Viewpoint: US regulators are not keeping up with lightning-fast advances in biotechnology. How can that gap be closed?

Improved crop genetics can help protect crops from pests and disease, reduce food waste, increase yields, limit deforestation, and decrease agricultural greenhouse gas emissions. Improvements in crop genetics have contributed roughly half of historical yield gains, and biotechnology is an increasingly important genetic tool used by developers to continue this success.

Biotechnology is accelerating improvement of specialty crops — most fruits, vegetables, and tree nuts — which have historically received less attention compared to commodities like corn and soy. Recent regulatory changes implemented by the US Biotechnology Regulatory Service (BRS) have reduced regulatory burdens and duplicative regulation faced by agricultural biotechnology companies. By streamlining gene editing regulation for crops, the SECURE Rule allows companies, as well as small developers like university labs and start-ups, to commercialize innovative products much faster.

But, these recent regulatory changes are just a first step. BRS must do more to support the use of crop biotechnology to improve US agriculture by further streamlining application review, clearing a backlog of applications, and keeping up with the increasing pace of submissions. Only with further improvements can BRS enable innovative developers to unlock the kinds of genetic breakthroughs capable of productivity and environmental improvements in a wider array of crop varieties.

Why do biotech crops matter and who regulates them?

Of all tools for crop genetic improvement, only biotechnology is subject to premarket regulation in the US. Three agencies have jurisdiction over different aspects of pre-market biotechnology regulation: USDA for plant health, FDA for food safety, and EPA for pesticides. Biotech crops are also subject to post-market regulations that protect farm workers, livestock, consumers, and the environment under the same three agencies.

The USDA Animal and Plant Health Inspection Service (APHIS) oversees regulations for some organisms developed using genetic engineering to ensure they do not pose a risk to plant health, which BRS then implements. USDA oversight is important to protect the health of both agricultural crops as well as wild plants in uncultivated areas. In addition, global trust in APHIS biotechnology regulation eases international trade of products of biotechnology produced in the US. For consumers, credible regulation by APHIS provides reassurance of the safety of biotech products.

APHIS published a final rule in May 2020 to update its biotechnology regulations under 7 CFR Part 340

for the Movement of Certain Genetically Engineered Organisms. The SECURE rule, as it's known, streamlined USDA biotech regulation by reducing application requirements and exempting some low-risk products of gene editing from oversight. The rule also set new target review timelines in which the agency should issue decisions for biotech product submissions. These range from 45 days for a permit for interstate movement or importation to 15 months for the second step of regulatory status reviews.

Developers of biotech crops must include various types of information and data for different regulatory submissions to APHIS. These submission types include regulatory status reviews (RSR), confirmation requests, and permit applications. Submissions to request a permit for interstate movement or importation are the simplest, requiring developers to provide information on the amount of material, genus and species, precautions taken to prevent release, and description of the intended genotype and phenotype.

Developer requests for RSRs are more intensive, requiring detailed information on the non-biotech comparator plant, the genetic change in the biotech plant, and the new traits of the biotech plant for an initial review, and whatever additional information APHIS requests for a subsequent full risk analysis.

The more data requirements, the more expensive for developers to prepare a submission. Submissions are required for every new biotech crop variety that does not fall within existing exemption categories. Recently, APHIS proposed five additional exemption categories for genetically modified plants that could be developed through conventional breeding.

Emerging trends under new and improved BRS regulations

All aspects of the new rule went into effect between August 2020 and October 2021. In the years since, BRS' implementation of the updated regulations has proved to increase both the number of applications submitted by small and medium sized biotech developers, and the diversity of plants and traits of focus.

At the end of 2023, BRS presented new data showing that the percentage of small and medium sized biotech product developers — compared to major biotech companies like Bayer — has increased under the new rule. These developers include Ohalo Genetics, Moolec Science, and the University of California, Davis.

BRS also presented data showing that, under the new rule, the agency received submissions for a wider diversity of plants and traits. Recent completed regulatory status reviews include potatoes with disease resistance and altered nutrition, teff that can withstand more wind without falling over, and walnuts with disease resistance. Exemption confirmations include blackberry, pennycress, citrus and sorghum, in addition to cotton, soybean, and corn.

Well before the US, Argentina was the first country in the world to exempt many gene edited crops from existing GMO regulations, and a study of the first 4 years after implementation showed similar outcomes to those BRS presented — with increases in submissions made by smaller developers and for a greater number of products.

Remaining barriers

Fast and reliable RSR and permit application reviews are crucial for biotechnology innovation. Since implementing the new rule, BRS has increased the efficiency and pace of its reviews for permit application and exemption confirmations. While completing RSRs, however, the agency continues to struggle with delays.

During FY2023, BRS regularly did not meet the review timeframes outlined in the new rule for RSR applications. The agency completed less than 20% of its RSRs within the set timeframe — 180 days and 15 months, respectively, for the first and second steps of RSR — leaving 80% of applications delayed in FY2023. The agency completed 21 initial reviews (compared to 3 in FY2022) and indicated there is currently a backlog of “less than 50” RSRs.

BRS has had more success meeting timeframes set in the new rule for processing confirmations — 120 days — and permit applications — 45 and 120 days for interstate movement or importation, and release into the environment, respectively. In FY2023, all confirmation requests were processed on time, and 10% of permit reviews were delayed. BRS should endeavor to maintain these low rates of delay across all of its regulatory reviews, including for RSRs.

Longer reviews make regulatory compliance expensive for developers, biasing participation toward large developers and commodity crops. The uncertainty associated with unreliable timelines disproportionately hurts small developers with few or no other products to rely on while awaiting a decision. When regulatory burdens are too much for small developers to shoulder, it limits the diversity of products reaching the market, stifling innovation and ultimately depriving farmers of important tools to fight pests and disease and increase productivity.

Next steps for BRS

Reducing the burden of premarket regulation for biotech crops supports a wider diversity of developers working with more varied traits and crop species. Further reduction in premarket regulation for biotech crop traits that present low plant pest risk should continue this diversification.

In addition to further relieving regulatory burdens, BRS must address the significant percentage of RSR applications experiencing delays, curtail backlogs, and keep pace with the increasing rate at which the agency is receiving applications. Congress will need to ensure consistent and reliable funding for APHIS and BRS to enable these improvements over the next several years. This will ensure the agency is equipped with the resources and staff with specialized expertise needed in order to complete reviews as expeditiously as possible and further minimize delays.

Emma Kovak is a senior Food and Agriculture Analyst at Breakthrough. Find Emma on X @EmmaKovak

Emily Bass is Federal Policy Manager for the Food and Agriculture program at Breakthrough. Find Emily on X @emilyjane_bass

A version of this article was originally posted at the Breakthrough Institute and is reposted here with permission. Any reposting should credit both the GLP and original article. The Breakthrough Institute can be found on X @TheBTI