

United States
Department of
Agriculture



Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

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APHIS Guidance Regarding the Testing of Petunia Varieties

The Plant Protection Act gives the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) the authority to regulate genetically engineered (GE) organisms that may present a plant health risk, referred to as “regulated articles.” APHIS’ Biotechnology Regulatory Services (BRS) regulates the introduction—meaning the importation, interstate movement, and environmental release—of GE organisms that may pose a pest risk to plants under APHIS’ biotechnology regulations at 7 CFR part 340.

BRS is aware that GE petunia have been imported, distributed, and grown in the United States without appropriate authorization. GE petunias are regulated articles.

The following guidance applies to organizations that are voluntarily testing petunia varieties for the presence of genetic sequences from plant pests that may be regulated under 7 CFR part 340. Organizations should test for Cauliflower mosaic virus 35 S RNA promoter (35S P) and Nopaline synthase promoter/neomycin phosphotransferase II junction (PNOS/NPTII junction).

For varieties implicated as potentially being genetically engineered in APHIS Guidance Regarding the Destruction of Potential Genetically Engineered Petunias:¹

1. Letter of Attestation: Upon receipt of test results, send a letter of attestation indicating the variety or varieties submitted to a USDA validated third-party laboratory for genetic analysis. Send attestation letter and laboratory results via email to BRSCompliance@aphis.usda.gov. Subject line: Petunia Testing – *[insert company name]*.
 - a. Attestation letter (see attached template) should contain, at minimum:
 - i. The address of the submitting organization (e.g., breeder),
 - ii. A point of contact for the submitting organization,
 - iii. Name of validated laboratory conducting the testing,
 - iv. Address and contact information for laboratory,
 - v. Specific varieties of petunia submitted, and
 - vi. Any internal identifying number or code that identifies the specific stock or breeding line associated with the variety submitted for analysis AND sample numbers.

¹ The document is located at https://www.aphis.usda.gov/biotechnology/downloads/disposition_guidance_petunia.pdf. This is a “living” document and may change. Please check back for updates.

These numbers will be used for tracking /traceability purposes and must follow the sample throughout the entire testing process, e.g., samples from the company to the lab, results from the lab to the company, results from the company to USDA.

2. For USDA validation of laboratory, request the laboratory to submit to USDA – **Kira Metz at Kira.Metz@aphis.usda.gov and Eric Fang at Guang-Chen.Fang@aphis.usda.gov**
 - a. International Organization of Standards (ISO) accreditation/registration certificate(s),
 - b. 35S P and PNOS methods, controls, **and/or** validation reports of their methods, and
 - c. Any results from the most recent proficiency program the laboratory participated in.

For varieties not implicated as potentially being genetically engineered in APHIS Guidance Regarding the Destruction of Potential Genetically Engineered Petunias (see footnote 1):

The industry should voluntarily analyze other petunia varieties. If any other varieties test positive for genetic sequences from plant pests, the company should report results to the USDA using the above process (steps 1-2). In addition:

- o Provide the steps taken by the organization to ensure any variety that test positive for genetic engineering does not enter commerce (e.g., application of remedial actions described in the APHIS Guidance Regarding the Destruction of Potential Genetically Engineered Petunias (see footnote 1)).

USDA recommends prioritizing the analysis of the varieties implicated as possessing genetic sequences from plant pests listed in the APHIS Guidance Regarding the Destruction of Potential Genetically Engineered Petunias (see footnote 1). USDA seeks to confirm the regulatory status of these implicated varieties and will update its guidance (see footnote 1) as information becomes available.

For questions, contact BRS at (301)851-3935 or BRSCompliance@APHIS.USDA.gov



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