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BETTER POLICIES FOR BETTER LIVES

Policy Brief

Boosting biotechnology innovation through agile regulation and finance instruments

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Key messages

- **The United States attracts substantially more venture capital funding than the European Union across the different fields of biotechnology**. In Europe, investment in biosolutions (non-medical biotechnologies) also lags behind that of the Unites States, but the gap is smaller in these domains.
- **Regulatory hurdles to biotechnology innovations are particularly acute in the European Union.** Innovators cite regulatory complexity, lengthy approvals and fragmented oversight as major barriers to bringing innovations into the market.
- **Predictable and transparent regulations can strengthen investor confidence.** Evidence points to a correlation between how well governance systems are perceived to function and the level of financing that the two regions attract.
- **Agile regulation and collaboration across jurisdictions are needed**. Governments could ease bottlenecks by promoting early engagement between innovators and regulators, well before formal approval reviews, and by experimenting with tools such as regulatory sandboxes and innovation test beds.
- **Smarter financing can de-risk innovation and boost demand**. Driving biotechnology innovation will require a mix of financial instruments to de-risk investment and to stimulate demand. A coherent strategy could combine targeted de-risking tools, blended finance, and market-shaping policies – all anchored in predictable and transparent regulation.

What's the issue?

Biotechnology—the use and modification of living organisms and derived elements to produce knowledge and products—has become a cornerstone of modern innovation. Spanning health, agriculture, and manufacturing, biotech applications promise to be powerful tools to tackle global challenges from pandemics to food security to environmental crises. As a result, policymakers worldwide are seeking to strengthen the biotechnology capabilities of their economies and participation in the global bioeconomy.

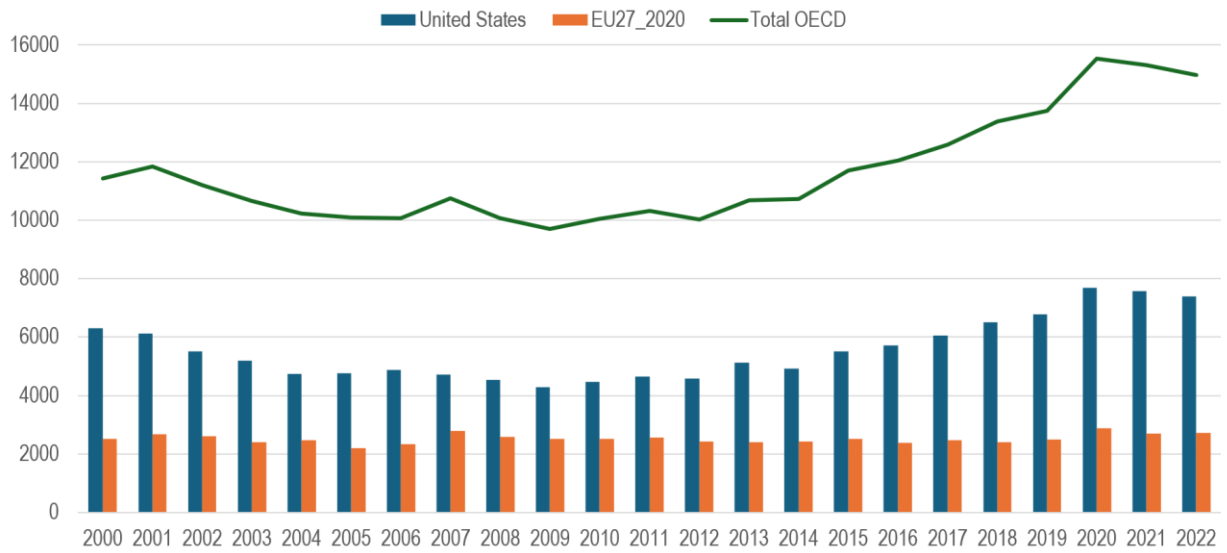
Within this landscape, biosolutions—biotechnology innovations beyond biomedical applications —are emerging as a major opportunity. According to the European Commission, biosolutions could save up to 2.5 billion tons of CO_2 equivalent per year by 2030 by substituting fossil-based products with other environmental and technical improvements. They can bring other benefits like creating new markets and jobs in rural and coastal regions where biological resources are produced.

This brief explores the biotechnology innovation landscapes in the European Union and the United States to identify shared challenges and lessons that can accelerate innovation on both sides of the Atlantic.

Why is this important?

Strong biotechnology ecosystems depend on several factors such as skilled people, R&D infrastructure and sustained investment. To identify where they stand, policymakers can assess their country's capacities across key innovation indicators: from human and physical resources (specialised workforce, research facilities) to the research environment (publications, patents), and the ability to translate ideas into commercial applications (start-up creation, trade balances). Patents can serve as a bridge between research output and commercialisation, offering a comparable indicator of innovation potential across regions (Figure 1).

Figure 1. Patent applications in the biotechnology sector by jurisdiction and OECD member countries



Source: Patents in the biotechnology sector - applications filed under the Patent Co-operation Treaty, OECD Main Science and Technology Indicators (MSTI database), March 2025 edition, https://data-explorer.oecd.org/s/33e.

Yet patents only tell part of the story. Biotechnology innovation requires consistent capital flows along the full innovation cycle, from R&D to commercialisation and from start-ups to SMEs to larger organisations. Because biotechnology is capital-intensive and perceived as high-risk due to long development timelines and costly testing, ensuring access to funding is often a decisive factor. Governments use a mix of approaches to support investment: direct funding and public-private partnerships (PPP), and market creation through incentives for specific bio-based product demand. Financial and market creation instruments in the European Union and the United States (Table 1) indicate a strong support to biosolutions ecosystems in these jurisdictions.

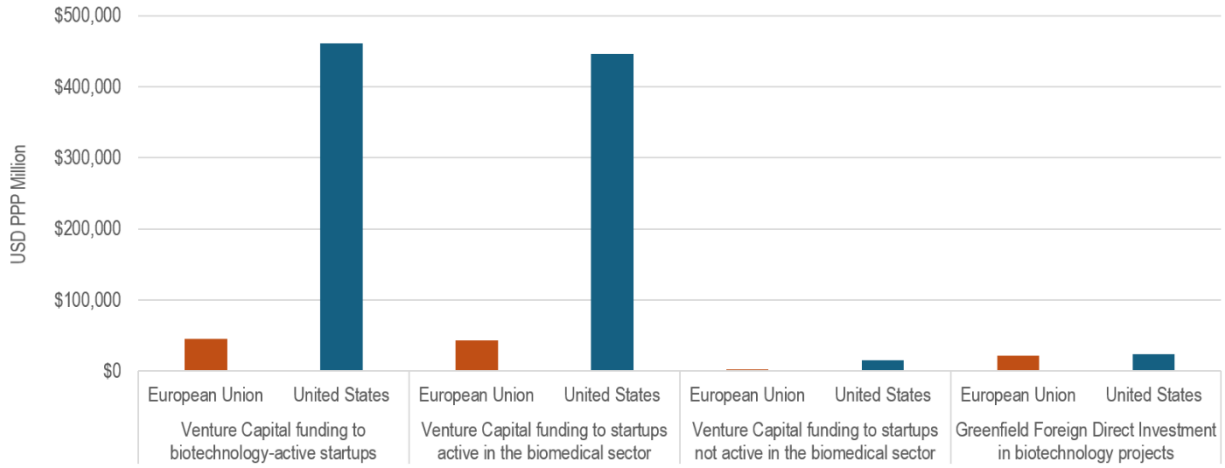
Table 1. Financing and market creation instruments for biosolutions in the European Union and the United States

European Union	United States
The European Circular Bioeconomy Fund (ECBF)	**BioMADE**
• €300 million public-private investment fund backed by the European Investment Bank and by private investors • A growth-stage venture capital fund focused on accelerating the commercialization of sustainable innovations in agri-food and industrial biotechnology sectors	• Public-private partnership launched in 2021 to catalyse U.S. biomanufacturing by de-risking investment in infrastructure and sponsoring workforce development • Has distributed around $200 million as of 2025 through cooperative agreement awards with clearly defined deliverables
The Circular Bio-based Europe Joint Undertaking (CBE JU)	**BioPreferred Program**
• €2 billion public-private partnership between the European Commission and the Bio-based Industries Consortium • Funds research, demonstration, and industrial deployment projects • By de-risking investments, helped fund novel biorefineries and supported the scale-up of biotechnology solutions	• U.S. Department of Agriculture: (i) mandatory purchasing requirements for federal agencies and their contractors; and (ii) a voluntary labelling initiative for biobased products • Aims to increase the purchase and use of biobased products, to stimulate economic development and create new jobs

Source: OECD

In addition to government investment and PPPs, private financing sources such as business R&D expenditures, bank loans and foreign direct investments (FDI) are critical. In research intensive fields such as biotechnology, where regulatory processes are often lengthy, private investment can complement public funding to push biotechnology innovations into the market. However, market-focused investments in biotechnology innovations remain uneven across regions, sectors and stages of development (Figure 2). OECD analysis shows that the United States attracts substantially more venture capital funding than the European Union for biotechnology start-ups. In Europe, investment in non-medical biotechnologies also lags that of the Unites States, but the gap is smaller in these domains.

Figure 2. Financing for biotechnology innovations for startups and greenfield facilities across the European Union and the United States, 2013-2022



Notes: 1) 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 U.S. and the E.U., 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. 2) Foreign direct investment data from Greenfield FDI in biotechnology, 2013-2022, Financial Times - FDI Market. Data include only greenfield FDI – new facilities and/or expansion of existing facilities.
Sources: Start-up venture capital funding data from "The OECD Start-ups Database: A New Lens on the Global Start-up Ecosystem", OECD Science, Technology and Industry Working Paper, Forthcoming. OECD based on FDI Market Financial Times and OECD (forthcoming) and OECD, forthcoming - Biotech WP - Title forthcoming.

Financial patterns can reflect broader governance conditions. Evidence suggests that regulatory burden, unpredictability, and long approval times can deter investors and impede innovations to enter the market (Fernández Ríos et al., 2025[1]) (Gargate, Laws and Rahman, 2025[2]; Gargate, Laws and Rahman, 2025[2]). Investment mechanisms, in turn, are most effective when paired with certain enabling conditions, including stable regulation, institutional coordination and well-planned infrastructure (IEA, 2025[3]) (OECD, 2024[4]). Regulatory approaches also differ in ways that shape market entry. The European Union pursues a process-based biotechnology regulatory approach grounded in the precautionary principle, while the United States follows a product-based approach that seeks to prove substantial equivalence of biotechnology products vis-à-vis conventional counterparts.

Table 2. Biotechnology regulatory barriers across the E.U. and U.S.

	European Union	United States
Regulatory 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.
Regulatory 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.
Communication	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.

Table 2 summarises some of the key regulatory barriers that arise from each approach and how they can impact the market entry of biotechnology innovations. In practice, innovators in the European Union report regulatory challenges around multiple layers of regulation (general biotech, and sector-based regulation), complexity in navigating country jurisdictions, lack of clarity for approval pathways for new technologies, and limited flexibility and communication with regulators. Innovators note some pitfalls of the approach in the United States where product characteristics can trigger the application of multiple regulatory regimes, e.g. those for environmental protection, food and drug safety, and chemicals.

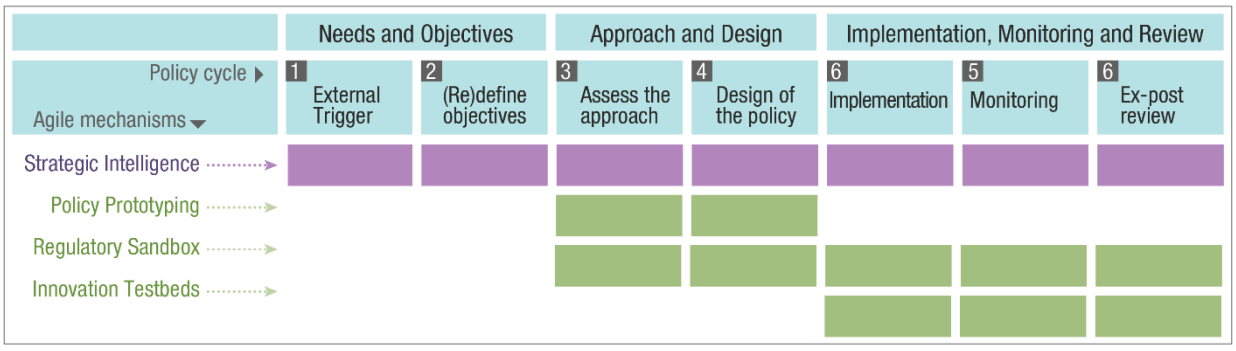
Understanding these differences can inform policymakers to design mechanisms to make biotechnology innovation ecosystems more agile, coordinated and investment friendly, ensuring that safe and beneficial innovations reach the market faster.

What can be done about it? Agile governance and financial mixes.

Boosting biotechnology and biosolutions innovation requires a policy mix that strengthens both the framework conditions and the resources for the ecosystem to grow. Policymakers can accelerate progress by making regulatory systems more adaptive and predictable, while deploying financial tools that reduce risk and attract private capital.

First, agile governance, as a whole-of-government approach, seeks to adapt tools, processes and frameworks to ensure that governance can appropriately respond to and enable innovation (OECD, 2025[5]). It can introduce adaptability and responsiveness into the policymaking and regulatory processes, with mechanisms that are complementary and reinforcing when applied at different stages of the policy cycle (Figure 3). At the same time, the success of agile regulation extends beyond individual tools and into the broader governance foundations that enable learning, coordination, and trust-building across the regulatory system. In practice, this requires strengthening regulators' institutional capacities and skills – including foresight, data analysis, and technological literacy – to manage iterative and evidence-driven regulatory cycles. It also calls for adaptive regulatory management tools that embed continuous review, *ex post* evaluation, and real-time monitoring into policy-making processes, as well as coordination mechanisms that bridge sectors and levels of government to prevent fragmentation. Including these systemic enablers alongside specific agile mechanisms provides a more complete picture of what it takes to build innovation-friendly regulatory environments for biosolutions.

Figure 3. Distribution of selected agile mechanisms across the policy cycle



Source: Diagram adapted from (OECD, 2025[5])

Deploy strategic intelligence tools

Strategic intelligence refers to analysis and knowledge of the possible directions and economic stakes of technology developments, societal support, possible ethical and societal aspects that may need to be considered and potential impacts, benefits and risks. Strategic intelligence provides anticipatory and adaptive knowledge that can help policymakers understand policy implications and further inform their policy decisions, in this case to ensure a more agile regulatory environment to support biotechnology innovation.

- ***Strategic foresight*** enables the identification of potential opportunities, risks, and interconnections that may influence the success and resilience of policies across different future scenarios. Strategic foresight has been used by Policy Horizons Canada – the government's foresight arm – to provide policymakers with a better understanding of the convergence of biotechnologies with artificial intelligence and automation tools, and their governance implications (Policy Horizons Canada, 2024[6]).
- ***Participatory technology assessments*** bring together experts and broader stakeholder groups to generate deeper understandings of technology development paths and their implications (e.g. societal, ethical, economic). These processes can enhance public trust in the technologies by engaging broader stakeholders in the deliberation process.
- ***Emerging risk assessments*** aim to anticipate potential risks from technologies and identify whether existing governance structures can sufficiently manage them, which can be especially difficult to determine for emerging technologies where there is not yet much data available (OECD, 2024[7]).

Although many biosolutions are well established and have a wealth of regulatory data, it may be less certain for newer applications like targeted genetic modifications. Such assessments could therefore be used to better understand which information is necessary for thorough regulatory review of biosolutions at different risk levels. Emerging risk assessments could clarify and streamline the data and testing required as part of a regulatory submission and help steer communication and knowledge sharing between innovators and regulators before regulatory submissions.

Engage innovators in prototyping, sandboxes and testbeds

- ***Policy prototyping*** is the preliminary testing of a policy solutions using stakeholder engagement exercises like workshops and scenarios at the design stage, before implementation. Prototyping allows policymakers to assess feasibility, test assumptions, identify potential gaps, and envision outcomes. In the case of biotechnology, policymakers could policy prototype new governance frameworks to tackle fragmentation and jurisdictional overlaps and test whether policy solutions are coherent and feasible with a broad range of experts in the regulatory submission process. This engagement could ensure new policies improve the status quo and would support innovative products undergoing a smoother assessment and approval process.
- ***Regulatory sandboxes*** create a controlled and cooperative environment where innovators and regulators work together to test policy at the design and implementation stages aiming to reduce long regulatory approval times and high associated costs. This often involves providing participating companies with temporary regulatory flexibility (e.g. waivers) so their products can be developed and tested with fewer constraints from regulatory requirements. Regulatory sandboxes provide a learning tool for regulators as they can benefit from better understanding the impact of those innovations and thus develop more effective policies (Box 1). This would allow innovators to validate their products in the market on a temporary basis in view of deployment and scale-up.

- ***Innovation testbeds*** aim to demonstrate products' market viability after policies have been enacted by providing a space where innovators can work on technical details and develop, test, and scale their technologies. They could take the form of networks of advanced facilities, technologies, and experts – such as those coalesced in a biofoundry – and support biosolution start-ups with limited regulatory knowledge navigate the complex biotechnology and sector-specific policies. An existing example is the EU Horizon 2020 program 'Phoenix-OITB", which aimed to tackle the upscaling challenge that nano-pharmaceutical start-ups and SMEs face due to the lack of large scale, good manufacturing practices-compliant processes.

Box 1. United Kingdom Engineering Biology Sandbox Fund

The U.K.'s 'Engineering Biology Sandbox Fund' aims to foster business innovation and investment and inform pro-innovation regulation. It allocates up to £5 million for 3 to 5 regulator-led engineering biology sandbox projects, each running through 6—24 months. It is designed to promote active collaboration between stakeholders - industry, regulators and others such as civil society groups and academia - to shape regulatory actions, such as labelling, that balance the need for innovation with the necessity of managing risks.

The first round was awarded in 2024 to the Food Standards Agency Cell-Cultivated Product (CCP) Regulatory Sandbox, providing £1.6 million in funding to help government make informed decisions on product safety by staying up to date on emerging technologies. The project also aimed to reduce the time and costs involved in securing regulatory approval (e.g. by providing companies with pre-submission consultations to answer questions on data requirements and labelling) and support CCP companies in attracting the investment needed to scale up production.

Source: (UK DSIT, 2024[8]) and (UK DSIT, 2025[9])

Introduce de-risking instruments

The impact of agile regulation can be enhanced through innovative financing mechanisms for the bio-based industries, particularly those that target the difficult phases of demonstration and scale up. In industrial biotechnology – which uses biotechnology to synthesize a large range of products e.g. fuels, plastics, and chemicals -- this phase often requires the development of manufacturing facilities, biorefineries, or other capital-intensive infrastructure whose development carries major risks for investors. Growing the bioeconomy, therefore, may require instruments that that de-risk innovation, build enabling infrastructure and create robust markets.

- **Risk Transfer Mechanisms** such as guarantees, insurance, and risk-sharing facilities are promises by a public institution to cover certain losses on an investment. A *partial risk guarantee* will cover private investors against specified political or regulatory risks in a project (such as government non-performance) (OECD, 2025[10]). By improving the odds of recovery, guarantees reduce downside risk, encouraging institutional investors to finance projects that would otherwise be deemed too risky**.**
- **Blended finance structures** -- implemented by public or philanthropic actors -- often provide first-loss capital or insurance, offering a potential creative financing solution if the right partners can be assembled. These tools have broad applicability – from renewable energy to new bio-based industries – wherever risk perception is a barrier to investment. However, they should be targeted to specific risks (e.g. technology performance risk, regulatory risk) and priced appropriately so as not to distort markets.

- **Public co-investment and guarantees in R&D intensive fields** like biomanufacturing of vaccines, biofuels, or climate-smart agriculture, allow governments to directly co-invest alongside industry to share costs and reassure private investors. Such joint public-private investments not only bring more capital but can also align regulatory support and reduce information asymmetry. When coupled with the guarantees and insurance described above, co-investments can significantly de-risk innovation. Leveraging insurance and guarantee instruments alongside public funding is key to mobilising capital for R&D-intensive ventures (OECD, 2020[11]).

Demand-side measures

- **Public procurement** refers to the purchase by governments and state-owned enterprises of goods, services and works. Public procurement can help create a demand in the market that helps boost prices and stimulate investment. In the arena of biosolutions, the United States Department of Agriculture has instituted a mandatory purchasing programme for bio-based products (so-called BioMade) and a voluntary labelling programme to help give it effect (Figure 2).

Green and results-oriented finance

- **Green bonds** are standard debt instruments issued to finance green or climate-related projects. They attract institutional investments by offering a familiar investment format with the added assurance that proceeds finance sustainable activities. Private sector issuers and governments have issued green bonds to fund projects like renewable energy, sustainable forestry, or clean transportation (OECD, 2025[10]). They often experience high demand from pension funds and asset managers with green investment mandates.
- **Results- or outcome-oriented investments** such as impact bonds can mobilise private capital by guaranteeing payment for outcomes. These instruments can effectively turn development impacts into an asset with financial value (OECD, 2020[11]). Policymakers designing such mechanisms must set clear, measurable indicators and ensure verification systems to make these instruments credible to investors and service providers.

What can policymakers do?

- **Implement public policies to adopt more agile approaches to regulation**, particularly in encouraging earlier communications between innovators and regulators prior to formal approval application review through direct communication or regulatory experimentations like regulatory sandboxes and test beds.
- **Build capacity in strategic intelligence.** Leverage tools like horizon scanning, foresight and technology assessment to better identify strategic investments and to better anticipate regulatory needs in the area of biosolutions and broader biotechnologies. Attention should focus on building robust, inclusive and multidisciplinary approaches.
- **Engage stakeholders and the public in communicative and deliberative processes** to build accountability and trustworthiness into biotechnology regulation and policymaking.
- **Draw on a deeper arsenal of financing instruments** to help unlock new private finance flows and scale-up sustainable biomanufacturing value chains that deliver on climate, biodiversity, and development goals.

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