Modernizing Plant Biotechnology Regulation

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). Since the release of the report, the NSCEB conducted extensive stakeholder outreach to identify specific Congressional actions to achieve those outcomes. 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.

American farmers already rely on biotechnology to help reduce land, water, and other inputs for over 90% of corn, cotton, canola, soybeans, and sugarbeets.[1] Developers are using biotechnology to create promising new plant varieties, but outdated regulatory frameworks slow their path to market. Redundant reviews, unclear processes, and inconsistent timelines create uncertainty for developers and discourage private investment in next-generation crops that could strengthen American agriculture.

Opportunities to Modernize Plant Biotechnology Regulation

The United States divides regulation of plants produced with biotechnology among three primary agencies working under multiple statutes.[2] Developers often must consult more than one agency before bringing a product to market.

- Under the Plant Protection Act (PPA), the Animal and Plant Health Inspection Service (APHIS) within the U.S. Department of Agriculture (USDA) oversees biotech plants that may pose a risk to plant health.
- Under the Federal Food, Drug, and Cosmetic Act (FFDCA), the Food and Drug Administration (FDA) reviews the safety of ingredients in human and animal food, including from biotech plant varieties.
- Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Environmental Protection Agency (EPA) regulates pesticides and plants engineered to produce pesticidal compounds.

Future Plants Within Reach Today

Developers are using biotechnology to produce innovative plants that will benefit American farmers and consumers, such as:

Short-stature corn that can withstand storms and can deliver higher yields per acre.[3]

Thornless, seedless blackberries that that are easier to harvest and easier to eat.[4]

Orange trees that can resist the devastating citrus greening disease and protect Florida's orange groves.[5]

Avocadoes that stay fresh for longer, including when bruised or cut, which reduces food waste.[6]

Regulatory complexity discourages developers from bringing new crops to market. For smaller developers in particular, navigating this complex system can be a significant barrier to market entry and pushes development overseas. For example, some companies noted that they are moving research to countries such as Argentina and Brazil, where common sense regulatory reform has already taken place.[7] Notably, these countries have taken steps to exempt gene edited crops that could have been produced with traditional breeding from more burdensome regulatory review. Further, U.S. regulators spend the majority of their limited time and resources re-reviewing previously approved traits instead of focusing on genuinely novel products. Without Congressional action and regulatory modernization, the United States risks ceding leadership in plant biotechnology innovation to other countries with more streamlined, science-based regulation.

American farmers have safely and successfully cultivated biotech crops the last three decades, demonstrating both the strength of existing regulation and the potential of modern plant breeding. The United States has many promising biotech plants ready for deployment, but outdated regulatory processes slow their path to market. Congress can modernize the relevant laws and equip agencies to review biotech plants more efficiently. The following policy options focus on streamlining existing pathways and establishing new ones that support innovation while protecting human health and the environment. If implemented, these policy options would streamline oversight for innovative plant products, strengthen U.S. competitiveness in agricultural biotechnology, and ensure that Americans benefit from the next generation of resilient, nutritious crops.

Overview

Policy Options for Modernizing Plant Biotechnology Regulation

Building on NSCEB's prior recommendations, this paper describes eight policy options across three key areas for modernizing oversight of plants produced with biotechnology: plant health, pesticides and related products, and food and feed safety. These should be considered alongside the NSCEB's overarching policy options for modernizing biotechnology product regulation. The NSCEB also developed detailed policy options for microbes, animals, and medical products, which are presented in separate discussion papers.

Policy Options for Plant Health

1. Focus APHIS regulation on plausible risks to plant health.
2. Provide risk-proportionate permitting processes for biotech plants.

Policy Options for Pesticides and Related Products

3. Clarify definitions and exemptions.
4. Streamline review for familiar plant products.
5. Eliminate unnecessary requirements for biological pesticides.

Policy Options for Food and Feed Safety

6. Focus FDA consultation on plausible risks to food safety.
7. Instruct the FDA to coordinate internally on food and feed safety review.
8. Address impacts of asynchronous approvals.

Policy Options for Plant Health

Well-understood biotech plants often face unnecessary review, taking time away from novel products that may warrant more attention. APHIS oversight of biotech plants hinges on "plant pest risk," an outdated interpretation of its statutory authority to protect plant health.[8] Under this framework, plant pests are organisms that can damage or cause disease in plants. APHIS's regulatory approach depends on whether a plant was engineered with DNA from a plant pest or with older transformation tools, rather than on potential risks. In 2020, APHIS adopted a new rule that successfully focused regulators on risks and reduced regulatory burden, but a federal court vacated the rule in 2024.[9] The court found, in part, that APHIS did not adequately consider its rulemaking record in the updated regulations.[10] By shifting toward a more risk-proportionate approach, Congress can focus oversight where it matters and reduce burden for safe, well-understood products.

1. **Focus APHIS regulation on plausible risks to plant health.**
   Stakeholders noted that APHIS should regulate biotech crops based on potential risks, not the method used to create them.[11] APHIS's current approach subjects well-understood plants to unnecessary review while diverting attention from genuinely novel products. Congress should instruct APHIS to build on its 2020 rule and regulate biotech plants based on plausible risks to plant health or the environment, reserving the highest scrutiny for novel products, such as plants that produce pharmaceuticals or industrial enzymes. Congress should ensure that APHIS has sufficient staffing and technical expertise to regulate plants under their plant health authority. Congress should also direct APHIS to use exemptions or fast-track review for plants with changes achievable through conventional breeding or that are similar to previously-approved plants. Replacing the outdated plant pest framework with tiered, risk-based review would allow APHIS to bypass full reviews for products that pose minimal risk to plant health or the environment, while maintaining oversight of novel products.

2. **Provide risk-proportionate permitting processes for biotech plants.**
   APHIS and the EPA both regulate outdoor field trials of biotech plants: APHIS regulates field trials under the PPA, and the EPA regulates larger field trials of biotech plants with pesticidal traits under FIFRA. Developers noted that compliance requirements for field trials and movement of biotech plants often emphasize documentation rather than real-world risk. Congress should instruct APHIS and the EPA to adopt performance-based permit standards that focus on plausible risk pathways, while reducing requirements for well-understood products. For pesticidal traits, Congress should direct APHIS and the EPA to collaboratively develop clear guidance for developers, and to share information as appropriate to ensure a harmonized permitting approach. These improvements would enable a smooth transition from small-scale to larger trials and appropriately focus APHIS and EPA resources, without imposing unnecessary barriers to innovation.

Policy Options for Pesticides and Related Products

Some biotech plant traits and biological products are regulated under the same frameworks as chemical pesticides. Small developers stressed that this adds unnecessary steps and slows review for safe, familiar products. The EPA has undertaken some regulatory streamlining and provided limited exemptions from pesticide registration, but additional improvements are needed.[12] Clearer definitions and right-sized data requirements would simplify review and allow safe products to enter the market more quickly.

3. **Clarify definitions and exemptions.**
   The EPA broadly interprets the definition of "pesticide" to include products such as plant incorporated protectants (PIPs) and plant growth regulators.[13] Developers emphasized that this creates unnecessary regulatory burden for plant traits that are not intended to function as pesticides, such as traits that affect plant growth. Congress should update definitions in FIFRA, building on the Plant Biostimulant Act of 2025 (S.1907 and H.R.3783), which the NSCEB previously endorsed in its December 2024 interim report. Congress should also instruct the EPA to clarify exemptions and remove ambiguity around which products are subject to pesticide regulation. Regulatory agencies, including APHIS, the FDA, and the EPA, should work collaboratively to shift non-pesticidal products to more appropriate regulatory pathways. Products that are exempt from pesticide regulation should also be exempt from requirements for pesticide residues, known as "tolerances," or should be covered by broad tolerance categories.

4. **Streamline review for familiar plant products.**
   The EPA requires developers to submit extensive data packages, even when a product is substantially

similar to a previously approved product. These data requirements are especially burdensome for smaller companies that do not have access to previously submitted data. Congress should instruct the EPA to expedite review for previously approved PIPs and familiar products, such as "stacks" built from previously approved traits, traits from related species, loss-of-function edits, and RNA interference (RNAi). Congress should also ensure that the EPA has appropriate, sufficient staffing and technical expertise to regulate plants that are intended for pest management. Modeled after the more efficient generic drug approvals process, this approach would reduce regulatory burden while maintaining safety.

5. **Eliminate unnecessary requirements for biological pesticides.**
Biological pesticides, including PIPs, fundamentally differ from conventional chemical pesticides, yet the EPA evaluates them under the same framework. This mismatch imposes inappropriate requirements that slow market entry for safe, well-understood products. Congress should instruct the EPA to evaluate and reduce regulatory requirements for biological pesticides, when appropriate. Reducing unnecessary requirements would maintain safety while supporting innovation.

Policy Options for Food and Feed Safety

Food and feed safety reviews for biotech plants often apply to well-understood products, adding unnecessary regulatory burden. Overlapping responsibilities and unclear pathways can further slow approvals and create uncertainty for developers. A more focused and coordinated approach would maintain food and feed safety and improve public confidence in foods from biotech plants while lowering administrative hurdles.

6. **Focus FDA consultation on plausible risks.**
The FDA regulates food safety of biotech plants through voluntary premarket consultation, with an option for voluntary premarket meetings for gene-edited plants.[14] This is a step in the right direction, but developers have noted that consultation has become a de facto requirement as nearly every biotech plant has gone through the process.[15] Congress should instruct the FDA to limit consultation to biotech plants with plausible food safety risks, such as meaningful changes in nutrients or toxins. Congress should also ensure that the FDA has sufficient staffing and technical expertise to regulate plants that are intended for food uses. Limiting consultations would reduce unnecessary burden and free up FDA resources for novel products while maintaining safety and consumer confidence.

7. **Instruct the FDA to coordinate internally on food and feed safety review.**
Within the FDA, the Human Foods Program (HFP) oversees food for humans, while the Center for Veterinary Medicine (CVM) oversees food for animals. Developers noted that the HFP and CVM review many ingredients separately, including those derived from biotech plants, which can slow regulatory approvals. Some differences in risk assessment are appropriate, in part because animals typically have less varied diets than humans. Even so, the FDA could consolidate parts of the review, such as nutrient composition. Congress should require a coordinated FDA approach to ensure that the right expertise is applied without duplicative review.

8. **Address the impacts of asynchronous approvals.**
Developers stressed that approval by U.S regulatory agencies is often insufficient for commercializing a biotech crop in the United States. Many other countries maintain separate regulatory approvals for domestic cultivation and imports. If a trading partner has not approved import of a biotech crop, shipments that include that crops could be rejected at foreign ports, creating trade disruptions and financial risk for farmers and developers. Consequently, American farmers often cannot plant a biotech crop until key trading partners approve importation. This situation, called asynchronous approval, occurs when one country has approved a biotech crop while others have not. Congress should direct regulatory agencies, along with trade-focused agencies such as the Department of State and the Office of the United States Trade Representative (USTR), to identify and implement strategies that would address asynchronous approvals and accelerate trading partner review of U.S. biotech crops for import.

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Acronyms

- APHIS: Animal and Plant Health Inspection Service
- CVM: Center for Veterinary Medicine
- EPA: Environmental Protection Agency
- FDA: Food and Drug Administration
- FFDCA: Federal Food, Drug, and Cosmetic Act
- FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act
- HFP: Human Foods Program
- NSCEB: National Security Commission on Emerging Biotechnology
- PIPs: plant-incorporated protectants
- PPA: Plant Protection Act
- RNAi: RNA interference
- USDA: U.S. Department of Agriculture
- USTR: Office of the United States Trade Representative

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