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# Regulatory Status Review (RSR)

Last Modified:



Developers have the option of requesting a regulatory status review of a plant developed using genetic engineering to determine whether the plant requires regulatory oversight.

When a developer requests a regulatory status review, APHIS evaluates whether the plant requires oversight based on the characteristics of the plant itself rather than

on the use of a plant pest in its development. If a plant developed using genetic engineering is found to be unlikely to pose a plant pest risk, APHIS will not require regulation under 7 CFR part 340. If APHIS is unable to reach such a finding, it will regulate the plant and it would be allowed to move only under permit. Once APHIS determines that a plant is not regulated, subsequent transformation events using the same plant-trait-mechanism of action combination would not be regulated.

This process replaces the petition process in the preexisting regulations. Under the legacy rule, developers could submit a petition requesting an agency determination that a plant developed using a plant pest is unlikely to pose a plant pest risk, and therefore, is no longer subject to APHIS' biotechnology regulations. The petition process was discontinued on October 1, 2021. See below for links to the petition table and petition resources.

### RSR Evaluations

Under the revised regulations, developers have the option of requesting a permit and/or a regulatory status review of a plant developed using genetic engineering that has not been previously evaluated and determined to be nonregulated. This process replaces the petition process in the preexisting regulations. When a developer requests a regulatory status review, APHIS evaluates whether the plant requires oversight based on the characteristics of the plant itself rather than on the use of a plant pest in its development. If a plant developed using genetic engineering is found to be unlikely to pose a plant pest risk, APHIS will not require regulation under 7 CFR part 340. If APHIS is unable to reach such a finding, it will regulate the plant and it would be allowed to move only under permit. Once APHIS determines that a plant is not regulated, subsequent transformation events using the same plant-trait-mechanism of action combination would not be regulated.

### **RSR evaluates plant pest risk based on**

- the biological properties of the plant; and
- the trait (or new characteristic); and
- the mechanism of action (or how the genetic modification causes the new trait to occur)

### **RSR will include one or two steps, depending upon the plant**

**STEP 1** (APHIS will complete Step 1 in 180 days)

Evaluate the characteristics of the plant developed using genetic engineering relative to an appropriate comparator plant to identify whether a plausible pathway to increased plant pest risk exists and the corresponding factors of concern.

- If APHIS **does not** identify a plausible pathway to increased plant pest risk, the plant is not subject to regulation.
- If APHIS **does** identify a plausible pathway to increased plant pest risk, the developer may:
  - elect to take no further action
  - request a permit to move the plant and/or perform field trials
  - request that APHIS complete the second step in the process

**NOTE:** A developer can request both a permit and that APHIS complete the second step in the process.

**STEP 2** (APHIS will complete its entire evaluation within 15 months)

Evaluate the identified factors of concern involving the plant developed using genetic engineering to determine the likelihood and consequence of the plausible increased plant pest risk.

- Publish the results of the evaluation in the *Federal Register*
- Solicit and review comments from the public
- If APHIS finds the plant is unlikely to pose an increased plant pest risk, the plant is not subject to the regulations
- If APHIS does not make such a finding, the plant will remain regulated

#### RSR Guidance and Resources

**[Final RSR Guide](#)** (548.41 KB)

- [Response to Comments: RSR Guide](#) (209.28 KB)
- [Table of RSR Requests and APHIS Responses](#)
- [Guide for Submitting Confidential Business Information](#) (492.34 KB)
- [Contact us about submitting a Regulatory Status Review](#)

#### Additional Resources

- [Learn more about the Revised Regulations](#)
- [Learn more about the Legacy Petition Process](#)

- [Learn More About the RSR Process in APHIS Biotechnology Regulations 340.4](#)

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