USDA's Modernized Regulatory Approach
Questions & Answers

What does USDA's modernized regulation do? How is it different from the current approach?

The U.S. Department of Agriculture (USDA) broadly regulates organisms created through "genetic engineering," which it defines as any techniques that use recombinant, synthetic, or amplified nucleic acids to modify or create a genome. However, certain categories of genetically engineered organisms, for which the agency has a great deal of experience or are similar to traits that could have been developed via conventional plant breeding, do not require pre-market review by USDA. These categories include:

1. All new plants with crop-trait combinations USDA has already reviewed.

2. Plants with certain enumerated gene edits or with genetic changes that could have occurred naturally.

For those plants not falling in these categories, two regulatory pathways are available: 1) USDA would issue a permit for importation, interstate movement, or environmental release; or 2) USDA would conduct a "regulatory status review" (RSR) to determine whether the plant should be subject to USDA regulations. Plants clearing the RSR process would be added to the categories above and future plants with the same traits would not require additional pre-market review.

Technology developers and plant breeders are allowed to self-determine whether they fall into one of the categories above and, if they do, are not required to notify the agency before commercializing. USDA has decades of experience regulating in this area and a strong scientific basis for its regulatory approach.

Note that the new USDA regulations do not change oversight of agricultural biotechnology by the U.S. Food and Drug Administration (FDA) or the U.S. Environmental Protection Agency (EPA), which, respectively, oversee food safety and the safety of any pesticide-like properties of the plants or alter USDA's extensive post-market authorities.

Why did USDA decide to modernize its regulatory approach for plant biotechnology?

Both the Obama and Trump administrations have prioritized the modernization of food and agricultural biotechnology regulatory approaches – to better keep pace with innovation, to drive investment and small business success, and to grow American global leadership while maintaining safety and risk-proportionate oversight.

In 2015, the Obama administration initiated an effort to modernize the biotechnology regulatory system. In 2017, it unveiled the results of this exercise in an action plan designed to increase transparency, coordination, and predictability of the U.S. biotechnology regulatory system. The Trump administration operationalized many aspects of this initiative through collaboration across agencies and with stakeholders and through rulemaking. The new USDA regulation is an example of the government acting on logical next steps in this bipartisan effort.

USDA's modernized approach to regulation is consistent with the Obama initiative and with recommendations identified by the 2017 Rural Prosperity Task Force to improve life in rural

America – including proposals to harness technological innovations, like biotechnology, through regulatory streamlining. It is also consistent with the 2019 Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products "to conduct Federal oversight of agricultural biotechnology products that is science-based, timely, efficient, and transparent." The Executive Order directs USDA, EPA, and FDA to align existing biotechnology regulations with actual risk, to coordinate across agencies and with global partners, and to grow public confidence in biotechnology food and farm solutions.

Does USDA's modernized regulation mean some plant biotechnology products will not be regulated?

No. All food in the United States is held to the same high food safety standards. The new USDA regulations do nothing to change the fact that broad mechanisms for oversight of food safety remain in place. FDA also administers a plant biotechnology consultation program, which enables product developers and FDA experts to evaluate food safety before products enter the marketplace. While this program is voluntary, it is commonly used and highly beneficial.

USDA's final rule, which represents a new approach in some respects, reflects the agency's decades-long experience assessing genetically engineered plants and the fact that plants created through conventional breeding have a history of safe use related to plant pest risk. Because developers are not required to notify the agency before commercializing some products, however, important stakeholder groups will ask for information about what is in their food and whether their food is safe.

BIO and its member companies encourage and will prioritize increased openness about products entering the marketplace and best practices developers use in advancing beneficial products to the commercial marketplace.

What information will the rule provide about what plant biotechnology products are in the marketplace?

USDA will maintain a publicly available list of categories of plant-trait combinations that do not require pre-market review and will update the list as new categories are added. USDA has also provided a process by which a developer may voluntarily seek from USDA confirmation that a particular product was not subject to premarket review and has indicated that voluntary confirmation will be public information. FDA will continue to review products individually and make completed food safety reviews available to the public.

BIO and its member companies encourage and will prioritize increased openness about products entering the marketplace and best practices developers use in advancing beneficial products to the commercial marketplace. To address the general demand for increased information, we support the development of a website to complement transparency initiatives. The U.S. government, BIO and other stakeholders will work cooperatively so information about a myriad of topics will be proactively posted, including topics like: notification of products or classes of products entering the market, peer-reviewed papers examining innovation in food and agriculture, the international regulatory landscape, and best breeding practices in plants and animals and the use of beneficial microbial innovations.

BIO's press release references transparency and driving greater awareness about biotechnology in food and agriculture – what does that mean?

BIO understands that consumers want more information about what is in their food and whether their food is safe. Our members will be a driver of that endeavor. "Transparency" is interpreted broadly by both industry and stakeholders. Therefore, for the purposes of our work, we use "transparency" as an umbrella term under which we define specific focus areas.

Within the broader agri-food ecosystem, diverse stakeholder priorities are driving an interest in transparency and assurances provided by government agencies. Examples include: the assurance by independent verifiers of stewarded use of the technology; timely notification of what is coming to the marketplace; how safety measures were applied in product development; and how potential risk is managed and mitigated across a supply chain.

From these key insights, we believe that an effective approach for transparency includes:

- Defined roles for all participants, including government, public and private developers, civil society, the food value chain, and the public
- Clear principles and goals for building trust and answering questions
- A mechanism for independent verification and the use of best management practices in the development and introduction of new products
- Diversity of perspectives represented in governance systems
- Resources that enable small and emerging company participation
- A publicly available repository of information about plant, animal and microbial biotechnologies and breeding methods
- A comprehensive and connected communications approach

How does USDA's new approach to regulating plant biotechnology compare to other governments around the world?

The rule is a positive step in the evolution of regulatory oversight. USDA is applying the learnings from more than 30 years of regulating biotechnology in determining what falls within the scope of premarket review. This move by APHIS of applying lessons learned to streamline pre-market review is consistent with what other governments, such as Japan, have done. For products developed using newer tools like gene editing, the scope of products that are not required to undergo pre-market safety review is similar to the policy direction being taken by other governments, such as Argentina, Brazil, and Japan.

Does USDA's new rule require regulatory changes at the state or local level?

No. USDA's final rule on agricultural biotechnology is based on a strong scientific record, including the Agency's 30 years of experience in evaluating products of biotechnology for plant pest risk and ensuring the safe introduction of GE organisms, and arises from USDA's ample pre- and post-market authorities over products of agricultural biotechnology, including those products using innovative breeding tools.

Educational Background Q&A

What is biotechnology?

At its simplest, biotechnology is technology based on biology - biotechnology harnesses cellular and biomolecular processes to develop technologies and products that help improve our lives and the health of our planet. The use of biotechnology in food and agriculture has the potential to meet some of society's most urgent and pressing challenges, including climate change, sustainability, hunger and improving health and wellness. With the use of innovative new methods like gene editing, we can see improvements within a few years instead of over decades.

How does biotechnology compare to the kind of plant and animal breeding humans have been doing for centuries?

Humans have been making genetic improvements to economically important plants and animals for centuries, by selecting varieties found in nature with the most useful traits, and then breeding them together to create new and improved types. This slow cycle of selection and breeding gradually led to the creation of most of the economically important plants and animals we have today.

Biotechnology brings several improvements to the process of breeding, speeding up the process of making improvements and greatly diversifying the kinds of beneficial traits we can bring to plants and animals. Biotechnology methods developed in the 1990s allowed breeders to add new beneficial traits to plants that might not exist within the plant's own family. These "transgenic" plants are commonly referred to as "GMOs" (genetically modified organisms). Newer biotechnology methods like gene editing allow breeders to make very targeted modifications to a plant or animal's DNA in order to enhance existing traits or to significantly speed up the addition of traits that could have been created through other existing breeding methods.

What's the difference between "GMOs" and gene editing?

Gene editing, transgenic techniques (resulting in organisms commonly called "genetically modified organisms" or "GMOs"), and older, conventional kinds of breeding all create genetic changes to plants and animals. In many ways, biotechnology is on a continuum of genetic improvement techniques humans have been refining for centuries. Both the newer gene editing methods and the older transgenic methods are methods used to improve or strengthen a plant or animal, but there are some important distinctions between them. Unlike the process to develop a GMO, gene editing can allow us to work within the plant or animal's own gene pool (without the need to introduce DNA from outside the plant or animal's gene pool in the final product). This use of gene editing can reach the same endpoint as more traditional breeding methods, but in years, rather than decades. In many cases, the same changes made through gene editing could happen naturally through an evolutionary process.

BIO Q&A

What is BIO?

BIO is a big-tent organization representing biotechnology innovation across a variety of economic sectors. BIO is the home of biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than

30 other nations. BIO's vision is "a world where scientific innovations made possible through biotechnology conquer disease, sustain our environment, and advance nutrition and healthfulness." We achieve this vision by advancing innovation through sound public policy and collaborations and by staying true to six key drivers of biotechnology innovation success. See more information here.

What are the values that guide BIO's approach?

BIO members developing technologies and products for the food and farm innovation marketplace operate through the lens of core values. Our goals & strategies and the way we operate as an organization & a staff team are reflective of these values, which are:

- Advocacy rooted in science but with an understanding of consumer and marketplace trends
- Horizon scanning and commitment to the frontier of innovation
- Transparency, trust, and credibility
- Relationships and partnerships built on shared values and ideals
- Inclusivity and diversity
- Accountability, flexibility, and continuous improvement

Who are the members participating in BIO's food and farm innovation policy development?

BIO members participating in the food and farm innovation workstream include companies developing state-of-the-art biotechnologies and products used throughout the food, farm, and animal feed supply chain, from agricultural inputs to ingredient applications to whole foods, as well as ag and food tech investors.