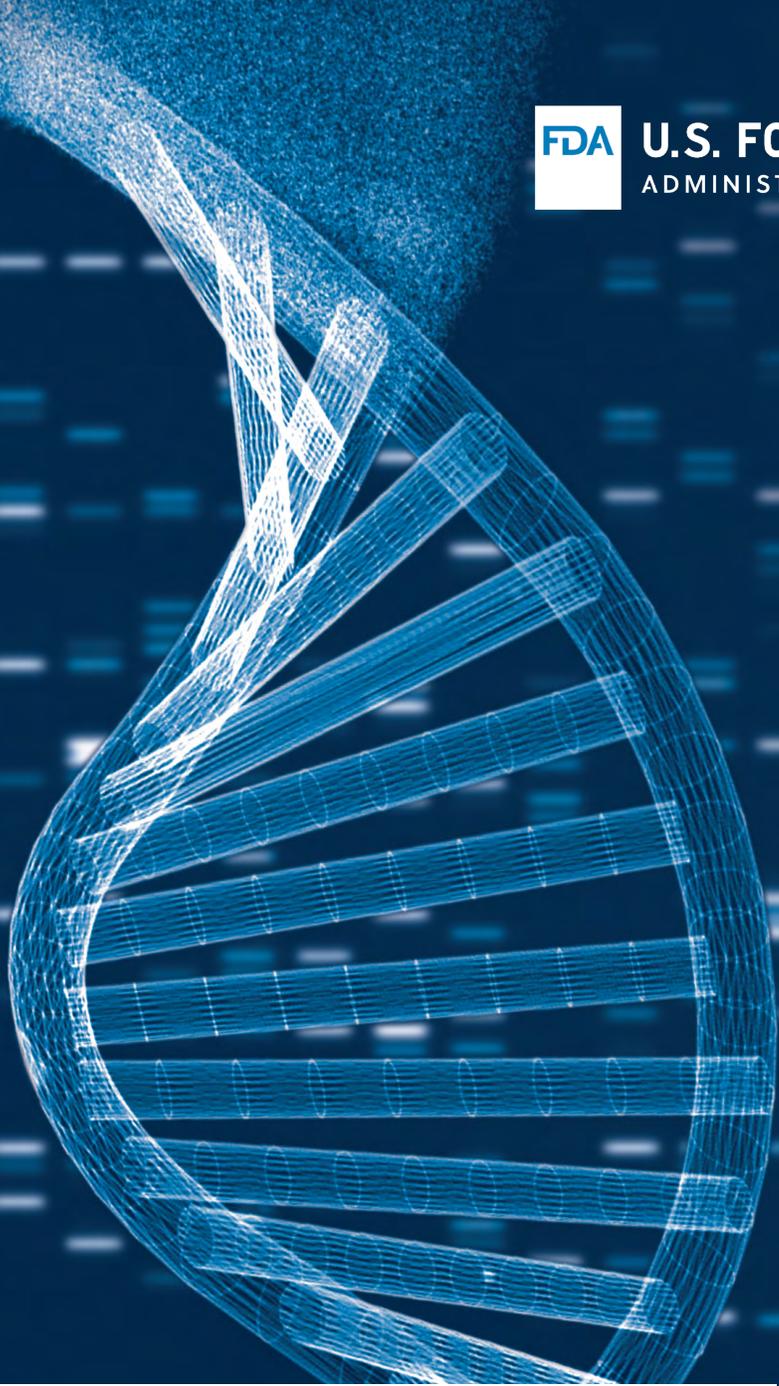
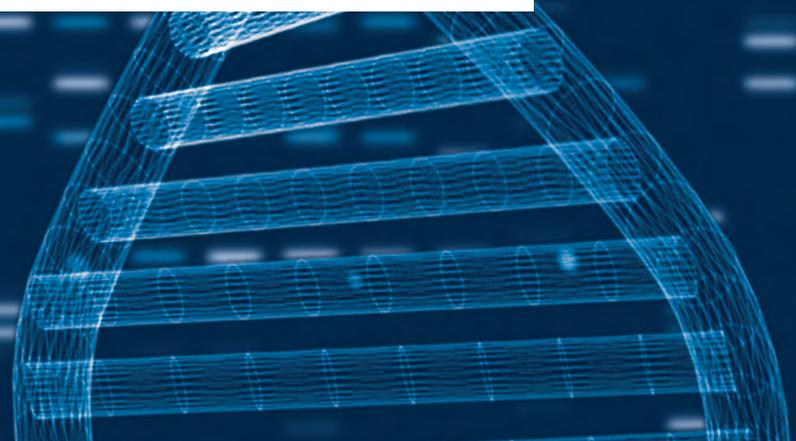




**U.S. FOOD & DRUG
ADMINISTRATION**



Plant and Animal Biotechnology Innovation Action Plan





FDA's Plant and Animal Biotechnology Innovation Action Plan¹

The U.S. Food and Drug Administration is pleased to share the Plant and Animal Biotechnology Innovation Action Plan. This plan provides an overview of the key priorities the FDA will pursue to support innovation in plant and animal biotechnology and to advance the agency's public health mission.

Many of the priorities outlined within this Action Plan are well underway and will be rolled out, including for public input as appropriate, over the course of the next 12 months. We expect to continue implementation of the commitments made under this Action Plan through 2020.

Background

Scientific advancements such as genome editing have led to the ability to more efficiently and precisely alter the genomes of plants and animals to produce desired traits. Genome editing technologies, including use of gene drives, in plants and animals are generating great excitement about potential applications in areas including food (for humans and animals), agriculture, and health – as well as questions about potential risks. Applications being explored include:

- Altering specific traits of plant foods or fungi (e.g., increased tolerance to environmental stresses, improved fatty acid profiles of oilseeds for human diets);
- Improving the health and welfare of food-producing animals (e.g., pigs resistant to diseases such as African swine fever as well as porcine reproductive and respiratory syndrome virus);
- Producing plants or animals for human medical use (e.g., xenotransplantation, production of pharmaceutical substances); and
- Altering organisms to reduce or eliminate their ability to carry or transmit infectious diseases (e.g., mosquitoes that are vectors of viruses or parasites causing dengue fever, Zika virus, or malaria; ticks that transmit bacteria causing Lyme disease).

¹ Human medical products such as human drugs, biologics, and medical devices are not within the scope of activities envisioned under this Action Plan.

Modernizing the biotechnology regulatory system

In 2015, the FDA, U.S. Environmental Protection Agency, and U.S. Department of Agriculture began to modernize the regulatory framework for biotechnology products to ensure the preparedness of federal regulatory agencies for future products of biotechnology. The agencies published two key documents:

- the [2017 Update to the Coordinated Framework for the Regulation of Biotechnology](#), which improved Federal government transparency by clarifying the current roles and responsibility of the three primary agencies responsible for regulation of biotechnology products – the FDA, EPA, and USDA; and
- the [National Strategy for Modernizing the Regulatory System for Biotechnology Products](#), which sets forth the Federal government’s vision for ensuring that the regulatory framework is equipped to both support product innovation and efficiently assess any associated risks.

To better understand the landscape of future products of biotechnology, the FDA, EPA, and USDA commissioned a study conducted by the National Academies of Sciences, Engineering, and Medicine, which published a report titled, “[Preparing for Future Products of Biotechnology](#)” in 2017.

In addition, the FDA issued key documents to update and help improve the predictability of our regulatory decision-making. For example, in October 2017, the FDA, working with EPA, issued [Guidance for Industry #236](#) to clarify the delineation of responsibilities between the FDA and EPA for oversight of mosquito-related products (including those involving the application of biotechnology). In January 2017, the FDA published two documents to begin the process of clarifying our regulatory approach to genome editing in animals, and in plant varieties used for food: (1) a draft revised [Guidance for Industry \(GFI\) #187](#) on the oversight of intentionally altered genomic DNA in animals (in the corresponding Notice of Availability published in the Federal Register (FR), the FDA asked for public input on a series of questions to help inform our thinking (82 FR 6561; January 19, 2017)); and (2) a Request for Comments on questions related to use of genome editing in new plant varieties used for food for humans and animals (82 FR 6564; January 19, 2017).

Moreover, the FDA worked with federal partners on the Interagency Task Force on Agriculture and Rural Prosperity, which [issued its report in January 2018](#), identifying several recommendations on harnessing technological innovation in agricultural production. The goals of this Action Plan align with the objectives of that ongoing effort and we look forward to the continued close collaboration and engagement with our federal partners.



Plant and Animal Biotechnology Innovation Action Plan

The FDA's Action Plan aims to implement and clarify risk-based policies with the goals of ensuring that developers know what they need to do to efficiently bring a product to market, and that consumers and the public understand how the FDA's regulatory system helps ensure the safety of such products. The Action Plan identifies concrete priorities in three key areas:

I. Advancing public health by promoting innovation

The FDA has a flexible, risk-based approach to the oversight of food and animal products of biotechnology, focusing on safety, effectiveness, and/or regulatory questions relevant to each product for its intended use. Our approach includes, when appropriate, updating and clarifying science-based policies to support innovation and ensure that our regulatory processes are efficient, predictable and proportionate to risk.

Fostering innovations in animal biotechnology

The FDA will continue to support innovation in animal biotechnology through key policy activities. As we implement the priorities identified here, we recognize the importance of enabling developers to bring innovative and transformational products of benefit to consumers and animals. We intend to clarify and appropriately tailor our regulatory oversight considering the unique factors relevant to animals developed with biotechnology, including food-producing and biopharm (i.e. that produce medical products) animals.

The FDA has reviewed the feedback we received on the draft revised GFI #187 and, considering the concerns some stakeholders have raised, we believe a public dialogue and exchange of information with stakeholders is an important element of the plan. A first step in this dialogue is to hold a webinar on December 3, 2018 (see [public webinar announcement](#)), to review the science behind genome editing in animals, the promising uses of this technology in animals, the potential risks, and information about CVM's risk-based approach to the oversight of intentional genomic alterations to animals. We also would like to communicate our regulatory approach directly to our stakeholders using plain language that is more easily understandable than in our regulatory documents. Such a webinar will also be helpful in explaining to product developers how our approach seeks to be as flexible as possible within the law.

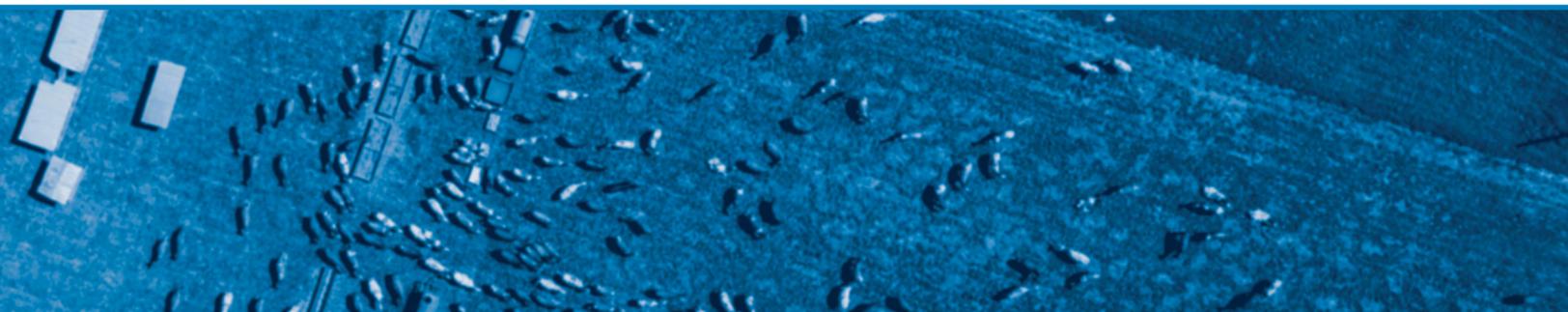
The FDA is committed to adopting and clarifying a comprehensive policy framework for the development and oversight of animal biotechnology products, including for drug and food products derived from intentionally genetically altered animals. Our comprehensive framework – to be detailed in a set of guidance documents that we intend to release over the next year – will more clearly describe how the FDA is applying its regulatory oversight based on the risk profile of different types of products. Through various guidance documents, taken together, the FDA intends to advance an efficient, science-based pathway to market for safe animal biotechnology-derived products. The FDA believes this modern framework will balance the agency's commitment to safety with mechanisms to drive innovation to help usher in new, beneficial products to consumers and animals.

The FDA is establishing a new pilot program, [the Veterinary Innovation Program \(VIP\)](#), to provide intensive assistance, both technical and programmatic, for developers seeking FDA approval of intentionally altered genomic DNA in animals and animal cells, tissues, and cell- or tissue-based products that provide a benefit to human health, animal health, animal well-being (e.g. husbandry improvements), or food production. The goal of the VIP is to facilitate advancements in the development of innovative animal products by providing greater certainty in the regulatory process, encouraging development and research, and supporting an efficient and predictable pathway to approval for certain innovative animal products.

In 2019, the agency intends to publish guidance to clarify the FDA's regulatory approach to the regulation of intentional genomic alterations in animals, including through genome editing. This regulatory approach would be characterized by risk-based categories that include: an FDA decision not to enforce approval requirements with no prior review, an FDA decision not to enforce approval requirements following a review of data that address specific risk questions, and an FDA decision to review for approval with data requirements proportionate to the risk associated with the particular product. This regulatory approach includes flexibility to transfer products across these categories based on specific conditions as we gain familiarity with different product risk profiles. In a complementary draft guidance, the FDA intends to clarify its regulatory approach for categories of intentionally genetically altered animals used in research and plans to outline, based on risk, when the FDA intends to exercise enforcement discretion (i.e., the FDA's decision not to enforce approval requirements in certain situations, as outlined above) or when it intends to enforce the requirement for an approved new animal drug application. Such clarification will enhance regulatory predictability for developers.

Also in 2019, to further support early efforts in animal biotechnology research and development, the FDA intends to publish draft guidance for industry to establish an alternative type of file as a repository for information exchanges with the FDA's Center for Veterinary Medicine (CVM) for products that are in early development stages or that are developed for pure research and that may never progress to a marketable product. This would provide a means for CVM to ensure basic standards of safety for such products (e.g. keeping such animals out of the food supply) while also avoiding imposition of user fees and lessening certain administrative burdens of maintaining an Investigational New Animal Drug file.

Finally, to enhance the transparency of our decisions, the FDA intends to list on its website the specific animals or categories of animals with intentional genomic alterations for which the FDA has made a risk-based determination to exercise enforcement discretion with regard to premarket approval requirements.



Advancing innovations in plant biotechnology

In the area of plant biotechnology innovation, the FDA's policy priorities will be aimed at helping to ensure the safety of food (for humans and animals) derived from genome-edited food crops. The FDA has over 25 years of experience overseeing the safety of foods from new plant varieties produced through genetic engineering. The agency will take lessons learned from this long-standing experience to clarify our policy approach to evaluation of the safety of food from genome edited crops. Having reviewed the comments received on the Request for Comments, we intend to develop guidance for industry explaining how the FDA's current regulatory policy for foods derived from new plant varieties applies to foods produced using genome editing. We intend to publish the draft guidance for public comment in early 2019. In addition, over the next two years, we intend to begin updating the existing procedures for voluntary premarket consultations with industry to reflect the FDA's 25 years of experience with foods derived from biotechnology plants and considering any additional issues related to genome editing of food crops.



II. Strengthening public outreach and communication

The agency will use a robust public communication strategy, with direct support and involvement from the FDA's Commissioner and senior agency leaders, to engage with our stakeholders on innovations in plant and animal biotechnology. The agency's efforts will be aimed at explaining our science-based regulatory approach, increasing understanding of our regulatory frameworks that protect public health, keeping our stakeholders informed of our ongoing work, and providing opportunities for public input.

As we adopt, clarify, and implement our policy approaches to future plant and animal biotechnology products, the FDA will actively engage with stakeholders to ensure understanding and provide opportunity for dialogue. Where appropriate, the FDA may hold public meetings in coordination with the issuance of guidance documents. The FDA also intends to perform active outreach to industry, particularly small developers, animal producers and farmers, and other stakeholders. These outreach efforts will be aimed at increasing understanding of the FDA's regulatory oversight approaches and how best to engage with the agency on questions related to regulatory status or safety evaluations of products. The FDA is also reviewing plant and animal biotechnology information available on our website to streamline the information and make it more accessible.

Moreover, as part of our continuous education and outreach efforts, we will issue information on scientific and regulatory issues pertaining to biotechnology derived human and animal food products, as we implement these initiatives.

III. Increasing engagement with domestic and international partners

Strong partnerships with our domestic and international public health partners are an essential aspect of our efforts to advance plant and animal biotechnology innovation. The FDA will actively engage with our federal and international partners through coordinated and collaborative actions to support regulatory alignment and efficiency, and enhance regulatory science to inform our decisions. For example, the FDA will continue to work with EPA and USDA on regulatory approaches to products obtained using genome editing and other new plant and animal development techniques, consistent with our respective regulatory authorities and with the Coordinated Framework. The FDA and USDA have recently announced a formal agreement to bolster interagency coordination and collaboration, and biotechnology is a targeted area of focus for an FDA-USDA working group under this agreement.

The FDA will work with foreign regulatory agencies to support scientific and, where possible, regulatory alignment regarding products of genome editing. Our efforts will include working through FDA's foreign offices. FDA also will explore existing or new memoranda of understanding or similar agreements with foreign governments as mechanisms to share information and incorporate efficiencies into our regulatory processes. Moreover, we will continue to provide leadership in international fora to enhance understanding of the FDA's science- and risk-based regulatory approach that ensures safety of FDA-regulated biotechnology products.

The FDA believes that public-private partnerships that are able to bridge a broad range of disciplines, expertise, and experience will help to ensure safe use of potentially transformative biotechnology tools, such as gene drives that may help control vector-borne disease. The FDA will work with domestic and international partners and engage in a dialogue about how such tools may eventually strengthen measures to address diseases conveyed by vectors such as mosquitoes and ticks. The dialogue will address the novel ecological, environmental, and public health challenges posed by the cross-border nature of such diseases and the potential permanence of gene drive solutions to vector-borne disease.

Taken together, these priorities are intended to ensure the safety of plant and animal biotechnology products, foster continued public confidence in the FDA's regulation of these products, and avoid unnecessary barriers to future innovation consistent with the FDA's mission to protect and promote public health.





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