



Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Case Studies of Modified Plants not Subject to the USDA Modernized Biotechnology Regulations—Purple Tomato

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The Role of USDA APHIS BRS



- Protects U.S. agriculture and agriculturally important natural resources (the environment) by regulating certain organisms developed using genetic engineering that may pose a plant pest risk.
- Plant Pest Risk: The potential for direct or indirect injury to, damage to, or disease in any plant or plant product resulting from introducing or disseminating a plant pest, or the potential for exacerbating the impact of a plant pest.

Basis of BRS Activities

- Authority: Plant Protection Act (PPA) of 2000
- Regulation: 7 CFR part 340 – Movement of Organisms Modified or Produced through Genetic Engineering
 - Updated May 14, 2020
 - ***Move (moving, movement).*** To carry, enter, import, mail, ship, or transport; aid, abet, cause, or induce the carrying, entering, importing, mailing, shipping, or transporting; to offer to carry, enter, import, mail, ship, or transport; to receive to carry, enter, import, mail, ship, or transport; to release into the environment; or to allow any of the above activities to occur.
 - ***Genetic engineering.*** Techniques that use recombinant, synthesized, or amplified nucleic acids to modify or create a genome.

Regulatory Status Review (RSR)

RSR evaluates plant pest risk based on:



The biological
properties of the
plant



The trait (or new
characteristic)



The mechanism of
action (or how the
developer caused
the new trait to
occur)

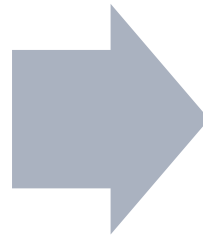
Regulatory Status Review (RSR)

The RSR is a two-step process:

1

Initial review problem formulation
to identify whether there are
plausible pathways to increased
plant pest risk

Complete in 180 Days

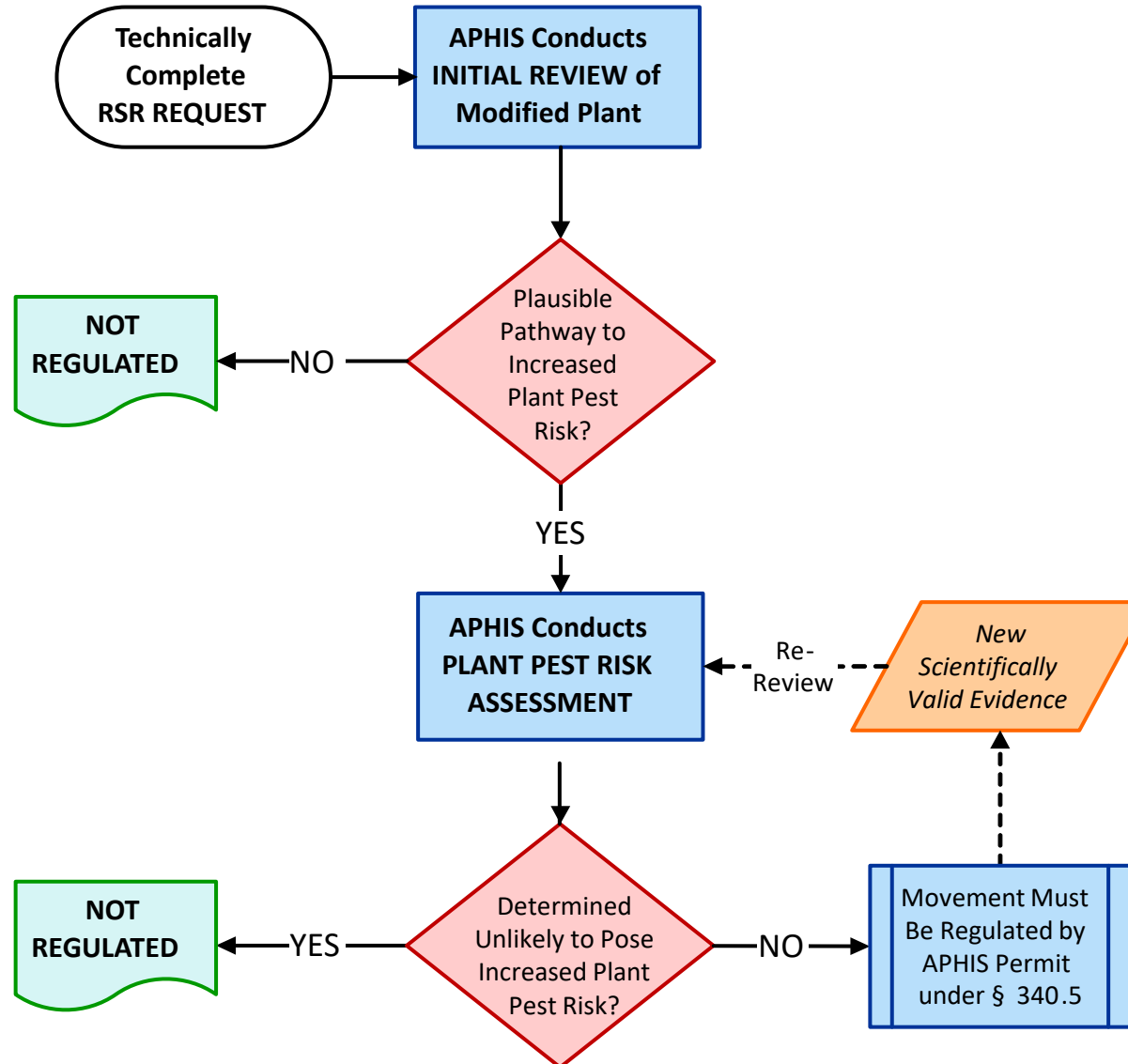


2

Plant Pest Risk Assessment (PPRA)
Determines likelihood and
consequence of any plausible
pathways in the initial review

**Full Evaluation Complete
within 15 Months**

The RSR Process



Plant Pest Risk in the RSR

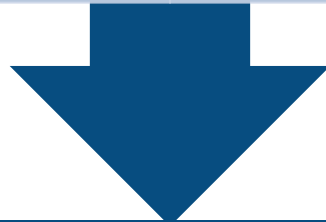
Initial Review identifies plausible changes in:

The distribution, density, or development of the plant and its sexually compatible relatives;

The production, creation, or enhancement of a plant pest or a reservoir for a plant pest;

Harm to non-target organisms beneficial to agriculture; and

The weedy impacts of the plant and its sexually compatible relatives.



Plant Pest Risk Assessment examines:

Likelihood and consequence of increased plant pest risk based on the factors of concern identified in the initial review.



Case Study: Purple Tomato 21-166-01rsr

- Norfolk Plant Sciences submitted a request for regulatory status review for transgenic tomato.
- 3 genes were inserted
 - *Del* and *Ros1* to increase anthocyanin production in fruit
 - *nptII* as an antibiotic resistance marker
- APHIS evaluated the potential for these changes in tomato or any species that could acquire the traits by outcrossing in the field to cause increased plant pest risk relative to the comparator.





Case Study: Purple Tomato 21-166-01rsr: Initial Review

Review of plant biology for *Solanum lycopersicum*

- No sexually compatible relatives present in the United States
- Occurs as a crop and volunteer
- Described biological properties related to occurrence
- Identified properties that, if changed, could affect occurrence
- No impacts related to plant pest risk were described





Case Study: Purple Tomato 21-166-01rsr: Initial Review

- Reviewed 1 Mechanism of Action related to anthocyanin production:
 - *Del* and *Ros1* from *Antirrhinum majus* worked together
 - Tomato *E8* promoter led to greatest expression in fruit
 - Linked to potential changes in biology due to changes in Propagule Dispersal, Propagule Longevity, and Ability to Withstand Pathogens and Herbivores
 - > None of these changes were expected to change the occurrence of tomato
 - Linked to potential changes in adverse consequence for beneficial non-target organisms and plant pest populations, but no pathways to increased plant pest risk were identified
 - > Biocontrol organisms do not rely on tomato pollen or fruit
 - > Pollinators are not highly affected by flavonoid compounds
 - > No pest organism where increased anthocyanin content in tomato would lead to higher pest pressure on other plants was identified





Case Study: Purple Tomato 21-166-01rsr: Initial Review

- Reviewed 1 Mechanism of Action related to antibiotic resistance marker:
 - *nptII* is a well-known marker gene with a long history of use
 - No linkages to changes in the biology of the plant
 - No linkages to changes in adverse consequences of the plant



Case Study: Purple Tomato 21-166-01rsr: Initial Review

Risk = Exposure x Adverse Consequence

No Expected Change in Exposure

The posited changes in plant biology are not expected to affect the occurrence pattern

No Expected Change in Adverse Consequence

Although flavonoids are known to affect NTOs and pests, these specific changes are not expected to alter risk

No plausible
pathway to
increased risk was
identified

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

Decision published
on 9/6/2022

Thank you!

