BIO ISSUE BRIEF

FDA Guidance for Plant Biotechnology

Innovations in agricultural biotechnology, such as new gene-editing tools like CRISPR, are crucial to transforming agriculture and food systems. With biotechnology, America's farmers can sustainability increase production and resilience in the face of climate change, enhance America's food supply through more affordable and nutritious products for consumers, and boost economies by lowering the cost of production and creating jobs.

Bringing new plant biotech innovations to market, however, will depend on clear, science-based, and timely regulations from federal agencies. To maintain the United States as the global leader in biotechnology development, the U.S. Food and Drug Administration (FDA) must issue its draft guidance for plant biotechnology as expeditiously as possible.

Background

The FDA plays a critical role in the coordinated oversight of plant biotechnology. Beginning with the Obama Administration, and continuing through the Trump Administration, the U.S. Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the FDA took actions to modernize regulations for biotech plants.

- In May 2020, USDA released its final rule for biotechnologies at 7 CFR Part 340.
- In September 2020, EPA proposed its updates to the regulatory treatment of Plant-Incorporated Protectants (PIPs) developed using new technologies such as gene editing.
- FDA announced its plan to publish a draft guidance by 2019 as part of the Plant and Animal Biotechnology Innovation Action Plan in 2018. However, FDA has yet to take any public action.

FDA should promptly clarify the agency's approach to plants derived from these new techniques under its 1992 guidance on Foods Derived from New Plant Varieties. Further, the FDA should also address the timeliness of its reviews of biotech plants which have declined significantly in recent years.

Need for Resources to Advance FDA Guidance

To establish regulatory consistency, we urge Congress to provide FDA with the necessary resources to complete timely reviews of biotech plants and to issue clarifying guidance as expeditiously as possible.

FDA's guidance is needed to obtain a risk-appropriate system across domestic regulatory agencies. In the absence of the agency's guidance, beneficial biotechnologies cannot reach agricultural producers or consumers.