Overview of the Draft Guide for the Regulatory Status Review Process

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Background

- Revised 7 CFR § 340 published in May 2020
- The Regulatory Status Review (RSR) is described in 7 CFR § 340.4
- RSR began in April 2021 for 6 plants, available for all plants October 2021
- Draft Guidance is open for public comment until October 25, 2021

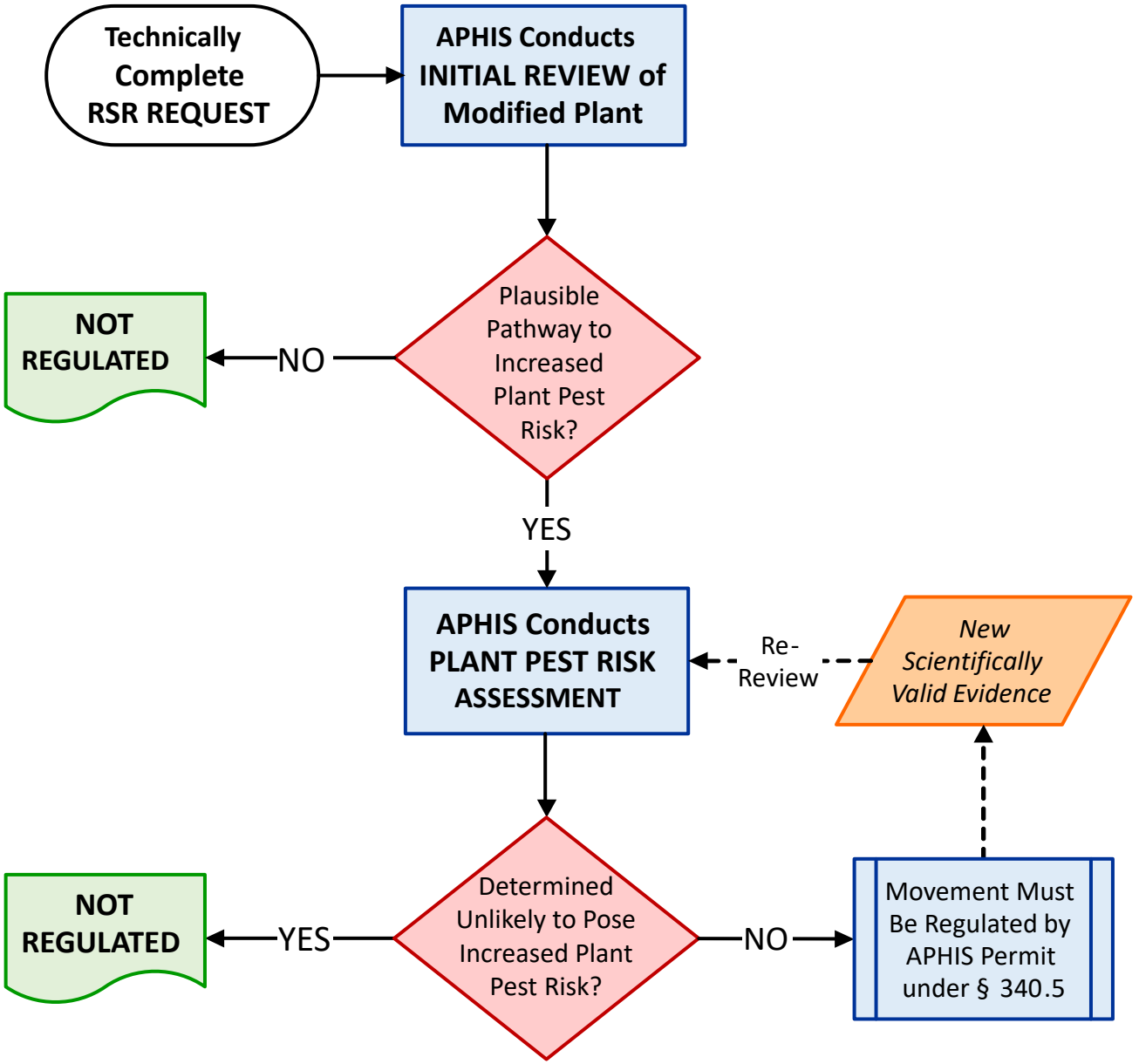
Regulatory Status Review (RSR)

- Evaluation of a modified **plant** to determine whether it falls within the scope of the regulations
- Not event specific
- Plants found not subject to the regulations; the same plant-trait-mechanism of action combination will qualify for regulatory exemption.
- We encourage consultation prior to submission

Regulatory Status Review (RSR)

- RSR evaluates plant pest risk based on:
  - the biological properties of the plant;
  - the trait (or new characteristic); and
  - the mechanism of action (or how the developer caused the new trait to occur).
- The RSR is a two-step process
  - Step 1: Initial Review
    - Problem formulation to identify whether there are plausible pathways to increased plant pest risk
  - Step 2: Plant Pest Risk Assessment (PPRA)
    - Determines likelihood and consequence of any plausible pathways in the initial review

The RSR Process



The RSR Process

Timelines:

- Initial Review –180 days after complete request received
- PPRA—15 months after complete request received
- Does not count any time process is paused by requestor

Postings:

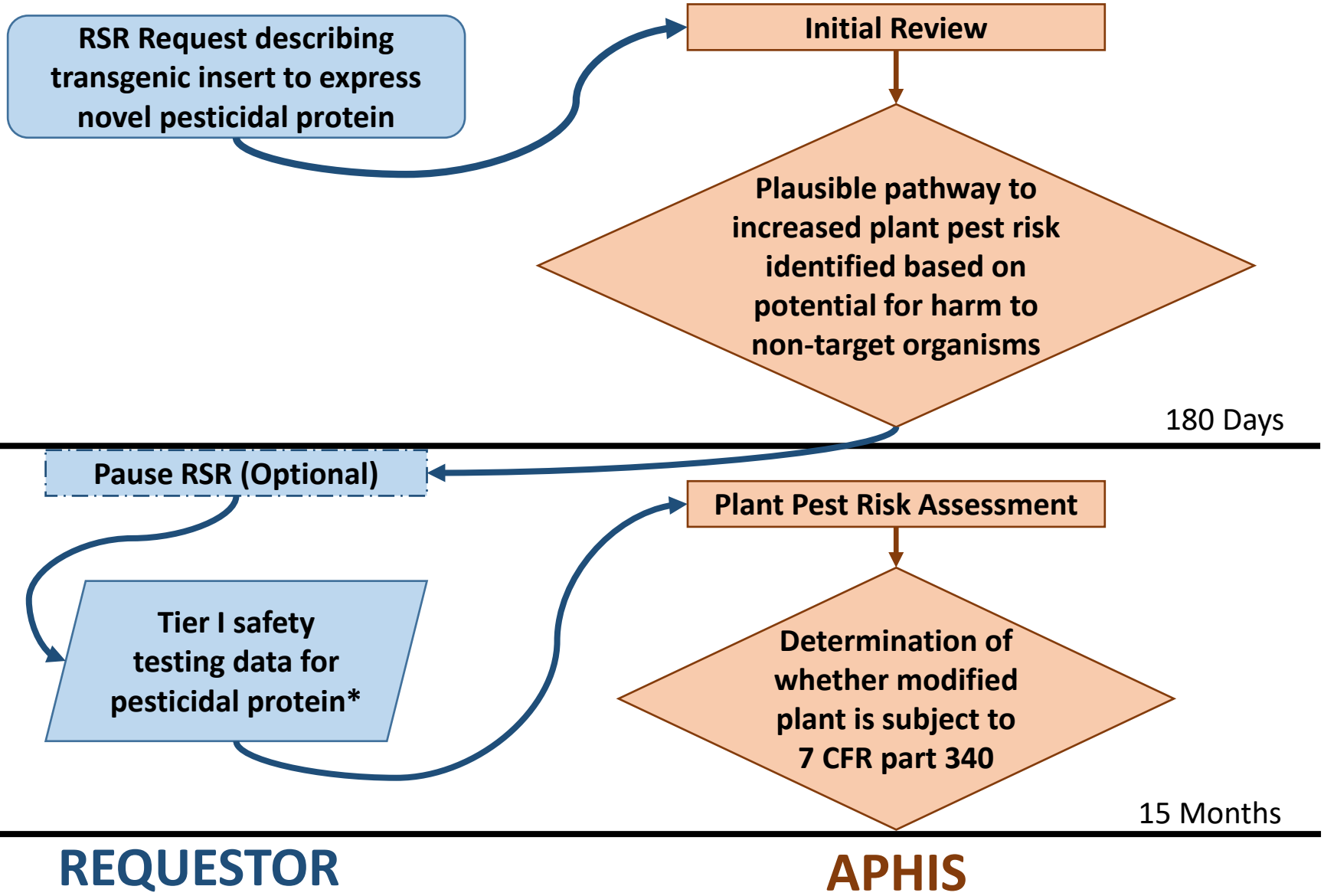
- Initial Review (no pathway identified): APHIS website
- PPRA: Federal Register (preliminary and final)
- Plant not subject to regulation: Plant-Trait-MOA table

Plant Pest Risk in the RSR

Risk = Exposure x Adverse Consequence

- 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.

Example—Insect Resistant Corn



RSR Submission Requirements

- Fully described in draft guidance
- Submissions and Questions
  - RSRRequests@usda.gov
- Personal Information & Contact Information
- Confidential Business Information (CBI) statement
  - CBI Submission Guidance: https://www.aphis.usda.gov/brs/pdf/CBI_Submission_Guidance.pdf
- Scientific name of plant

RSR Submission Requirements

Genotype of the modified plant

- Inserted material
  - Sequence of the insert in FASTA format
  - Publicly available reference numbers (when available) for each component
  - Annotation along with function description of inserted genetic material (component type, name, genetic donor, function, and base pair location)

RSR Submission Requirements

Genotype of the modified plant

- When genetic material is not inserted
  - Nature of modification
  - Sequence of modified region in FASTA format
  - Sequence alignment of modified region with unmodified region

RSR Submission Requirements

- Description of intended trait(s)
  - The observable characteristic that changes
- Description of intended phenotype(s)
  - The manifestation of the observable characteristic
- Description of Mechanism(s) of Action (MOA)
  - How will the modification affect the plant?
  - Include any expected changes in metabolism, physiology, and development due to the trait/genetic modification
  - The requestor may cite references in this section

Plant Pest Risk Analysis (PPRA)

- When plausible pathway(s) to plant pest risk are identified in the Initial Review, the requestor will be informed
- Requestor can choose to ask APHIS to proceed with PPRA
  - Process pauses in the interim
  - Consultation with BRS encouraged
- Optional data package should address only the factor(s) of concern identified in Initial Review
  - PPRA data package will vary
  - The PPRA data package should include the exact package, submitted at the initial review stage, followed by new information pertinent to the PPRA

For More Information

- RSR site:
  https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions
- View Draft Guidance for RSR:
  https://www.aphis.usda.gov/brs/pdf/rsr-guidance.pdf
- Comment on Draft Guidance (open until 10/25/21):
  https://www.regulations.gov/docket/APHIS-2021-0062
- APHIS BRS CBI Submission Guidance:
  https://www.aphis.usda.gov/brs/pdf/CBI_Submission_Guidance.pdf
- RSR Inbox:
  RSRRequests@usda.gov

Thank you!

Questions?