OECD Science, Technology and Industry Working Papers
2026/02

A comparison of the innovation and regulatory environments for biotechnology and biosolutions across the European Union and the United States

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https://dx.doi.org/10.1787/1ec20342-en

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Abstract

Biotechnology has significant potential to drive economic growth and address major societal challenges, but realising this potential across sectors requires effective and well-designed policies. This OECD Working Paper strengthens the evidence base for biotechnology policymaking by examining two critical dimensions: innovation-enabling conditions and regulatory practices. It provides quantitative and qualitative analysis comparing innovation performance and regulatory environments in the European Union and the United States. The paper first assesses innovation conditions through indicators related to venture capital, patenting, financing, workforce skills and manufacturing capacity. It then compares regulatory frameworks across the two jurisdictions, highlighting shared challenges such as regulatory uncertainty, fragmentation and complexity, limited adaptability, insufficient pre-submission engagement, and lengthy approval processes with high associated costs. Together, the findings support policymakers on both sides of the Atlantic in designing policies that foster innovation, unlock the economic potential of biotechnology, and facilitate market entry to strengthen competitiveness.

Acknowledgements

This report is authored by Cesar Barraza-Botet, Daniel Nadal, Maya Rosen and David Winickoff. The authors would like to thank Alessandra Colecchia and Jerry Sheehan for their guidance. The authors would also like to thank Guy Lalanne, Sara Calligaris, Andrea Greppi, Marius Berger and Alfonso Muñoz Alvarado from the Productivity, Innovation and Entrepreneurship Division of the Directorate for Science, Technology and Innovation for providing data from the OECD Start-ups Database. Many thanks also to Fares Al Hussami and Nunzia Francesca Saporito from the Investment Division of the OECD Directorate for Financial and Enterprise Affairs for providing data on Foreign Direct Investment to Biotechnology projects. The authors are also grateful to Jane Richardson and Satoshi Nakano from the Working Party on Harmonisation of Regulatory Oversight in Biotechnology in the OECD's Environment Directorate for their support and review of the Working Paper. Fernando Galindo-Rueda, Brigitte Van Beuzekom, and Leonidas Aristodemou also kindly supported this work.

Empirical material for this report was gathered from a series of 17 interviews, an online consultation, and written feedback (full methodology described in Annex A). The authors would like to thank the multitude of experts (from industry, trade associations, public agencies, and policymakers) engaged in this activity via interviews, online events, and written exchanges throughout summer 2025.

This study was financed by a voluntary contribution from Think Tank Europa, a Danish independent think-tank developing analyses on European affairs and their impact on Denmark. The authors would particularly like to thank Ditte Maria Brasso Sørensen and Emmanuel Molding Nielsen from Think Tank Europa for their support.

Preliminary results from this work were presented at the BioSolutions High Level Summit on 10 September 2025 in a keynote speech by David Winickoff titled "Comparing across the Atlantic: A Trends Report from the OECD". Policy recommendations stemming from this work were published in the OECD policy brief "Boosting biotechnology innovation through agile regulation and finance instruments" on 23 November 2025. This Working Paper discusses the evidence base underpinning those policy recommendations.

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Executive Summary

Biotechnology applications have a transformative societal and economic potential and could contribute to addressing major global challenges. Beyond health applications, which historically have dominated policy discussions, biotechnology applications in other sectors – termed "biosolutions" in some countries – could also bring great economic and social benefits. To do so, governments need to create enabling conditions for innovation, while facilitating biosolutions entry into the market. This report focuses on two jurisdictions – the European Union[1] and the United States – to deliver a comparative assessment of the innovation potential of biotechnologies as well as of their respective regulatory landscapes. Both jurisdictions have achieved advanced biotechnology research and innovation ecosystems, industries, and regulatory regimes, but have followed diverging approaches. Understanding how these differences come into play and how they impact biotechnology products can shed light on how countries shape policies that foster innovation, harness the economic potential of biotechnologies, and enable their market penetration to support competitiveness. The analysis unfolds in two parts:

- Section 1 assesses enabling conditions for biotechnology in both jurisdictions, looking at quantitative and qualitative evidence (see Annex A for methodology) in the areas of intellectual property, entrepreneurship, finance, manufacturing capacity, and skilled workforce across.
- Section 2 examines the regulatory landscape, providing a general background on the respective regimes, illustrating the regulatory pathways that a series of biotechnology products undergo in each jurisdiction, and summarising the cross-cutting challenges they face.

Key findings on enabling conditions

Patent applications across the European Union and the United States have been relatively stable since 2000 with a slight trend upward, but the United States files twice as many patents. In the European Union, fragmentation of patents across member states was only recently addressed, the impact of which is still being measured. In the United States, patenting rules have been supportive of transferring academic discoveries into the market, but concerns about patent thickets remain.

Venture capital, which can provide start-ups with sizeable funding without heavy loan burdens, is orders of magnitude higher in the United States than in the European Union. The two jurisdictions are broadly recognised to have different private investment and risk-taking cultures. Venture capital tends to be more risk-averse in the European Union, which may make it harder for early-stage European companies to develop domestically and may be incentivised to seek foreign income sources and relocate.

Although governmental financial support through public R&D and indirect supports such as tax incentives is critical source of financing for biotechnology, so is the private sector. This includes **blended finance that combines public, philanthropic, and private resources in a coordinated investment instrument or project to catalyse commercial investment**, aiming to share risks or accept lower returns on the public portion so that private investors can participate with confidence. **Foreign direct investment (FDI) by international companies into one country can provide smaller biotechnology companies with much-needed capital as well as knowledge, scaling opportunities, global markets, and new**

collaborations. A specific type is greenfield FDI, which refers to foreign companies building brand-new facilities in a country. Greenfield FDI in the biotechnology has grown drastically in both the European Union and the United States between 2003-2013 and 2014-2024.

Skill levels, education, and labour costs are broadly comparable across the European Union and the United States, but opinions diverge on whether and where a biotechnology-specific skill shortage exists. There is great job-creation potential in biotechnology, but these opportunities require anticipating education needs across the public and private sector and the evolution of the industry.

The European Union leads in biomanufacturing capacity in biosolutions, putting it in a prime position to support scaling up of promising industrial biosolutions. Yet global leadership in biosolutions is increasingly challenged due to administrative costs of building new plants and competition from abroad. Concrete efforts are underway in the European Union and the United States to expand biomanufacturing capacity further mostly through public-private financing mechanisms.

Biotechnology start-up creation has been decreasing in recent years. Start-ups are rarely active in both biomedical and biosolution applications, with biomedical active ones being predominant in both the European Union and the United States, although the recent decreasing trend in start-up creation affects both equally. Patents by start-ups exhibit the same trends as for the broader biotechnology field.

Key findings on regulatory frameworks

Several challenges and opportunities spanning both approaches across the European Union and the United States were identified, including:

- **Regulatory overlaps**: There co-exist both biotechnology and sectoral (e.g. food, agriculture) regulations across European Commission and Member States. In the United States, there is jurisdictional overlap between regulatory agencies for genetically modified (GM) products in agriculture, environment and food.
- **Regulatory complexity:** In the European Union, the process-based approach can be intensive and lack clarity with respect to where new technologies fit into the regulatory regime, whereas the United States is comparatively streamlined and rapid as GM products are often determined to be of “substantial equivalence” to conventional counterparts.
- **Flexibility:** The European Union system features strict data requirements from regulators with modest possibility for derogations. In the United States, there are more streamlined processes of voluntary applications and limited reviews since liability rests on the producer, although some are concerned about gaps in reviews.
- **Pre-submission consultation:** In the European Union, these discussions between innovators and regulators are limited, which can lead to inefficient review processes and time-consuming requests for additional data. The United States system offers more interaction which allows innovators to clarify and negotiate data requirements and discuss petitions of non-regulated status.
- **Approval times and cost**. Length and complexity of regulatory approval process is greater in the European Union. The United States features shorter timeframes and costs due to clearer testing requirements and faster approval/notification processes.

This is a timely analysis as several major policy developments in biotechnology are taking place in both the European Union and the United States. Policymakers and other interested stakeholders shaping these efforts may wish to leverage each jurisdiction’s experience, including those detailed in this report.

1 Enabling conditions for biotechnology innovations

The OECD defines biotechnology as the "application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services" (Friedrichs and van Beuzekom, 2018[1]). Novel applications in human healthcare could develop personalised gene therapies, crops could be genetically modified for improved nutritional profiles, and biomanufacturing could enable decentralised and distributed manufacturing for more sustainable and resilient practices (Robinson and Nadal, 2025[2]).

Some European Union countries have adopted the term "biosolutions" as the subset of biotechnology applications consisting of products derived from biological resources and the biotechnology-based processes to produce them, excluding biomedical applications (See Figure 1.1). These applications have a transformative societal and economic potential and could contribute to addressing major global challenges. According to the European Commission, biosolutions could save up to 2.5 billion tons of CO_2 equivalent per year by 2030 by substituting fossil-based products with other environmental and technical improvements (European Commission, 2025[3]). Biosolutions may also bring economic and social benefits—such as new markets and job creation—in a variety of sectors and in rural and coastal areas, where the biological resources are produced (European Commission, 2025[3]). However, biotechnology innovation indicators for decision-making in specific sectors of application are not well defined, while those same applications are subjected to distinct regulation procedures. This report therefore aims to fill this gap by, where possible, identifying biotechnology innovation indicators in application sectors and linking them with both sectoral and national/regional regulatory regimes.

Policymakers can assess and benchmark their country's capacities, strengths and performance using a series of key innovation indicators of their research and development ecosystem. Bringing biotechnology innovations into the market requires a strong enabling policy environment. To transit towards commercial and industrial applications of biotechnology, governments can foster necessary skills, invest and maintaining physical infrastructure, incentivise entrepreneurship, manage intellectual property and create new markets (OECD, 2025[4]).

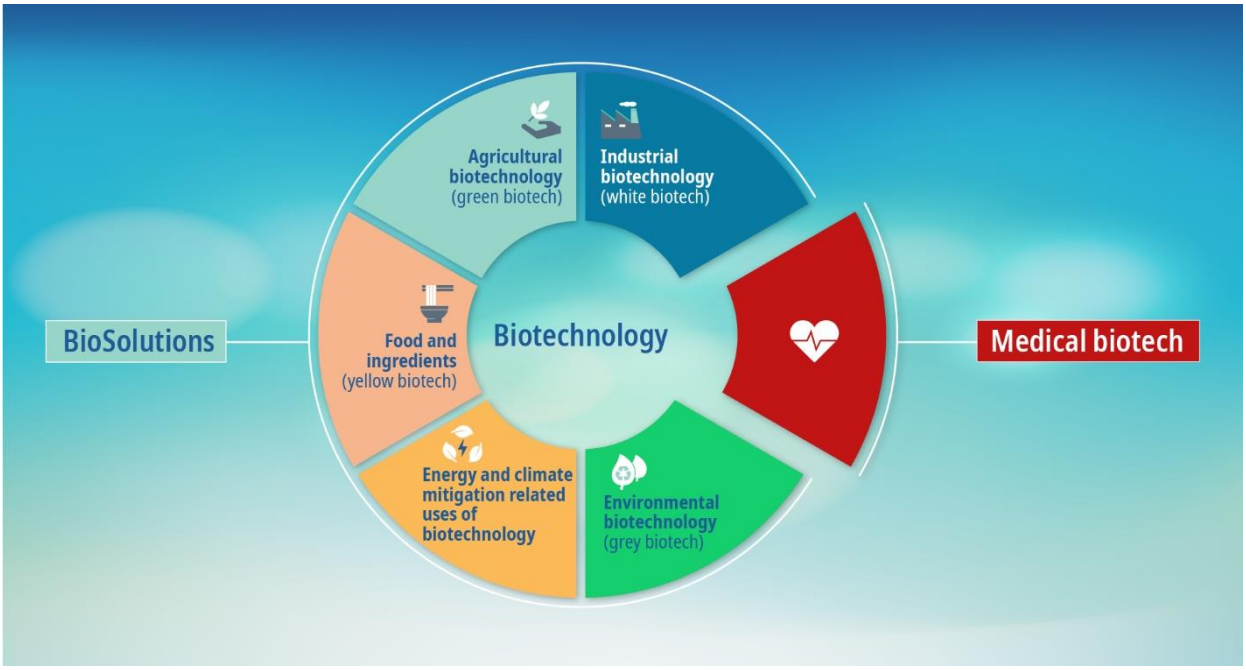
This section brings together a number of innovation indicators to help draw out a comparison between the enabling environments for biotechnology and biosolutions in the European Union and the United States. Given the capital-intensive nature of biotechnology, investment drivers are further analysed across two main mechanisms, venture capital and foreign direct investment. Both qualitative and qualitative analyses point towards United States leadership in this domain mainly driven by biomedical applications.

On the quantitative side, this section presents data relevant to the commercialisation environment such as patent fillings, start-up activity and venture capital funding, as well as foreign direct investments and related job creation. In general, those indicators show clear United States leadership in patent filings. Data suggests that the European Union is a global leader in biomanufacturing capacity to support scaling up of

promising industrial biosolutions, with the European Union leading globally, but with emerging competition in the context of the global bioeconomy.

Finally, special emphasis here is given to a quantitative analysis of start-ups given their critical role in translating academic knowledge into marketable solutions. Looking at availability of data, the United States outpaces the European Union by some margin. In both jurisdictions, biomedical start-ups greatly outsize biosolutions start-ups, illustrating that most R&D and investment in biotechnology is taking place in the healthcare field.

Figure 1.1. Categories of biotechnology applications by sectors



Source: OECD, adapted from Think Tank Europa.

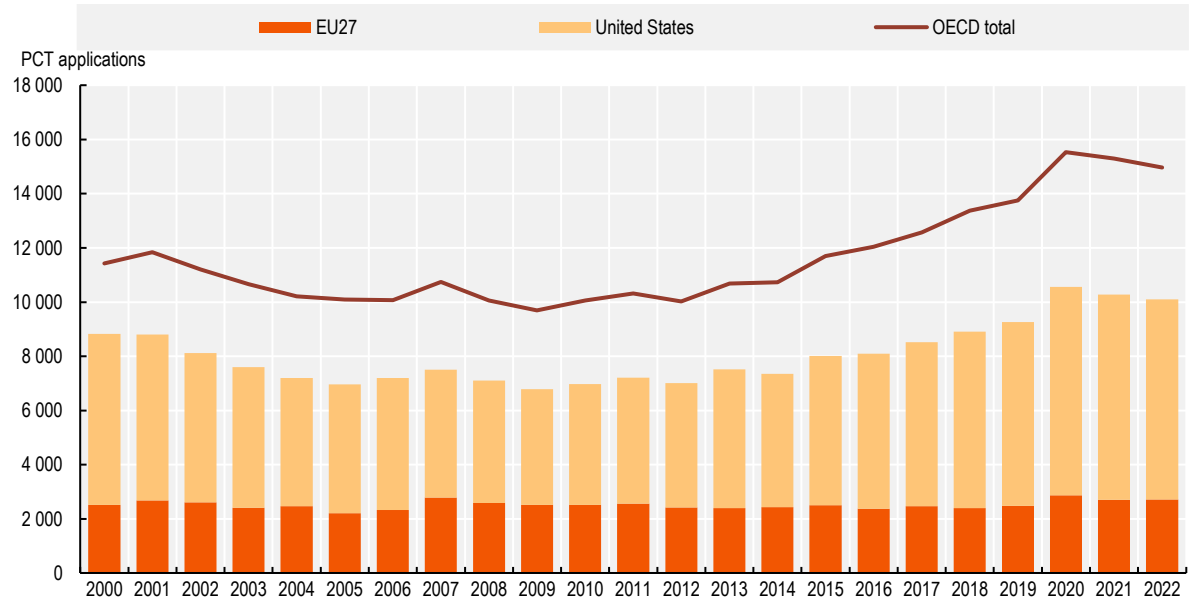
Patents

In the European Union, fragmentation of patents across member states has been a historic bottleneck recently addressed. In 2023, a new Unitary Patent System came into force that aims to remediate the situation by creating a one-stop-shop for a single patent offering protection across all signatory European Union states, with its own court – the Unitary Patent Court – for disputes. Since it was so recently implemented, it may be too soon to understand its impact. However, 18 European Union countries are already participating in the system (covering 80% of the bloc's GDP), and 48,000 patents have been registered (European Commission, 2025[5]). Since 2017, organisms produced by conventional breeding techniques are no longer patentable by the EPO, whereas those produced by technical processes (i.e. transgenic, genetically modified crops) can be[2]. It should be noted that any biotechnology applications with ethical concerns (e.g. human cloning, commercial use of human embryos…) are not patentable (EPO, 2024[6]). The European Commission is currently carrying out a study on the impact of patents for plants produced via new genomic techniques (NGTs) which may impact future IP rules in the field (European Commission, 2023[7]).

In the United States, patenting rules have been supportive of transitioning academic discoveries into the market, but issues such as patent thickets remain. The United States 1980 Bayh-Dole Act enables universities and their researchers to retain near unconditional ownership of intellectual property developed with federal support (Eisenberg and Cook-Deegan, 2018[8])[3]. After 15 years of precedent of the United States Patent system finding GMOs patentable under the patenting statute Congress passed a dedicated Biotechnology Process Patent Act (P.L. 104-41) in 1995 to further establish a standard for judging what qualify as novel and unobvious modifications to living material (Hemphill, 2012[9]). To obtain a patent for a GMO, applicants must also deposit a sample of the organism with a recognized depository, making it accessible to the public as part of the disclosure process (World Intellectual Property Organization, 2024[10]).

Patent applications across the European Union and the United States have been relatively stable since 2000 with a slight trend upward, but the United States files twice as many patents as the European Union. Patent applications are a good indicator of research productivity translating into commercial activity. Figure 1.2 presents patent applications in the biotechnology sector in the European Union and the United States between 2000 and 2022, as compared to the OECD total. Results shows that patent filing across the European Union and the United States are relatively stable across this period, with a slight trend upward. Together, the European Union and the United States have historically represented between 60% and 75% of patent filings in OECD countries, exhibiting their global leadership in biotechnology. However, out of these, 60-75% of patent applications are filed in the United States. The European Union is recognized to be a leader in foundational research, so this lag in patenting – with the United States filing double the patents than the European Union – is likely due to it having a less competitive ecosystem for translating academic discoveries into patentable and marketable innovations.

Figure 1.2. Number of PCT patent applications in the biotechnology sector originating in the European Union 27, the United States, and in OECD countries, 2000-2022



Note: Patents in the biotechnology sector - applications filed under the Patent Co-operation Treaty
Source: OECD Main Science and Technology Indicators (MSTI database), September 2025 edition, https://oe.cd/msti, based on OECD patents statistics, accessed on 28 November 2025

These differential trends between the United States and the European Union in biotechnology patent filings are backed by existing literature. A 2024 study by the European Commission (EC) analysing biotechnology patenting trends across a broader range of countries corroborate this report's findings that the United States is leading the space in an increasingly widening gap (followed by China, which is quickly catching up). In addition, the EC found that most patents were for applications in health and industrial biotechnologies. Existing literature suggests the need to explore divergence across European Union member states. For instance, the Netherlands and Denmark have a large proportion of industry patents (Pelissier, Grabowska and Bergamini, 2025[11])

There are several possible explanations for these differences, including cultural mindsets in each jurisdiction. Some interviewees highlighted that there seems to be a stronger belief amongst European Union policymakers that prices for products based on public research should be kept low. In fact, the President of the European Patent Office said in 2017 that "*we always start from the basis that a patent is an exception to the principle of free trade, free industry, free competition*" (Embling, 2017[12]). Industry perspectives tend to argue that the cost of developing these products is higher than just the costs of the research and that the profits need to also repay all the failed research paths. Interviewees mentioned that whilst development failure may not be as factored in in the European Union mindset as it is in the United States mindset, this may be evolving. This narrative is well-known for pharmaceutical products, but it is worth noting that it also applies to biosolutions like agricultural biotechnology.

Intellectual property is key for startups to attract investment. Expert interviewees noted that when United States startups enter incubation environments to receive guidance and financing for commercialization, funding from venture capital is often dependent on these startups being able to develop separate, independent IP from that which their academic institution holds. This is because it is this new IP that can be best leveraged to support their royalty stream and become part of the company's valuation that will be critical should the startup be sold. These issues will be further explored in the 'Start-ups' and 'Venture Capital' sections below.

IP regimes can also impact the ability of large companies to participate in public research projects. Anecdotally, one large multinational company noted that European funded projects require shared IP, which is not a direct deterrent, but the high level of uncertainty associated with the administration of these rules is. This includes, for example, the need to make all research information public but without clear guidelines on how to manage that disclosure and what can still become private company IP. Multinational companies seeking efficiencies may therefore focus on other jurisdictions (like the United States) where such research projects have with clearer outcomes, including on IP rules. This issue will be further explored in the 'Foreign direct investment' section below.

Public R&D and Innovation Funding

Estimates of public funding of R&D/innovation for the biotech sector are not readily available. Nevertheless, certain things can clearly be said about comparative funding patterns. Biotechnology funding in the European Union includes both domestic and European Commission initiatives. The latter of which is more straightforward to map given its centralisation: it includes examples like Horizon Europe, the biggest foundational research and innovation funding program in the world with many projects on biotechnology research (€93.5 billion for the 2021-2027), and the Circular Bio-based Europe Joint Undertaking (CBE JU), a public-private partnership between Horizon Europe and Bio-based Industries Consortium (BIC) which seeks to accelerate the innovation, market deployment and environmental performance bio-based industrial systems (€2 billion between 2021-2031). In addition to direct funding, the Commission also offers tools to help innovators identify funding and scaling opportunities, such as

consolidated funding databases, mapping of pilot infrastructures, and support in reviewing business models.

In contrast, public funding in the United States is funnelled into both academia and industry via a range of agencies and streams. Public research funding into biotechnology is coordinated across many agencies, such as the National Institutes of Health (NIH), the National Science Foundation (NSF), the Department of Energy (DoE), the Department of Defence (DoD), etc. Mapping United States public funding for biotechnology is challenging due to its dispersion across multiple federal agencies and sources in various Congressionally appropriated streams. In the area of biotechnology, one notable example of government programs include the United States Department of Agriculture's Biotechnology Risk Assessment Grants, which fund risk assessment and management research applied to cases of genetically modified life (plants, animals, insects, microorganisms). The program also funds expert gatherings for the review of the latest risk assessment and management protocols. It is funded by withholding 2% of the United States Department of Agriculture's budget for biotechnology research and receives $5-6 million annually. Criticisms of the program suggest that such funding is inadequate and that the program's exclusion of multi-season, multi-location studies and focus on agriculture cannot fully capture the risks of biotechnology projects (USDA, 2025[13]).

There is a perceived gap in funding for higher-TRL biosolutions in the European Union. For example, one interviewee noted that the public European Union tools to support scale-up, including public-private partnerships like the Circular Bio-based Europe Joint Undertaking (CBE JU), tend to be limited to TRLs 7-8 and don't always reach the final stage of commercialisation. However, there seems to be awareness among European Union policymakers as new solutions have arisen to potentially address this gap, with dedicated tools such as the European Circular Bioeconomy Fund (see Box 1.1).

Box 1.1. Key financing and market creation instruments for biosolutions in the European Union and the United States

European Union

The **European Circular Bioeconomy Fund (ECBF)** is a growth-stage venture capital fund focused on accelerating the commercialization of sustainable innovations in sectors such as agri-tech, food tech, and white biotechnology. Backed primarily by the European Investment Bank (EIB) and complemented by private investors, ECBF is a public-private investment fund and was one of the first Article 9 ESG-aligned funds. ECBF was established in response to a recognized funding gap—the so-called "valley of death"—between technical validation and market entry. As such, ECBF targets companies that have already demonstrated proof of concept and are poised for scale, at Series B or higher, typically with a Technology Readiness Level (TRL) of 6 or above (ECBF, 2025[14]).

The **Circular Bio-based Europe Joint Undertaking (CBE JU)** – and its predecessor, the Bio-based Industries Joint Undertaking (BBI JU) – is a €2 billion partnership between the European Commission and the Bio-based Industries Consortium (BIC) which funds research, demonstration, and industrial deployment projects. By de-risking investments, it has helped fund novel biorefineries and supported the scale-up of biotechnology solutions to demonstrate their economic viability (CBE JU, 2025[15]).

United States

BioMADE is a public-private partnership launched in 2021 to catalyse United States biomanufacturing by de-risking investment in infrastructure and sponsoring workforce development programs. Its funding

for technology innovation is designed to help innovators overcome the Valley of Death before the pilot scaling phase, also financing the building of biomanufacturing facilities with fermentation capacity. It distributes funding through cooperative agreement awards: clearly defined deliverables which are monitored throughout the project lifecycle, co-funded with both BioMADE and the awardee matching financial investments. Crucially, unlike grants, recipients are expected to return value to BioMADE in the form of tangible outcomes (e.g. technical knowledge, written reports, or intellectual property filings).

As of 2025, the organization has reached 300 members ranging from academia to small and large industry partners, funding $200 million for projects like testing new bioreactor systems, creating new fabrics from fermentation-enabled proteins, and a bio-based alternative to petroleum-based acrylic acid (BioMADE, 2023[16]).

Source: OECD Research. In addition, the authors interviewed representatives from BioMADE and ECBF who kindly provided clarifications and additional information.

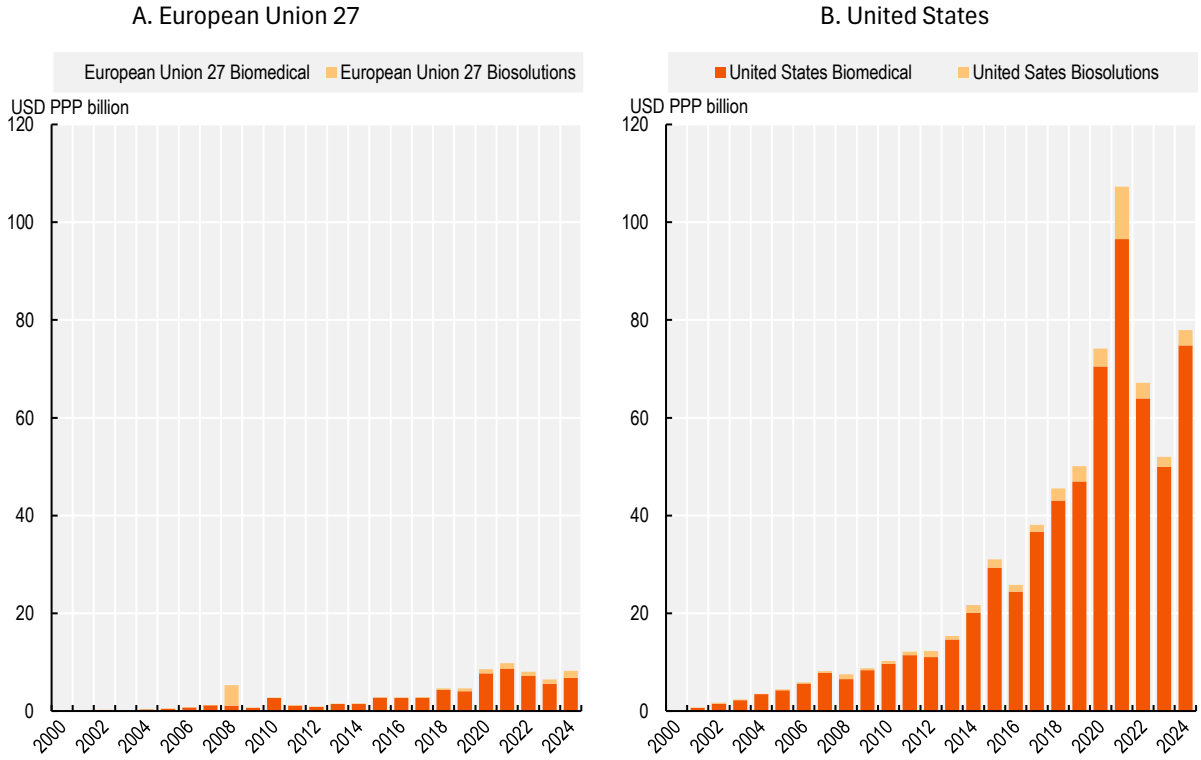
Indirect government support (e.g. fiscal Incentives, public procurement)

Governments have additional tools that can complement direct public funding to help foster biotechnology innovation, scale up, and market penetration. For example, fiscal incentives like tax credits, increased capital allowances, and payroll tax rebates for employing scientific staff are commonly employed. In 2022 across OECD countries, government tax relief for general R&D expenses was 0.13% of total GDP, whilst direct funding for R&D was 0.1% (OECD, 2025[17]). Non-fiscal tools are also available, such as public procurement of biotechnology products to drive market pull of these solutions, which some trade associations in the European Union are calling to extend to non-health biotechnology products (EuropaBio, 2025[18]). Preferential loan guarantees have been used by both the United States and European Union. For example, the United States "Biorefinery, Renewable Chemical, and Biobased Product Manufacturing Assistance Program" offers $250 million in loan guarantees for projects developing, building or retrofitting of technologies like biofuels and bio-based products (USDA, 2025[19]). Also, InvestEU Fund uses the European Union budget guarantee to raise €372 billion in additional investments, including for bio-based fermentation technologies (EIB, 2025[20]).

Venture Capital

Venture capital can provide start-ups with sizeable funding without heavy loan burdens, and it is orders of magnitude higher in the United States than in the European Union. Figure 1.3 describes the size of venture capital funding for biotechnology active start-ups (both in biomedical and biosolutions applications) across both jurisdictions. It illustrates that VC funding in the United States is several orders of magnitude larger than in the European Union, a difference which peaked in 2021 by almost 100 BUSD. Furthermore, whilst funding levels have been fairly stable in the European Union, they have seen substantive variation across the years in the United States. Lastly, and following a similar trend as with patenting, the biomedical field dominates the biotechnology start-up funding ecosystem in both jurisdictions, although this is slightly more predominant in the United States.

Figure 1.3. Venture capital funding for start-ups in the European Union 27 and the United States by field of activity, USD PPP billion 2013-2022



Note: The OECD Start-ups Database provides data on venture capital funding for start-ups, offering broad coverage of innovation- and growth-oriented young companies founded in the United States and the European Union, along with their funding events from 2013 to 2022. Start-ups were classified according to industry filters in the database, e.g., the category "start-ups active in the biomedical sector" contains startups with "biotechnology"- and "health"-related industry filters. VC amounts are linked to the field of activity of the start-up receiving funding.
Source: OECD, (Forthcoming[21]).

Differences in venture capital funding in the two jurisdictions are due to both differences in the availability of private investment and risk-taking cultures. European VC investors were generally considered more risk-averse than their United States counterparts. This may make it harder for early-stage European companies to develop domestically and may thus be incentivised to seek foreign income sources and/or relocate. Being more risk-savvy, United States companies may be valued higher at the point of entry than in the European Union which follows a more cautious approach. Whilst this approach may help United States companies raise funds, being more sensitive to risk is not inherently negative as it can avoid creating market bubbles (see Box 1.2).

Box 1.2. The Enabling Environment for Biosolutions: The Case of LanzaTech

LanzaTech is an international biotechnology company that has developed a process for converting carbon emissions - such as those from steel manufacturing - into valuable products. Using biomanufacturing and gas fermentation, the company transforms industrial carbon oxides (CO and

CO_2) into ethanol, which can be sold to the transportation sector as a road fuel blend, as marine fuel, or as feedstock for sustainable aviation fuel (SAF). Beyond transportation, the ethanol can be made into surfactants for cleaning products or polyester for textiles for consumer brands.

Primarily a licensing company, supplying its technology to industrial partners, LanzaTech's technology is used at six commercial facilities - 4 in China, 1 in India, and 1 in Belgium. Notably, it took the same time to build one plant in Belgium as it did to build 4 of the same plants in China. The company employs around 200 people globally, with Headquarters and R&D facilities in the United States, and offices and teams in China, India, and across the European Union (including the UK, Belgium, and the Netherlands).

As the biocatalysts, LanzaTech uses naturally occurring microbes that are highly evolved but not defined as genetically modified microbes (GMMs). Therefore, LanzaTech hasn't needed to submit for regulatory approval in the United States (though its sister company, LanzaJet, has).

Policy frameworks are, however, a key part of the business case for technologies like LanzaTech as they create markets and incentives for the products they make. Tax credits in the United States are particularly important for project deployment. Previously, only plant-derived fuels qualified for incentives under the EPA's Renewable Fuel Standards. The Inflation Reduction Act (IRA), passed in 2022, provided new tax credits for Sustainable Aviation Fuel (SAF) production and for Carbon Capture and Utilization applications under the 45Q provision. However, under the IRA, the incentive for sequestration remained greater than for utilization. The 2025 One Big Beautiful Bill Act has now created parity between sequestration and utilization, which benefits products like LanzaTech which use organisms to ferment carbon rich gases to create fuels and chemicals.

LanzaTech - and the broader sector of environmental biotech - also faces mounting macroeconomic and geopolitical challenges. Rising defense budgets and shifting priorities in both the United States and European Union have dampened some enthusiasm for green technologies.

Source: The information in this box comes directly from LanzaTech, who the authors contacted and who kindly provided additional information and clarifications.

Another critical challenge for investment in the European Union is the fragmentation of its capital markets. A long-identified issue by European policymakers is that each of the 27 Member States have different rules and tax regimes, unlike in other jurisdictions like the United States which have a single market for capital (Draghi, 2024[22]). The European Union appears to have the ambition to address this with its stated policy objective of creating a Capital Markets Union. Achieving a savings and investments union that removes barriers to bringing together funds across Europe – as the European Commission is currently attempting - would help expand the funding available to European biotech innovators through venture capital, equity markets and bonds (European Commission, 2025[23]). Another original idea raised by some trade associations is to create a European Biotech and Life Sciences Index (a biotech equivalent to the NASDAQ) to allow biotech companies to raise additional capital (EuropaBio, 2025[18]).

Public-private funding and partnerships

Public-private partnerships and blended finance combine public, philanthropic, and private resources in a coordinated investment instrument or project to catalyse commercial investment (OECD, 2020[24])**.** Blended finance can help support biosolutions ecosystems by sharing risks or accepting lower returns on the public portion so that private investors can participate with greater confidence.

Common structures include public-private investment funds, pooled financing facilities, or joint ventures where government or development banks take junior equity or provide subordinated loans. By structuring capital in tiers (a "waterfall"), these mechanisms align different investors' risk appetites. Such arrangements have been used for innovations in the health and energy sectors to great effect, bringing in pension funds, insurers, and other institutional investors that require stable returns (OECD, 2020[24]).

For biosolutions, blended funds can provide the biomanufacturer high-risk capital needed to get new technologies off the ground while attracting institutional capital to co-invest. A careful design is critical: clear governance, alignment of interests, and an exit strategy for public support help ensure that the private sector truly "crowds in" rather than becoming dependent on subsidies. Box 1.1 showcases selected financial and market creation instruments in the European Union and the United States, which also illustrate their support to biosolutions ecosystems in these jurisdictions.

Foreign direct investment

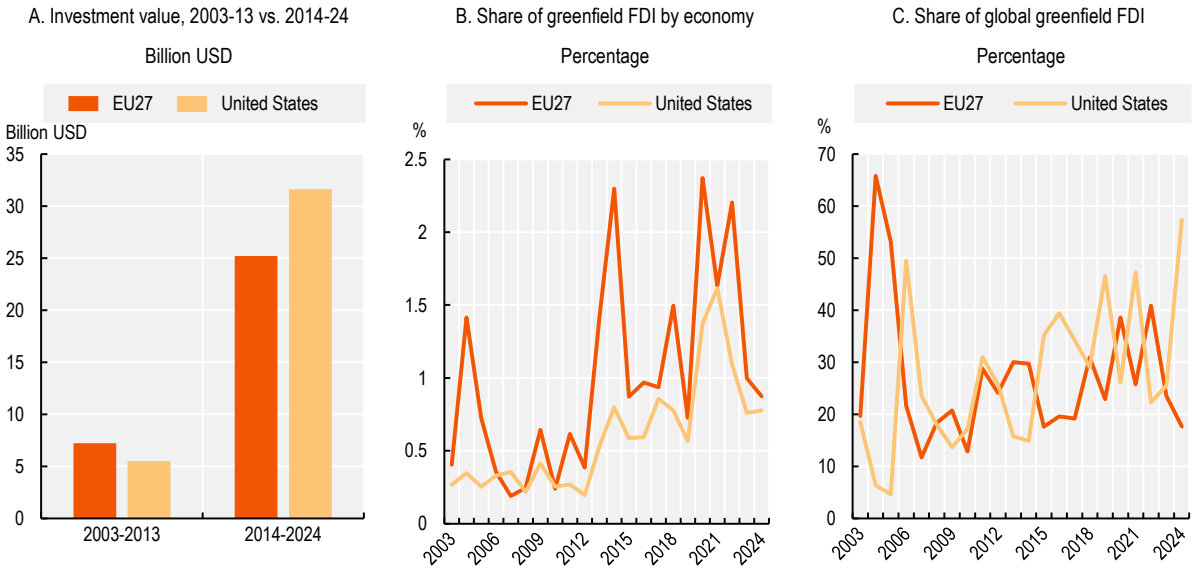
Foreign direct investment (FDI) by international companies into one country can provide smaller biotechnology companies with much-needed capital as well as knowledge, scaling opportunities, global markets, and new collaborations (OECD, 2025[25]). A specific type is greenfield FDI, which refers to foreign companies building brand-new facilities in a country. Countries often hope to attract such investments because they help drive employment, regional development, new infrastructure and productive capacity – usually in a more long-term commitment than other forms of funding like acquisitions (OECD, 2019[26]).

Greenfield FDI in the biotechnology has grown drastically in both the European Union and the United States between 2003-2013 and 2014-2024. Panel A in Figure 1.4 shows that greenfield FDI grew almost 5 times higher in the European Union and 6 times in the United States between these two periods. It is noteworthy that the European Union had a slight lead in absolute terms of greenfield investment over the United States in the earlier period, whereas in the most recent the United States is considerably ahead.

This upward trend in Greenfield FDI could reflect an overall increase in the interest in biotechnology by multinational enterprises across the world over this period. Panel B Figure 1.4 shows greenfield FDI in biotechnology, as a percentage of the total greenfield FDI within each jurisdiction. The portion of greenfield FDI allocated to biotechnology increased in both the European Union and the United States between 2003 and 2022. This is slightly more so the case for the European Union, for whom biotech greenfield FDI represents a slightly higher share than in the United States - particularly in the last year on record, where it is 1 percentage point higher. However, the European Union also sees more variability in this indicator as opposed to the United States where the increase in share has been fairly regular.

Over this period, both jurisdictions have done well in attracting biotechnology FDI relative to other jurisdictions (Panel C Figure 1.4). Both jurisdictions' share of the global greenfield FDI in biotechnology increased overall between 2003 and 2022 (from 20% to around 30%). However, there is a strong variation year-on-year, including times where their global share has dipped below the original levels of 2003. Comparatively speaking, the European Union and the United States have seen similar trends in this space and regularly alternate which overtakes the other.

Figure 1.4. Greenfield FDI in biotechnology



Note: Foreign direct investment data from Greenfield FDI in biotechnology, 2013-2022, Financial Times - FDI Market. Input using data provided by the Financial Times' FDI Markets was produced by Nunzia Saporito, Policy Analyst, FDI Qualities and Impact Team, Sustainable Investment Unit, Investment Division (DAF). Data include only greenfield FDI – new facilities and/or expansion of existing facilities.
Source: OECD based on FDI Market Financial Times and OECD (forthcoming) The evolution of biotechnology: Implications for FDI and SME linkages across Europe.

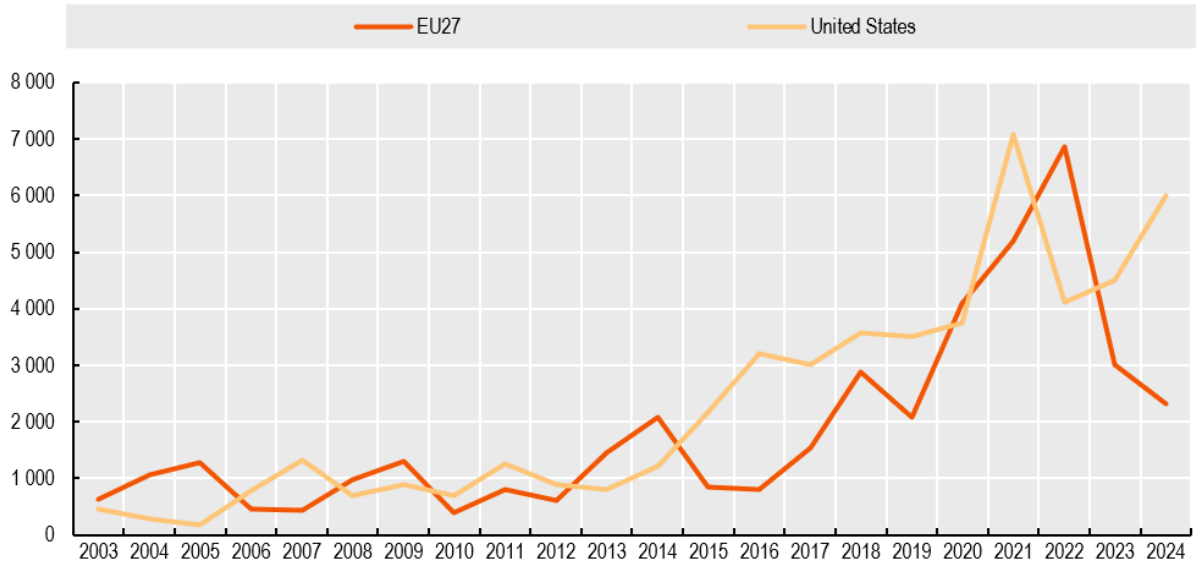
FDI-related skills and workforce

Emerging technologies like biotechnologies can help create jobs in the bioeconomy, but making the most of these opportunities requires anticipating education needs. Figure 1.5 shows an increase in the number of jobs generated through greenfield FDI in biotechnology across both the European Union and the United States, particularly since 2014. The timing matches the increased greenfield FDI in biotechnology seen in Figure 1.4, suggesting that the increased investment does indeed translate to new jobs. The United States slightly leads the European Union, likely due to the former attracting more absolute amounts of greenfield FDI as seen in Figure 1.4. Meeting this increased demand for jobs calls for a sufficiently trained workforce. Since job profiles in biotechnology may range from trained manufacturing professionals to academic PhDs, governments should seek to anticipate skill needs and developing appropriate education and training curricula to ensure the labour market is equipped with the right knowledge and capacity (Robinson and Nadal, 2025[27]).

Interviewees considered that skill levels, education, and labour costs are broadly comparable across the European Union and United States, but opinions diverged on whether and where a biotechnology-specific skill shortage exists. Where industry experts point to a shortage, they identify the biomanufacturing sector as a critical site where gaps in foundational biotechnology knowledge hinder scalability. Larger companies suggested that despite an extensive workforce with experience in traditional manufacturing there may be a lack of specific competencies required for biosolutions. This could potentially be applied across disciplines in, for example, responsible job replacement programmes for workers in incumbent industries. Start-up interviewees, on the other hand, generally reported little difficulty in recruiting skilled personnel. This disparity between workforce availability between the manufacturing sector and the start-up ecosystem echoes concerns, primarily in the United States, about an oversupply of

advanced-degree holders and a shortage of technicians proficient in equipment operation, automation, and standard procedures.

Figure 1.5. Greenfield FDI in biotechnology, number of jobs announced, 2003-2022



Note: Greenfield FDI data are sourced from Financial Times' fDi Markets Database, which compiles project-level information on company activities, including capital investment and associated job creation. Where direct information is unavailable, jobs and investment are estimated using a standardized proprietary methodology. This approach differs from official government statistics, which rely on surveys of foreign-owned firms and related sources, but it provides the advantage of capturing employment effects that are otherwise not available in national FDI data. Foreign direct investment data from Greenfield FDI in biotechnology, 2013-2022, Financial Times - FDI Market. Input using data provided by the Financial Times' fDi Markets was produced by Nunzia Saporito, Policy Analyst, FDI Qualities and Impact Team, Sustainable Investment Unit, Investment Division (DAF). Data include only greenfield FDI – new facilities and/or expansion of existing facilities
Source: OECD based on FDI Market Financial Times and OECD (forthcoming) The evolution of biotechnology: Implications for FDI and SME linkages across Europe.

Both governments and private companies are implementing policies to meet current and future job demand in biosolutions. Although now defunct, the Biden Administration's Executive Order on Biotechnology and Biomanufacturing had focused on addressing talent shortages and barriers and developing recognized credentials (Biden, 2022[28]). They also highlighted positive examples of biotechnology companies like Manus, which is working with local partners like technical colleges near their production facilities to develop apprenticeships and on-site training programs (Manus, 2025[29]). Further examples can be found in Box 1.3. Emerging solutions such as micro credentialing and regional certification programs may also help bridge these divides and better align workforce capabilities with the dynamic needs of the biotechnology sector. Some stakeholders advocate for pan-European (including United Kingdom and Switzerland) education programs and mutual recognition of biotech qualifications to address emerging gaps (EuropaBio, 2025[18])

Policymakers, regulators, and investors also need new knowledge and skills to understand and support the rise of biosolutions. The bioliteracy of these stakeholder groups has emerged as an area of concern in both the European Union and United States. Whilst they may be aware of more established sectors like fossil fuels, policymakers may not have comparable knowledge of biotechnology. Yet

policymakers and regulators need to understand both the benefits and risks of biosolutions to develop policies on research funding, risk assessment and management, and education. When it comes to regulators, industry interviewees complained that working within an agency allows them to acquire expertise and institutional knowledge. However, they may also become entrenched in their processes and not be as up to date with the newest scientific knowledge and how it can impact and update risk assessments. Investors' lack of understanding is also an issue, as they may perceive biosolutions as inherently riskier if they do not understand the technology, and therefore not invest (Keating, 2023[30]).

Box 1.3. Examples of Biotech Skilling Initiatives

United States National Academies Biotech Regulatory Fellowship Program

The National Academies of Sciences, Engineering, and Medicine (with support from Schmidt Sciences and the Moore Foundation) runs a 6-month, full-time paid fellowship in Washington, D.C. to equip early-career professionals with the skills and insight needed to navigate and shape the evolving regulatory landscape for novel biotechnology products. Fellows engage directly with federal agencies and scientific laboratories to better understand the regulatory pathways and new technologies themselves. Each fellow collaborates with a mentor from the United States Department of Agriculture, Environmental Protection Agency, or Food and Drug Administartion and partner with a cohort member from a complementary discipline—pairing scientific or technical expertise with legal or policy insight to execute a capstone project. These projects will identify and brainstorm solutions for biotechnology products that lack regulatory pathways or currently undergo conflicting risk assessment pathways (National Academies of Sciences, Engineering, and Medicine, 2025[31]).

BioMADE

The workforce initiatives of BioMADE (see Box 1.1) have three targets: K-12, higher education, and professional training. In the K-12 domain, BioMADE aims to expose young students to the field of biomanufacturing to build interest in future careers in the industry. These initiatives have included camps and hands on exhibits that introduce young students to biotechnology basics like DNA sequencing and career options. At the university level, BioMADE is sponsoring courses and certificate, including trainings to help universities create their own DIY bioreactors based off off-the-shelf parts, to broaden access to bioindustrial capacities in a cost-effective manner. BioMADE's vocational training efforts include the development of a virtual reality training platform that immerse students into a bioindustrial manufacturing environment as part of their education (BioMADE, 2023[32]).

Source: OECD Research (2025).

Biomanufacturing capacity

The European Union is the global leader in biomanufacturing capacity, putting it in a prime position to support scaling up of promising industrial biosolutions. For example, in terms of precision fermentation-derived protein production, a study by the Good Food Institute found in 2023 that the European Union currently hosts 47% of the world's biomanufacturing capacity, followed by the United States at 34% (Good Food Institute, 2023[33]). This does not include the capacity from other sectors (e.g. breweries and wineries) that could be leveraged[4]. In the United States, the limited availability of pilot-scale facilities has been identified as one of the main bottlenecks for biomanufacturing the United States (President's Council of Advisors on Science and Technology, 2022[34]), with some reports mentioning that

American innovators seeking to scale their capacity have gone to European facilities to do so (Blois, 2023[35]). The lack of fermentation capacity is critical as assessing whether biotechnology processes are technically and financially viable at a large scale requires demonstration. Yet the investment needed to create the production infrastructure and gather the expertise is considerable, and a particularly risky endeavour when a product has not yet proven itself profitable.

Yet global competition for leadership in biosolutions is intensifying. A few interviewees noted anecdotally the high cost and administrative burden of building new production plants in Europe were driving some companies to regions like Southeast Asia, which were offering additional incentives and support to help companies develop their infrastructure and production capacity in their jurisdiction.

Concrete efforts are underway in the European Union and the United States to expand biomanufacturing translational infrastructure. The "Bio Base Europe Pilot Plant" in Belgium is a leading example. Since 2008, this independent and open-access facility helps academics and companies translate their foundational research protocols into large scale industrial capacity (e.g. process design and optimization, and manufacturing). By providing the infrastructure and expertise, it can help reduce the costs and risks for innovators to prove the viability of their products (European Commission, n.d.[36])[5]. Efforts are underway in the United States to develop similar structures, with BioMADE announcing in 2025 large investment to develop demonstration and pilot-scale facilities in Minnesota and California (BioMADE, 2025[37]). Additionally, some interviewees considered supporting biofoundry initiatives could also be useful, since they can be used both to support foundational research but also some large-scale testing and production.

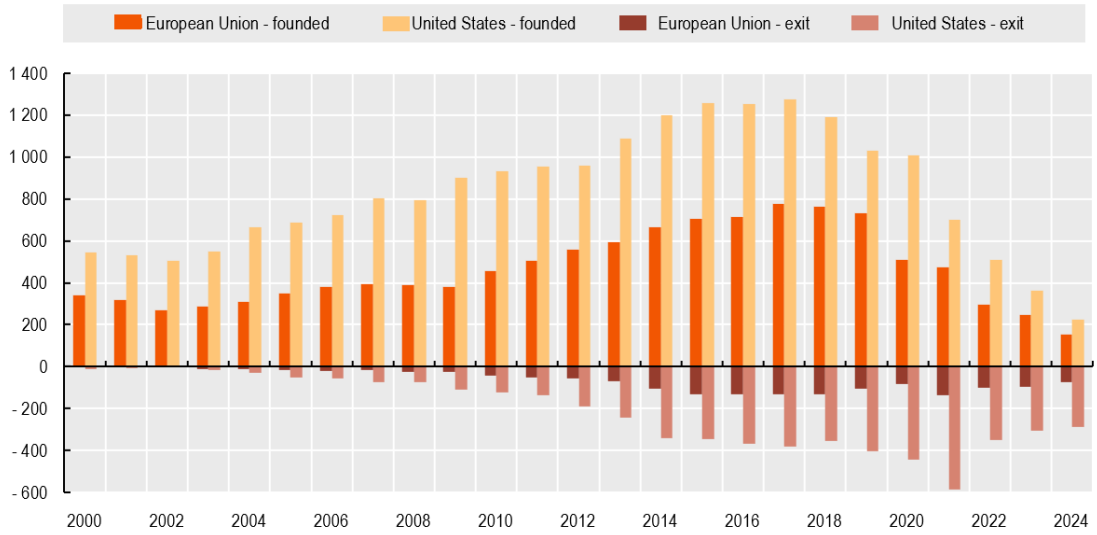
Start-ups

The entry of new biotechnology start-ups has been decreasing in recent years. Start-ups play a critical role in innovation ecosystem by taking discoveries from academic environments and implementing them as products in the market, fostering innovation, driving investment, and creating employment. Countries with strong start-up ecosystems could therefore be considered more conducive to innovation. Figure 1.6 shows an upward trend in the creation of biotechnology start-ups in the European Union and the United States peaking in 2017, followed by a sharp drop. Throughout this period, almost double the number of start-ups were created in the United States rather than the European Union. Start-up exits, on the other hand, have been increasing only in the United States, peaking in 2021. Although this could in part be due to positive outcomes for start-ups like acquisitions and IPOs, it could also be due to start-ups closing. In the European Union, start-up exits have been fewer and more stable. These broad dynamics are further unpacked by biotechnology sectors in the next section.

Sectors of start-up activity: biomedical and biosolutions

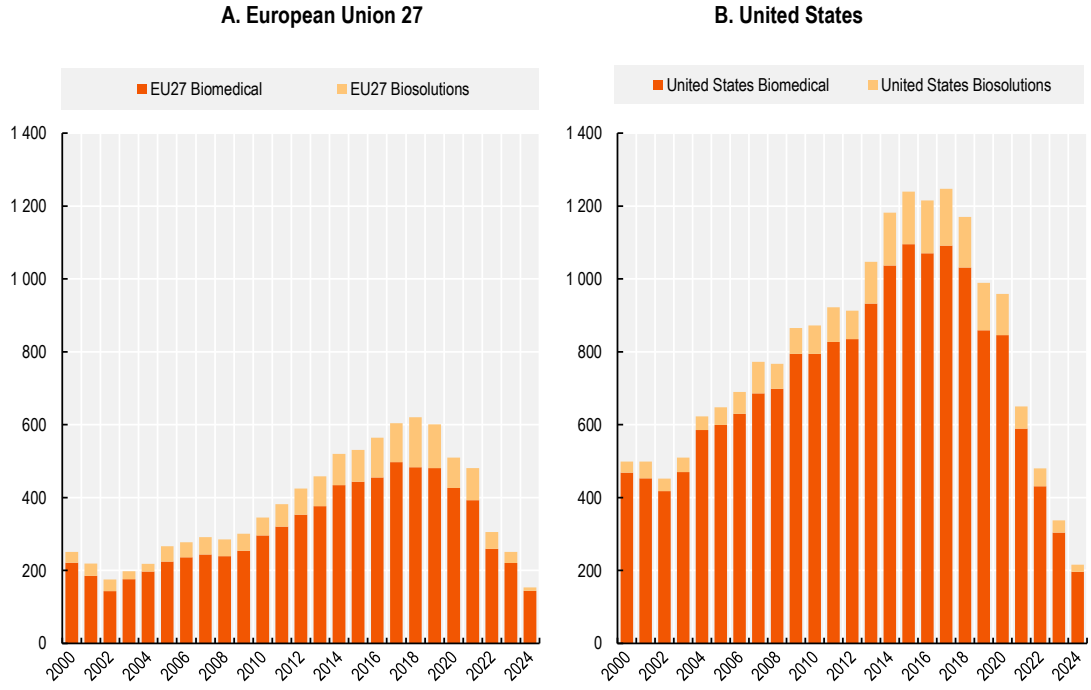
Start-ups in biomedical technologies far outnumber start-ups in biosolutions in both the European Union and the United States, although the recent decreasing trend in entry of new start-ups affects both equally. As Figure 1.7 shows, the biomedical sector dominates the biotechnology start-up ecosystem, outpacing biosolutions along the entire period studied across both jurisdictions. In the European Union, less than a fourth of biotechnology start-ups are active in biosolution sectors, whilst in the United States, less than a fifth of those startups are active in biosolutions sectors, indicating a slightly less dominant and more competitive ecosystem for non-biomedical applications in the former. Although biomedical applications are outside the scope of this paper, Figure 1.7 presents a direct comparison with biosolutions' start-ups, as it can provide a useful contrast on which biotechnology sector sees more commercial interest.

Figure 1.6. Number of biotechnology start-ups founded and exits (by IPO, acquired or closed) in the United States and the European Union, 2000-2022



Note: Start-ups from the OECD Start-ups Database were classified according to industry filters in the database, e.g., the category "biotechnology" industry filter.
Source: OECD, (Forthcoming[21]).

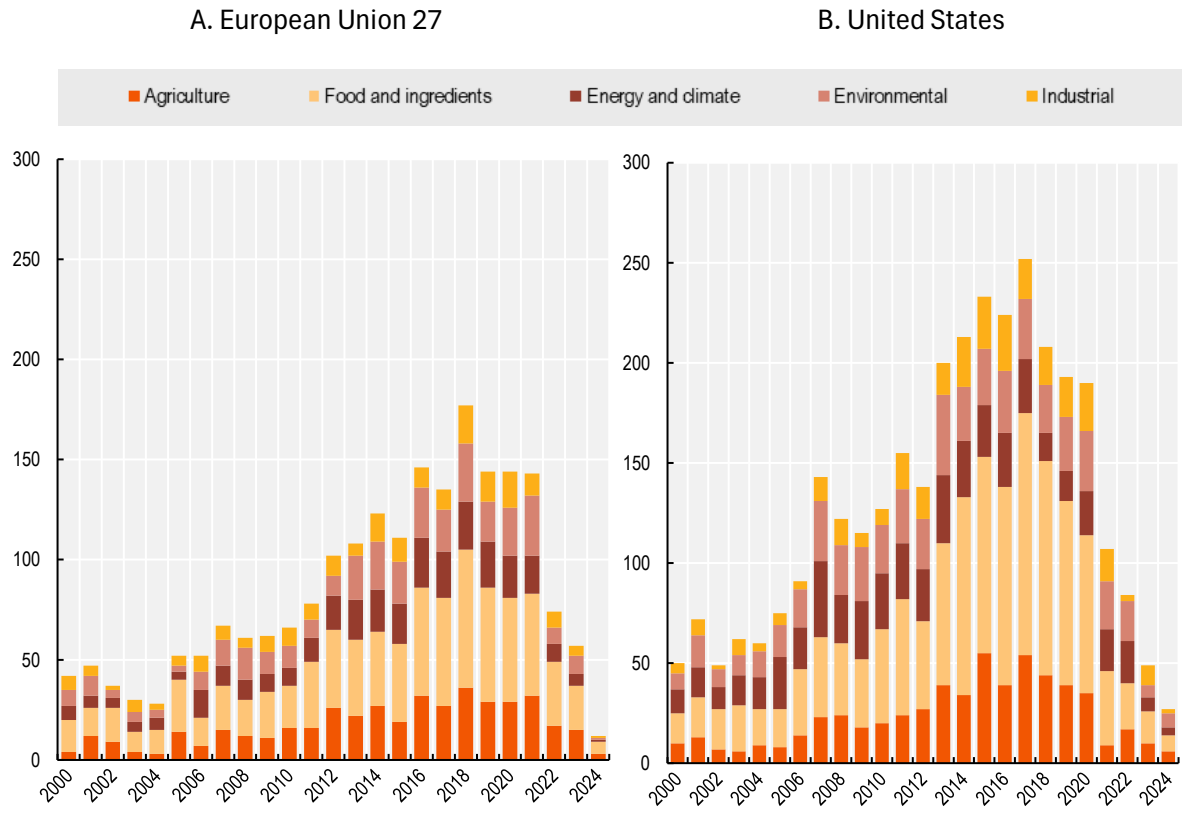
Figure 1.7. Number of start-ups founded in the European Union 27 and the United States by field of activity, 2000-2022



Note: Start-ups from the OECD Start-ups Database were classified according to industry filters in the database, e.g., the category "start-ups active in the biomedical sector" contains startups with "biotechnology"- and "health"-related industry filters. Start-ups active in both fields of activity are double counted.
Source: OECD, (Forthcoming[21]).

Within the biosolutions sectors, the European Union and the United States exhibit similar trends, with start-ups in food and ingredients as the most prominent. Figure 1.8 breaks down the individual biosolution sectors where start-ups are active. There are little substantive differences across the two jurisdictions, either in terms of magnitude or sectoral breakdown. For example, the "Food and ingredients" sector seems to be the most active in both the European Union and the United States, followed by "Environmental" and "Agriculture". This seems to indicate that the biosolutions market for start-ups is more competitive between the European Union and the United States than for the biomedical market, where the United States is clearly in a stronger position.

Figure 1.8. Number of start-ups founded in the European Union 27 and the United States, active in biosolution sectors, 2000-2022



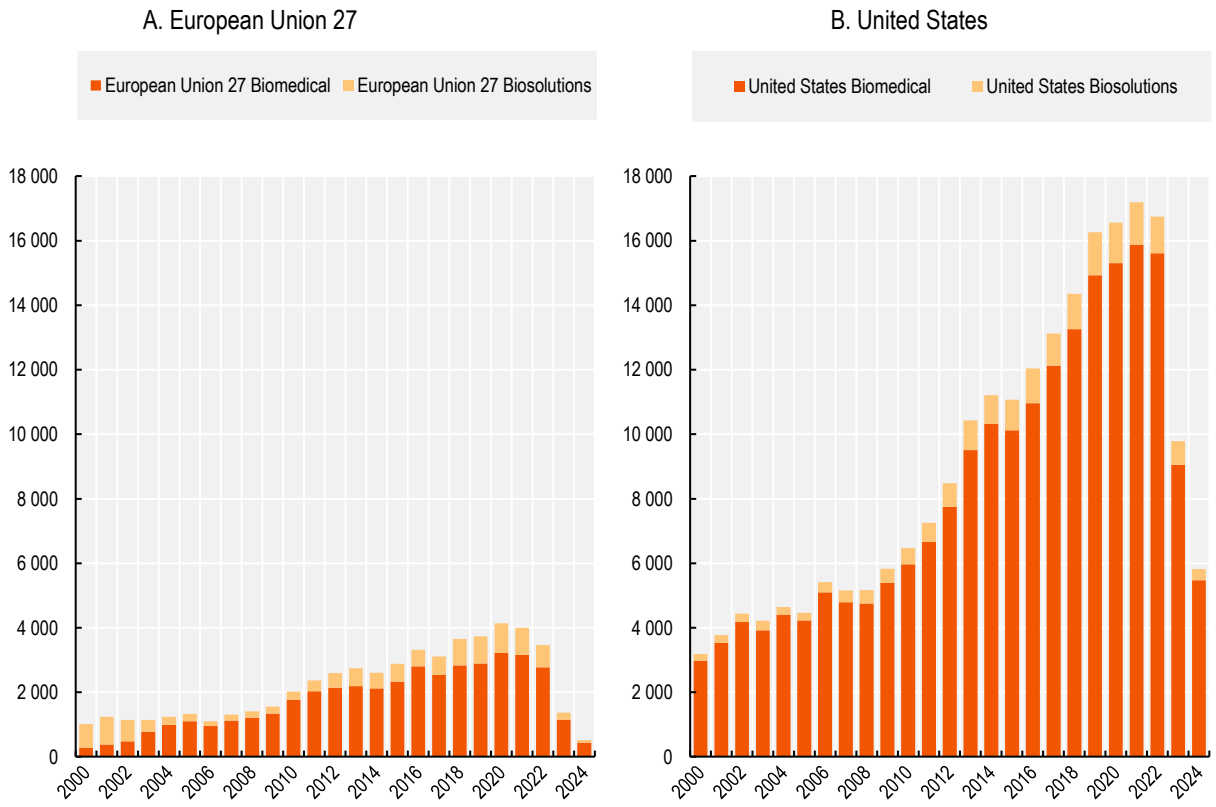
Note: Start-ups from the OECD Start-ups Database were classified according to industry filters in the database, e.g., the category "start-ups active in biosolutions sectors" contains startups with "biotechnology"- and sector-specific industry filters. Start-ups active in more than one sector are counted as many times as sectors they are active in.
Source: OECD, (Forthcoming[21]).

Patents by start-ups

Patents by start-ups exhibit the same trends as for the broader biotechnology field: United States patents well outpace those in the European Union, and biomedical patents outpace those of biosolutions. Building on the patent analysis in Figure 1.2, Figure 1.9 illustrates patents specifically filed by start-ups in national patent offices in both jurisdictions. The United States is again clearly more

innovative, with their start-ups filing almost 4 times as many patents than their European Union counterparts. Similarly, patents for the biomedical sector also outperform other biotechnology applications in the start-up ecosystems of both jurisdictions, although this difference is less pronounced in the European Union than in the United States, meaning biosolution start-ups may be innovative and competitive within their local context in the former.

Figure 1.9. Number of patents nationally filed by start-ups in the European Union 27 and the United States by field of activity, 2000-2022



Note: Start-ups from the OECD Start-ups Database were classified according to industry filters in the database, e.g., the category "start-ups active in the biomedical sector" contains startups with "biotechnology"- and "health"-related industry filters. Patents are linked to the field of activity corresponding to the start-up category that filed it.
Source: OECD, (Forthcoming[21]).

Box 1.4. Case Study: Food Biotechnology Start-Ups

The evolving landscape of food biotechnology start-ups provides an illustrative example of the trends in the biotechnology sector. One interviewee anecdotally shared that a handful of years ago, it was rare to see pitches for food or chemical products produced using biotechnology. However, a "fermentation boom" saw innovation hubs and biotech valleys arise in the Netherlands, Belgium, and other European countries that have made the technologies more widely known and accepted. However,

since 2021, the food biotech sector has seen a drop in the growth of new start-ups (SynBioBeta, 2025[38]).

Whilst macro-economic pressures like inflation likely played a role, interviewees also felt a hype bubble had formed with overly high valuations which have since been lowered, in part due to unmet expectations and evolving market dynamics. Several startups, particularly in the alternative protein space, failed to deliver on their initial promises, leading to a loss of investor confidence. A notable example involves a cell-based meat company whose products were not made in advanced bioreactors as some promotional videos as had been claimed; rather, they used laborious hand-made processes (Reynolds and Fassler, 2023[39]). These types of revelations can erode trust among investors and cast doubt on the credibility of certain ventures.

Another critical challenge, which applies to all biosolutions albeit differently, is consumer adoption. while public education around novel food technologies is essential, it tends to progress slowly. As a result, consumer-facing startups often struggle to secure sustained funding, prompting VCs to redirect their focus. There is therefore now a discernible trend toward investing in B2B companies rather than B2C ventures. Investors are adopting a more holistic approach, expanding their portfolios beyond alternative proteins to include agricultural technology software, feed innovations, and pet food sector.

EIT Foods

EIT Foods is a public-private partnership funded predominantly by the European Union. As part of its mission to drive innovation and entrepreneurship in the food sector, it supports start-ups through a range of programs, including an Incubator Program for idea validation, an Accelerator Program for startups with minimum viable products, and the Rising Food Stars initiative for pre-scaleups aiming to expand internationally. Since 2018, these programs have supported nearly 700 start-ups. It also provides direct investments - up to €500,000 - in promising agri-food and biotech ventures. Since 2020, EIT has invested €17.8 million in 37 start-ups. Beyond funding, EIT Food plays a strategic role in shaping the future of food innovation through its think tank on protein diversification, which produces white papers and policy recommendations. EIT conducts consumer surveys to map their behaviours and expectations, and is exploring the creation of a biotech academy to upskill technologists across Europe.

Source: Unless otherwise stated, the information in this Box was provided by interviewees. The information on EIT Foods was provided by representatives of the organisation which the authors interviewed.

2 Regulatory landscape

The regulatory landscape represents a key pain point for innovators seeking funding and scaling. Even if a product has demonstrated technical performance, the uncertainty of the regulatory process and its outcomes (e.g. how long will it take, what testing will be needed, will it be successful), makes it difficult to know when a product will be commercialised and can start making a profit. In turn, this makes it difficult for investors to know whether and when to invest, yet obtaining funding is critical to ensure companies have the capital to finance the lengthy regulatory submission stage.

Every country regulates genetically modified organisms (GMOs) differently depending on their historical context and their balance of trade-offs calling for different risk identification and management strategies. However, regulatory approaches can be broadly classified into two general categories: process-based where it is the method for creating a product determines the regulatory requirements (e.g. European Union, Australia); and product-based where it is the end product's characteristics which are mainly assessed (e.g. United States, Canada) (Anyshchenko and Yarnold, 2021[40]). There is nuance to this, as some jurisdictions can hybridize these approaches, or two jurisdictions following the same approach can be more or less restrictive depending on several factors (e.g. the scope of their GMO regulations, agency oversight procedures…) (Hundleby and Harwood, 2022[41])[6]. In addition, some countries would further distinguish based on the gene editing technique used (more 'traditional' GMOs vs those derived from new genomic techniques) and apply a different regulatory scope which can significantly influence product development and may reflect underlying philosophies.

Whilst the European Union and the United States are not the only countries to follow these divergent approaches, they are illustrative examples and showcase the rationale behind each. As a general matter, the European Union, prioritises the consideration of human and environmental harms over potential benefits in the face of scientific uncertainty. In the United States, on the other hand, the principle of 'substantial equivalence' is more prevalent: comparing novel products to their conventional counterparts to determine whether they are as safe or need additional risk assessment (Anyshchenko and Yarnold, 2021[40]). These differences are rooted in each jurisdiction's historical context, expressed in the regulation of different biotechnology products, and translated into varying innovation environments.

This Section 2 explores the regulatory landscape for biosolutions in the European Union and the United States, providing a historical background on both jurisdictions and deep-diving into a series of product pathways illustrating the current regulatory processes. Notably diverging approaches are identified across jurisdictions and product types, as well as examples of regulatory bottlenecks hindering market entry. A series of implications, challenges, and good practices that cut across both jurisdictions are also identified. For example, regulatory fragmentation and complexity is an issue for both, although for the European Union this happens in terms of overlap between biotechnology- and product-specific regulations as well as divided authority between the European Commission and Member States, whilst for the United States, fragmentation occurs due to the jurisdictional ambiguity of the relevant federal agencies. Others include diverging flexibility in the regulatory approval process, pre-submission communication between regulatory agencies and innovators, and the lengthy and costly nature of the submission process.

The European Union regulatory regime

Whilst there had been some national activities across European countries since the 1970s, the first European Union-wide legislations regulating GMOs came about in 1990, establishing the precautionary principle and setting out notification and authorisation procedures with case-by-case reviews to ensure human and environmental safety. They created two separate regimes – one for contained use and another for deliberate environmental release - a critical distinction which perdures today, underlying the different risk profiles and management measures for each set of applications (Belgian Biosafety Server, 2025[42]).[7]

The contained use regime has seen relative stability, whereas the regime for environmentally released products has seen greater legislative revision. The former was mainly updated via the 2009 Directive (*2009/41/EC*) that introduced a risk-based classification but kept approvals as the responsibility of Member States (EUR-Lex, 2009[43])[8], and the Novel Foods regulation (*Regulation EC 2015/2283*) which applies for food products produced via contained microbial fermentation and where the European Commission is responsible for approvals (EUR-Lex, 2015[44])[9]. The latter has faced more updates, in part due to public trust issues around food safety regulation and products like GMOs since the late 1990s (Lynch and Vogel, 2001[45])[10],and Member States' political responses to those. *Directive 2001/18/EC,* for example, made the "precautionary principle" explicit, maintaining the case-by-case pre-market notification and authorisations, but also expanding environmental risk assessments, limiting approvals to 10-year periods, and mandating labelling and post-market monitoring requirements (European Commission, 2004[46]). *Regulation 178/2002* in 2002 introduced the general principles of food law at the European Union level and created the European Food Safety Authority (EFSA), which is tasked with providing the EC with independent scientific advice and which has become the main agency for reviewing GMO products in the European Union (EUR-Lex, 2002[47]) (EUR-Lex, 2003[48]). Other legislation has followed over the years.[11]

Recent legislative efforts have sought to increase the European Union's competitiveness in the sector, aiming to support innovation and sustainability whilst maintaining protection of human and environmental health. For example, in 2023, the Commission put forward a legislative proposal for a "*Regulation on plants produced by certain new genomic techniques*" which would equate plants derived from some novel biotechnology techniques to conventional plants and thus streamline their market authorisation requirements (as long as the plants contain genetic material from the same plant or from crossable plants) (EUR-Lex, 2023[49])[12]. This aims to address that fact that new gene editing tools have been developed since the aforementioned regulations were drafted[13]. Another effort is the 2024 "*Communication on Building the Future with Nature: Boosting Biotechnology and Biomanufacturing in the EU*", which proposed a range of efforts to support the European biotechnology sector. For example, the Commission will carry out an assessment of existing European Union legislation and how it can be streamlined to minimize fragmentation and expedite market entry of biotechnology innovations, taking the form of a highly anticipated Biotech Act in 2026.

Other measures included support for companies (e.g. creating tools like the Biotech and Biomanufacturing Hub to help them navigate regulation and funding opportunities), boosting market demand (e.g. implementing bio-based content requirements), leveraging existing research infrastructures, and international partnerships (EUR-Lex, 2024[50])[14]. Several non-sectoral regulations also impact biotechnologies, like the Net-Zero Industry Act, the Strategic Technologies for Europe Platform (STEP), the Commission Recommendation *2023/2113* on critical technologies, and the new Unitary Patent System.[15]

The United States regulatory regime

The evolution of United States biotechnology policy has been led by Executive Branch directives, with limited legislative intervention. In fact, to this day, biotechnology products are regulated under the *Coordinated Framework for the Regulation of Biotechnology*, developed by the White House's Office of Science and Technology Policy (OSTP) in 1986 as the first all-of-government regulatory effort for biotechnology (National Research Council, 2000[51]).[16] Since the Framework derives its authority from pre-existing statutes, oversight of biotechnology remains fragmented and dispersed across three federal agencies: the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA) (FDA, 2024[52]). Each agency requires certain procedures for risk analysis and public deliberation according to the product type which they oversee and as specified in their statutes (National Academies of Sciences, Engineering, and Medicine, 2017[53]). As laid out by the Framework, the product - its specific application and characteristics, rather than their productions methods - determines which agencies are responsible for oversight: USDA for genetically engineered plants and pests, EPA for microbes and pesticides, and FDA for human and animal drugs, cosmetics, food, and genetically engineered animals (USDA, EPA, FDA, 2023[54]) (Kuiken, 2022[55]).

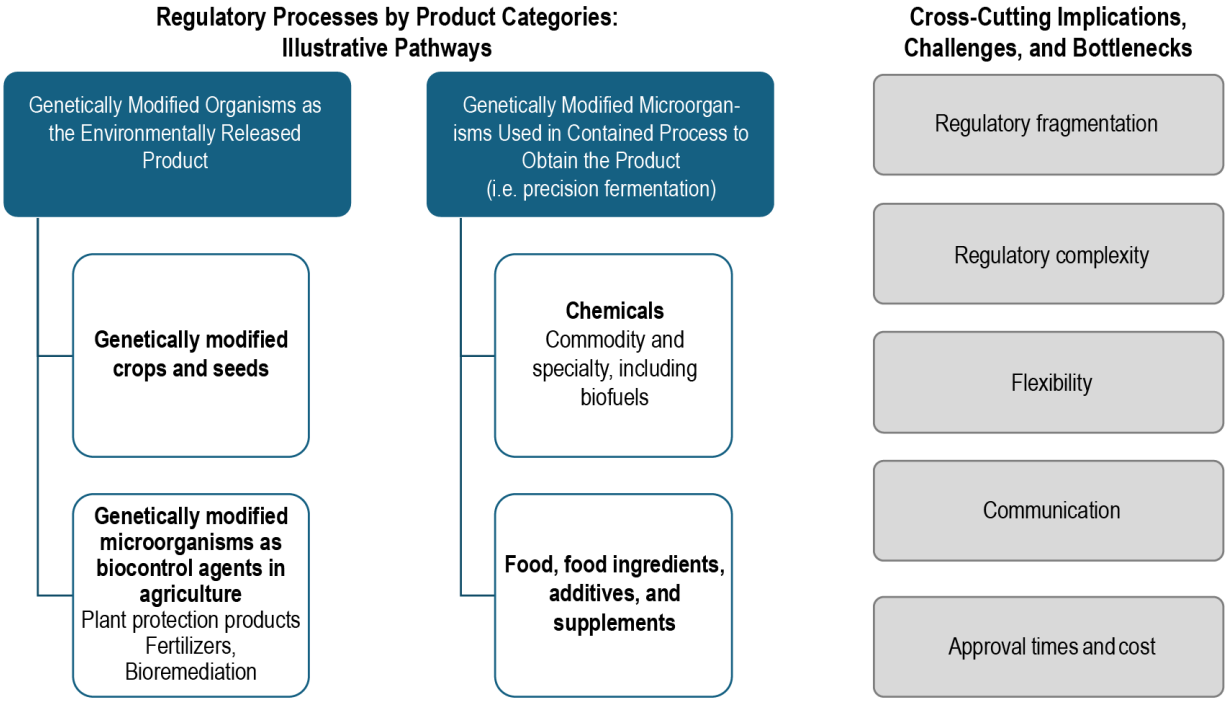
Updates to the Framework have tended to limit, rather than expand, government oversight of the development and commercialization process. The 1992 update limited federal oversight to cases where "the risk posed by the introduction is unreasonable." (Federal Register, 1992[56]), followed by updates in 2015-2017 which equally sought to reduce regulatory burdens, with particular attention to the costs imposed at the time on small and mid-sized companies and academics (National Science and Technology Council, 2016[57]). The 2019 Executive Order 13874 (*Modernizing the Regulatory Framework for Agricultural Biotechnology Products*) called for the streamlining of existing regulations, increased use of scientific and technical evidence in regulatory decisions, and the creation of a Unified Biotechnology Web-Based Platform to allow innovators to more easily navigate the regulatory system (Trump, 2019[58]). In addition to efforts to reduce the burden of government review processes, the Executive Branch has sought to develop the bioeconomy as a national security priority through investments in workforce and manufacturing capacities. The 2022 Executive Order 14081 (*Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy*) launched a whole-of-government approach to biotechnology and a $29 billion investment plan for biomanufacturing, focusing on workforce development and the translation of basic science into applications (Biden, 2022[28])[17]. More recent Executive Branch efforts have focused on ensuring American competitiveness while protecting safety and security: the 2025 Executive Order 14292 (*Improving the Safety and Security of Biological Research*) prioritizes maintaining United States competitiveness in biotechnology research while restricting federal funding for high-risk research like gain-of-function (Trump, 2025[59]).

While Executive Branch policies have focused on research security concerns and reduced funding for basic science research, Congressional interest in biomanufacturing has expanded. The National Security Commission on Emerging Biotechnology 2025 report called for a coordinated, whole-of-government strategy to ensure the United States' global leadership in biomanufacturing (NSCEB, 2025[60]). This report was followed by the introduction of '*The National Biotechnology Initiative Act of 2025*' which would create, if passed, a National Biotechnology Coordination Office to facilitate and coordinate research grant solicitations, standards for measuring the outputs and economics benefits of biotechnology, workforce development, and regulatory streamlining efforts – calling for $22-35 million in funding per year between 2026-2030 (Congress.gov, 2025[61]).

Regulatory Processes by Product Categories: Illustrative Pathways

Whilst the section above describes the overarching regulatory regimes for biotechnology products in the United States and European Union, there are notable practical differences depending on the type of biotechnology application. To illustrate these nuances, **the following section takes the most common biotechnology applications in scope of this paper and describes in more detail the applicable regulations and approval processes they must undergo to enter the United States and European Union markets**. These are divided into two categories: applications where the GMOs themselves are the products released into the environment, and those where the GMOs are only the means of producing the desired end product.

Figure 2.1. Regulatory processes by product category and cross-cutting implications



Source: OECD authors.

Genetically Modified Organisms as the Environmentally Released Product

Biotechnology can create genetically modified organisms whose function requires them to be released into the environment either through planting, spraying, or other forms of distribution. For example, many commodity crops like soybean, cotton, and corn can be genetically modified to express desirable traits like pest resistance or herbicide tolerance faster than through generational cross-fertilization (Wechsler and Fernandez-Cornejo, 2016[62]). Micro-organisms can be genetically modified to act as biofertilizers, pesticides, and herbicides, potentially providing more sustainable solutions than traditional chemical alternatives. Lastly, modified micro-organisms can also be injected into contaminated groundwater or sprayed on oil spills to restore soil or water. This section uses these three examples to compare and

contrast the regulatory pathways necessary before products can be employed in the United States and European Union.

Genetically modified crops and seeds

European Union

Process: **GM crops to be used as food and feed, including those that are to be cultivated within European Union territory, would be under the purview of *Regulation 1829/2003*[18] and require European Commission and EFSA review**. It requires innovators to submit an application to their Member State, followed by a 6-month review by EFSA to develop a risk assessment a scientific opinion, and based upon which the European Commission would draft a decision. A qualified majority of Member States are needed to vote either in favour or against for decision to move forward – otherwise, the EC can make the executive decision[19].

Discussion: **This regulatory process has in practice created separate regimes for cultivation and import of GM crops.** In over 20 years, only 2 GM crops have been approved for cultivation, only one of which (see Box 2.1.) is still currently grown, in limited amounts, and with 18 Member States requesting for it to not be grown in their country (European Commission, n.d.[63]). Experts interviewed therefore commented that the European Union was not seen as a potential market for GM crops, and no major industry players were seeking new cultivation approvals. However, the European Union is considered a major importer of GM crops for animal feed (EFSA, 2025[64])[20], with a total of 86 GM crops currently being approved for import as food and feed (most being commodity crops like maize, soyabean, cotton and oil rapeseed) (European Commission, 2025[65])[21]. Therefore, this regulatory process is creating an environment where the European Union does not grow any GM crops in its territory but is still reliant on its imports to meet domestic demand, and its domestic farmers are facing competition from GM crops without being able to grow them themselves (Halford, 2018[66]).

It could in part be explained by the politically sensitive nature of GM approvals. Whilst the comitology procedure may seem redundant, all GM crops currently available in the European Union market have had to follow the entire process as Member States have not found sufficient qualified majorities in support or against GM crops despite positive EFSA opinions, reflecting the political divisive nature of the topic in the European Union. It has therefore been up to the European Commission to make a decision (European Commission, 2015[67]), and whilst it has been able to do so for GM crop imports, some interviewees suggested doing the same for GM crop cultivations on European Union territory may be too politically sensitive.

The process has been described as onerous and lengthy. The details are described in the "*Cross-Cutting"* section below, but for GM crops and feeds specifically: legislation calls for this process to take 6 months, but EFSA states that provision of its opinion can take between 2-24 months depending on how much follow-up information it needs from the submitter (EFSA, 2025[64]). An industry study claimed this could actually take as much as 6 years (as opposed to other jurisdictions: 1.8 years in United States, 1 year in Australia, and 5 months in Canada) (Garcia-Alonso et al., 2022[68]). To these timeframes should be added the time for administrative committee approval, which legislation states should take around 3 months but which industry estimates set at around 1 year (CropLife Europe, 2022[69]).

United States

Process: **GM crops and seeds are primarily regulated by the USDA - under its authority to manage plant pest risks (under the *Plant Protection Act CFR 340*)**. In general, plants that do not contain DNA

sequences from plant pests, are not modified using plant pests, and do not contain DNA sequences from unclassified organisms are exempt from USDA regulation (USDA, 2025[70]). Those that are regulated must receive a permit from USDA (USDA, 2025[70]), unless the plant has already been deemed safe or is environmentally contained (i.e. grown in a greenhouse) in which case developers can use the notification process (USDA, 2025[71]). After field testing, developers may apply for a petition for nonregulated status which affirms that the transgenic plant does not expose other plants and organisms to harm; successful receipt of the petition allows for the product to be commercialized without conditions (USDA, 2025[72])[22].

The EPA and FDA may also be involved depending on the product characteristic and end use. For GM plants exhibiting pesticidal properties, EPA oversight is required under the agency's purview under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as these plants are considered pesticides by EPA. This process is generally more data-based than the USDA's and requires several studies about the toxicity of the GM crop (to humans, the environment, and non-target organisms) and plans to manage insect resistance (EPA, 2024[73]). GM crops that become food and feed also fall under the FDA's oversight. Developers regularly undergo the voluntary Plant Biotechnology Consultation Program. This involves submitting food safety assessment data to the agency (e.g. nutritional composition assessed for substantial equivalence, allergenicity tests, feeding studies with laboratory animals or livestock, etc.) which evaluates and completes its consultation once it resolves any issues related to the safety of the GM plant for human or animal food, keeping a public inventory of these consultations (FDA, 2024[74]).

Discussion: **Over the past 25 years, GM crops have seen varying periods of increased and lessened scrutiny following lawsuits and public media attention to the risks of GM products**[23]. Changes to GM crop regulation, especially those occurring over the 2024-2025 year due to court action, make it difficult to concisely and comprehensively discuss the historical changes and current state of GM crop regulation.

Regulatory processes have shifted following the implementation and then vacated judgment of the SECURE rule. Following Executive Order 13874 on increased regulatory streamlining, the USDA APHIS (Animal and Plant Health Inspection Service) released its SECURE rule in 2020. It introduced expedited timelines - capped permit reviews at 45 days, and limited the second phase of regulatory status evaluations to 15 months (Hoffman, 2021[75]) (Kovak and Bass, 2024[76]) – and exempted the "*vast majority*" of GM crop developers from pre-market field testing and risk assessments by deeming these products sufficiently akin to conventionally bred plants and unlikely to pose plant pest risks (Kuzma et al., 2023[77])[24]. It allowed producers to self-exempt so they would not have to submit any public information before going to market[25] although experts were concerned this would limit opportunities for public accountability (Kuzma et al., 2023[77]). However, a California Supreme Court vacated the SECURE rule in December 2024, reverting to the pre-2020 regulatory framework (Auslander, Sachs and Szmuszkovicz, 2024[78]).

Similar legal uncertainties can be seen in the environmental reviews that agencies must conduct. The National Environmental Protection Act (NEPA) called for agencies to evaluate the environmental impact of their decisions. Following legal actions in the 2010s, the USDA was forced to conduct full Environmental Impact Statements (EIS), which some industry interviewees claimed could add an estimated 1-2 years to the review process. However, the resource-intensity of this process contributed to the USDA deciding to limit its oversight over GM crop regulation (as exemplified by the SECURE rule) (Kuzma, 2022[79]). After a spring 2025 Supreme Court case reduced agency requirements for compliance with NEPA at large (Vinson&Elkins, 2025[80]), APHIS announced it would no longer conduct NEPA analyses as part of its review of petitions seeking nonregulated status for GMOs, and instead would only evaluate whether the organism poses a plant pest risk (USDA, 2025[81]).

While the regulatory approval process for GM crops has seen many changes in short succession, and it may be a challenge to coordinate between the multiple agencies involved and their changing requirements, GM crops have become a cornerstone of United States agriculture. The first GM crop

- Bt corn - was approved in the United States in 1996. By 2016, 94% of soybean, 93% of cotton, and 92% of corn acreage in the United States employed GM seeds (Wechsler and Fernandez-Cornejo, 2016[62]) (Dodson, 2025[82]). At the same time, experts have expressed concerns about the current regulatory system leaving gaps in regulatory review and not providing sufficient information to the public about GM products (Kuzma, 2022[79]).

Box 2.1. Product Case Study: MON810

European Union

The only GM crop currently cultivated in the European Union is MON810, an insect-resistant variety of maize. It is only grown in 2 Member States (Spain and Portugal) and in fewer than 50,000 hectares. It was submitted by Monsanto (now Bayer) in 1995 under *Directive 90/220/EEC*, and was approved for cultivation in 1998 after reaching a qualified majority of supportive votes by Member State experts (based on a favourable opinion from the European Commission's Scientific Committee on Plants) (Bayer Agriculture BV, 2023[83]).

Before the expiration of the original 10-year authorisation in 2007, Bayer sought to renew its authorisation. This received a positive opinion from EFSA in 2009, but the Commission and Member States are yet to find a political agreement to authorise an extension for cultivation, although authorisation has been renewed for its use as food and feed and additives. Until such a decision is made, the legal framework allows MON810 to continue being cultivated (Bayer Agriculture BV, 2023[83]). In the meantime, Bayer has regularly submitted post-market surveillance reports in accordance with the original authorisation, as well as annual monitoring of any adverse effects to human, animal or environmental health that were not anticipated in the risk assessment. These have consistently shown no unanticipated adverse effects (Bayer Agriculture BV, 2023[83]), which EFSA has recognised (EFSA et al., 2022[84]).

United States

In the United States, MON810 was originally approved for cultivation in 1996, after notification to all three relevant agencies. The USDA's APHIS supported its classification as nonregulated status (proving substantial equivalence to "natural" crops in the market) in 1996 after successful field trials in 1993 and 1994 (Federal Register, 1996[85]). The FDA, responding within a month of Monsanto's submission of safety and nutritional assessments of MON810, found no issues that would require further review before placing them on the market (FDA, 1996[86]). Furthermore, the United States regime does not require approval renewals since GM crops are considered non-regulated once they have been reviewed by the agencies.

Source: OECD Research (2025).

Box 2.2. Trade, globalization, and industry practices in agricultural biotechnology

One of the challenges in the global trade of biotech products, particularly GM crops, is the patchwork of laws that shape how different countries regulate and import/export these technologies. Differences in regulatory systems across countries will lead to some jurisdictions approving GM crops before others –- known as asynchronous authorisation. However, porous global supply chains may mean a GM crop cultivated in an authorised jurisdiction could still find its way to a country where that genetic modification is not yet approved. This creates low-level presence (LLP): trace amounts of recombinant DNA plant material in seeds or crops imported into a country in which the risk and safety assessment for that recombination has not been carried out[26] (Takeuchi, n.d.[87]). Historically, some countries would destroy entire shipments upon detecting LLP, rather than returning them or allowing remediation, which lead to large losses that prompted industry advocacy with regulators. As more countries approve and cultivate GM crops, the likelihood of LLP increases and zero-tolerance approaches that reject imports may disrupt trade and food security (Global Low-Level Presence Initiative, 2020[88]). Whilst one approach pursued by developers has been waiting for all relevant import countries to approve a GM crop first before its cultivation (see below), both industry and regulators have called for more harmonized international controls to manage LLP incidents (OECD, 2013[89]).

Excellence Through Stewardship (ETS): Industry Practices in Global Supply Chains

The industry-coordinated Global Stewardship Group offers the Excellence Through Stewardship program, designed to promote and support agricultural biotechnology companies in implementing product stewardship practices across the plant product lifecycle. These include thorough safety testing, compliance with regulatory requirements, and maintaining product integrity via traceability and purity. Companies undergo regular 3rd party audits to verify that these practices are implemented. ETS members come from all continents and include the largest agricultural biotechnology multinationals like BASF, Bayer, Corteva and Syngenta (Excellence Through Stewardship, 2022[90]).

Crop Life International – a trade association for small- and large-scale agrochemical companies - has additional Product Launch Stewardship Guidelines which commit companies to not launch a new GM product in a cultivation country before they have obtained all necessary regulatory approvals for food/feed imports in all targeted import markets. For example, even if a GM crop will be cultivated in the United States alone, it will not be grown there until regulatory approval is achieved in all import countries, which would likely include the European Union, Japan, South Korea or China (CropLife International, 2012[91]). Experts interviewed used this example to showcase industry's commitment to responsibility, since they engage in this commitment voluntarily and despite the fact that delays in approvals in some of these import countries, particularly the European Union, can add an average 3–5-year delay to product launch.

Source: OECD Research (2025).

Genetically modified microorganisms as biocontrol agents in agriculture (e.g. plant protection products, fertilizers) and bioremediation

Genetic modifications of microbes (e.g. bacteria, yeast, and fungi) can transform them into biological pesticides and fertilizers that replace traditional chemical alternatives, aiming to support agricultural practices (e.g. increasing yields) in more sustainable ways. Genetically modified microbes (GMMs) can also be used in bioremediation: the use of biological products (not necessarily genetically modified) to

clean up environmental pollution (e.g. oil spills, chemical contamination) by neutralising or breaking down pollutants. Many of these applications were first developed in the 1970-80s but have never been commercialised due to mixed efficacy results during field trials and regulatory prohibitions (Chemla et al., 2025[92]).

European Union

Process: **Environmentally released GMMs require risk assessments by EFSA and authorisation by the European Commission (under Directive 2001/18/EC) as well as product-specific regulations which apply regardless of whether the product is a GMM or produced with other technologies.** This follows a similar process as Regulation 1829/2003, requiring EFSA review, European Commission decision, and Member State voting. Following that, products would be under the purview of their product-specific regulations[27]. The only major bottleneck is for biofertilizers, as the European Union Fertilizing Products Regulation (2019/1009) explicitly states that the use of microbial strains in fertilizer products are only allowed as long as these are not genetically modified (EUR-Lex, 2019[93]).

Discussion: **Currently, there do not seem to be any such products approved for commercial use in the European Union**, and thus no EFSA opinion or European Commission decision. Whilst in the case of genetically modified biofertilizers there is a clear regulatory barrier, in the case of GMM plant protection products and bioremediation, this may be more due to immature technology. In fact, an EFSA-commissioned horizon scanning found that for example genetically modified biofertilizers would be placed within the next 10 years (EFSA Panel on Genetically Modified Organisms (GMO), 2024[94]).

United States

Process: **GMMs for environmental release are mainly regulated by the EPA under different acts depending on the product type.** Pesticides – including biopesticides made from GMMs - are regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA*)* and administered by the Office of Pesticide Programs (OPP). As of 2024, the EPA has registered 8 such products, largely disseminated by spraying (EPA, 2024[95]).[28] If the pesticidal microorganism is considered a plant pathogen or is derived from outside the United States, then the product would also have to go to the USDA for approval (Chemla et al., 2025[92]). GMMs as biofertilizers and bioremediation are regulated by the EPA under the Toxic Substances Control Act (TSCA) and subject to pre-manufacture submission requirements. The use of engineered microbes to remediate pollution is a form of bioremediation regulated under the existing frameworks for GMMs and activities such as the protection of surface waters from contamination (Bilyard et al., 1996[96]).

Discussion: **There are examples of registered GMMs as biopesticides, biofertilizers and bioremediation.** Although it is difficult to identify the exact products due to limited public information by the EPA (Klein, 2023[97]), some are known (see Box 2.3.). However, some approved GMMs have yet to be commercialised. For example, *Pseudomonas fluorescens* strain HK44 was developed for bioremediation purposes, as it could degrade petroleum components that can leak into the soil from gas/oil spills or car exhaust, but despite undergoing field trials in 1996-1998 it has yet to be commercialised due to economic viability and requirements for regulatory approval given concerns about antibiotic resistance transfer to other microbes (George et al., 2025[98]).

Some experts believe technical definitions are holding back further progress. EPA interprets TSCA to regulate "significant new uses" of GMMs or any intergeneric microorganisms (i.e. created by insertion of genes from a species outside the taxonomic genus) (Chemla et al., 2025[92]). For non-intergeneric microorganisms (such as those produced by modification using genes from within the genus), the EPA has general authority to evaluate the environmental and health impacts of the product but it is unclear exactly

what requirements the EPA subjects these products to (Mandel, 2012[99]), and in most cases would thus avoid TSCA oversight (see Box 2.3.). The definition of intergeneric has been subject to much scrutiny as some have seen it as outdated' (Chemla et al., 2025[92]), with some experts interviewed opining that intergeneric mechanisms of editing do not necessarily pose greater risks than non-intergeneric, and therefore that such a distinction in regulation could be revised.

Box 2.3. Product Case Study: PivotBio

United States-based Pivot Bio was founded in 2011 out of academic research, with the aim to reduce the need for synthetic nitrogen fertilizers – which account for 2% of global energy use, contributing to greenhouse gas emissions and run off pollution – by using GM microbes that fix atmospheric nitrogen and deliver it to plant roots in a more environmentally sustainable manner (Chemla et al., 2025[92]). Its product has been estimated to have replaced 32,000 tonnes of synthetic fertilizer (Pivot Bio, 2023[100]) – with microbe use could eventually replace about 20% of fertilizer need (Lipton, Eric, 2024[101]) – and reporting over $100 million in revenue in 2023 (Marston, 2023[102]).

Regulatory Process

United States: Pivot Bio has worked with United States regulators to ensure it met requirements, but since its GM bacteria utilized DNA from the same bacterial species (i.e. intrageneric), it benefitted from a streamlined regulatory process. It followed the "*Am I Regulated*" process by USDA - which has the authority to regulate GM organisms if they pose a plant pest risk – requesting exemption from its regulation by demonstrating that their product did not pose such a risk because it does not contain DNA from plant pests nor is the microbe a plant pathogen, which USDA granted. As its products are non-pesticidal, they are not regulated under the EPA's *FIFRA*, and as an intrageneric GM it was also exempt from *TSCA* review, since this only oversees intergeneric (genes from outside the phylogenetic genre). The product underwent state-level approval in its capacity as a soil amendment, which considered whether the product can be labelled as safe rather than investigating the risks of GMMs in the open environment. Pivot Bio has received this approval in 47/50 states thus far (George et al., 2025[98]).

European Union: Pivot Bio was one of the case studies identified in the EFSA-commissioned horizon scanning exercise that identified new biotechnology products that could be placed in the European Union market within the next 10 years (EFSA Panel on Genetically Modified Organisms (GMO), 2024[94]). However, the regulatory process currently does not provide a foreseeable pathway: any environmental release of GMOs would need to be authorized by Member States and the European Commission (which may face political deadlock similarly to GM crops for cultivation). In addition, the European Union Fertilizing Products Regulation (2019/1009) explicitly allows the use of microbial strains in fertilizer products as long as they are not genetically modified. Legislative changes – such as the proposed regulation on New Genomic Techniques in plants, if expanded to GM microbes in the future - could provide a pathway for Pivot Bio.

Source: Unless otherwise stated, the information in this box comes directly from Pivot Bio, who the authors contacted and who kindly provided additional information and clarifications.

Genetically Modified Organisms in the Contained Process to Obtain the Product (i.e. precision fermentation)

Organisms can be genetically modified and grown in large fermentation vats to produce a broad range substances of interest, including chemicals like fragrances and biofuels[29], as well as food products like dairy alternatives and additives (i.e. precision fermentation). These products, while produced via GMOs, can be purified to ensure there is no trace of microbial DNA left in them (ECBF, 2025[103]).

Chemicals (commodity and specialty, including biofuels)

European Union

Process: **Contained use of GMMs in industrial production of non-food/feed substances is regulated under Directive 2009/41/EC at the national level, which after which European Union-wide product-specific regulations that apply**. For this regulatory process, it is critical than the end product (e.g. fragrances, solvents and platform chemicals, biofuels, etc.) does not consist of or contain any GMMs or parts of them like DNA fragments. It calls on developers to submit a notification to competent national authorities, providing information to assess whether the proposed application and facilities create risks of the application to human and environmental health, as well as containment measures to prevent environmental release. The lowest risk applications (class 1) can proceed immediately after, those with slightly higher risk (class 2) can proceed only if the facilities have been approved in the past or after 45 days from submission, and those with the highest risk (class 3 or 4) cannot proceed without written consent (EUR-Lex, 2016[104]). Once the chemical compound is extracted and purified to remove any traces of GMM material, it would have to undergo relevant sectoral regulations depending on their end use[30].

Discussion: **This regulatory process is mostly considered effective, although future-proofness and harmonisation could be improved**. From the perspective of public authorities, a 2021 European Commission report evaluating Member States' experience implementing Directive 2009/41/EC during the 2014-2018 period found no major issues. Most reported few incidents and were able to process notifications within allotted timelines, although they raised the increasing complexity of applications and growing administrative burden as a risk to this. The majority of countries had extended the scope to include the contained use of GMOs like plants and animals to no issue, although a few raised the potential difficulty of distinguishing GMOs created by NGTs from those derived from more classical methods (European Commission, 2021[105]). Private sector experts interviewed agreed that this system was generally effective and only flagged that they had to seek approval from each Member State where they were operating production plans rather than receiving a centralised European Union approval.

United States

Process: **GMMs used to produce non-food or feed chemicals follow the standard regulatory process for all chemicals, under the EPA and TSCA.** They regulate all products deemed chemical substances, whether they are produced by precision fermentation or more traditional methods[31]. This is because the United States follows the product-based regulatory approach, so as long as the end product does not consist of or contain any GMMs or its parts, it does not need to follow a GM-specific path (Wozniak et al., 2013[106]). The only exception is when the GMM is not intrageneric or has intergeneric modifications that are coding or not well-known. In these cases, developers need to file a Microbial Commercial Activity Notice (MCAN) in their regulatory submission with further information on the microorganisms, by-products, health and environmental impact, etc. (Marrapese, 2017[107]). Developers intending to manufacture or import a new chemical substance (i.e. one which doesn't already appear on the TSCA Inventory) for

commercial use must submit a Premanufacture Notice (PMN) to the EPA at least 90 days before manufacture with key data (EPA, 2025[108])[32]. If the chemical already exists on the inventory but is being used in a novel way, developers must file a Significant New Use Notice (SNUN).

Discussion: **The EPA approval process is competitive but becoming increasingly complicated.** Developers interviewed reported that EPA's PMN and MCAN reviews have become more demanding, restrictive, and lengthier in recent years, often taking longer than the 90 days mandated by EPA's statute. On one hand, this could be due to the sharp increase in the number of biotechnology products reviewed under TSCA (National Academies of Sciences, Engineering, and Medicine, 2017[109]). At the same time, the 2016 Lautenberg Chemical Safety Act amended TSCA to require the EPA to reassess existing chemicals and proactively evaluate the safety of new ones and making it a requirement for developers to have written EPA approval before commercialization. Some industry interviewees found this process to now include stricter data requirements that may not be always relevant to a product's risk profile, and the EPA to perhaps follow a more precautionary approach where it conducts more rigorous safety assessments rather than relying on precedent from previous reviews (Marrapese, 2017[107])[33].

Food, food ingredients, additives, and supplements

European Union

Process: **The use of GMMs for food-related products also falls under Directive 2009/41/EC at the national level, followed by European Union-wide product-specific legislation and crucially the Novel Foods regulation which requires EFSA review**. Again, the end product (e.g. food, ingredients, additives, supplements) must be purified to ensure there are no remaining cell parts or DNA. This is also the case for food chemicals that may not themselves be part of the final product (e.g. enzymes used as processing aides). Relevant sectoral legislation that governs those products regardless of the method of production (including traditional chemical synthesis) would then apply[34]. Crucially, *Regulation 2015/2283* on Novel Foods would also apply, as it includes in scope all foods produced via new production processes like precision fermentation, and calls for an additional application, approval, and registration via EFSA[35].

Discussion: **The vast majority of companies working on precision fermentation in the European Union have been able to meet purification requirements so that no detectable cell parts or DNA are in the final product, and thus fall under the process detailed above** (Biosafe, 2023[110]). Experts interviewed mentioned that whilst purification to such degree could be expensive (potentially representing up to 70-80% of production costs (ECBF, 2025[103])), it was a more cost-efficient option that having to go through the regulatory process described in the European Union's GMO regulations. For example, Impossible Foods was not able to lower the percentage of detectable modified DNA in their soy leghemoglobin product and thus had to follow GMO regulations instead of Novel Foods (EFSA Panel on Genetically Modified Organisms (GMO), 2024[111]), which four years since their regulatory submission is still pending approval despite the product being available in a number of other countries (Mridul, 2025[112]).

However, that is not to say that the product-specific legislations are straightforward, especially given new European Union rules calling for re-evaluating legacy food enzymes and additives. In 2008, the Commission set out to create a list of European Union-wide approved food enzymes used as 'processing aides', calling on companies to submit their enzymes already on the market to EFSA for safety evaluation and subsequent approval[36]. Over 300 applications were received, which to this day are still under review. New enzymes developed since are being reviewed in parallel, and whilst EFSA opinions on them are being provided, they will not be authorised for European Union-wide use until the Union list is published, which requires all legacy enzymes to have been approved first. Until this backlog is addressed, the placing on the European Union market of food enzymes is governed by national laws (European

Commission, n.d.[113]), which may hinder European Union harmonisation. A similar situation is taking place with food additives[37].

The biggest barrier cited by experts was the lengthy and onerous Novel Food approval process. It follows a similar structure to those already described: application to the European Commission, followed by a risk assessment and scientific opinion by EFSA, then a European Commission decision to be voted on by Member State experts (Le Bloch et al., 2025[114])[38]. Yet in practice, the timelines are not as speedy as described in the regulation: a 2024 study found that the average time required from submission to publication of the EFSA opinion was 2.6 years, with outliers taking as long as 6 years. The validation stage took almost 300 days, whilst the EFSA risk assessment took over 600 days - mostly due EFSA requests for additional information, which in average it makes thrice (Le Bloch et al., 2025[114]). Although it is worth noting that over 86% of EFSA's opinions are ultimately positive (Le Bloch et al., 2025[114]), the Commission has explicitly stated that its upcoming Biotech Act will seek to ease and speed up the approval process for Novel Foods (Sanchez Manzanaro, 2025[115]) [39].

United States

Process: **Food ingredients, additives, and chemicals fall under FDA oversight and can follow the GRAS process.** Products that are GRAS (generally recognized as safe)[40] need not undergo a formal FDA approval process. Producers can instead voluntarily notify the agency when they make a GRAS self-determination. Within 30 days, the FDA acknowledges receipt of the GRAS notification and confirms the appropriateness of GRAS identification (Gaynor, 2006[116]).[41] If a product cannot be determined as GRAS, it would require premarket submission to the FDA for their review (Dunn and Turow, 2025[117]).

Discussion: **Industry interviewees found the GRAS system very flexible and supportive of early commercialisation.** One important advantage of the GRAS system is that once the notice has been submitted, the innovator can go to market in parallel to FDA review and start earning profits to cover R&D and regulatory costs – unlike in other jurisdictions where regulatory approval is a prerequisite to entering the market and can delay income by years. Some companies may therefore prefer to launch their products first in the United States as a way to reap funds that can pay for the slower processes in other jurisdictions. For example, companies like Vivici (The Netherlands), Onego Bio (Finland) and 21st.Bio (Denmark) all launched their products in the United States first following the GRAS process (Mridul, 2025[112]).

However, the GRAS system is not without critiques. Historically, some experts have been concerned about the voluntary nature of this notification process as companies need not disclose information about their product before releasing to market, only self-affirm it is GRAS (Neltner and Maffini, 2014[118]). More recently, some are calling for its reform: tightened standards to qualify as GRAS, making more products undergo pre-market review, and overall increased FDA oversight (Dunn and Turow, 2025[117]). There have also been calls for manufacturers to submit GRAS notifications for all products currently in the market as self-affirmed GRAS, not just new ones (Covington, 2025[119]). In response, some experts interviewed mentioned an active campaign by industry and regulators to educate policymakers and the public on the benefits of the GRAS system, advocating for a more targeted re-evaluation of problematic older molecules (especially those that were approved decades ago when safety assessment methods were not as sophisticated) rather than all products self-affirmed as GRAS.

Box 2.4. Cultured or cellular meat

Cellular agriculture employs lab-based animal and plant cell cultivation methods to produce tissues that are similar on a cellular level to animal or plants derived through traditional agriculture (Eibl et al., 2021[120]). When such cell-based tissues are intended to replace traditional animal meat, they are referred to as cultivated or cellular meat (Reinhardt and Monaco, 2025[121]). In June 2023, there were 159 companies globally developing cell tissue cultivation (48 in the United States and Canada, and 47 in Europe), raising $2.8 billion in capital in 2016-2022 (Good Food Institute, 2023[122]).

United States

Cell-based meats have received federal approval in the United States. Per a 2019 agreement, the FDA and USDA-FSIS jointly regulate human food that is made from cells cultured from livestock and poultry (FDA, 2019[123]). FDA oversees the cell collection, cell banks, and cell growth and differentiation while USDA-FSIS oversees the harvesting stage to the production process (FDA, 2019[123]). The FDA completed its first pre-market consultation for cultured meat in November 2022 (FDA, 2019[123]). In June 2023, the USDA announced approval for two lab grown chicken products from California companies Good Meat and Upside Foods (Wiener-Brinner, 2023[124]), which upscale restaurants in DC and San Francisco announced would introduce into their menus (currently, the high costs of production may drive these products to be used mainly in higher end restaurants). However, both restaurants have stopped offering them due to a lack of product supply (Nebeker, 2024[125]). Cultivated meat development in the United States has been hindered by a lack of scale up capacity (partially due to regulation, as scaling up may require changes to the production process which could lead to re-evaluation) as well as increasing scepticism from the public. While cellular agriculture has received safety approvals on the federal level, the products have seen pushback at the state level with Florida and Alabama banning cultivated meat not due to safety concerns but rather to protect cattle ranchers and farmers (Robledo, 2024[126]).

European Union

Thus far, extracts derived from plant cell cultures, along with compounds produced through precision fermentation have been approved in the European Union. The first application for a cell-based meat product was submitted in the European Union in July 2024 (Reinhardt and Monaco, 2025[121]). In December 2023, Italy banned cellular agriculture to pre-empt any safety risks, protect local farmers, and preserve gastronomic tradition (Kirby, 2023[127]). Italy's decision prompted other European Union member states to submit a note to the European Commission arguing that the Novel Foods Regulations needed to be updated to respond adequately to the environmental, ethical, and social challenges posed by cellular agriculture (Reinhardt and Monaco, 2025[121]).

Source: OECD Research (2025).

Cross-cutting implications, challenges, and bottlenecks

While the specific implications for each of the product categories of the relevant regulations is described above, a number of implications, challenges, and bottlenecks were identified in the literature as well as in the expert interviews that cut across through these applications – although differently across the European Union and United States jurisdictions. These are summarised in Table 2.1. below and developed in this section.

Table 2.1. Biotechnology regulatory barriers across the European Union and United States

	European Union	United States
Fragmentation	Both biotechnology and sectoral regulations across European Commission and Member States.	Jurisdiction overlap between regulatory agencies for GM products in agriculture, environment and food.
Complexity	Process-based approach can be intensive and lack clarity on where new technologies fit into the regulatory regime.	Comparatively streamlined and rapid as GM products can be determined to be of "substantial equivalence" to conventional counterparts.
Flexibility	Strict data requirements from regulators with modest possibility for derogations.	Streamlined processes of voluntary applications and limited reviews since liability is on producer, but some concerns about gaps in review.
Pre-submission consultations	Limited pre-submission consultations between innovators and regulators, leads to common requests for additional data which add time to process.	Extensive pre-submission consultation for innovators to clarify and negotiate data requirements and discuss petitions of non-regulated status.
Approval times and cost	Length and complexity of regulatory approval process (submissions to risk assessment and risk management).	Shorter timeframes and costs due to clearer testing requirements and faster approval/notification processes.

Source: OECD Policy Brief "Boosting biotechnology innovation through agile regulation and finance instruments" (2025)

Regulatory fragmentation

The European Union's and the United States' long history of biotechnology regulation has led to a complex overlay of responsibilities across agencies and jurisdictions. As high-income economies with large markets, they are often some of the first jurisdictions where cutting-edge products are launched, meaning their regulatory systems have the incentive and often the experience to address innovative applications. However, their history has also created a complex overlay of regulations, guidance, and responsibilities, which may make these systems difficult for new innovators to navigate, although this is expressed differently in each jurisdiction.

In the European Union, there is dedicated GMO regulation, but it overlaps with product-specific regulations and authority is divided between the European Commission and the Member States. Environmentally released GM products (from GM crops to biopesticides) would all follow a similar process, with EFSA responsible for risk assessment and the European Commission for risk management. However, in the case of contained industrial use of GMMs, national authorities are involved in providing permits to developers in their jurisdictions. Then, resulting products of precision fermentation - like food ingredients, additives, or chemicals - would have to follow European Union-wide product-specific legislation which could again involve review by EFSA and a decision by the European Commission and Member States.

In the United States, the main challenge facing many products is that they can be classified as various types of products and thereby regulated by multiple agencies. Regulatory oversight of biotechnology is fragmented by sectors due to the absence of dedicated GMO legislation, resulting in some jurisdictional ambiguity among the USDA, EPA, and FDA. These agencies rely on pre-existing laws related to food, chemicals, and environmental protection, as outlined in the Coordinated Framework, which has led to an ad hoc approach, especially challenging for emerging biotech products[42]. Beginning with the 1992 update and followed in the 2015 memorandum, United States regulatory reforms have prioritized drawing precise jurisdictional boundaries among federal agencies. Nonetheless, redundancies and gaps persist[43].

Regulatory complexity

European Union regulations on GM products follow a process-based approach, there has been unclarity in the past as to where new technologies fit into the regulatory regime. NGTs are the main

example here, which also reveals the speed of European Union policymaking process: whilst this issue of advanced gene editing has been around for years (with countries like Argentina and Chile clarifying the regulatory process as far back as 2015 and 2017 respectively (Vieira et al., 2021[128]), the European Union only published a regulatory proposal in 2023, which still has to be approved and in any case would not apply for a few more years. In the United States, this is comparatively streamlined as producers of GM products like crops can prove 'substantial equivalence' to non-GM versions already in the market and therefore be classified as nonregulated status.

Flexibility in submission processes

In the United States, the regulatory submission process is generally regarded as fairly streamlined and rapid, although there are concerns about limited public accountability. For example: many GM products can be exempted from regulations[44], some can be exempted from labelling as 'bioengineered'[45], and self-determination of GRAS status in the FDA also allows innovators to shape their submission requirements. There are some notable exceptions to this: EPA review of PMNs and MCANs under TSCA have become lengthier and more data intensive. However, new court rulings and Executive Orders shift applicable requirements on a regular basis, creating uncertainty about the exact process and testing that innovators must pursue and submit. Furthermore, TSCA regulates items engineered with intergeneric DNA only, which has been described as an outdated way of distinguishing the risks posed by engineered products. Streamlined regulatory processes of voluntary applications, limited reviews, and light labelling obligations have also made some experts express concerns about the current regulatory system leaving gaps in regulatory review and not providing sufficient information to the public about GM products (Kuzma, 2022[79]). The GRAS system, for example, has been particularly under fire in recent months, with growing calls for its reform to tighten standards and increase FDA pre-market oversight (Dunn and Turow, 2025[117]).

In the European Union, the rigidity of the regulatory approval process is regularly cited as one of the main bottlenecks to biotechnology innovation's entry into the market (Garcia-Alonso et al., 2022[68]). A paper written by industry representatives stated that whilst the data requirements in the European Union seem in line with those required in other jurisdictions, the methods used to generate that data must follow strict requirements, which in practice translates to applicants having to design their studies specifically to meet European Union requirements (Garcia-Alonso et al., 2022[68]). Furthermore, some industry experts opined that several checkbox exercises on toxicological tests and animal studies may be done more by default than by scientific need to test risk hypotheses - the mandatory 90-day rat feeding studies example is extensively corroborated in existing literature[46] [47]. Industry interviewees described this as indicative of the European Union having a strict culture of adherence to official guidelines, with EFSA offering limited capacity to deviate from pre-existing guidelines despite the regulations allowing for derogations of data if applicants can provide justifications – although there is indication that EFSA has the willingness to improve their strategies (EFSA Panel on Genetically Modified Organisms (GMO), 2025[129]). In contrast, industry experts interviewed welcomed regulatory systems like the United States's which they found more flexible and dynamic, where innovators could negotiate with regulators about the relevance of certain data requirements or the possibility of leveraging previous studies. It is worth pointing out that some stakeholder groups are believe the opposite, that EFSA's risk assessments are not scientifically rigorous enough and should require additional studies and data (Chvátalová, 2019[130]) (Hilbeck et al., 2020[131])).

These divergent levels of flexibility within regulatory cultures may be explained in part by agency mandates and the politicised debate around GMOs. The European Union and the United States differ not only on the rigidity of data requirements, but also on differing authorization periods and treatment of GM stack products (see Box 2.6.). Some interviewees pointed towards the politicized nature of the GMO approval process in the European Union - with Member States voting on the final decision - and the limited

societal acceptance of GMOs in Europe. Some authors have also pointed out that United States agencies like FDA and USDA have more decision-making power over regulatory submissions than EFSA, whose remit is to provide scientific advice and it is then up to the European Commission and the Member States to decide risk management measures (Anyshchenko and Yarnold, 2021[40]).

Box 2.5. Examples of divergent biotechnology regulatory cultures in the European Union and United States

Authorization periods and renewals.

In the European Union, authorization for GMOs is granted for 10 years, after which innovators have to apply for a renewal. A similar system holds in China, where environmentally released GMOs have a validity of 5 years (ISAAA, 2023[132]). However, it is not the case in other jurisdictions, like the United States, Canada and Brazil, where GMO permits are indefinite, and renewals are only needed should safety issues or new scientific data arise, or if the intended use changes. Some industry interviewees advocated for the middle ground approaches: implementing a single renewal after 10 years rather than a recurring effort.

GM stack products

This refers to crossing together two organisms which have undergone a single mutation event to express a desirable trait, thus creating an organism with combined desirable traits i.e. “stacking” edits or mutations[48]. Stacked applications have outnumbered applications for single mutations since 2008, yet there is no internationally harmonised approach to their regulation. Countries like the United States, Canada, Australia, and New Zealand do not require separate applications for stacked applications - they consider that if the individual events have been proven safe, then stacking them via conventional breeding should be safe as well (Sul et al., 2021[133]). This is the view generally supported by industry (Goodwin et al., 2021[134]). Other jurisdictions (such as the European Union, Japan, and Brazil) require a separate approval to ensure the combined traits remain stable and there are no unintended effects in comparison to the parent organisms, but in Japan and Brazil they follow a simplified process compared to the European Union (Sul et al., 2021[133]).

Source: OECD Research (2025).

Communication (pre-submission consultation)

Pre-submission consultations offered by regulatory agencies are regularly identified as a best practice to support innovators in anticipating and streamlining their regulatory submission processes. Such programmes involve (regular) meetings between innovators and regulators before the former files their authorisation submission, in order to discuss the specifics of the product, the regulations that would apply, and the data and testing requirements that would be needed. Not only does this engagement help clarify the process innovators will undergo but also allows them to anticipate the tests and data they will need to gather, helping reduce costs by not running redundant or unnecessary experiments. It also saves time, since these exchanges limit the likelihood of regulators having to come back after submission to ask for additional data (e.g. field trials for GM crops would take an additional season).

United States agencies like FDA, USDA, and EPA offer pre-submission services. The USDA's Animal and Plant Health Inspection Service (APHIS) offers and encourages such consultations for modified plant

developers who are planning to submit a petition of non-regulated status (USDA, 2025[135]). Similarly, the EPA also offers pre-application consultations in the case of new uses of old chemicals, new technologies, or data waiver requests for unregistered products (EPA, 2025[136]). The FDA runs the Plant Biotechnology Consultation Program to work with developers of new plant varieties (FDA, 2024[137]). Industry interviewees noted that these consultations are particularly important because they allow innovators to discuss confidential data with regulators, without needing to publicly disclose commercially sensitive information (e.g. product sequences)[49].

The European Union's EFSA also offers general pre-submission advice, but this is much more limited, and industry interviewees did not find it as helpful. Whilst EFSA is working to increase advice to developers[50], certain limitations are prescribed in legislation, such as limiting the advice the agency can provide to the content of the application rather than providing insights on what it considers to be the applicant's responsibility (e.g. study and protocol design) (EFSA, n.d.[138]). Experts interviewed mentioned that communication with the agency was always electronic and there was not as much access to the regulators as in other jurisdictions like the United States. Even those interviewees which had engaged via EFSA's dedicated advice programs for SMEs found they had received limited support. Furthermore, although they acknowledged there is perhaps more written guidance available in the European Union than elsewhere, they did not find it exhaustive nor that it sufficiently clarifies which tests and data will be accepted. This leaves innovators partially guessing what EFSA will need to review their applications, and may in part explain why EFSA often pauses reviews to ask for additional information, which calls for additional experiments to be run, adding length and cost to the submission process (Searby, 2024[139]).

Approval times and costs

The length of the European Union regulatory process is regularly cited by experts to be one of the main barriers to innovations entering the market. Approval for GM crop imports, as mentioned in previous sections, can take as much as 6 years according to industry estimates – as opposed to 1.8 years in the United States, 1 in Australia, and 5 months in Canada (Garcia-Alonso et al., 2022[68]). For Novel Foods, it can take 2.6 years (Le Bloch et al., 2025[114]). The recent introduction of the *Transparency Regulation (2019/1381)* may further extend these timelines. It requires a non-confidential version of the application dossier to be made public, public consultations, and prior notification to EFSA of all the studies to be used in the application to avoid selective reporting. If the latter is not complied with, applicants can be punished with a 6-month stop-the-clock (Expana, 2021[154]). On the other hand, industry interviewees lauded the United States regulatory process for being speedier, in part due to more pre-submission consultations, but also from increased exemptions, pathways for self-designation, and more flexibility in data requirements.

The cost of bringing a new biotech product to market has a large price tag, and regulatory costs represent a big portion. It is difficult to estimate the exact cost as these figures are often only available to the companies pursuing that research, who may not want to divulge sensitive financial information. However, some trade associations have published agglomerated data. For example, a EuropaBio FactSheet found that the cost for GM food and feed approval into the European Union between €11 and €16.7 million (EuropaBio, 2019[140]). A report from CropLife International and AgBio Investor found that the average cost of bringing a new GM crop to market in 2017–2022 was over $115 million, with the regulatory phase representing 37.6% of the costs and over half of the time (AgbioInvestor, 2022[141]). However, there is great variation (e.g. type of crop, where is approval sought, and the company's strategy on which data it will be provide and how many submissions it makes) (Kalaitzandonakes, Alston and Bradford, 2007[142]). This data should be further caveated by the fact that it is provided by the private sector (often to be used for advocacy purposes) and may therefore represent higher-end estimates: it may also include expenses

for assessments that companies would do for their own peace of mind regardless of whether they are mandated by regulation (e.g. toxicity analyses) or that could be re-used across different jurisdictions (Kalaitzandonakes, Alston and Bradford, 2007[142]). Studies have in fact seen that the cost estimates from private sector are higher than those from non-profit developers, although this variance could be due to many factors[51] (Schiek et al., 2016[143]). Lastly, one could argue that it is ultimately the regulators' responsibility to ensure the utmost safety of products that go into the market.

A critical cost not often mentioned in the literature is hiring external regulatory consultants, which illustrate the complexity of navigating regulatory process, and which disproportionately affects smaller innovators. Extensive experience within a complex regulatory process can aid the submission process moving forward efficiently. Whilst large companies have longer experience and larger budgets to hire that knowledge, this may not be the case for smaller, younger companies. Whilst they can try to develop it themselves as they go, one interviewee noted it is often more cost- and time-efficient to resort to consultants[52]. Another reason to seek out external expertise, according to one interviewee, is that working with regulators for a long period of time creates a cultural and institutional awareness of the informal expectations that regulators have developed over time, which may not be formally written down but can become de facto requirements (or at least help smoothen the submission process).

Length and cost considerations impact where innovation takes place, and jurisdictions which allow innovators to reap economic gains will likely be the first to benefit. One aforementioned example shared by industry interviewees is that a key advantage of the GRAS system is the ability of innovators to go to market once a notice has been submitted, in parallel to FDA review, so they can start earning profits and covering costs. In the European Union, however, developers need to wait until EFSA approval to enter the market, which could mean several years with no profits and cost millions of dollars. Some companies may therefore prefer to launch their products first in the United States to reap funds to pay for the slower process in the European Union, delaying or even altogether preventing entry into the European Union market of these products (as above, see Vivici (The Netherlands), Onego Bio (Finland) and 21st.Bio (Denmark) who all launched their products in the United States first).

Regulatory process can direct innovation and should account for the opportunity cost of their decisions. Some industry interviewees argued that it is these large development and regulatory costs that restrict biotech innovation to large, wealthy companies. In the case of GM crops, the need to recuperate the large investment often means innovation is centred on "cash crops" (like maize, cotton and soyabeans) that are grown in large amounts (Dodson, 2025[82]). Investing in other types of innovations may not be as incentivised, such as engineering new traits like increased protein content or other plants like vegetables, although there have been examples in the past (e.g. Flavr Savr tomato) and this difference may also be due to other factors[53]. The opportunity cost of not pursuing certain biotechnology innovations is also a growing consideration. For example, the United States' NEPA includes as part of the assessment a consideration for what will happen if there is no action from the regulators to approve a biotechnology product and what alternatives exist (USDA, 2025[144]). Some interviewees found value in these efforts as a means to recognise the benefits of some biotechnology innovations in achieving sustainability objectives vis a vis the traditional alternatives that may persist should the former not be approved (e.g. continue to use toxic chemical pesticides instead of GM microbes).

Conclusion

Biotechnology policies around the world are currently being reconsidered and debated. This Working Paper provides quantitative and qualitative evidence on biotechnology-related innovation and regulatory landscape in the United States and the European Union. The main points will not be rehearsed here, as they can be found in the paper's Executive Summary. One final point to emphasise, however is the connective tissue across the two main sections of the report. Interviewees have agreed that the regulatory system has had a major impact on the innovation system and vice versa, as developer engagement has an impact on the regulatory process. Regulation, in other words, should be considered a key piece of the innovation policy system. Speed of the regulatory stage determines the ability of innovators to seek funding and scale up. Even if a product has demonstrated technical performance, the uncertainty of the regulatory process and its outcomes (e.g. how long will it take, what testing will be needed, will it be successful), makes it difficult to know when a product will be commercialised and can start making a profit. In turn, this makes it difficult for investors to know whether and when to invest, yet obtaining funding is critical to ensure companies have the capital to finance the lengthy regulatory submission stage. Early engagement and information sharing with regulators and is essential to overcome these challenges. This provides further rationale for treating both sections of the Working Paper as two sides of the same coin.

Policy recommendations stemming from this work were published in the OECD policy paper "Boosting biotechnology innovation through agile regulation and finance instruments" on 23 November 2025. This Working Paper provides the evidence base to support those policy recommendations.

Annex A. Methodology

Section 1 'Enabling conditions for biotechnology innovations' of this report includes a series of indicators to provide a quantitative overview of the innovation landscape for biotechnology and biosolutions in the European Union and the United States. The quantitative analysis of the biotechnology innovation landscape mainly includes indicators created with data from reliable OECD databases or widely used in OECD analyses. These databases include the OECD Main Science and Technology Indicators (MSTI database), the OECD Start-ups Database and the FDI Market Financial Times database. The relevant source is noted under each figure.

Section 1 '*Enabling conditions for biotechnology innovations*' and Section 2 '*Regulatory Landscape,*' were initially informed by desk research and literature review carried out by the OECD Secretariat. This research was reinforced by a series of 17 online interviews carried out between May 2025 and August 2025 with 24 experts, as well as follow-up written exchanges. Interviewees came from both the European Union and the United States and represented a broad array of backgrounds: regulators, public officials, industry actors (both large multinationals and start-ups), trade associations, academia, and research organisations. Their contributions were made in a personal capacity, not necessarily reflecting the views of their organisations. A non-attribution protocol was followed so no input could be traced back to individual experts in order to maximise openness in discussions.

These semi-structured interviews all followed the same protocol to ensure consistency across conversations and improve the reliability of the ensuing data. All interviewees were asked about the same core topics: key challenges for their stakeholder group in developing and deploying biotechnologies, financing considerations, their experience with regulatory approval processes, skill and labour dimensions, and their impressions of the differences between the European Union and United States ecosystems.

An online workshop was held on 29 July 2025 inviting interviewees and additional experts from the OECD Biofutures Expert Group - a group of biotechnology experts from across OECD member states who are regularly engaged on the BNCT's activities in this domain. During this event, the Secretariat shared initial insights from the research – both quantitative and qualitative - to allow experts the opportunity to provide feedback and further thoughts.

Preliminary results from this work were also presented at the BioSolutions High Level Summit on 10 September 2025 in a keynote speech by David Winickoff titled "*Comparing across the Atlantic: A Trends Report from the OECD*". Feedback received following that presentation from experts, policymakers, and other actors was also integrated into this report.

The Secretariat sought to confirm all claims made by interviewees with independent literature during the drafting of this report. Where that was possible, those sources have been provided as in-text citations or as endnotes. Claims which could not be corroborated (either due to the novelty of the developments or the lack of external writings) where either ignored or, if suggested by several experts, included in the text with explicit mention that they were provided by interviewees.

As part of the publication process, this report has also been reviewed by colleagues from the OECD's Environment Directorate and the Directorate for Science, Technology and Innovation.

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Endnotes

[1] Note that with regards to the European Union, this report's scope only covers activities taken at the European Commission-level, rather than national initiatives pursued by individual member states.

[2] The patentability of biotechnological innovations in the EU sought to be harmonised in the 1998 Biotech Directive (*98/44/EC*). It stated that whilst sequenced DNA was a discovery rather than an invention and thus not patentable, what can be patented are DNA sequences released from their natural environment or produced via technical processes that are then made available for industrial applications (European Commission, 2000[180]). It intended to exclude organisms (e.g. crops, animals) produced by conventional breeding techniques (i.e. biological processes), but ambiguity arose with what the European Patient Convention deemed patentable (Eyre, 2019[181]).

[3] In that year, Stanford researchers became the first to be awarded a patent for a biotechnology method, namely that of recombinant DNA techniques (Winickoff, 2013[179]). In the typical American university-to-industry pathway, graduate students and faculty identify promising innovations, encourage the university to secure patent protection, and subsequently license the IP to establish a spinout company or sell the IP to a pre-existing enterprise. This process is referred to as technology transfer (Winickoff, 2013[179]). In fact, the 1980 Stevenson-Wydler Technology Innovation Act required federal laboratories to take an interest in technology transfer with the view that federal funding for research should lead to commercialization (Winickoff, 2013[179]).

[4] One interviewee noted growing interest in gas-based fermentation, but since it is not as developed as traditional fermentation, there is especially limited capacity. Furthermore, it would require a different model for biomanufacturing plants: for gas fermentation to be effective and economically competitive, it would need to take place continuously for several weeks, as opposed to traditional fermentation which can take place in a few days.

[5] Another example is the Netherlands' Biotechnology Fermentation Factory (BFF). This project is supported by a €12.5 million grant provided by the Dutch National Growth Fund for Cellular Agriculture Netherlands, in-kind co-financing by NIZO, and investments from 'Perspectieffonds Gelderland' (fund manager Oost NL). Construction of the new large-scale facility is already underway, while smaller-scale production needs are being served by the existing facilities. More information is available online at https://oostnl.com/news/boost-for-

the-protein-transition-and-food-innovation-new-precision-fermentation-facility-in-the-netherlands

[6] The OECD '*Recommendation of the Council concerning Safety Considerations for Applications of Recombinant DNA Organisms in Industry, Agriculture and the Environment*' leans towards advocating for a product-based approach. It calls for ensuring that, on a case-by-case basis, recombinant DNA organisms are evaluated for potential risks prior to applications in agriculture and the environment, by means of an independent review. This means that an individual review of a proposed application of a recombinant DNA organism should be carried out against assessment criteria which are relevant to the particular proposal.

[7] They took the form of two Directives -- legal acts that establish goals for Member States but allows them the flexibility in the execution. The first delineated that Member States are responsible for approvals of the contained use of genetically modified micro-organisms (*Directive 90/219/EEC*), for example in enclosed manufacturing systems. The second (Directive 90/220/EEC) centralised approvals by the European Commission (EC) for the deliberate environmental release of genetically modified organisms while allowing Member States to remain part of the decision-making process.

[8] Recognising the rapid pace of technology development, international practices on the safety of contained uses, and the regulatory frameworks of other jurisdictions like the United States, the Directive was supplemented by minor updates between 1994-2003 and consolidated in 2009 with a new Directive (*2009/41/EC*).

[9] Originally *Regulation EC 258/97,* updated in *Regulation EC 2015/2283*, it governs foods and ingredients not consumed in the European Union prior to 1997, including food products produced via microbial fermentation.

[10] In the 1990s, on the basis of *Directive 90/220/EEC*, biotechnology innovators began seeking approvals for GMO crops in Europe. Unfortunately, this timing coincided with the 'mad cow disease' crisis, which caused major harm to public trust in food safety regulation, and whilst not directly connected, it created public distrust of new food technologies like GMOs (Lynch and Vogel, 2001[45]). This resistance culminated with several Member States (Austria, Luxembourg, France, Greece, Germany and Italy) invoking the 'safeguard measure' in *Directive 90/220/EC* that has allowed them to ban GM products in their territory since 1997. In an attempt to address these growing public concerns and political impasse, the European Commission developed a new legislative proposal that increased regulatory oversight of GMO approvals from the original Directive. However, until this came into effect, the Council of the European Council agreed to not approve any new GM products, creating a *de facto* 'moratorium' until 2003 that led to several countries (including the United States, Canada and Argentina) to file a dispute in the World Trade Organisation against the EU to increase pressure (Lieberman and Gray, 2006[148]).

[11] Many follow-up legislations have been adopted over the years: *Regulation 1829/2003* which in 2003 established the pre-market authorisation process for GM food and feed for humans and animals to be carried out by EFSA (EUR-Lex, 2003[48]); guidance on the

traceability and labelling of GMOs (*Regulation 1830/2003*) (EUR-Lex, 2003[149]); transboundary movements of GMOs to implement the Cartagena Protocol on Biosafety (*Regulation 1946/2003*) (EUR-Lex, 2003[150]); standard reporting formats for post-market monitoring of GMOs (*Implementing Regulation 2009/770/EC)* (EUR-Lex, 2009[151]). A notable update was adopted in 2015, where an opt-out was introduced to original *Directive 2001/18/EC* that allowed Member States to ban GMO cultivation in their territories even if the GMO had been approved for cultivation at the EU-level by the European Commission (*Directive 2015/412*) (EUR-Lex, 2015[152]).

[12] A legislative proposal was thus put forward by the Commission in 2023 for a '*Regulation on plants produced by certain new genomic techniques*', which would exempt NGT-derived plants that could have been developed via natural breeding from GMO regulations, treating them like conventional plants to ease their market authorisation requirements, and support innovation and sustainability in agri-food systems whilst maintaining protection of human and environmental health (EUR-Lex, 2023[49]). It should be noted that the proposal still needs to undergo the legislative procedure and will thus not come into effect for a few years, and in addition will only apply to plants (NGT microorganisms would remain in scope of GMO legislation).

[13] These regulations were drafted to govern the technologies that were mature around the early 2000s, but since then, new gene editing tools have been developed that allow for more precise and complex genetic modifications. Termed 'precision breeding' or 'new genomic techniques' (NGTs) in EU policy, these include, for example, targeted mutagenesis (e.g. genome editing via CRISPR/Cas 9). However, a 2018 ruling by the European Court of Justice clarified that these products still fall in scope of the European Union's GMO Directive (*2001/18/EC*).

New Genomic Techniques (NGTs) can modify organisms' genetic profiles without inserting genes from other species, essentially the same outcome as conventional breeding techniques but much faster[13] (EFSA, 2025[153]). Yet the European Union's GMO Directive (*2001/18/EC*) defines GMOs as organisms "*in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination*", creating unclarity as to whether these NGT-derived products fell under the scope of the Directive. A 2018 European Court of Justice ruling found that these products did indeed fall in scope and thus should follow the same regulatory requirements (*Case C-528/16*) (Garnett, 2019[154]). This ruling caused mixed reactions: environmental groups and consumer organisations welcomed it (Bioökonomie.de, 2018[156]), whilst scientists and biotechnology innovators lamented it did not reflect scientific arguments and would hinder research (Hjort, Cole and Frébort, 2021[155]).

Recognising potential consequences of this ruling, and after commissioning studies on the matter, the Commission produced a study on NGTs and their impact in 2021, which identified their potential to contribute to sustainable agri-food systems and that there were challenges in applying the current GMO legislation to these new techniques (European Commission, 2021[158]). Crucially, it was informed by an EFSA report on NGTs in plants, which concluded that a) there are no new hazards from NGTs when compared with conventional breeding, b) they may result in the same or even fewer unintended effects

than with conventional breeding techniques, and c) the ensuing genetic modifications can also arise in natural environments without human intervention (EFSA, Paraskevopoulos and Federici, 2021[157]).

[14] The EU Bioeconomy Strategy (to be updated in 2025) includes support for bio-based materials and biomanufacturing solutions, with the 2018 revision calling for promoting standards, facilitating deployment of biorefineries, and supporting bio-based substitutes to fossil-fuel-derived materials (European Commission, 2018[159]).

[15] The Net-Zero Industry Act, which aims to boost the contribution of net-zero technologies in European manufacturing by simplifying regulatory frameworks for sustainable technologies, includes biotechnology applications (EUR-Lex, 2024[160]). The Strategic Technologies for Europe Platform (STEP) aims to direct funding and skills development in critical technologies, and includes biotechnology as one of three target investment areas (Directorate-General for Budget, n.d.[161]). The Commission Recommendation 2023/2113 identified biotechnology as one of 4 critical technologies for the European Union's economic and technological security, and called for collective risk assessments with Member States to inform future promotion or protection measures (EUR-Lex, 2023[162]). The new Unitary Patent System launched in 2023 creates a one-stop-shop for innovators seeking patent protection across participating EU countries with reduced administrative and financial costs, and includes protections for biotechnology innovations (European Commission, 2024[163]).

[16] When recombinant DNA technologies first emerged in the 1970s, the American scientific community responded with self-regulation efforts. At the 1975 Asilomar meeting, scientists initially committed themselves to the principle of containment: the separation of genetically engineered organisms between the lab and the environment and human society (Institute of Medicine, 1991[167]). NIH guidelines followed recombinant DNA research, but the 1986 Coordinated framework. The Coordinated Framework also established the core attitude of United States biotechnology policy: protecting health and the environment while maintaining regulatory flexibility to foster innovation.

[17] Notably, this Executive Order included a focus on climate-smart bioenergy and bio-based products like the production of sustainable biomass through incentives for agricultural producers and forest landowners. While the three relevant agencies announced their Joint Regulatory Plan in 2024 in response to EO 14081, the subsequent administration rescinded EO 10481 in March 2025 (Trump, 2025[172]).

[18] In the EU, genetically modified seeds and crops can be under the purview of two regulations: *Directive 2001/18/EC* for GM crops to be cultivated and thus requiring the deliberate release of GMOs into the environment, and *Regulation 1829/2003* for GM crops that will be used as food and feed, including those that are cultivated. Most GM crops would therefore be covered by the latter, except for applications in field testing or ornamental purposes like flowers. GM crops for food would also be classified as novel foods since they would not have been consumed in the EU prior to 1997, but because the risk assessments set out in GMO legislation are thorough, these crops do need to file an additional separate application as described in the Novel Foods Regulation (*2015/2283*).

[19] The process in more details is as follows. Innovators would have to submit an application to a Member State (not the EC); if the GMO is to be cultivated, the Member State would carry out an initial risk assessment and pass the application on to EFSA; if the GMO is only imported for food and feed, the application is directly passed on to EFSA. EFSA then has 6 months to carry out a risk assessment to provide a scientific opinion, which then goes on to the EC. The EC would draft a decision on this basis, which Member States would vote on via representatives in expert committees. If a qualified majority is in favour, the product would be authorised. If there is no majority against it either, then the EC takes this to an appeal committee (also formed by Member State experts).

[Note: The European Commission's Standing Committee on Plants, Animals, Food and Feed (PAFF) is responsible for the first vote on the European Commission decision. It is composed by representatives from all Member States. Should the vote not pass, it is taken to the Appeals Committee, which is also composed of Member State representatives but at a higher political level.]

If no qualified majority is found there either, then the EC is able to make the final executive decision. Although these authorisations are valid across all EU countries, the opt-out introduced in *Directive 2015/412* allows Member States to prevent approved GM crops from being cultivated in their territory, as long as their justification does not contradict the EFSA's assessment (European Commission, 2015[67]) (Garcia-Alonso et al., 2022[145]). Note: GMOs for environmental release for non-marketing purposes (e.g. supporting scientific research via field trials) also require authorisation, but this is the competency of national authorities.

[20] In 2013, over 60% of the European Union's soy protein for feed demand being satisfied by imports and with 90% of this coming from countries where cultivated soyabean is GM (European Commission, 2015[67]).

[21] As of September 2025, based on data from the European Commission's Food and Feed Information Portal Database.

[22] In 2010, the USDA introduced its *"Am I Regulated?*" Process which allowed developers to inquire with the agency as to whether their genetically modified seed was subject to regulation.

[23] For example, in 2000, investigative journalism revealed that Bt (pesticide-resistant) corn that had been approved by the EPA for animal use only (due to "amino-acid sequence homology and indigestibility to human allergens") had been found in Kraft taco shells. The FDA recalled over three hundred corn products and the StarLink corn withdrew its license. (Kuzma 2023).

[24] USDA estimated that this rule would save the private sector $8.3 million (USDA, 2020[173]).

[25] This came in addition to the separate USDA National Bioengineered Foods Disclosure Standards (NBFDS), which allows GM foods not containing foreign DNA to be exempt from

the bioengineered label, meaning that many of the current gene-edited crops and their products will not be labelled as such when they go to market as food (Kuzma, 2022[79]).

[26] This can be common in bulk commodities like corn and wheat, where this unintentional mixing might occur naturally from (e.g. pollen dispersion) or from human processes (e.g. field testing) (Takeuchi, n.d.[87]).

[27] For example, for plant protection products this would be *Regulation 1107/2009* plus implementing regulations from 2022 (*2022/1438, 2022/1439, 2022/1440, 2022/1441*) that updated assessments to distinguish between more traditional chemical-based pesticides and those based on microorganisms (European Union, 2009[147]) (European Commission, 2023[146]).

For bioremediation, there a number of relevant EU legislations: the *Waste Framework Directive (2008/98/EC)*, the *Landfill Directive (2018/850/EU)*, the *Water Framework Directive (2000/60/EC)* and *Groundwater Directive (2006/118/EC)*, etc. In addition, in 2023 the European Commission published a proposal for a '*Soil Monitoring Law*' that would call on Member States to identify contaminated lands and seek risk reduction measures, including bioremediation (European Commission, 2023[174]).

[28] The EPA, in their evaluation of microbial pesticide products, would also have to evaluate potential impact of residues in food and feed – under the Federal Food, Drug, and Cosmetics Act (FFDCA) and its amendment by the Food Quality Protection Act (FQPA) – as well as the potential effects on endangered species under the Endangered Species Act (ESA) (EPA, 2025[168]).

[29] Biofuels are a renewable fuel made from biomass e.g. biological material like plants or cooking oil. Well-known examples include the fermentation of crops like corn to create bioethanol. Biofuels produced with microbes use fermentation processes to convert waste gas, such as the carbon monoxide produced by steel plants, into fuel, with the advantage of lower carbon emissions and greater sustainability than traditional methods which use corn or wheat fermentation (LanzaTech, 2024[169]).

[30] For example, cosmetics would have to follow *Regulation 1223/2009* and detergents *Regulation 648/2004,* both of which set obligations for safety assessments and labelling. Other chemicals would have to follow the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) legislation, which calls for registration and risk assessment by the European Chemicals Agency (ECHA). Biofuels would have to follow the relevant sectoral regulation that would apply to chemically synthesized biofuels as well, such as the Renewable Energy Directive (*2023/2413*).

[31] It does not apply to chemical substances which are regulated by other pathways, such as drugs, food additives, cosmetics, pesticides, tobacco, or radioactive materials (EPA, 2025[108]).

[32] Data includes chemical identity, process diagrams, production volume, intended use information, effects on human and environmental health, etc. There are some exemptions

for new substances (e.g. for small-scale R&D, with low environmental release and human exposure, specific polymers…) (EPA, 2025[108]).

[33] Another factor contributing to the extended review process suggested by interviewees may be the EPA's need to consider the Endangered Species Act in their risk assessments.

[34] For example, food improvement agents would go through a common authorisation procedure (*Regulation 1331/2008*) -- with details for food enzymes (*Reg 1332/2008*), food additives (*Reg 1333/2008*), and flavourings (*Reg 1334/2008*) -- entailing a risk assessment by EFSA. Food supplements would be covered by *Directive 2002/46/EC* (Precup et al., 2024[175]).

[35] In all the cases detailed above, if the GMMs are used to produce food and feed and part of the product contains or consists of GMMs, then GMO Regulation 1829/2003 applies, and the approval process described in the previous section is required.

[36] Until EU *Regulation 1332/2008*, food enzymes used as 'processing aides' did not require approval at the EU level, only requirements for due diligence and safety assessment kept in file, except for a handful of Member States which had stronger national laws.

[37] A similar situation arose for food additives, where 315 of them approved in the EU market also had to undergo re-evaluation of risk assessments via EFSA starting in 2009 – as of July 2025, 74 food additives remain to be reviewed (European Commission, 2025[164]).

[38] The full process is as follows: After a scientific application is submitted to the European Commission for validating the proposal (90 days allotted in the legislation), it is forwarded to EFSA to carry out a risk assessment and provide a scientific opinion to the EC (9 months allotted in the regulation, but can be extended should EFSA require additional information from the applicants i.e. the 'stop the clock' mechanism). On the basis of this opinion, the EC prepares a draft implementing regulation on risk management, which is then voted on by committees composed of Member State experts, and after which the EC has 7 months to publish in the Official Journal of the European Union (Le Bloch et al., 2025[114]).

[39] EFSA published in 2025 new guidance for applications using microorganisms (genetically modified or not) in the food chain, which involves the use of Qualified Presumption of Safety (QPS) and bioinformatics (EFSA Scientific Committee, 2025[185]).

[40] A product can be qualified as GRAS if there is consensus amongst qualified experts and well-established evidence of its safety, or if there is historical safe use of the food prior to 1958 (FDA, 2024[170]). To establish the safety of a product, developers may need to organize what is referred to as a GRAS Panel: a body of experts representative of the scientific community which reviews data and methods like basic toxicology to affirm the safety of a product (FDA, 2022[171]).

[41] Before the GRAS notification process begins, the FDA has a voluntary process which allows food producers to consult with the agency. These consultations allow the agency to review safety issues (using the manufacturer's data) without commencing a formal food additive regulatory process (Pew 2001).

[42] Section 2.1. 'Simplify Regulation for American Biotechnology Companies' of the National Security Commission on Emerging Biotechnology report discuss this issue in detail.

[43] For example, fuel enzymes and yeast which can be used to maximize ethanol production must submit a Microbial Commercial Activity Notice (MCAN) to the EPA, but companies developing these enzymes may find themselves also needing to submit approval to the FDA's veterinary medicine division because the yeast can end up as biomass which serves as animal feeds. Similarly, as an interviewee explained, one product might be regulated by the FDA as a living therapeutic gut microbe and also by the EPA because it is an intergeneric microbe released to the environment.

[44] For example, USDA exempts from regulation GM plants which do not contain plant pest DNA sequences, are not modified using plant pests, and do not contain DNA sequences from unclassified organisms.

[45] For more details, see the USDA's National Bioengineered Food Disclosure Standard.

[46] Applicants seeking to import GM crops into the EU must include in their application to EFSA the results of a 90-day study feeding the whole crop to rats, to detect whether sub-chronic exposure causes any harm. It was adapted to food/feed assessment from the 'OECD Guideline for the Testing of Chemicals 408' (Hong et al., 2017[166]). This requirement is enshrined in *Implementing Regulation 503/2013* as mandatory, even if no hazards from the GM crop had been previously identified that would need to be tested. Therefore, it is not unanimously accepted by all stakeholders -- including by EFSA authors -- as some argue that without a clear safety concern it is difficult for such studies to provide meaningful results (Devos et al., 2016[165]). Furthermore, in the case of stacked products, applicants may not be able to leverage previous feeding studies carried out for crops with the individual mutations, calling for them to be run again (Garcia-Alonso et al., 2022[68]). Industry experts interviewed pointed to other jurisdictions where these tests may be requested on a case-by-case basis should there be any potential safety hazards identified, and which could be replaced by acute studies or shorter-term tests. In addition, interviewees also mentioned anecdotal examples of companies - especially in the alternative food space - whose mission is to be vegan and animal-friendly yet are forced to carry out animal testing studies as part of their regulatory submissions.

[47] This long-standing issue may be due to reluctance to open up adopted regulations as approval by all member states may not be achieved. Yet within current legal frameworks, this issue could also be solved via problem formulation and data waiving, as EFSA has an assessment for this but it is not routinely applied in regulatory assessments (Paoli et al., 2022[184]). The OECD pursues this approach for environmental releases of transgenic plants (OECD, 2023[183]).

[48] Another approach would involve using molecular methods, where two or more traits are simultaneously or sequentially introduced into a host plant. The key difference between the two approaches is that stacked trait products produced via conventional breeding do not contain new events that have not previously been assessed and approved by regulatory authorities (Goodwin et al., 2021[134]).

[49] Furthermore, while filings are publicly available, many agencies allow companies to withhold data under a 'confidential business information' claim (although the EPA in particular has become more stringent about these claims since the passage of the Lautenberg Act) (EPA, 2025[176]).

[50] For example, EFSA launched a 'Call for expressions of interest in EFSA's advice for Novel Food SMEs – 2025 edition'. It aimed to support SMEs working on novel foods who would like to receive guidance on the requirements to submit a novel food authorisation (EFSA, 2025[182]).

[51] For example, corporations have bigger budgets and thus are able to spend more on additional tests or state-of-the-art technologies, whilst non-profits with smaller budgets need to be more targeted in their expenses.

[52] Anecdotally, one interviewee shared these consultants are often regulatory staff from larger organisations that spin out and monetise the institutional knowledge they have gained over the years.

[53] For example, due to more negative consumer perceptions of GM vegetables and that unlike cash crops vegetables have fragmented markets with many varieties and shorter shelf lives, making biotech investment riskier and less scalable (Qaim, 2009[177]) (Madrigal, 2007[178]).