

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 plant breeding innovation, such as genome editing, in research projects on important crops such as citrus, lettuce, wheat and soy. Appropriate policies can incentivize investments in plant breeding innovation, creating new jobs and market opportunities, and boosting sustainability along the agriculture and 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.

Genome editing is the most recent breakthrough in a continuum of breeding methods that have been used to improve seeds and plants for centuries. Plant breeding innovation allow plant scientists to work more precisely and effectively, within the plant's own family, to reach the same endpoint as older 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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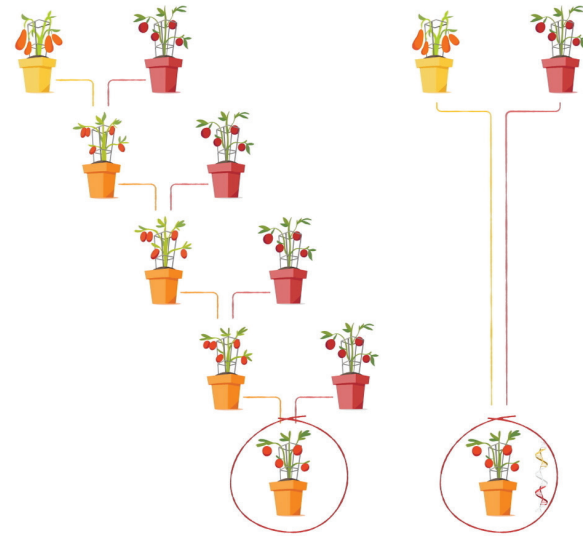
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Federal Agency Action

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 collaborative actions on issues important to the agriculture community, including consistent implementation of domestic regulatory policy on plant breeding innovation such as genome editing.**



U.S. Department of Agriculture (USDA): In 2020, USDA published the Final Rule revising its biotechnology regulation to include, among other things, exemption of certain applications of genome editing that resulted in plant varieties that could have been developed through older plant breeding methods. The implementation of the revised rule in the last few years has revealed the need for further refinement to achieve the policy goals of regulatory reform.

- **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 reflect and improve on regulatory implementation to expand access to small and medium enterprises and public sector researchers. This includes finalization of additional exemptions, and streamlining processes to reduce regulatory burden and inconsistencies.**

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 February 2024, FDA released Guidance for Industry, Foods Derived from Plants Produced Using Genome Editing, clarifying the applicability of its 1992 Statement of Policy: Foods Derived from New Plant Varieties. In the guidance, FDA views plant breeding innovation, such as genome editing, as a method with greater control compared to older approaches. It also reaffirmed that its approach to ensuring food safety with regards to new plant varieties are focused on the characteristics of the food regardless of the production process. Further, that premarket food safety review is not necessary due to the long history of safe food from new plant varieties developed through the plant breeding process. The guidance outlined two voluntarily processes for developers to inform FDA.

- **ASTA Position: ASTA commends FDA for releasing clarifying guidance, and urges FDA to engage with the plant breeding community in support of the development of new plant varieties.**

Environmental Protection Agency (EPA): In 2023, EPA published the Final Rule: Exemptions of Certain Plant-Incorporated Protectants (PIPs) Derived from Newer Technologies. The Final Rule created exemptions for PIPs created using genetic engineering, stipulated criteria to qualify for exemptions, and outlined procedures to notify and seek confirmation from EPA.

- **ASTA Position: The EPA Final Rule creates differential regulatory requirements for similar PIPs solely based on the method of development. ASTA urges EPA to engage with the plant breeding community and, in implementing the rule, to consider risk-proportionate regulatory oversight.**

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