USDA APHIS' Approach to Evaluating Modified Plants

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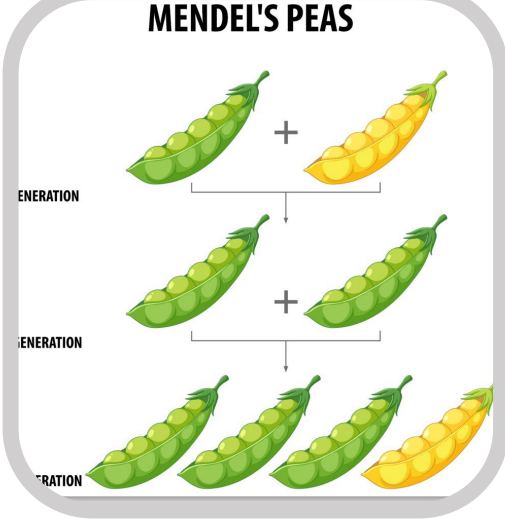
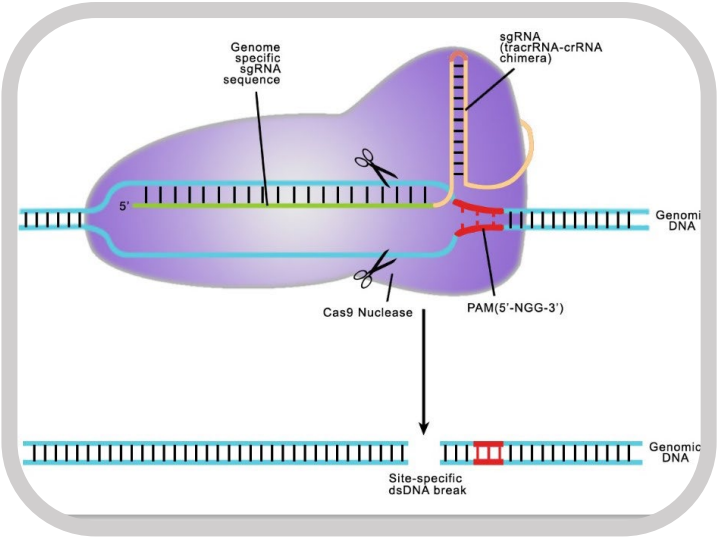
Genetic Engineering is One of Many Ways to Improve Plants





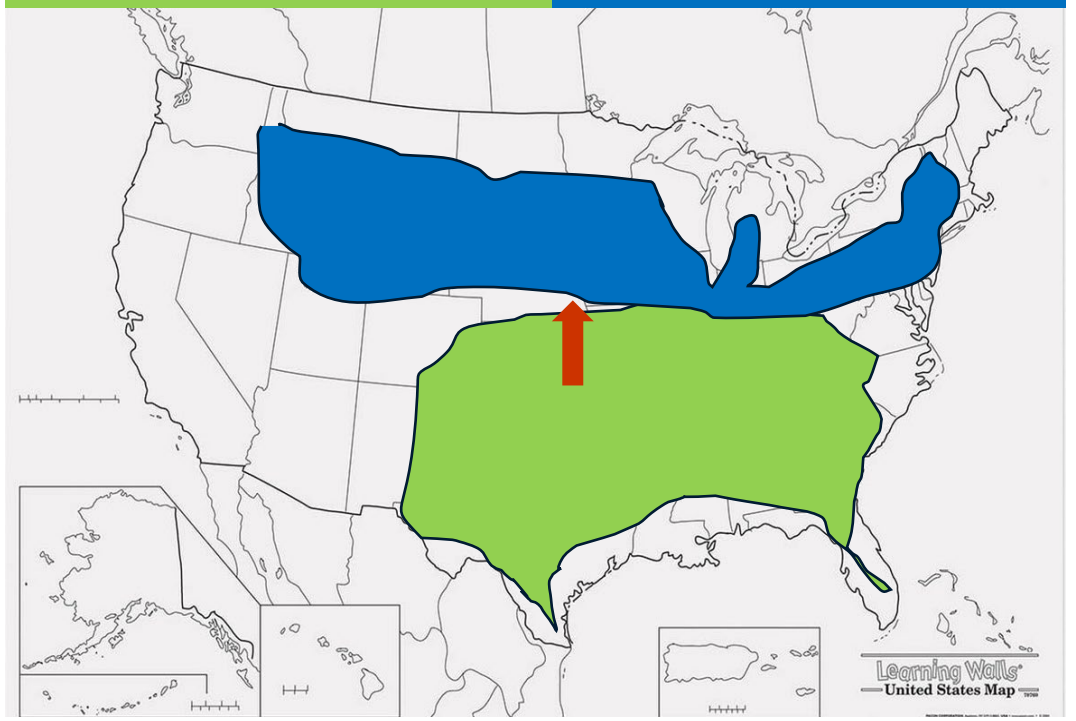
Not All Products of Biotechnology Are the Same

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

Plausible Changes in GE Plant?

When, Where, and How the Plant Grows	Plant Pest Impacts	Harm to non-target organisms beneficial to agriculture	Weedy impacts
EXPOSURE	ADVERSE CONSEQUENCES		

Plant Pest Risk Assessment

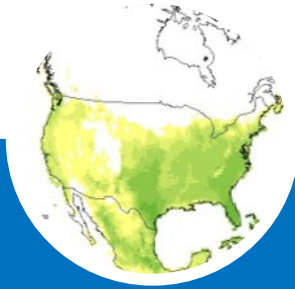
Examines the factors of concern identified in the initial review

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

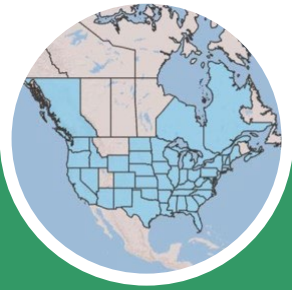
Biology of Unmodified Plants

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:
https://www.cabidigitallibrary.org/doi/full/10.1079/cabicompendium.21631#fv-image-114166
Plants.usda.gov

Mechanisms of Action—3 Genes made Nonfunctional

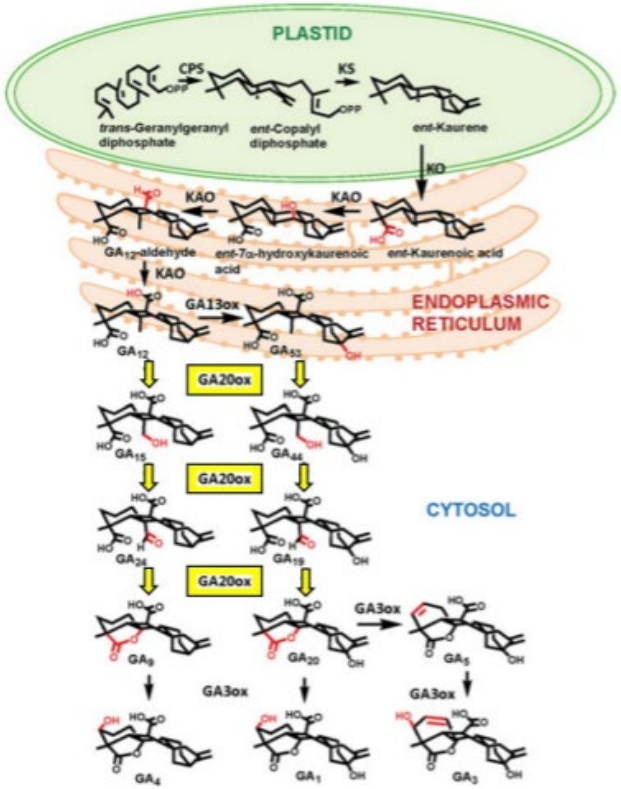
- Dwarfing1 (DW1)—brassinosteroid signalling
- Dwarfing3 (DW3)—auxin efflux transport
- Semidwarf1 (SD1)—gibberellin biosynthesis

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

MOA for the Green Revolution Dwarf Rice (SD1)



Picture credit: Hedden P and Thomas SG. 2012. *Gibberellin biosynthesis and its regulation.* Biochemical Journal 444, pp. 11-25. Retrieved from https://pubmed.ncbi.nlm.nih.gov/22533671/

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

https://www.danforthcenter.org/news/usda-clears-danforth-centers-genome-edited-teff/

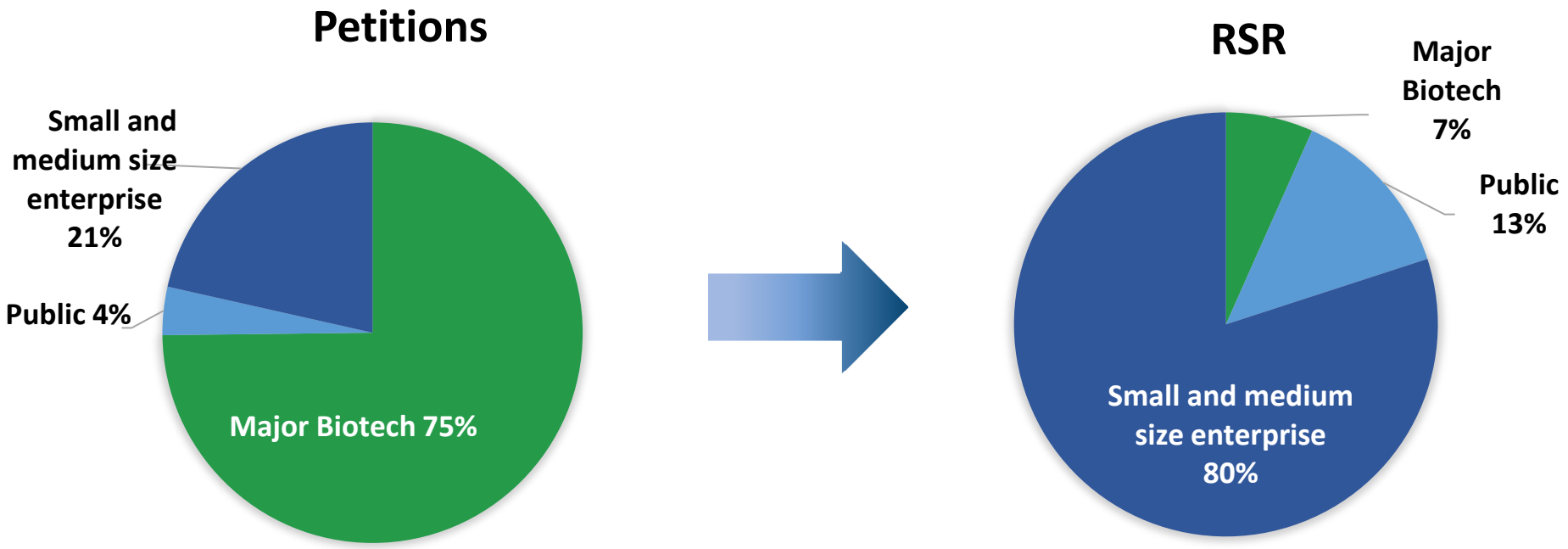
Danforth Center Short Stature Teff

No Expected Change in Occurrence X **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



19 Crops Submitted 1992-2020

33 Crops Submitted 2021-Present

Plant and Trait Diversity is Increasing in RSR


1 Purple Tomato


1 Tomato


1 Banana


4 Camelina


1 Blue Mum

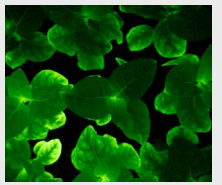

7 Corn


1 Cotton

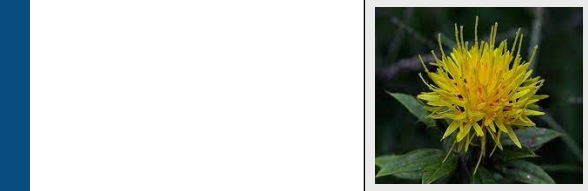
1 Hemp


1 Mustard


1 Pennycress


1 Glowing Petunia


5 Potatoes


1 Safflower


10 Soybean


1 Teff


1 Walnut

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!