

## USDA Modernizes Plant Biotechnology Regulations

On May 14, 2020, the U.S. Department of Agriculture (USDA) released a modernized, science-based regulatory system for plant biotechnology aimed at maintaining oversight while driving innovation.

BIO, overall, supports the USDA's final rule implementing its plant biotechnology regulatory system. USDA's updated regulatory approach builds on decades of scientific knowledge about biotechnology in food and agriculture.

Now government and industry must do more to build an informed and trust-based dialogue about biotechnology innovation in food and agriculture and its potential to achieve greater outcomes for the planet, our food system and human well-being.

### USDA's Modernized Approach

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USDA's update of its agricultural biotechnology regulations (7 CFR Part 340, aka "Part 340") represents the first major overhaul of U.S. regulation of plant biotechnology in more than twenty years, the culmination of a years-long effort to modernize USDA's regulatory system that began under previous administrations. USDA most recently published proposed regulations in both January 2017 and June of 2019, and the rule published on May 14 represents their finalization.

In the final rule, 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:

- New plants with crop-trait combinations USDA has already reviewed.
- 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 FDA or 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.

Most components of the final rule, including the exemption categories, become effective within 90 days. The new RSR process will begin to be implemented for a few crop species in April of 2021; the remainder of plant species can use the new process in October of 2021.

## BIO's Take

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BIO, overall, supports the USDA's final revisions to its plant biotechnology regulatory system. USDA has an excellent track record regulating plant biotechnology based on science and risk. The final rule acknowledges a history of safe use of plant biotechnology and the similarity of many gene edited plants to those derived from conventional breeding techniques.

Biotechnology is key to building more resilient food and farming systems. The COVID-19 crisis shows us the fragility of these systems and shines a bright light on the essential role of biology and technology in our lives. The rule will accelerate the development of innovations that will improve lives globally.

Innovation flourishes when science and consumer values are aligned and complement one another. The U.S. government's regulatory approach cannot exist in isolation. It should be supported by credible transparency measures. 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.

During the public comment period, BIO advocated for a process to improve public access to information about agricultural biotechnology products. In March 2020, BIO led a diverse group of stakeholders calling on the Administration to implement such a mechanism. While the final rule does not contain a mechanism for mandatory notification, BIO encourages increased openness about products entering the marketplace and best practices developers use in advancing beneficial products to the commercial marketplace.

## What's Next

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BIO will work closely with USDA, member companies, and stakeholders across the food supply chain to understand how the new regulations may affect them as the new regulatory system is implemented.

BIO will continue to drive a process to develop an inclusive and impactful approach to transparency for biotechnology in food and agriculture. We encourage agencies to articulate to the public the rationale for their approach, including how they approach their safety assessment for innovative technologies. As a part of the U.S. government's "Coordinated Framework," the FDA and EPA also play important roles in ensuring the safety of biotechnology in food and agriculture. BIO will continue to work with those agencies and encourage them to follow USDA's lead and modernize their regulatory programs as well.