

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.

In order to help 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, and science-and risk-based.

Small companies and universities have already begun to utilize gene editing tools in research projects on important crops such as citrus, lettuce, wheat and soy. With the appropriate policies in place, these projects can ultimately lead to new jobs and market opportunities 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 with other countries to secure as much alignment in regulatory approaches as possible. 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 develop more beneficial food for centuries. It can allow plant scientists to work within the plant's own family to reach the same endpoint as more traditional breeding methods, but in years instead of decades.



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

U.S. Department of Agriculture (USDA): On March 28, 2018 U.S. Secretary of Agriculture Sonny Perdue issued a statement providing clarification on USDA oversight of plants produced through innovative new breeding techniques including gene editing.

The statements says "Under its biotechnology regulations, USDA does not regulate or have any plans to regulate plants that could otherwise have been developed through traditional breeding techniques as long as they are not plant pests or developed using plant pests."

The proposal makes the strong argument that these products have genetic differences that can occur naturally or through long-standing more traditional breeding methods, and as such, they should be treated in the same way from a policy perspective.

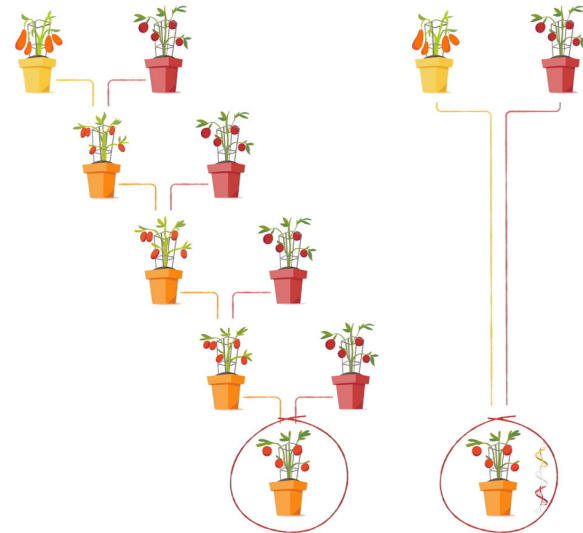
- **ASTA Position: ASTA is supportive of the USDA policy statement. ASTA urges USDA to formalize this policy by updating their existing regulatory framework known as Part 340 regulations.**

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: In 2019, FDA should publish guidance for gene edited plants that is consistent with its 1992 policy.**

Environmental Protection Agency (EPA): has consistently stated that its intent is to focus its regulatory efforts on Plant Incorporated Protectants (PIPs) to those plant defense mechanisms which may present novel, unknown and/or unfamiliar toxicological profiles and which incorporate a pesticidal substance. EPA further recognized the strong safety record of plant breeding in the United States. Based on this safety record, EPA exempted PIPs derived through conventional plant breeding from FIFRA regulations.

- **ASTA Position: The EPA should not regulate disease-resistant plants developed through gene editing as PIPs when they are or could have been developed through conventional breeding.**



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