USDA APHIS’ Approach to Evaluating Modified Plants

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Genetic Engineering is One of Many Ways to Improve Plants
Not All Products of Biotechnology Are the Same

Change in Color

- Conventional Breeding
- Genetically Engineered

Change in Range

- Conventional Breeding
- Genetically Engineered
Goals for Regulatory Status Review

1. When a modified plant is understood and there is no pathway to risk, don’t regulate it.

2. When there is a scientifically plausible pathway to risk, regulate unless/until there is data that shows that risk is unlikely.
What We Do in the Evaluation

<table>
<thead>
<tr>
<th>Plausible Changes in GE Plant?</th>
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<tbody>
<tr>
<td>When, Where, and How the Plant Grows</td>
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**EXPOSURE**

**ADVERSE CONSEQUENCES**

**Plant Pest Risk Assessment**

Examines the factors of concern identified in the initial review
Danforth Center
Short Stature Teff

- Gene edited teff
- 3 gene edits to contribute to reduced plant height
- May use 1, 2, or all 3 of these edits
Biology of Unmodified Plants

- Lovegrass interbreeds with teff

Most of the conterminous US is suitable for teff, but it is grown in limited areas
  - Limited by cold and seed regeneration

Lovegrass occurs throughout the US
  - No climatic limits to occurrence

Neither plant is associated with plant pest risks, but lovegrass can be an agricultural weed

Photo Resources:
Plants.usda.gov
Mechanisms of Action—3 Genes made Nonfunctional

- Dwarfing1 (DW1)—brassinosteroid signalling
- Dwarfing3 (DW3)—auxin efflux transport
- Semidwarf1 (SD1)—gibberellin biosynthesis

Photo source: https://ricetoday.irri.org/indian-farmer-kick-starts-two-green-revolutions/
Review of Mechanisms of Action

- Experience with grasses since the 1930s or 1950s and in teff for two genes
- Affect signaling of 3 different plant hormones
- All result in shorter internode length
- One may affect leaf shape
- No other phenotypic effects described

Mechanisms of Action

- Semidwarf traits have been used in a variety of plants
- Agronomic performance may improve, but other changes not expected
- All 3 traits may lead to reduced competitive ability
  - May decrease fitness outside cultivation

Danforth Center
Short Stature Teff

No Expected Change in Occurrence

No Expected Change in Adverse Consequence

No plausible pathway to increased risk was identified

This modified teff is therefore not subject to regulation by 7 CFR part 340

Decision published on 3/31/2023
Different Stakeholders Engage with the RSR

### Petitions
- Major Biotech: 75%
- Small and medium size enterprise: 21%
- Public: 4%

**19 Crops Submitted 1992-2020**

### RSR
- Small and medium size enterprise: 80%
- Public: 13%
- Major Biotech: 7%

**33 Crops Submitted 2021-Present**
Plant and Trait Diversity is Increasing in RSR
APHIS BRS’ Regulatory Status Review

- Science-based and risk-proportionate regulatory review
- Enables wide participation in the regulatory process
- Greater pace and diversity of modified plants found not subject to our regulation
Thank You!