) and Multiannual Financial Framework (MFF) underway, Europe has a critical chance to reshape food systems for greater resilience, sustainability, and competitiveness. Addressing these issues requires urgent, coordinated action, as food systems play a critical role in achieving broader SDG objectives, driving economic growth, alleviating poverty, and ensuring social stability worldwide.

As the European Union seeks to bolster its strategic autonomy, competitiveness, and resilience in an increasingly complex geopolitical and economic environment, the role of **biotechnology** and the **bioeconomy** has become central to its policy agenda. The European Commission is advancing a series of strategic initiatives to strengthen Europe's innovation capacity by creating a regulatory environment that supports accelerated progress from research to market while maintaining high safety and environmental standards. The goal is to enhance the EU's competitiveness, resilience, and strategic autonomy through targeted initiatives that foster innovation, particularly in areas such as health, agriculture, and sustainable industry.

Among the key developments is the **Biotech Act,** of which the first part *Biotech Act I* was published on 16 Dec 2025 and the second part *Biotech Act II* is expected in Q3 2026. Taking both parts together, the Biotech Act aims to better connect the EU's scientific capabilities with technological applications. A call for evidence was concluded in June 2025 to gather input from all relevant actors, businesses, researchers, civil society, and others on how to shape this legislative effort to reflect the realities on the ground. In parallel, the Commission published an updated **EU Bioeconomy Strategy** in November 2025, focusing on unlocking the potential of bio-based innovation to contribute to environmental goals and long-term economic growth. Complementing these strategies is the recently launched **Biotech and Biomanufacturing Hub**, designed as a practical resource to support innovators, particularly SMEs and start-ups, in accessing EU funding, navigating regulatory processes, and scaling up their ideas responsibly. Together, these efforts reflect a broader commitment to ensuring that innovation in biotechnology and the bioeconomy can contribute to Europe's green and digital transitions while remaining inclusive and responsive to diverse societal interests.

Despite considerable progress and growing momentum in biotechnology and related fields in the life sciences, a noticeable gap remains between the rapidly evolving scientific and

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technological realities and how these innovations are perceived and discussed in the public sphere. Public narratives often rely on outdated assumptions or partial understandings, which can lead to misconceptions, heightened scepticism, or polarised debates. Such disconnects have tangible consequences: they can erode public trust, create uncertainty among policymakers, influence law-making, and slow down the adoption of innovations that might help address urgent societal challenges.

Streamlined and proportionate regulatory measures can not only enhance the competitiveness of biotechnology but also contribute to economic resilience and innovation in key sectors such as sustainable agriculture, food security, and climate resilience. This concise review, which will be further elaborated as the project develops, identifies challenges and opportunities to streamline the regulatory process concerning biotechnology and agricultural technologies without compromising safety and environmental standards. It addresses five cases or examples where streamlining can lead to substantial benefits:

- The use of existing information in risk assessment for Genetically Modified Organisms (GMOs) utilising OECD instruments (case A).
- The regulatory process for stacked GM events (case B).
- The regulatory framework for biopesticides (case C).
- A 90-day whole food feeding study in rodents (case D).
- The regulatory framework for precision fermentation (case E).

Each of these cases has involved difficult discussions in the EU in the past. Discussions concerning GMOs have led to controversy for more than three decades. The current emphasis in the EU on competitiveness and simplification may lead to a more permissive environment for discussions. At the same time, each of these cases has also been selected because they would involve modest changes to EU law or implementation and will not necessitate opening up, for example, major EU directives or regulations. Reimagining regulatory and governance approaches can assist in realising new market opportunities for innovation in biotechnology and agricultural technologies within the EU.

2. Case A: The use of existing information in risk assessment for GMOs utilising OECD instruments

2.1 Description

Products derived from modern biotechnology have been increasingly adopted over several decades as sustainable options for food and feed production, as well as, amongst other things,

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for pharmaceutical and bio fermentation production processes. Such products, especially GMOs, are assessed by many governments and food safety authorities (e.g., European Food Safety Authority) to ensure that they meet safety standards. The OECD has been working since 1986 with its member countries and some non-members, as well as other stakeholders, to assist them by developing OECD legal instruments as well as guidance to identify and evaluate the potential risks of products derived from modern biotechnology. This has been especially important in crop production, which often involves major trading commodities. The major aims of the OECD activities have been:

- to increase the efficiency of the risk assessment process.
- to foster mutual understanding amongst authorities.
- whilst ensuring high safety standards.

2.2 International best practices

The OECD Council adopted a Recommendation on 16 July 1986 concerning Safety Considerations for Applications of Recombinant DNA Organisms in Industry, Agriculture and the Environment. This Recommendation was revised and adopted by the OECD Council at ministerial level on 17 September 2024. An OECD Council Recommendation is adopted by the OECD Council and is not legally binding. It represents a political commitment to the principles it contains and entails an expectation that adherents will do their best to implement it.

The 2024 revision of the 1986 Recommendation has taken into account developments in biotechnology and the successful development and release of multiple products of biotechnology, scientific advances, increased knowledge and the accumulated regulatory experience, as well as the functioning of the regulatory systems. In the revised Recommendation, the OECD developed or reinforced a series of basic concepts, tools and key documents that set up the founding principles of the risk/safety assessment of applications of recombinant DNA organisms (or GMOs). All EU member states that are member countries of the OECD (together with other OECD member countries) endorsed this legal instrument. The European Commission participated in the work.

It is worth noting that OECD and its member countries proceed on a consensus basis. In other words, if one member cannot join the consensus on an initiative, it does not proceed.

The OECD Council Recommendation refers to the use of existing information in the risk assessment of products developed by so-called **'consensus documents'** that are intended to assist authorities in the conduct of risk/safety assessment of recombinant DNA organisms and products derived from them. They offer practical tools that compile science-based information. These documents are publicly available and widely recognised as sustainable references for regulatory biosafety evaluation. They are currently used by national authorities in many jurisdictions worldwide.

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There are two types of consensus documents. The first type addresses the biology of non-genetically modified (or conventional) organisms (such as plants, trees, or micro-organisms) as well as some introduced novel traits and supports the comparative elements of the risk assessment process. The second type focuses on the material composition of organisms (nutrients, toxins, antinutrients, and micronutrients). This type is intended for use in food/feed risk assessments.

The OECD recommendations are based on a **Comparative Safety Assessment approach**. A specific GMO is compared to a conventional counterpart. Molecular characteristics, composition (nutrients, toxins, allergens), agronomic traits, and environmental impact are examined to identify unintended effects of genetic modification. If significant differences are found, further testing is conducted to establish the safety of the modified organism.

2.3 Legal situation in the EU

The OECD Consensus Documents are intended as a resource in support of risk assessment and help to reduce the duplication of necessary basic information in risk assessments of a specific species, for example, a specific crop plant. In the EU, the European Food Safety Authority (EFSA) conducts scientific assessments to support decision making by the Member States' competent authorities and the European Commission. The EFSA follows a highly structured approach that includes reviewing molecular characterisation of the insert, expression of inserted genes, agronomic and phenotypic evaluation, environmental risk assessment (ERA), allergenicity and toxicology testing, as well as post-market environmental monitoring plans. EFSA opinions undergo public consultations and scientific peer review. EFSA considers the OECD Consensus Documents as a useful reference and uses them in its case-specific risk assessment approach aligned with EU law. While the OECD Consensus Documents are developed through international expert consensus, they are not as well-known in the EU institutions and member states as they could be. Considerations about some specific characteristics are replicated instead of taken over from the Consensus Documents, leading to a less streamlined risk assessment process than might otherwise be the case.

Importantly, food safety assessment and environmental risk assessment (ERA) serve distinct purposes. Food safety assessment focuses on evaluating risks to human health posed by hazards in food, whereas ERA examines the potential environmental impacts of activities such as the cultivation of genetically modified (GM) plants, the use of certain substances in food, feed, and plant protection products, and the introduction or spread of plant pests.

Another OECD document, *Consensus Document on Environmental Considerations for Risk/Safety Assessment for the Release of Transgenic Plants*, is of value for at least two reasons. First, it indicates the value of the information included in the Consensus Documents on specific crop plant species for environmental risk assessment. It identifies a number of environmental considerations in environmental risk assessment, including:

- invasiveness and weediness;

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- vertical gene flow;
- interactions with other organisms (animals);
- soil functions.
- plant health.
- crop management practices; and
- biodiversity (protected species and habitats/ecosystems).

It relates these considerations to problem formulation in risk assessment.

2.4 The Way Forward

By using the OECD Consensus Documents to their full potential in case-specific risk assessments, the EU can improve market access for many innovative GMO crops. In this way, it may improve its competitiveness in global food markets, supply chain resilience and alignment with global risk assessment practices. This would allow farmers and consumers to access the potential benefits of advanced GMO crops whilst ensuring a high level of safety and greater environmental sustainability. Action is needed to make the OECD Recommendation and the Consensus Documents better known in the institutions of the EU, including its member states, and to align the EU risk assessment framework with internationally recognised standards as defined by the OECD and other international standards, such as those of Codex Alimentarius FAO-WHO.

An increased knowledge of the information used in risk assessment, as well as the practice of science-based risk assessment as understood in a global context, should lead to a more internationally harmonised system based on increasing knowledge and 28 years of experience with GMO risk assessment and successful and safe use in commercial settings of GM crops.

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3. Case B: GM stacked traits

3.1 Description

GM crop plants are cultivated in certain parts of the world ('cultivation countries') but are widely consumed globally, either directly or indirectly. Typically, a GM crop carries an insertion in its genome of one or more genes of interest, usually including DNA sequences from one or more unrelated species (a transgene). Each insertion of transgene(s) in a defined genetic location (locus) is called an "event", short for (genetic) *transformation event*, which implies the integration of the transgenic DNA into the host genome. GM events incorporate new or enhanced plant traits, for example, insect resistance, herbicide tolerance, disease resistance, or nutritional value. Such traits in a GM crop can lead to improved agronomic performance(increased yield, more flexible management practices) or an added-value harvested product (e.g., a more nutritious food ingredient).

"Gene stacking" refers to the process of combining two or more single events into the same plant line through conventional (sexual) crosses, like for any other gene/trait present in the species due to natural occurrence or human-induced mutation. The result from this process is colloquially referred to as stacked genes/traits or "stacks". Nowadays, the large majority of commercially cultivated GM crops worldwide are stacks.

The easiest and quickest way to stack traits into a plant is, as described, to make crosses between parental plants that have different traits, an approach described as **GM stacking by conventional breeding**. Iteratively, more and more traits (events) can be added in this way using conventional breeding as the stacking method. However, an alternative, less-used method of gene stacking known as **molecular stacking is** also possible. It involves the introduction of several transgenes (single events) simultaneously or sequentially into a single plant. The focus of this document is on the former, i.e., GM stacking by conventional breeding.

3.2 Legal situation in the EU

In the EU, the risk assessment of GM stacks is regulated by Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, Regulation (EC) No 1829/2003 on genetically modified food and feed and Implementing Regulation (EU) No 503/2013 on applications for authorisation of genetically modified food and feed. Article 5(2) and Annexe II §2.2 of the implementing regulation are of special interest.

In the EU, breeding stacks are considered new GM products that require additional authorisation, also if all the individual events have already been assessed and authorised for marketing (it is also possible that a stack of events that have not been evaluated before is presented for approval, but in this document, we are not focusing on this other scenario). Stacks in the EU must therefore pass through their own **separate regulatory approval**

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process, including risk assessment of their safety (performed by the EFSA), like single events.

Risk assessment of stacks that combine single events already authorised includes identifying additional risks that could arise from synergistic effects (possibility of a new or altered trait, not present in any of the singles but enabled by their combination).

The criteria adopted by other leading regulatory agencies in the rest of the world (see below for details) can be summarised as follows: since the safety of the single events has already been assessed, a new risk assessment for GM breeding stacks is redundant and is not scientifically justified UNLESS there is a clearly formulated risk hypothesis. Therefore, in other geographies, the priority is to discuss whether a synergistic or negative effect could arise and, if so, how. In case a defined hypothesis in this regard is possible, such a hypothesis leads to a focused experiment to test it. If no hypothesis is found, then there is no need for further studies to conclude that the stack is as safe as the already authorised singles.

However, in the EU, although the possibility of synergies is taken on board, the overall risk assessment and new data requirements for stacking are not very different from those of a new single event, even when there is no defined risk hypothesis to be tested. This makes the process unnecessarily lengthy and costly and deviates significantly from other regulatory agencies worldwide.

3.3 International best practices

In agencies such as the USDA and FDA in the US, FSANZ in Australia/New Zealand and Health Canada, **no separate or additional regulatory approval** is necessary for food or feed commercialisation of breeding stacks if the single events have been previously approved. This policy is based on the argument that interactions between events that have been shown to pose no environmental or health hazard individually would not result in new or altered hazards when combined.

In Japan, a streamlined process for GM breeding stack approval for food and feed uses has been in place since 2014 leveraging years of experience with GM risks assessments and the safety of the single parental events: for example, breeding stacks of traits that do not alter the crop's metabolic pathway (e.g. insect control, herbicide tolerance) no longer require a separate assessment (Iizuka, 2020).

In the Argentine agencies CONABIA (which is FAO´s Centre of Reference for Biosafety) and SENASA, as well as for the Brazilian agency CTNBio, although stacks require the same formal approval process as the single events, the data requirement is adjusted to the existence of hypotheses for synergies.

It should be noted that for these overseas agencies, the risk assessment process comprises about 90% of the approval time, with only 10% or so devoted to the bureaucracy of adopting a decisión once the risk assessment is completed. Therefore, a reduction in scientific

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evaluation time has about the same proportional impact on the applicant´s waiting time. In contrast, the EU´s comitology process for GMO approval usually takes longer than the risk assessment that justifies the sanitary regulatory intervention. Therefore, to achieve real impact, it is necessary that processes occurring after EFSA´s intervention are also fine-tuned for a case in which the product is essentially a combination of already-approved products.

3.4 The way forward

By carrying out redundant regulatory assessment for GM stacked traits, the EU is significantly delaying the import of many innovative crop commodities, thereby jeopardising its competitiveness in a global food market where other players, such as the USA, have more risk-proportionate regulations. This practice also hinders farmers, consumers and the environment of the many benefits of GM crops. The approval of stacks could be streamlined and improved, which is why experts of the EFSA GMO Panel and WGs are currently discussing how to optimise data requirements while maintaining scientific excellence in the risk assessment and high level of protection for humans, animals and the environment. The progress made in the last cross cutting WG will be reported at the next GMO Panel in December.

Nevertheless, this problem is not new, stacked GM events have been authorised in the EU since 2006 (for example, the approval of MON863 × MON810 maize for import and processing) - yet it has never been properly addressed either by EFSA or the EC. In fact, in a publication dating back to 2014, several EU member state regulators highlighted the disproportionate approach to GM stacked trait regulation in the EU, proposing a more scientifically justified framework (Kok et al, 2014), an important point being that additional information is only needed when scientifically sound. The development of options to **bring the EU in line with other jurisdictions** in which GM events that have been approved do not need to be fully assessed and approved again when they have been combined in a two- or more stacked configuration would be of value to accelerate progress in this potentially important part of the European biotechnology sector. In addition, the EU should revisit the necessity of study requirements for renewal of an approval of a single event, as well as in the case of renewal of an approval of a stacked event.

There are several pathways to achieve streamlining of the regulatory approval process for GM stacking in the EU within the existing regulatory framework. This can include removing the need to regulate the stacking of authorised GM events through traditional breeding, consistent with the current approach that does not regulate the crossing of a GM event with a conventional crop. In addition, for cases where an evaluation is required, the approach outlined in Annexe II §2.2 of Commission Implementing Regulation (EU) No 503/2013 can be adopted under a fast-track process enabled by an initial assessment of whether there is a lack of hypotheses for potential interactions. This could speed up approval by as much as two or three years with the elimination of additional approvals for GM stacks.

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4. Case C: Biopesticides

4.1 Description

Biopesticides, derived from natural sources such as bacteria, fungi, plants, and minerals, are one tool in the toolbox for crop protection. Collectively, they cannot be regarded as a 'silver bullet' solution for all pest control issues. They are part of the sustainable innovations that can be used **as part of Integrated Pest Management (IPM) and as a complement to other tools**. With growing concerns over the farmers' crop protection toolbox depleting year after year because of non-renewal of active ingredients, together with growing pesticide resistance and soil degradation, biopesticides can play a role in integrated pest management (IPM), and are expected to enhance soil health and biodiversity while contributing to food safety. To address consumer demand for organic and even more sustainable farming practices, the development and adoption of biopesticides holds potential. However, biopesticides seldom show similar levels of efficacy to chemical pesticides.

4.2 Legal situation in the EU

In the European Union (EU), biopesticides are currently regulated under the same framework as chemical pesticides, specifically Regulation (EC) No 1107/2009, which governs the placing of plant protection products on the market. This regulation **does not distinguish biopesticides as a separate category, nor does it mention or provide a definition.** All plant protection products, including biopesticides, must undergo a comprehensive risk assessment to ensure they do not harm human or animal health or the environment. Specific data requirements for microbially active ingredients/products are laid out in complementary instruments.

In this way, the regulation requires applicants for authorisation of biopesticides to perform studies and conduct tests that are often ill-suited, highly complex, or even technically impossible to put in place for certain biopesticide solutions. Additionally, in the case of novel biopesticide technologies such as peptides or RNAi technology, specific guidance is not yet developed, which may have led to uncertainty among applicants, thus delaying or even preventing submission in the EU.

In addition, biopesticides may take a disproportionately long time to reach the market due to a lack of regulatory agility, procedural complexity, ambiguity in data requirements, and insufficient specialised capacity and resources allocated to competent authorities. Another challenge is determining how to handle products treated with unapproved biopesticides outside of the EU upon their entry into the EU, including the necessity of (and if applicable, how to verify) the absence of such residues or establishing acceptable residue limits. Only biopesticides that can potentially meet the low-risk criteria of Regulation (EU) 2017/1432 amending Regulation 1107/2009 can benefit from a simplified and expedited approval process, including reduced data requirements and shorter evaluation timelines. In August

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2022, the EU also adopted a new regulation to determine which specific data are required to better address and assess the specific properties of micro-organisms used in plant protection.

The European Commission adopted on 22 June 2022 a **proposal** **for a new Regulation on the Sustainable Use of Plant Protection Products (SUR)**, including EU-wide targets to reduce by 50% the use and risk of chemical pesticides by 2030, in line with the EU's Farm to Fork and Biodiversity strategies. The proposal was part of a package of measures to reduce the environmental footprint of the EU's food system and help mitigate the economic losses due to climate change and the loss of biodiversity. The proposal would have transformed the existing Sustainable Use of Pesticides Directive (2009/128/EC) into a Regulation which would be directly and uniformly applicable to all member states. A notable aspect of this proposal was the inclusion of the first EU-wide definition of biological control, or biocontrol, encompassing substances such as "micro-organisms, semiochemicals, extracts from plant products as defined in Article 3(6) of Regulation (EC) No 1107/2009, or invertebrate macro-organisms". This definition was anticipated to provide legal clarity on which substances were not included in the 50% risk and use reduction, also facilitating the development and adoption of biocontrol methods as alternatives to chemical pesticides. The proposal also required Member States to set in their national plan indicative targets for increasing the “percentage of all plant protection products used on those crops which were biological controls during the three calendar years preceding the adoption of the national action plan”.

On 27 March 2024 the Commission withdrew the proposal since **no agreement** was foreseeable, in view of the non-adoption of the proposal by the European Parliament and the lack of progress of the discussions in the Council. The Sustainable Use of Pesticides Directive (2009/128/EC) remains in force. However, some stakeholders still see potential in a new regulation. During their presidency of the European Council in the first half of 2024, the Belgians have tried actively to finalise the SUR project. They proposed an action plan with as key component the enhancement of the market placement of biocontrol tools. However, the proposal was withdrawn.

In summary, while the SUR proposal intended to enhance the regulation of biopesticides by providing clear definitions and setting biocontrol targets, its withdrawal means that these specific changes have not been implemented. However, other regulatory updates, particularly concerning micro-organisms, continue to support the EU's objectives for sustainable plant protection.

4.3 The way forward

The registration process for biopesticides in the EU is more complex and lengthier compared to other countries and regions, such as the United States, Latin America, India, or China. The primary reasons for this include:

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1. **Lengthy Approval Process:** The registration process (active substance approval at the EU level, followed by product authorisation at the national level) can take several years as for conventional pesticides, often delaying market access for biopesticides compared to other regions.
2. **Inappropriate Data Requirements and Guidance:** Not all biopesticide technologies are covered by tailor-made data requirements and fit-for-purpose guidance, making the preparation of the application dossier challenging and the outcome uncertain.
3. A **workable and simple solution for the potential presence in imported products**. In many cases, it may be scientifically straightforward to demonstrate that many biopesticides do not pose a risk to human health or the environment when potentially present as traces in imported commodities or other products. In contrast, adopting a strategy that requires a complete absence using analytical (detection) methods may be troublesome and unjustified for many biologicals. Biopesticides are being developed in many cases by local SMEs in the country of export, which can´t afford the usual regulatory process in the EU. Therefore, options should be explored, including cross-recognition of approvals in trustworthy foreign regulatory agencies of supplier countries (only for traces on importations, not for use in Europe), incorporating affordable but sufficient reassurances, like country visits/inspections.
4. **No dedicated expert resources:** Compared to countries like the U.S., where the Environmental Protection Agency (EPA) has a dedicated team of assessors for biopesticides, the EU does not have dedicated resources at EFSA level nor in most of the member states. The expertise in these innovative technologies is also lacking, as many assessors continue to operate with a synthetic pesticides framework.
5. **Variability Among Member States:** Since product authorisation is handled at the national level, companies must navigate different requirements and interpretations of regulations and guidance across EU countries, further complicating approval.
6. **Limited Use of Low-Risk Fast-Track Approvals:** While the EU has introduced provisions for "low-risk" substances, the criteria are very restrictive even for biopesticides, so it is limited to a few substances.

As a result, fewer biopesticides are registered in the EU, limiting farmers' access to these sustainable tools while withdrawing from the market active ingredients with no effective alternative options.

4.4 Next Steps

To improve market access, it is essential that the EU develop a new regulation enabling **a tailored and proportionate approach for biopesticides**, on top of the already existing data requirements concerning micro-organisms. Initiatives for regulatory streamlining can be based on the biopesticide provisions included in the failed SUR and in international best practices. The biopesticide provisions could be revived in the absence of the other provisions of SUR. There are a number of measures that could be taken in the short-term to improve the

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situation, which would not entail adopting new legislation or the re-opening of Reg. 1107/2009, such as the development of fit-for-purpose data requirements and dedicated specialised guidance documents streamlining dossier compilation and evaluation for all categories of biopesticides following the example of micro-organisms, facilitating the mutual recognition process (art. 40, Reg. 1107/2009), enabling minor uses provisions for biopesticides (e.g. "administrative extension" by the Dutch Board for approval of Plant Protection Products), and boosting expertise on biopesticides in Member State authorities and EFSA via training of experts and the creation of a dedicated unit/team within EFSA and the national competent authority bodies. In the mid-term, targeted modifications of existing legislation are desirable as part of the simplification ambition of the EU Commission. This could include introducing a future-proof legal definition of biopesticide, reinstating workable provisional approvals of biopesticide solutions whilst they undergo assessment (in the spirit of Article 30, Reg. 1107/2009) to make them available quicker to farmers, and introducing specific provisions for low-risk PPPs and biopesticides, such as longer approval periods or interzonal assessments or facilitating label extension for biopesticides. Additionally, there is a need for a more flexible and evolutionary system at the EFSA level that is able to respond quickly to new developments in order for the EU to keep pace with advancements in the field.

The work on biopesticides as outlined in this proposal will be informed by an EC-funded research project, RATION, which stands for Risk Assessment Innovation for Low-Risk Pesticides (LRPs). There is an overlap between what are understood to be LRPs and biopesticides. RATION started on 1st November 2022 and will last for four years. It is intended to address a problem in the EU that concerns the regulatory constraints that hold back the full potential and market expansion of Low-Risk Pesticides. At the same time, it is intended to motivate research innovation in plant protection. RATION is a multi-sectoral effort with 22 partners from academia, industry and regulatory bodies from ten member states and two non-EU member states. One partner of RATION is IBMA, which assists with the annual conference ABIM in Switzerland (Basel). The main organiser of the ABIM conference is the Research Institute of Organic Agriculture (FiBL), which is one of the world's leading institutes in the field of organic agriculture. Participants from the EU attend the conference every year, together with the industry and scientific communities.

As the Danish presidency is now coming to an end, it would be most helpful if the EU Commission, as part of its simplification agenda for biotech, would include a new proposal for biopesticides in addition to the other proposals in this text.

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5. Case D: 90-day whole food feeding study in rodents

5.1 Description

In Europe, a 90-day whole food feeding study in rodents is a mandatory regulatory requirement when submitting an application to place foods derived from a genetically modified organism (GMO) on the EU market, as specified by Commission Implementing Regulation (EU) No 503/2013. This requirement applies to all applications containing a single genetic modification, regardless of whether specific hazards have been identified in earlier analyses (EFSA, 2014a), subject to the possibility of obtaining a derogation under Article 5 para. 2. The purpose of the study is to detect any potential adverse effects that might not have been identified in prior molecular, phenotypic, and compositional assessments of the GM plant or animal. There are two scenarios: (1) if a hazard is identified in previous analyses, the study is conducted to clarify the associated risks (targeted study), and (2) if no hazards are identified, the study is still required as a routine part of the safety assessment (exploratory study) (EFSA, 2014b). In many instances, EFSA has historically required applicants to redo 90-day studies at the time of renewal of the single event, as well as in the case of stacked single events, including for the exact same gene or gene construct but in a different crop.

For a short case study, the IND-ØØ41Ø-5 drought-tolerant soybean (OECD, 2025) can be considered. This GMO expresses the protein HAHB4, a transcription factor from sunflower that confers drought tolerance. Being a transcription factor, it is required only in minute amounts; in this case it was confirmed to be present because of achieving the intended effects, but the substance itself was hard to detect, being present below the typical LOD (limit of detection) of standard methods for protein analysis. The product has been approved by several regulatory agencies in the Americas, which did not require a toxicity study in rodents, considering the history of safe use of sunflower and the detectable amounts of protein potentially present in the derived foodstuffs.

5.2 Legal Situation in the EU

Commission Implementing Regulation (EU) No 503/2013 introduced the obligation for a 90-day oral toxicity study using whole GM food/feed in rodents as part of the toxicological risk assessment. The European Food Safety Authority (EFSA) and the European Commission require that such a study be included in all single-trait GMO applications, even if no plausible risk hypothesis or hazard has been established (Devos et al., 2016). Studies must follow OECD Test Guideline 408 and Good Laboratory Practice, with technical instructions provided in EFSA's 2011 guidance and further details in explanatory statements and policy briefs (EFSA, 2019). Regardless of outcome, inclusion of these studies has been controversial due to questions about scientific added value when no risk hypothesis exists and concerns about animal welfare (Devos et al., 2016).

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In summary, the 90-day whole food feeding study is a default, regulatory requirement in the EU for most GM food and feed approval submissions under Implementing Regulation (EU) No 503/2013, irrespective of prior hazard identification.

5.3 The Way Forward

A number of toxicologists have accepted that the 90-day feeding studies for genetically modified (GM) food risk assessment face several scientific, technical, and ethical limitations that impact their value and interpretation in regulatory contexts (EFSA Panel on Genetically Modified Organisms, 2008). This is especially the case when the gene comes from a species having a prior history of safe use as food, and/or when the protein expression levels are negligible. It is also burdensome on applicants.

Furthermore, for many observers, the use of animal testing in this context is not consistent with foundational ethical principles, which guide the humane and responsible use of animals in scientific research and testing. The European Union is legally and policy-wise committed to the 3Rs - Replacement, Reduction, and Refinement - in animal testing. This commitment is explicitly embedded in Directive 2010/63/EU, which harmonises animal research legislation across all EU member states and makes the application of the 3Rs principles a legal requirement for all scientific projects involving animals.

It is time to amend Commission Implementing Regulation (EU) No 503/2013 to bring it in line with the objectives of Directive 2010/63/EU, using alternative testing methods that protect animal welfare. Besides, the decision about whether to actually require toxicity studies should be left to EFSA experts, who should base their decision on factors such as the history of safe use and familiarity.

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6. Case E: Precision Fermentation

6.1 Description

According to the Joint industry definitions of fermentation and precision fermentation, the former refers to a "process in which micro-organisms such as bacteria, fungi, yeasts and micro-algae are used to preserve and/or transform raw materials into e.g. food, feed, chemicals, pharmaceuticals, fuel, biomass", while the latter refers to a "sub-category of fermentation, using biotechnological approaches and innovations for the controlled cultivation of selected and/or modified microbial cells, to produce specific substances. These fermentation-derived products can be a single molecule or multiple molecules purified from the fermentation broth or biomass"[1]. These processes are carried out in controlled bioreactors and can yield substances for food, beverages, or industrial applications with a high degree of purity and consistency compared to the same substance derived from other sources. Plant cells in bioreactors can also be used to produce specific ingredients, but this would not be 'fermentation'.

This new alternative source of ingredients poses many opportunities for innovation and bioeconomy development, as well as for contributing to improving food security and safety, the reduction of environmental footprints, and reducing animal welfare impacts of food supply.

At the same time, it poses many challenges like establishing technical criteria for evaluating food safety, public communication of scientific aspects that are fundamental to these innovative technologies and their risk assessment, proper labelling/naming of the products for transparency to the consumer, concerns of socioeconomic nature about competition with traditional agriculture, amongst other things.

6.2 Legal Situation in the EU

- Novel Food Regulation: Precision fermentation products that were not consumed to a significant degree in the EU before May 15, 1997, are considered "novel foods" and fall under Regulation (EU) 2015/2283. These products require pre-market authorisation by the European Food Safety Authority (EFSA) to ensure safety, nutritional adequacy, and proper labelling. The authorisation process typically takes at least 18 months and in some cases even more than 5 years (Ministry of Future Affairs, 2025).
- GMO Regulation: If the final ingredient produced by precision fermentation contains genetically modified organisms (GMOs) or their viable cells, the product is also subject to the Genetically Modified Food and Feed Regulation (Regulation (EC) No

[1] The absence of recombinant DNA is not required and should not be used as a regulatory classification criterion for products produced by fermentation.

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1829/2003), which entails an additional set of safety, labelling, and approval requirements.

- Sectoral legislation for precision fermentation products that do not fall under the GMO and/or novel food scope. e.g., food additives regulation & feed additives regulation are also relevant.
- Labelling and Consumer Protection: EU law strictly regulates how precision fermentation-derived foods are labelled to ensure transparency and prevent consumer deception, especially if the product is an animal-free version of traditional foods like milk or cheese.
- Innovation Support: The EU actively invests in fermentation technologies as part of its sustainability and food innovation strategy, with substantial public funding and dedicated initiatives, but regulatory constraints remain.

Aspect	**Main Regulation**	**Key Criteria**
Market Access	Novel Food (EU) 2015/2283 / GMO Reg. 1829/2003 Food Additives (EC) No 1333/2008 Feed Additives (EC) 1831/2003 Contained Use of Genetically Modified Micro-organisms Directive 2009/41/EC	EFSA assessment, safety, nutritional value
Labelling	Food Information to Consumers Reg. (EU) 1169/2011	Clarity, no deception, ingredient source accuracy
Innovation	EU grants, Biotech Act (second part in preparation)	Financial support, roadmap for biofood adoption

Precision fermentation is recognised as a promising, innovative technology in the EU, and it faces regulatory oversight to ensure safety, transparency, and consumer protection before products can be sold across all member states. Within the context of the upcoming Biotech Act, it is recommended to reassess to what degree the current regulatory oversight is proportionate and adequate to enable innovation and allow for a competitive EU market environment to develop.

The EU's Biotech Act Part I and Part II are expected to significantly influence public acceptance of precision fermentation foods by modernising and accelerating the approval

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processes for novel foods, including those derived through precision fermentation. Additionally, on 16 December 2025, the European Commission proposed a simplification of EU food and feed safety legislation. This omnibus initiative includes measures aimed at facilitating market access for fermentation-based products and regulating the use of genetically modified micro-organisms in fermentation processes, which is expected to reduce administrative burdens and legal uncertainty for operators in the sector. Based on the current discussions, the following items might be expected to be covered in the second part of the Biotech Act.

- Faster Approval and Regulatory Clarity: The Biotech Act could offer significant benefits to novel foods produced through precision fermentation by providing scientific pre-submission advice. Such guidance would help future applicants prepare more robust dossiers, reduce "stop-the-clock" instances, and ultimately accelerate the EFSA authorisation process. In addition, the horizontal regulatory sandboxes proposed under the Act present a valuable opportunity for innovation testing; it will be important that these sandboxes explicitly include novel foods produced by precision fermentation, ensuring that developers can explore, refine, and scale their products under a controlled, supportive regulatory environment.
- Improved Pre-Submission Advice: The Act may strengthen scientific pre-submission advice by providing clearer guidance to future applicants, facilitating better navigation of authorisation requirements, reducing procedural delays, and improving the overall quality of submissions.
- Horizontal Regulatory Sandboxes: The Biotech Act is expected to promote the use of horizontal regulatory sandboxes to support experimentation and innovation in biotechnology. It will be important that such sandboxes explicitly cover novel foods produced through precision fermentation, enabling developers to test products and processes within a supervised regulatory environment.
- Enhanced Communication and Public Education: The Act calls for improved communication strategies to educate the public about biotechnology's benefits and safety. Highlighting the already widespread use of biotechnology in everyday life - including healthcare, agriculture, and environmental protection - can help demystify precision fermentation and reduce polarisation of opinion.
- Building Consumer Trust: The EU strategy incorporates efforts to transparently label and regulate these foods while promoting industry collaboration and stakeholder dialogues, such as an annual Food Fermentation Conference. This fosters trust by ensuring consumers are well-informed and that products meet high safety and quality standards.
- Investments and Innovation Support: Significant EU funding for food and biotech innovation to support startups and SMEs working on fermentation technologies, which can lead to higher-quality, cost-effective, and appealing products. Successful

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commercialisation often drives public acceptance as consumers experience tangible benefits.

In summary, the Biotech Act's combination of regulatory modernisation, public education, transparency, and financial backing is designed to enhance public acceptance by making precision fermentation foods remain safe, more accessible, and better understood in the EU. This addresses both the supply side and consumer perception challenges critical for widespread adoption.

6.3 Addressing Regulatory Gaps

The Biotech Act has been widely anticipated as a potential instrument to support innovation in food biotechnology, including novel foods derived from precision fermentation. However, recent intelligence suggests that the European Commission's current approach may **not explicitly address novel foods**, and some proposed initiatives, such as regulatory sandboxes, could explicitly exclude them. This creates a risk that long-standing challenges in the pre-market authorisation process under Regulation (EU) 2015/2283—where timelines often extend from 18 months to over five years—will persist, potentially slowing the deployment of sustainable and innovative food technologies in Europe.

From a strategic perspective, the Biotech Act represents a critical opportunity to **strengthen Europe's position as a global leader in sustainable food systems**. To realise this potential, the legislation could incorporate **targeted measures for novel foods**, including:

1. **Adaptive authorisation pathways** for precision fermentation products with established safety profiles, reducing unnecessary delays while maintaining rigorous safety standards.
2. **Inclusion in regulatory sandboxes**, allowing innovators to pilot new foods under monitored conditions, providing regulators with early insights and supporting agile, evidence-based policymaking.
3. **Clear guidance on labelling, risk assessment, and compliance**, offering predictability for developers and transparency for consumers.
4. **Alignment with sustainability and circular economy objectives**, incentivising food technologies that reduce environmental impacts, promote resource efficiency, and support the EU Green Deal.

By integrating these elements, the Biotech Act could **proactively address regulatory gaps** that currently hinder innovation, while fostering a predictable, science-based, and strategically aligned environment for next-generation food technologies. This approach would enable the EU not only to maintain competitiveness in emerging food sectors but also to advance its broader sustainability, health, and economic objectives.

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7. Proposed Pathways

The emphasis placed on regulatory streamlining and simplification during the current mandate by the European Commission represents a critical strategic window to reassess how biotechnology regulation functions in practice and how it can better support the Union's long-term objectives. Beyond improving administrative efficiency, regulatory reform offers an opportunity to strengthen the EU's capacity to translate scientific and technological advances into societal, environmental and economic advantages. As illustrated by the cases analysed in this review, more proportionate, coherent and predictable regulatory frameworks can simultaneously support innovation, sustainability and public confidence.

To seize this opportunity, regulatory simplification should be approached not as a technical exercise alone, but as a **strategic governance process**, grounded in broad-based engagement and shared ownership. In a policy area such as food and agriculture, where debates are often polarised and characterised by low levels of trust, it is essential that dialogue is inclusive from the outset. Academia, industry, farmers, consumer organisations and civil society actors should be systematically involved alongside policymakers and regulators, not only to express concerns, but to help define what "more effective regulation" means in practice from their respective perspectives.

A first step in this direction could be the establishment of a **structured, high-level multi-stakeholder platform** dedicated to regulatory efficiency and innovation in agricultural biotechnology. This could take the form of a conference or forum convened by the European Commission, serving both as a stocktaking exercise and as a space to articulate a shared strategic vision. Such a platform would allow stakeholders to discuss the lessons emerging from the five cases, identify common regulatory challenges across technologies, and clarify where simplification could improve outcomes without compromising safety or societal objectives.

Building on this strategic dialogue, **dedicated thematic working groups** could be set up to address specific regulatory and procedural bottlenecks identified through the case analysis. These working groups, bringing together Commission services, Member State authorities, scientific experts and relevant stakeholders, could focus, for example, on authorisation timelines, data and evidence requirements, risk assessment methodologies, or coordination across regulatory frameworks. Operating over a defined mandate, they could deliver concrete recommendations aimed at improving coherence, transparency and predictability across the regulatory lifecycle.

At a broader level, these processes could contribute to the development of a **shared EU narrative on biotechnology**, rooted in evidence and aligned with the Union's strategic priorities in competitiveness, innovation, climate resilience and sustainability. Articulating

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how different biotechnological approaches can contribute to these objectives is key to moving beyond case-by-case debates and towards a more forward-looking policy framework.

Following the input already provided by the RIE Task Force on the five priority areas, an important next step would be to **expand and deepen stakeholder consultation**. This should occur both at the level of individual cases and with respect to the regulatory reform process as a whole. Targeted consultations, expert workshops and iterative feedback mechanisms could help ensure that stakeholder input meaningfully informs policy development and that proposed reforms are grounded in implementation realities.

Taken together, these steps would help position regulatory streamlining not merely as a response to administrative burden, but as a **strategic enabler of innovation**, strengthening the EU's capacity to deliver sustainable, resilient and competitive food and agricultural systems in the years ahead.

8. Conclusion

As illustrated by the five case studies, streamlined regulatory processes can not only enhance the competitiveness of biotechnology in Europe but also contribute to economic resilience and innovation in key sectors such as sustainable agriculture, food security and climate resilience. We have identified challenges and opportunities for reducing administrative burdens in five examples without compromising on safety and environmental standards. Regarding the regulatory approval process for stacked GM events and the safety assessment for GMOs more generally, there are opportunities to align the EU legislative framework with international standards and improve resource efficiency and timelines at EFSA. Regarding the regulatory framework for biopesticides, a more tailored and proportionate regulatory framework is needed. Structured dialogue between stakeholders is paramount to identify regulatory bottlenecks and stimulate coordinated action, contributing to a shared vision for biotechnology in the EU. Regarding the safety testing of GMOs, a shift toward ethically and scientifically justified approaches, such as revisiting mandatory 90-day feeding studies, would improve both efficiency and credibility. Currently, GM field trials are constantly subject to vandalism because their location is made public. A simple solution would be to amend existing legislation to permit researchers to conduct the trials under their own responsibility, subject to audit by competent authorities, but without being obligated to disclose their location. For precision fermentation, reforms such as the anticipated Biotech Act can support faster approval, increase transparency, and strengthen public confidence, helping promising food innovations reach the market more effectively. Reimagining regulatory approaches for biotech innovations within the EU is essential in achieving our ambitious food security, environmental, and competitiveness objectives.

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