Modernizing Animal 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.

Modern biotechnology offers tools to develop animals with traits that address major challenges in agriculture, conservation, and beyond.[1] These innovations could help strengthen food security, revolutionize human medicine, produce new materials, and contribute to conservation efforts.

Although scientific advances in animal biotechnology began decades ago, well before comparable developments in crops, animal agriculture has seen little of the resulting benefit.[2] Only a few biotech animals have reached the market, primarily due to regulatory hurdles. These products face long, uncertain, and costly regulation that discourages investment and delays promising traits that could support U.S. farmers and ranchers.

Biotechnology developers working with animals describe several unique challenges compared to other biotechnology products, including that the United States is the only country that uses a drug authority to regulate animals.[3] This regulatory approach creates delays and uncertainty that developers say are out of step with both science and international practice. Ultimately, regulatory barriers prevent American farmers from accessing agricultural innovations and push developers overseas.

Innovations in Animal Biotechnology

Biotechnology offers tools to develop animals that provide major benefits across agriculture, medicine, and natural resources, such as:

Heat-tolerant cattle that maintain production of meat and milk in high temperatures.[4]

Chickens with resistance to avian influenza that could reduce devastating outbreaks.[5]

Pigs with transport-ready organs that can save lives and address the shortage of human donors.[6]

Resilient, disease-resistant coral that can support healthy ocean ecosystems.[7]

Silkworms that produce strong, stretchy fibers for parachutes, wound dressings, and more.[8]

Opportunities to Modernize Animal Biotechnology Regulation

Animals produced with biotechnology are currently regulated by the Food and Drug Administration (FDA) under the animal drug authority in the Federal Food, Drug, and Cosmetic Act (FFDCA). The FDA regulates each intentional genomic alteration (IGA) as a "new animal drug," regardless of whether the animals are intended for medical or agricultural purposes. After review is complete, the FDA imposes additional requirements, such as facility registration and post-approval monitoring.

Developers of certain IGAs, including animals raised for food, may seek an expedited process, called Enforcement Discretion. However, the FDA requires that developers label domestic shipments and exports of live animals, genetics, and cells regulated under Enforcement Discretion as containing an "unapproved drug," which carries significant stigma and creates trade barriers. American developers are at a further competitive disadvantage because animals developed abroad may be imported into the United States without a full drug review.

Two agencies within the U.S. Department of Agriculture (USDA) also have authority to regulate animals, including those produced with biotechnology. Under the Animal Health Protection Act (AHPA), the Animal and Plant Health Inspection Service (APHIS) oversees animal health, focusing on pests and disease. Under the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA), the Food Safety and Inspection Service (FSIS) oversees food safety for meat, poultry, eggs, and catfish. However, the FDA oversees food safety for milk and foods from other animals, including deer, rabbits, and most fish.

Regulation of biotech insects raises additional complexity. Like other animals, biotech insects face potential regulation by the FDA under its animal drug authorities in the FFDCA and APHIS under the AHPA. In addition, biotech insects may be regulated by the FDA under its food safety authorities, by APHIS under the Plant Protection Act (PPA), and by the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These overlapping authorities create regulatory uncertainty for important applications of biotech insects, such as suppression of insect-borne diseases, agricultural pest management, and insect-based food and feed.

Outdated regulatory approaches have prevented animal biotechnology from meeting its full potential, and developers of promising biotech animal innovations will continue to move overseas without regulation that reflects modern science.[9] In 2017 and again in 2021, a bipartisan group of Members of Congress sent letters to the FDA and the USDA, instructing them to identify a path forward for coordinated, science-based regulation of biotech animals, but the agencies have made little progress due to remaining ambiguity in how to resolve overlapping regulatory authorities.[10] Congress must act to reduce unnecessary regulatory burden, empower and resource regulators to work more efficiently, and ensure safety and transparency for consumers. If implemented, the following policy options would streamline oversight for animal biotechnology applications, strengthen U.S. competitiveness, and enable these innovations to provide benefits to American farmers and consumers.

Policy Options for Modernizing Animal Biotechnology Regulation

Building on the NSCEB's prior recommendations and extensive stakeholder input, this paper describes ten policy options for modernizing oversight of biotech animals. These policy options should be considered alongside the NSCEB's overarching policy options for modernizing biotechnology product regulation. The NSCEB also developed detailed policy options for plants, microbes, and medical products, which are presented in separate discussion papers.

Policy Options for Livestock, Poultry, and Fish

1. Streamline current FDA processes for familiar animals.
2. Establish a clear pathway for APHIS animal health oversight of biotech animals.
3. Establish a clear pathway for FDA food safety oversight of biotech animals.
4. Establish clear pathways for biotech animals used for agriculture and medicine.
5. Ease regulatory barriers for research.
6. Provide consistent labeling of foods from animals produced with biotechnology.

Policy Options for Insects

7. Establish a clear pathway for EPA regulation of biotech insects for pest management.
8. Establish a clear pathway for APHIS animal health oversight of biotech insects.
9. Focus APHIS regulation of insects for biocontrol and sterile insect technique.
10. Provide a clear pathway for FDA food safety oversight of biotech insects.

Policy Options for Livestock, Poultry, and Fish

Livestock and poultry developers need clear, predictable regulatory pathways to bring safe, innovative biotech animals to market. In 2020, the USDA published an Advanced Notice of Proposed Rulemaking (ANPR) to modernize regulation of biotech livestock and poultry.[11] The USDA did not proceed with rulemaking, in part due to ongoing disagreement between the USDA and FDA over their respective jurisdictions and continued overlap of food safety authorities.[12] Developers emphasized that any regulatory approach should leverage each agency's expertise and statutory authority. For biotech plants, APHIS oversees plant health while the FDA oversees food safety. A similar approach for biotech animals, assigning animal health to APHIS and food safety to the FDA, would dramatically improve regulatory clarity, strengthen U.S. competitiveness in animal biotechnology, and align with international regulatory processes.

1. Streamline current FDA processes for familiar animals.
Current regulatory processes impose unnecessary burdens on developers of well-understood biotech animals, including animals engineered with traits that are already present in the species. These burdens slow review without improving safety. To provide interim relief while the USDA and FDA develop clear regulatory pathways, Congress should instruct the FDA to update existing guidance to reduce the burden associated with animal drug regulation that is not appropriate for regulating biotech animals. This should include to remove unnecessary data requirements,

reduce excessive adverse event reporting, and simplify supplemental filing obligations for minor facility changes. Congress should also instruct the FDA to remove the "unapproved drug" designation that comes with Enforcement Discretion for animals, genetics, and cells beyond the first generation. These actions would reduce some regulatory burden but would not resolve challenges associated with regulating biotech animals under an animal drug authority.

2. Establish a clear pathway for APHIS animal health oversight of biotech animals.

The absence of a clear pathway for animal health oversight has resulted in regulatory gaps and forced the FDA to use a regulatory authority that developers say is poorly suited for biotech animals. Building on USDA's ANPR, Congress should instruct APHIS to conduct expedited rulemaking for tiered, risk-based oversight of biotech animals under its animal health authority. Traits that could have been achieved with conventional breeding should be exempt from additional review. Congress should ensure that APHIS has sufficient staffing and technical expertise to regulate animals under their animal health authority. Congress should also clarify that APHIS's authority applies to both communicable disease and non-communicable conditions affecting productivity or welfare and to all animals used in agriculture or that may affect agriculture, including traditional and non-traditional livestock and poultry, fish and other aquatic animals, and wildlife. The FDA would continue to regulate animals raised exclusively in containment for non-agricultural purposes, such as human medicine and biomedical research, but these animals may be subject to APHIS permitting for interstate movement, imports, and exports. APHIS should consult with the FDA on traits related to human or animal disease and with the EPA on traits related to pest management. APHIS should also conduct its reviews in full compliance with applicable environmental laws and regulations, removing the need for the FDA to replicate that work. Together with FDA food safety oversight, APHIS animal health oversight would establish clear regulation for biotech animals and strengthen cross-agency collaboration for animals with overlapping considerations.

3. Establish a clear pathway for FDA food safety oversight of biotech animals.

At the same time, Congress should instruct the FDA to develop tiered, risk-based oversight of biotech animals under its food and feed safety authorities. Traits that could have been achieved with conventional breeding should be exempt from additional review. Congress should also ensure that the FDA has sufficient staffing and technical expertise to regulate animals under their food safety authority. Within the FDA, the Human Foods Program (HFP) oversees food for humans, while the Center for Veterinary Medicine (CVM) oversees food for animals. Congress should require a coordinated FDA approach to ensure that the right expertise is applied to biotech animals without duplicative review. In addition, the FDA should collaborate closely with the FSIS so that the FSIS can fulfill its regulatory responsibilities related to slaughter, processing, packaging, and labeling. Along with APHIS animal health oversight, FDA food safety oversight would further enable commercialization of biotech animals.

4. Delineate clear pathways for biotech animals used for agriculture and medicine.

Some developers are creating animals that are intended for both agricultural and biomedical uses, such as pigs with organs for transplantation into humans that can also be used for meat. These animals could be regulated by APHIS under the pathway described above and by the FDA under their animal drug authority. Congress should require the USDA and the FDA to establish a coordinated pathway for dual-purpose biotech animals. A lead agency should be designated based on objective criteria, such as projected market share, intended scope of deployment, or predominant use claims. Congress should also direct APHIS and the FDA to collaboratively develop clear guidance for developers and to share information as appropriate to ensure a harmonized approach.

5. Ease regulatory barriers for research.

The FDA's drug-based regulation of IGAs in biotech animals imposes inflexible requirements, onerous costs, and decades-long review timelines. Under current requirements, animals in research must receive approval from the FSIS prior to slaughter, and biotech animals must also receive food use approval from the FDA. Developers stressed that these hurdles are largely prohibitive for academic labs and discourage the use of biotechnology, including gene editing, in animal breeding programs.[13] Congress should instruct the FDA and FSIS to collaboratively develop research exemptions and expedited approval pathways that enable research. Agencies should communicate regulatory requirements clearly with small developers. The FDA should expedite food use approvals for meat and milk from biotech animals in research, and agencies should work with state regulators to reduce regulatory burden. In addition, the FDA should not require food use approval for animals with traits that could have been achieved with conventional breeding.

Easing these regulatory barriers would enable scientists to pursue breakthroughs with less red tape, accelerating innovation and delivering benefits to American farmers and to the American people more broadly.

6. Provide consistent labeling of foods from animals produced with biotechnology.
Under the Bioengineered Food Disclosure Law, USDA-regulated meat and poultry are exempt from "Bioengineered" labeling.[14] As a result, steak from a biotech steer would not be labeled, while stew containing pieces of the same steak would require the Bioengineered disclosure. Developers noted that this inconsistency can complicate marketing and confuse consumers. Congress should instruct the Agricultural Marketing Service (AMS), FSIS, and FDA to collaboratively investigate options for clear, consistent labeling for foods derived from organisms produced with biotechnology, including animals or animal cells, under their respective labeling authorities. Consistent food labeling across food sources would support consumer confidence.

Policy Options for Insects

As with livestock and poultry, developers of biotech insects need clear, predictable regulatory pathways. Developers expressed concern about duplicative processes and the lack of a clear commercialization pathway for biotech insects. In 2023, the EPA and FDA announced efforts to modernize regulatory oversight of biotech insects along with animal drugs and pesticides, but developers emphasized that problems remain.[15] Single-agency oversight of biotech insects would speed innovation and reduce unnecessary regulatory burden.

7. Establish a clear pathway for EPA regulation of biotech insects for pest management.
Developers stressed the importance of EPA pesticide registration to facilitate state regulation and to allow biotech insects to enter international trade. Developers also noted that the EPA has the strongest technical expertise for reviewing biotech insects. Accordingly, Congress should instruct the EPA to delineate a clear regulatory pathway for biotech insects intended for pest management. Congress should also ensure that the EPA has sufficient staffing and technical expertise to regulate such insects. When conducting regulatory review, the EPA should consult with the FDA for traits related to human disease, and with APHIS on insects that are plant or animal pests related to animal disease. Additionally, EPA-regulated insects may require APHIS permitting for interstate movement, imports, and exports. Clarifying EPA's lead role in regulating pest management traits in biotech insects would reduce ambiguity for innovators.

8. Establish a clear pathway for APHIS animal health oversight of biotech insects.
Insects intended for purposes other than pest management, such as conservation, need a clear regulatory pathway outside of animal drug and pesticide registration. Congress should instruct APHIS to include biotech insects that are not intended for pest management in its expedited rulemaking for tiered, risk-based oversight of biotech animals under its animal health authority. APHIS regulation should include all non-pest management traits relevant to animal health, including those intended to reduce pathogen load or transmissibility of disease. Along with EPA pesticide registration and FDA food safety oversight, APHIS animal health oversight would provide clear pathways for biotech insects and strengthen cross-agency collaboration for insects with overlapping considerations.

9. Focus APHIS regulation of insects for biocontrol and sterile insect technique.
Biocontrol, short for biological control, is a pest management strategy that aims to reduce pest populations by introducing natural predators or other organisms to control the pest, such as using ladybugs to control aphids.[16] A subset of biocontrol, sterile insect technique (SIT), involves the release of sterile insects as a way to reduce insect populations; when the sterile insects mate with wild insects, the resulting eggs are not viable and will not hatch.[17] APHIS Plant Protection and Quarantine (PPQ) currently regulates non-biotech insects for biocontrol, including SIT, but developers noted that PPQ does not provide any documentation to indicate that review is complete. Congress should instruct APHIS to provide developers with documentation for non-biotech biocontrol insects that they have reviewed, with the goal of meeting state and international requirements prior to release. Congress should also instruct APHIS to provide oversight for non-biotech biocontrol insects based on intended use, not the presence of biocontrol properties in the scientific literature. Such insects would not undergo extensive review but may require APHIS permitting for interstate movement, imports, and exports. These changes would better align APHIS regulation with international norms for scientific risk assessment.

10. Provide a clear pathway for FDA food safety oversight of biotech insects.
Insects can be an efficient, nutritious source of human and animal food, and developers are increasingly using biotechnology in this space.[18] Insects are also key elements of circular bioeconomy strategies that focus on the recycling of food waste and agricultural residues. Congress should instruct the FDA to develop tiered, risk-based oversight of these biotech insects under its food and feed safety authorities. Traits that could have been achieved with conventional breeding should be exempt from additional review. As with livestock, the FDA's HFP and CVM should coordinate on products that are intended for both food and feed. The FDA should consult with APHIS on insects that are plant or animal pests. Additionally, FDA-regulated insects may require APHIS permitting for interstate movement, imports, and exports. The FDA should also consult with EPA on insects with pest management traits, which may be subject to pesticide registration.

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Acronyms

- AHPA: Animal Health Protection Act
- AMS: Agricultural Marketing Service
- ANPR: Advanced Notice of Proposed Rulemaking
- APHIS: Animal and Plant Health Inspection Service
- CVM: Center for Veterinary Medicine
- EPA: Environmental Protection Agency
- EPIA: Egg Products Inspection Act
- FDA: Food and Drug Administration
- FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act
- FMIA: Federal Meat Inspection Act
- FSIS: Food Safety and Inspection Service
- HFP: Human Foods Program
- IGA: intentional genomic alteration
- NSCEB: National Security Commission on Emerging Biotechnology
- PPA: Plant Protection Act
- PPIA: Poultry Products Inspection Act
- PPQ: Plant Protection and Quarantine
- SIT: sterile insect technique
- USDA: U.S. Department of Agriculture

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