

# SEED:

## An Innovative Industry

Plant breeders have always strived to provide solutions to the new and emerging challenges facing farmers, consumers, and the environment. The continuous advancement in the understanding of plant genomes provides new opportunities to meet these challenges in a safe and sustainable way, both today and in the future.

To ensure that U.S. agriculture remains at the forefront of innovation and maintains its leadership role globally, government policies for plant breeding innovation must be clear, predictable, risk-proportionate, and based on the best available science.

Companies and universities are utilizing gene editing tools in research projects on important crops such as citrus, lettuce, wheat and soy. Appropriate policies can incentivize investments in plant breeding innovation, such as gene editing, creating new jobs and market opportunities, and boosting sustainability along the entire food value chain.

We encourage USDA, FDA and EPA to closely coordinate their activities to ensure a consistent regulatory approach across the U.S. government. We also urge the U.S. government to engage internationally to secure policy alignment and compatibility. ASTA and our partners at the International Seed Federation are working with regulatory authorities across the world towards this goal.

**Gene editing is the most recent breakthrough in a continuum of breeding methods that have been used to improve seeds and plants for centuries. These tools allow plant scientists to work more precisely and effectively, within the plant's own family, to reach the same endpoint as more traditional breeding methods.**



Founded in 1883, the American Seed Trade Association represents over 700 companies involved in seed production, plant breeding and related industries in North America. ASTA's broad membership offers varieties from alfalfa to zucchini and all production types including conventional, organic and biotech.

### LEARN MORE!

Join the conversation about innovation in food and agriculture, and what it means for the future of our planet, our health and food.

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# Federal Agency Action

**White House Office of Science and Technology Policy:** The OSTP has an important leadership role in ensuring the coordinated and consistent implementation of regulatory policies that are based on sound science. In prior administrations, the Agriculture Biotechnology Working Group, established under the leadership of OSTP, provided a mechanism for interagency coordination and collaboration in policy setting, implementation, and communication. The Working Group included representatives from the Office of Budget and Management, USDA, EPA, FDA, Department of State, and USTR.

- **ASTA Position:** ASTA urges OSTP to establish and lead an interagency working group on agriculture that brings together the various regulatory and trade agencies to ensure interagency actions on issues important to the agriculture community, including consistent implementation of domestic regulatory policy on emerging technology such as genome editing.

**U.S. Department of Agriculture (USDA):** On March 14, 2020, USDA published the Final Rule for its revision to the biotechnology regulations. Among other improvements, the Final Rule exempted certain applications of gene editing that are essentially equivalent to varieties developed through more traditional breeding method and established a process for regulatory statues review.

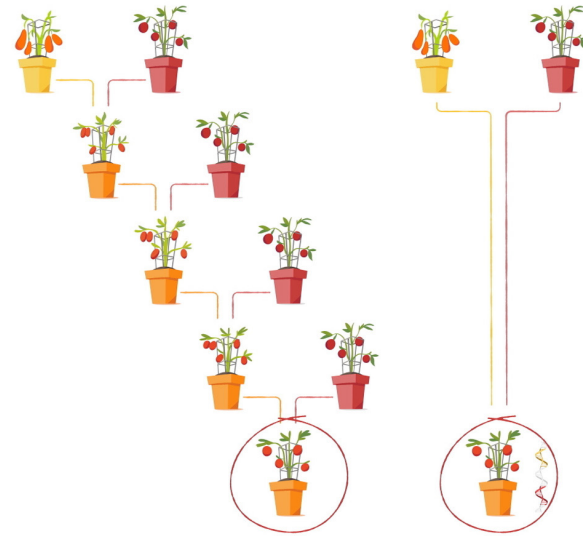
- **ASTA Position:** ASTA commends USDA for modernizing the biotechnology regulations to reflect its extensive regulatory experience and the best available science. ASTA urges USDA to consult with the plant breeding community in the implementation of the Final Rule to ensure that small and medium enterprises, as well as public sector scientists can equally benefit from the regulatory improvements.

**Food and Drug Administration (FDA):** FDA's 1992 policy statement provided guidance to developers for foods derived from new plant varieties as to when they should consult with FDA before a new plant variety is commercialized. In this guidance, FDA acknowledged the practices that plant breeders use to test their new plant varieties before seed is commercialized. On October 30, 2018, FDA released a Plant and Animal Biotechnology Innovation Action Plan in which it indicated that FDA would publish draft guidance for industry in early 2019 that explains its regulatory policy for foods derived from new plant varieties developed using gene editing.

- **ASTA Position:** ASTA urges FDA to publish guidance for foods derived from gene edited plants that is consistent with its 1992 policy statement.

**Environmental Protection Agency (EPA):** On December 9, 2020, EPA closed the public comment period to the Proposed Rule to exempt certain plant incorporated protectants (PIPs) developed through newer technologies. The Proposed Rule recognized the strong safety record of plant breeding, as well as the safety record of PIPs derived through conventional plant breeding currently exempted from EPA registration. Based on this safety record, EPA proposed to extend the conventional bred PIP exemption to those developed through biotechnology, though with certain criteria.

- **ASTA Position:** The EPA should consider the public comments to the proposed rule and revise the proposed exemption to be consistent in requirements and obligations with those of exempted conventionally bred PIPs.



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