

# EPA's New Plant Breeding Regulations Pose Major Setback for U.S. Economic, Environmental Sustainability

## 1 Threatens U.S. Competitiveness:

EPA's new rule on plant-incorporated protectants (PIPs) will regulate many common plant characteristics as pesticides, simply because gene editing was used in the breeding process. This policy causes identical plants to be regulated differently, based solely on the method used to create them, placing a higher burden on products of the latest precision breeding tool, gene editing. This policy disincentivizes using this Nobel Prize-winning U.S. invention and is out of step with a growing list of countries, including Argentina, Canada, Brazil, the United Kingdom, Japan and others, putting the U.S. at a strategic disadvantage.

### *U.S. vs. Canadian Biotech Regulatory Approach to Plants Created through Precision Breeding*

	Status	Biotech-specific Regulatory Cost	Biotech-specific Regulatory Phase
<b>U.S.</b>	Regulated Pesticide	Up to \$3M / edit	Up to 3 years
<b>Canada</b>	Not Regulated	None	None

## 2 Harms Small & Medium Sized Businesses:

By disproportionately impacting small and medium-sized entities —particularly in fruits, vegetables and other small acreage crops — the burdensome regulations will ensure that only the largest of companies can afford to develop innovative crops, driving additional industry consolidation and limiting the widespread benefits of these critical tools.

### *Case Study - Strawberries*



As much as 12% of berries can go bad before ever arriving at the grocery store; an additional 10-20% go bad while sitting on a grocery store shelf. That's a lot of food waste.

A unique variety of strawberries with a longer shelf life of approximately 15 days has the potential to dramatically reduce food waste and drive sustainability targets, while improving access to fresh nutritious fruits. However, due to its short fruit-bearing window, this variety is not commercially grown in the United States. This variety has the potential to reduce shipping waste from 12% to 2%, and grocer losses from 10-20% to 5%.

Some innovative family-owned companies are using precision breeding to make a single gene edit, modifying the strawberry’s own DNA — creating a food-waste-fighting variety that bears fruit all season long, making it commercially viable to grow this long-shelf-life berry. **But under EPA’s new policy, this berry faces unnecessary regulatory hurdles in getting to producers and the market.**

### 3 ) **Creates Non-Scientific Barriers, with No Added Safety Benefit:**

The rule creates differential treatment for the same or similar plant products due solely to the methods of development, creating a non-science-based system that discriminates against the latest precision breeding tools – even though EPA has stated the products are just as safe as their more traditionally-bred counterparts.

#### **ONE PLANT, THREE WAYS - DIFFERENT REGULATORY APPROACHES**

Developed in the mid-1940s-50s by Dr. Norman Borlaug and his colleagues, semi-dwarf wheat was a game-changer for global food security – increasing wheat yields and allowing developing nations to become more self-sufficient. Today, semi-dwarf wheat accounts for the vast majority of global acreage. The powerful impact of the semi-dwarf wheat breeding inspired the International Rice Research Institute’s semi-dwarf rice, thereby boosting food production in two of the world’s major food crops and elevating millions of farmers out of poverty.

#### *Case Study - Semi-Dwarf Wheat*



Method: <b>Conventional Breeding</b>	Method: <b>Mutagenesis</b>	Method: <b>Gene Editing</b>
No verification by EPA	No verification by EPA	PIP regulatory review

If similar genetic improvements had instead been created using more efficient gene editing tools, plant breeders would have to conduct years of additional research to prove that the changes they introduced already existed in wheat varieties elsewhere. Otherwise, the products would be subject to EPA regulation - simply due to the fact that gene editing, rather than an older form of plant breeding, was used to alter plant-growth regulators. The resulting years of regulatory assessments and millions of dollars in additional research and development costs, would very likely have prevented these life-saving varieties from ever reaching the market.

**The time is now for Congress to take action to ensure that U.S. agriculture can continue to innovate and respond to the environmental and crop production challenges faced by our farmers.**

We call on Congress to direct EPA to establish policy that is appropriately based on risk, treating plants the same way regardless of whether they are developed using precision breeding methods or solely through conventional breeding methods.