Creating Clear Regulatory Pathways for Biotechnology

Novel biotechnology products, which span defense, industrial, biomedical, agricultural, and other sectors, are emerging faster than regulations can keep pace. Innovators need efficient, risk-proportionate regulatory pathways to quickly bring safe products to market. This is the first in a series of discussion papers on the future of regulation. Subsequent papers include detailed policy options for medical products, plants, microbes, and animals.

In its April 2025 report, the National Security Commission on Emerging Biotechnology (NSCEB) recommended creating simple pathways to market (Rec. 2.1a) and preparing regulatory agencies for novel products (Rec. 2.1b). After the release of the report, the NSCEB conducted extensive outreach across industry, academia, and government, including a survey and a series of listening sessions. Stakeholders provided a wide range of thoughtful ideas and perspectives, which the NSCEB carefully weighed for their potential impact and feasibility. Through this additional engagement, the NSCEB identified specific Congressional actions needed to improve biotechnology product regulation and achieve the outcomes that were laid out in the report. The NSCEB looks forward to working with Congress, federal agencies, and other stakeholders to implement these policy options, including through legislation, oversight activities, and other efforts.

The NSCEB recommends passing the National Biotechnology Initiative Act of 2025 (S.1387 and H.R.2756), which would create a National Biotechnology Coordination Office (NBCO) to streamline and coordinate biotechnology product regulation. This office would map clear regulatory pathways, build shared digital tools for collaboration, and improve communication with developers. Alongside the NBCO, targeted efforts are needed to clarify agency roles, reduce duplication, and enable efficient, risk-based oversight. Appropriate resources would ensure agencies have the expertise they need to keep up with scientific advancements. Such reforms would make regulation more straightforward, focused on risks, and responsive to emerging biotechnology products, while maintaining safety.

Modernizing Regulation so the United States Can Compete and Win

Biotechnology developers in the United States face slow and complex regulatory processes that push research and development (R&D) overseas as China and other competitors charge ahead with faster, more predictable systems.[1] Regulatory delays raise costs, create uncertainty, and deter investment, especially for first-of-a-kind products such as microbes engineered for biomining critical minerals. The root cause of these challenges is a regulatory system built on laws that predate biotechnology, and that were not written with the rapid advancement of emerging biotechnology products in mind.

Three primary agencies are responsible for biotechnology product regulation: the Animal and Plant Health Inspection Service (APHIS) within the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA) within

the Department of Health and Human Services (HHS), and the Environmental Protection Agency (EPA). A federal policy called the Coordinated Framework for Regulation of Biotechnology directs these and other agencies to regulate products based on their intended use, not the method used to create them.[2] As a result, biotechnology products often fall under the jurisdiction of multiple agencies and statutes. Biotechnology developers and other stakeholders overwhelmingly support the Coordinated Framework and its product-based approach, but they report that the current system creates uncertainty, raises costs, and delays commercialization.

Forty years after its creation, the Coordinated Framework has not kept pace with scientific advances, leaving a system marked by regulatory gaps. Oversight is fragmented, duplicative, and spread across multiple agencies. Deviating from the Coordinated Framework's original premise of regulating based on intended use, reviews are often triggered by how a product is made, rather than actual risk, causing lengthy review for familiar products and uncertainty for new ones. Inefficient regulation hinders the deployment of biotechnology products that can help the United States defend, build, nourish, and heal. Without reform, the United States risks falling behind as other countries adopt more streamlined oversight that can adapt more quickly to scientific advances.

The United States now has advanced scientific and regulatory tools that did not exist when the Coordinated Framework was created, but Congress needs to unlock them. Regulatory agencies have made significant progress in streamlining regulation with the tools available to them. However, additional progress requires clear Congressional direction. Congress must act to reduce unnecessary regulatory burden, empower and resource regulators to work efficiently, and uphold safety and transparency for consumers. If implemented, the policy options below would reduce review times, increase U.S. competitiveness, and ensure that Americans can benefit from new technologies and products.

Case Study

How Regulation Can Save an Industry... or Slow It to a Crawl

Efficient, risk-proportionate regulation is possible. The USDA, EPA, and FDA conducted a thorough but expedited review of engineered, virus-resistant Rainbow papaya in just two years. Available for commercial planting in 1998, Rainbow papaya saved Hawaiian farms from the devastating ringspot virus, and it is still grown in Hawaii today.[3]

By contrast, U.S. approval of engineered mosquitoes that produce only non-biting male offspring has been delayed for over ten years because jurisdiction shifted from the USDA to FDA, then to the EPA.[4] In Brazil, regulators initiated a rigorous review in 2011 and approved commercial sale in 2020, leading to a 90% reduction of dengue-spreading mosquitoes.[5]

Virus-resistant papaya: 6 years from field trials to full U.S. approval and commercialization.

1991
Application for USDA field trials

1992–1995
USDA-regulated field trials

1996–1997
USDA, EPA, & FDA review & approve product

Sterile mosquito: 15 years without U.S. approval (compared to 9 years to approval in Brazil.)

2010
Application for USDA field trials

2011
Hand-off from USDA to FDA

2011–2016
FDA conducts Environmental Assessment

2018–2020
Application for EPA field trials

2021–2024
EPA-regulated field trials

Winning the Race with Smarter Regulation

Regulatory challenges impact U.S. national security by delaying biotechnology products used to defend, build, nourish, and heal. With extensive stakeholder input, the NSCEB developed targeted statutory amendments and regulatory reforms that are consistent with the themes below.

Regulatory Roadblocks	Clear Pathways
Ambiguous jurisdiction Developers can spend months or years just to learn what regulatory process to follow. Smaller companies are hit hardest because they lack resources to navigate complex regulations.	**Clear roles** Agencies clearly define responsibilities in interagency agreements so both developers and regulators know which agencies are involved and what processes to follow.
Process-based triggers Regulation is often based on how a product is made rather than its intended use. Familiar products face the same scrutiny as novel ones, wasting time and resources without improving safety.	**Risk-tiered processes** Agencies sort products into tiers: exempt or fast-track review for familiar products, streamline review for moderate-risk products, and reserve the highest scrutiny for novel products.
Redundant reviews A single product may face multiple, overlapping reviews. Agencies often ask for the same data but rarely share it with each other.	**Single point of entry** A short intake form confirms the lead agency and next steps. One application with product-specific annexes enables data sharing and reduces duplication.
Unpredictable and lengthy timelines Uncertainty deters investment and discourages companies from entering the market. Agencies are persistently understaffed even as backlogs grow.	**Streamlined review** Agencies coordinate effectively. Along with clear pathways, adequate staffing and focused expertise reduce backlogs and make timelines predictable.
No pathways for emerging products Truly innovative products fall into regulatory gaps with no clear process for review. Delays slow the commercialization of beneficial products.	**Continuous improvement** Horizon scanning identifies new products before they enter the regulatory system. Regulatory pilots are used to test new and improved regulatory pathways.
International competition Other countries are modernizing their regulations and putting U.S. global leadership at risk. Developers are seeking approval and building facilities in other countries rather than investing in the United States.	**Regulatory diplomacy** Working with allies and partners on shared solutions, such as international standards, data sharing, and complementary regulatory frameworks, helps to open markets for American-made products.

Overview

Policy Options for Modernizing Biotechnology Regulation

Building on the NSCEB's prior recommendations and extensive stakeholder input, this paper describes 30 policy options in six key areas for modernizing oversight of biotechnology products: clear regulatory pathways, preparing for future products, digital infrastructure and data, guidance and bioliteracy, regulatory agency resources, and international coordination. The ideas presented here apply across all product types. The NSCEB also developed detailed policy options for medical products, microbes, plants, and animals, which are presented in separate discussion papers.

Clear Regulatory Pathways

1. Establish federal coordination for biotechnology.
2. Require interagency agreements for clear regulatory pathways.
3. Expand exemptions for familiar products and increase use of tiered, risk-based review.
4. Leverage information from prior reviews to speed review of similar products.
5. Adopt platform-based regulatory frameworks.
6. Incorporate risk-benefit analysis into regulatory decisions.
7. Work with states to harmonize requirements.

Prepare for Future Products

8. Pilot new regulatory approaches for emerging products.
9. Use conditional approvals to manage uncertainty.
10. Establish horizon scanning for emerging technologies and products.
11. Remove barriers for regulated biotechnology research.
12. Reduce duplicative requirements for biotechnology research
13. Recognize voluntary consensus standards.
14. Conduct continuous regulatory improvement.

Digital Infrastructure and Data

15. Establish a single point of entry for biotechnology regulation for non-medical products.
16. Create a centralized public repository of regulatory decisions.
17. Require interagency sharing of regulatory submissions and reviews.
18. Invest in triage assisted by artificial intelligence (AI).
19. Tailor data requirements to risk.

Guidance and Bioliteracy

20. Require clear, consistent regulatory guidance.
21. Promote regulatory transparency.
22. Support early consultation between developers and regulators.
23. Train early career scientists in biotechnology product regulation.

Regulatory Agency Resources

24. Strengthen regulatory capacity.
25. Invest in training for regulators.
26. Establish a foundation to enable biotechnology commercialization.
27. Enable regulatory science to support efficient oversight.

International Coordination

28. Improve international regulatory coordination.
29. Form international data-sharing agreements.
30. Pilot reciprocal agreements with trusted countries.

Clear Regulatory Pathways

Clear, predictable regulation is essential for advancing emerging biotechnology. Stakeholders repeatedly noted that overlapping roles, inconsistent definitions, and outdated processes create confusion and waste resources.

1. **Establish federal coordination for biotechnology.** As the NSCEB described in its April 2025 report, the absence of coordination has resulted in scattered efforts across the federal government. This fragmentation is particularly evident for biotechnology product regulation, in which overlapping responsibilities and unclear processes delay innovation. To address this challenge, Congress should pass the bipartisan National Biotechnology Initiative Act of 2025 (H.R.2756 and S.1387) to establish a National Biotechnology Coordination Office (NBCO) within the Executive Office of the President. The NBCO would regularly convene federal regulators to identify and resolve processes that delay commercialization of biotechnology products. The NBCO would close key gaps in the U.S. Coordinated Framework for Regulation of Biotechnology by working with agencies to deduplicate regulatory processes and identify causes for regulatory delays.

2. **Require interagency agreements for clear regulatory pathways.** Biotechnology developers shared that they often face duplicative reviews and unpredictable timelines. Agencies have published some interagency agreements that help delineate regulatory pathways, though developers indicated that additional agreements would provide clarity across product types. Congress should instruct regulatory agencies to publish and regularly update interagency agreements that map clear regulatory pathways for each product type. These agreements would clarify existing processes or describe new processes, including to designate a lead agency, delineate agency roles, enable data sharing, and define timelines. Agreements should also set escalation procedures, including how agencies will resolve differences in interpretation and how developers can challenge unreasonable delays or overly burdensome requests for additional data. Congress should also instruct agencies to defer to the designated lead agency, while contributing relevant technical expertise where appropriate. For example, the EPA could defer to APHIS on non-target organism assessment, rather than conducting its own assessment. Clear regulatory maps would minimize regulatory burden and help deliver timely, coordinated decisions.

3. **Expand exemptions for familiar products and increase use of tiered, risk-based review.** Current regulations apply to many products that pose no new risks compared to conventional products. This results in disproportionate burden for biotechnology products, particularly for gene edited products with precise genetic changes that could otherwise have been produced without biotechnology. In recent years, agencies have taken steps to exempt or reduce scrutiny of such products.[6] However, stakeholders note that exemptions are inconsistent across agencies and limited in scope. Congress should direct agencies to reduce or remove regulatory hurdles for familiar products based on accumulated evidence and to use tiered, risk-based review frameworks that reserve intensive oversight for novel products. In addition, Congress should instruct agencies to conduct comparative risk assessments, and to consider potential risks of biotechnology products in the context of other human activities and comparable products that were not produced with biotechnology.

4. **Leverage information from prior reviews to speed review of similar products.** Biotechnology developers noted that regulators often require a full review even when a biotechnology product is nearly identical to other biotechnology products that regulators already deemed safe. Congress should require agencies to extend prior decisions to substantially similar products and to leverage post-market monitoring and other data from similar products to inform new risk assessments, where allowed by law. For example, the FDA could internally use data from a food safety review of a protein expressed in one plant species to inform assessment of the same protein in another plant species. Transparency on how prior reviews inform subsequent risk assessments would help developers better understand regulatory processes. For example, the EPA published documentation on how regulators leverage prior experience for ecological risk assessment of certain biotech plants.[7] This approach would reduce redundancy, speed market access, and free up resources for genuinely novel products.

5. **Adopt platform-based regulatory frameworks.** Current regulations often require agencies to review each biotechnology product as if it were entirely new, even when developers use the

same, well-characterized organism or process to develop those products. Congress should direct agencies to develop frameworks for regulating biotechnology products as platforms. Agencies should review unmodified organisms, such as a chassis microorganism, and other common components separately from engineered traits. Platform-based frameworks would better reflect development practices and enable faster review for subsequent modifications to the base organism or product.

6. **Incorporate risk-benefit analysis into regulatory decisions.**
Many regulatory frameworks focus narrowly on risks, even when risks are manageable. Formal risk-benefit frameworks would enable more balanced decisions. Congress should encourage agencies to consider benefits of biotechnology products and to approve products when the benefits outweigh the risks , where appropriate. Such consideration should minimize requests for additional data. For example, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) instructs the EPA to consider "the economic, social, and environmental costs and benefits" of pesticides, and the EPA meets this requirement without requiring efficacy data in most cases.[8] Agencies should also consider potential benefits of replacing existing products with a product derived from biotechnology. Flexibility to consider well-supported benefits could support more balanced and transparent decision-making.

7. **Work with states to harmonize requirements.**
In addition to federal regulation, developers shared that the patchwork of state requirements can add costs and delay commercialization of certain biotechnology products, such as food and feed ingredients, soil amendments, and pesticides. Stakeholders pointed to a successful agreement between the FDA and the Association of American Feed Control Officials (AAFCO) regarding shared terminology across industry, states, and the FDA, but this agreement expired in 2024.[9] For many products, lack of harmonization creates a resource-intensive regulatory environment that slows innovation and discourages manufacturers from bringing new products to market in the United States. Congress should direct federal agencies to collaborate with state counterparts to align key definitions, expectations, and labeling. Coordination would reduce duplicative requirements while preserving state authority.

Prepare for Future Products

In addition to improving regulatory pathways for today's biotechnology products, federal regulators must also ensure that oversight systems are equipped to handle what comes next. Forward-looking processes are essential to accommodate emerging technologies, novel product types, and uses that may not fit neatly within existing frameworks.

8. **Pilot new regulatory approaches for emerging products.**
Existing regulatory pathways were designed for older technologies and often cannot easily accommodate novel traits, production methods, products, or uses. Congress should instruct agencies to create "regulatory sandboxes" and short-term pilots to develop new regulatory pathways for emerging products, then expedite updated regulations or guidance based on the results. Pilots are time-limited, controlled trials of a new regulatory approach that allows agencies to test requirements, data expectations, and review processes before broader implementation. Using pilots to build flexible, risk-based frameworks would reduce uncertainty and accelerate innovation while maintaining safety.

9. **Use conditional approvals to manage uncertainty.**
Regulators sometimes need more information before allowing full commercialization of a biotechnology product. For example, developers may provide adequate data for a particular use or release in a particular location, but agencies may need more data about other uses or locations. Congress should instruct agencies to use conditional approvals with tools such as monitoring, usage restrictions, and staged or time-limited approvals to manage uncertainty through continued oversight. This would allow limited commercialization to proceed while developers gather additional data.

10. **Establish horizon scanning for emerging technologies and products.**
Researchers noted that regulators are often unprepared for emerging biotechnology products that do not fit existing regulatory pathways. Congress should direct regulatory and research agencies to conduct joint horizon scanning to identify emerging risks and opportunities, with participation from industry, academia, and international partners. This could include foresight exercises and preliminary risk assessments to help identify regulatory gaps and build familiarity with emerging products.

11. **Remove barriers for biotechnology research.** Federal research grants often prohibit use of funding for regulated activities, such as field trials, even when those activities are authorized by the appropriate regulatory agency and essential to the research objectives. These blanket restrictions slow innovation and disproportionately burden academic researchers. Congress should direct research funding agencies to remove categorical prohibitions on regulated activities and to coordinate with regulatory agencies to ensure compliance with applicable regulations. Aligning granting policies with regulatory oversight would accelerate research translation, improve interagency coordination, and ensure that federally funded research delivers timely, real-world benefits.

12. **Reduce duplicative requirements for biotechnology research.** In addition to biotechnology product regulation, the National Institutes of Health (NIH) provides oversight for organisms produced with recombinant DNA technology through the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (Guidelines).[10] The NIH is currently undergoing a modernization process for the Guidelines.[11] Congress should encourage the NIH and regulatory agencies to work together on appropriate standards for containment and encourage the NIH to exclude products from the Guidelines if they are under another agency's regulatory oversight. This would reduce duplicative oversight for products that are already regulated by another agency and allow the NIH to provide risk-proportionate oversight for biotechnology research.

13. **Recognize voluntary consensus standards.** Developers stressed that agencies often develop standards much more slowly than industry and other organizations, leading to costly delays. Organizations such as the American Society for Testing and Materials (ASTM) and the International Organization for Standardization (ISO) develop voluntary standards through expert-driven, transparent processes that are often more responsive to technological advances than agency rulemaking. Congress should instruct agencies to recognize voluntary consensus standards, when feasible, and to participate in domestic and international standard-setting bodies. For example, conforming to voluntary safety standards such as the Safe Strain Lineage could reduce downstream regulatory burden for engineered microbes.[12] For plants, the Global Stewardship Group facilitates development of a quality management system (QMS) and best management practices.[13] Adopting such standards could help satisfy regulatory requirements for containment of plants in field trials. Recognition of voluntary standards is consistent with longstanding federal policy and would harmonize approaches, align regulation with industry practices, and foster innovation while maintaining safety.[14]

14. **Conduct continuous regulatory improvement.** Biotechnology product regulation lags behind the science, and outdated requirements remain long after they lose value. Congress should require periodic assessment of regulations and guidance to ensure that oversight is current and risk proportionate. For example, agencies should update exemptions for familiar products and leverage information from prior reviews, as mentioned above. Agencies should report annually to Congress on regulatory targets, timelines, and performance, using outcome-based metrics to assess trends over time and to evaluate efforts to optimize regulatory processes. Regular review would align regulation with emerging technologies, reduce unnecessary burdens, and strengthen confidence in biotechnology product regulation.

Digital Infrastructure and Data

Fragmented portals, duplicative submissions, and paper-bound processes increase burden, slow reviews, and frustrate biotechnology product developers and regulators alike. Computational power constraints, including limited access to high-performance computing resources, prevent regulators from effectively analyzing complex data. By modernizing infrastructure and data practices, Congress can streamline oversight, increase efficiency, and improve transparency for American innovators.

15. **Establish a single point of entry for biotechnology regulation for non-medical products.** Developers expressed frustration that they must navigate multiple systems to submit applications, track progress, and receive feedback. Congress should direct agencies to develop a central portal for applications, data, reviews, and decisions for biotechnology products, excluding human medical products that are regulated solely by the FDA. The portal should enable coordinated responses and tracking of regulatory submissions. Developers should be able to submit data on a rolling basis, with appropriate data protections.

16. **Create a public repository of regulatory decisions.** Prior regulatory decisions and reviews are often inaccessible or scattered across multiple government websites. Congress should direct agencies to develop a central repository that aggregates regulatory reviews and decisions for biotechnology products, with appropriate data protections. Using this repository, developers could learn from prior approvals to design better applications, agencies could apply precedents more consistently, and policymakers would gain insight into how statutes are being implemented.

17. **Require interagency sharing of regulatory submissions and reviews.** Developers shared that regulators often require submission of the same information to multiple agencies in slightly different formats, wasting resources and complicating reviews. Agencies have entered into some information sharing agreements, such as a now-expired 2011 agreement on sharing non-public information related to plants produced with biotechnology.[15] However, developers report ongoing uncertainty about the scope of permissible information sharing. Congress should require agencies to enter into agreements that allow interagency sharing of submissions and reviews, with appropriate data protections. Congress should also require agencies to move toward interoperable data management systems and standardized application formats, while defining elements unique to each agency, program, or product. These actions would lower burden for developers, improve efficiency, and provide more consistent review.

18. **Invest in triage assisted by artificial intelligence (AI).** Backlogs regularly delay approvals, with familiar products waiting in the same queue as novel products. Congress should support agencies in developing AI-assisted triage systems that prioritize submissions by risk, complexity, similarity to previously-approved products, and data completeness. AI systems should meet established criteria for trustworthiness.[16] By accelerating the review of familiar products and directing attention to more complex cases, AI tools could help make regulators more efficient and provide more predictable review timelines.

19. **Tailor data requirements to risk.** Regulator requests for additional data, beyond what is necessary to determine safety, can increase burden and slow reviews. Congress should require agencies to regularly review data requirements and eliminate requirements that are no longer needed. Congress should also instruct agencies to limit requests to data directly tied to identified risks and to use adaptive risk assessment approaches informed by decades of safety data. Agencies should justify additional data requests, ensuring that reviews focus only on information critical to safety, and reduce burden by allowing the submission of aggregate data. Each agency should request only the data needed to evaluate plausible risk pathways that fall within its regulatory authority. Congress should also instruct agencies to allow the submission of innovative data sources, such as shared reference data, new approach methodologies (NAMs), non-animal models, digital twins, and in silico simulations. Tailored, risk-based data requirements would reduce costs to developers and shorten review times without compromising safety.

Guidance and Bioliteracy

Regulatory processes are often more complex than they appear, in large part because agencies do not consistently provide clear guidance and often use terms and definitions that are not well-understood. Developers and investors need clear guidance so they understand how regulatory processes work, how long regulation will take, and what data is needed. Bioliteracy, meaning the ability to understand and engage with biology and biotechnology, directly affects how effectively developers, investors, and consumers can interact with and understand the regulatory system. By requiring agencies to improve communication and enabling early consultation with developers, Congress can strengthen regulatory bioliteracy and make biotechnology regulation more transparent, credible, and effective.

20. **Require clear, consistent regulatory guidance.** Developers and investors are often uncertain about regulatory processes, data requirements, timelines, and points of contact, especially when multiple agencies are involved. Congress should require agencies to issue and regularly update guidance to explain details such as risk tiers, data requirements, fee structures, decision trees, and interim checkpoints in language that is clear to a broad variety of stakeholders, including investors in the biotechnology sector and developers who are entering the regulatory system for the first time. When oversight overlaps, agencies should jointly develop guidance, align exemptions, and move toward standardized analytical approaches. Agencies should also jointly develop and update terms and definitions that are consistent with

those used by researchers and developers. These actions would strengthen interagency coordination and improve predictability for developers.

21. **Promote regulatory transparency.**
Regulators often use unclear terms that can be confusing for developers, consumers, and trading partners. For example, APHIS uses the term "nonregulated" to indicate when a review is complete,[17] but some people interpret this to mean a product was never regulated. Congress should require agencies to use plain-language terms that clearly signal when review is complete and what that means for market entry. Additionally, Congress should require that agencies publish plain-language summaries of regulatory reviews and conduct biotechnology education and outreach initiatives for developers, investors, and consumers. For example, some stakeholders suggested that regulators could increase transparency by documenting regulatory decisions and methodologies in peer-reviewed journals, following the model used by the European Food Safety Authority (EFSA).[18] Clear communication would reduce misinformation and strengthen public trust in regulation.

22. **Support early consultation between developers and regulators.**
Developers often wait to approach agencies until their formal submission is ready, resulting in extended review times and requests for additional data. First-time applicants particularly struggle with complex, multi-agency processes. Congress should encourage each agency to open voluntary pre-submission consultation programs, similar to FDA's Pre-Investigational New Drug meetings and Veterinary Innovation Program.[19] With appropriate staffing, agencies could designate "regulatory navigators" or case managers to guide developers of novel products through multi-agency processes. Early engagement would improve submission quality and completeness and reduce review timelines.

23. **Train early career scientists in biotechnology product regulation.**
Early-career researchers face a steep regulatory learning curve when they identify a product for commercialization. In 2017, the National Academies of Sciences, Engineering, and Medicine called on federal agencies to support efforts that build regulatory awareness among students whose research may lead to biotechnology products.[20] Stakeholders emphasized that regulatory training would help researchers design products with regulation in mind, reducing costly redesign and delays. Such training could spur innovation in regulatory science. Congress should encourage federal research agencies to explore mechanisms to support regulatory training and raise regulatory awareness for graduate students in biotechnology and related fields. Improved regulatory literacy would accelerate responsible innovation, reduce development bottlenecks, and strengthen the talent base of scientists prepared to commercialize products in the United States.

Regulatory Agency Resources

Effective biotechnology regulation requires the right people and expertise. Limited resources create bottlenecks and slow reviews. By strengthening workforce capacity, training, partnerships, and regulatory science, Congress can give agencies the tools they need to keep pace with biotechnology innovation.

24. **Strengthen regulatory capacity.**
Agencies cannot conduct timely, science-based reviews without adequate staffing. Congress should empower agencies to hire and retain domain-specific experts, with surge capacity for specific needs, such as major reviews, regulatory updates, or policy development. Agencies should convene, hire, or contract outside experts to supplement internal expertise and support short-term projects, with safeguards against conflicts of interest. Congress should also instruct agencies to formalize reimbursable and non-reimbursable detail agreements. For example, research agencies could detail scientific or policy experts to regulatory agencies.

25. **Invest in training for regulators.**
Regulators want and need to maintain their expertise to keep pace with emerging biotechnology. Congress should require that agencies provide regular technical upskilling for regulators on topics such as scientific advancements; risk assessment, risk management, and risk communication; and new regulatory systems and processes. Agencies should support professional development through scientific conferences and partnerships with academic institutions, industry, and other organizations. A regulatory fellowship program would allow regulators and other federal employees to rotate across agencies and build cross-functional understanding. With appropriate protections in place, agencies should allow sponsored travel to increase access to professional development opportunities,

including site visits, building on the FDA's Experiential Learning Program.[21]

26. **Establish a foundation to enable biotechnology commercialization.**
Independent, government-affiliated foundations provide a flexible, efficient way to supplement federal activities. For example, Congress established the Reagan-Udall Foundation in 2007 to facilitate stakeholder engagement and advance regulatory science for FDA-regulated medical products.[22] Congress should pass the bipartisan Foundation for Enabling Biotechnology Innovation Act of 2025 (S.2696) to establish a foundation focused on biotechnology commercialization. This foundation would promote public-private partnerships, expand market access and international cooperation, and support federal agencies in bringing safe biotechnology products to market.

27. **Enable regulatory science to support efficient oversight.**
Regulators often lack the data needed to evaluate emerging technologies, such as multi-season, multi-location studies that assess potential environmental impacts. Congress should pass the bipartisan National Biotechnology Safety Act of 2025 (S.2697) to generate the necessary scientific data to justify simplified regulatory pathways. This research could support baseline assessments, new analytical methods and detection tools, and predictive risk models. Public-private partnerships would further expand capacity for early safety and performance data, ensuring regulators are prepared to evaluate novel products.

International Coordination

Resolving regulatory challenges in the United States is essential, but domestic action alone is not sufficient to enable commercialization of American biotechnology products. Global coordination is critical for U.S. biotechnology to compete abroad. Misaligned processes, duplicative reviews, and slow approvals by trading partners create costly delays. By strengthening collaboration and pursuing reciprocal agreements, Congress could reduce trade barriers and maintain U.S. leadership.

28. **Improve international regulatory coordination.**
Delayed approval of biotechnology products by trading partners can block or delay commercialization in the United States. Congress should require that regulatory agencies share information with trade and diplomatic agencies about domestic regulatory processes and approvals, with appropriate data protections. Congress should also conduct oversight to ensure adequate U.S. participation in international organizations such as Asia-Pacific Economic Cooperation (APEC) and the Organisation for Economic Co-operation and Development (OECD), as well as standard-setting organizations, such as the International Organization for Standardization (ISO) and the Codex Alimentarius Commission. Better international coordination would help open markets for U.S. products, reduce trade disruptions, and maintain U.S. leadership in shaping global regulatory norms.

29. **Form international data-sharing agreements.**
International regulators often independently review large data packages and require developers to repeat costly trials, even when comparable, high-quality data already exist. This duplication delays approvals without improving safety. Congress should instruct agencies to negotiate reciprocal data-sharing agreements with foreign regulators, with appropriate data protections, and to enter into reciprocal agreements to accept relevant data collected in a partner country, when appropriate. These agreements would enable partner regulators to rely on high-quality data generated in the United States, and would reduce costs, accelerate reviews, and improve consistency across global supply chains.

30. **Pilot reciprocal agreements with trusted countries.**
Regulators often repeat assessments even when peer agencies abroad have already assessed the same product. For example, reviewers across 18 countries and the European Union issued 162 separate approvals for a single bacterial protein that can protect crops from insects.[23] Congress should direct agencies to pilot reciprocal agreements with foreign regulators that have comparable regulatory standards. Options include "Trusted Foreign Reviewer" programs where approval by one partner triggers fast-track review by the other, coordinated reviews where one partner leads a scientific assessment while the other issues its own determination, and mutual recognition agreements where partners agree to accept part or all of each other's reviews. Successful models, such as the collaborative assessment by Health Canada and Food Standards Australia New Zealand (FSANZ), show that these tools can work.[24] Reciprocal agreements with allies and partners would help to align expectations and speed products to market.

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Acronyms

- AAFCO: Association of American Feed Control Officials
- AI: artificial intelligence
- APEC: Asia-Pacific Economic Cooperation
- APHIS: Animal and Plant Health Inspection Service
- ASTM: American Society for Testing and Materials
- EFSA: European Food Safety Authority
- EPA: Environmental Protection Agency
- FDA: Food and Drug Administration
- FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act
- FSANZ: Food Standards Australia New Zealand
- HHS: Department of Health and Human Services
- ISO: International Organization for Standardization
- NAMs: new approach methodologies
- NBCO: National Biotechnology Coordination Office
- NIH: National Institutes of Health
- NSCEB: National Security Commission on Emerging Biotechnology
- OECD: Organisation for Economic Co-operation and Development
- QMS: quality management system
- R&D: research and development
- USDA: U.S. Department of Agriculture

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