

Breadcrumb

1. [Home](#)
2. Print
3. Pdf
4. Node
5. Entity Print

# Biotechnology Permits

Last Modified:



APHIS regulates the importation, interstate movement, or environmental release (i.e., outdoor field trials) of certain organisms developed using genetic engineering (including plants, insects, and microbes) that may pose a plant pest risk.

Permit applications, which are carefully reviewed by APHIS regulatory scientists, provide details about the nature of the organism and the conditions that will be used to prevent the spread and establishment of the organism in the environment. A

permit may include additional conditions to help prevent unauthorized release into the environment.

## Permits Guidance and Resources

### Key Resources

- [Permit User Guide](#) (5.84 MB)
- [Guide for Submitting Confidential Business Information](#) (492.34 KB)
- [APHIS eFile Training Resources](#)

### Additional Guides

- [DRAFT Guide for Submitting Permit Applications for Microorganisms](#) (2.51 MB)
  - [Response to Comments](#) (299.66 KB)
- [Guide to Submitting Data for Reports and Notices in APHIS eFile](#) (748.02 KB)
  - [Response to Comments for Guide to Submitting Reports and Notices](#) (233.45 KB)
- [Guidance for Submission of Planting/Environmental Release Reports and Reports of No Planting /Release Submitted Via Email or Mail](#) (67.86 KB)
- [Guidance for Submission of Field Test Reports submitted via e-mail or mail](#) (64.53 KB)
- [Guidance for Submission of Volunteer Monitoring Reports submitted via e-mail or mail](#) (257.82 KB)
- [BRS User's Guide: General Document Preparation Guidelines for Submission to BRS](#) (150.13 KB)

### Additional Resources

- [SOP Template for APHIS BRS Plant Permits](#) (188.03 KB)
- [SOP Template for APHIS BRS Modified Microbe Movement Permits](#) (261.35 KB)
- [Q&As on Working with Modified Microorganisms](#)
- [Minimum Separation Distances to be used for Confined Field Tests of Certain Genetically Engineered Plants](#) (107.72 KB)
- [APHIS Recommendations for Best Management Practices for Authorized Field Trials of Regulated Herbicide-Resistant Crops](#) (85.8 KB)
- [List of Petunia Varieties](#) (148.41 KB)

## Download all BRS Permits and Notifications Data

- [Download all BRS Permit and Notification data from APHIS eFile in csv file](#) (1.62 MB)
- [Download all BRS Permit and Notification data from ePermits in csv file](#) (14.79 MB)

## Paper Application

[APHIS Form 2000](#) (67.52 KB)

**Mail to:** APHIS Biotechnology Regulatory Services, Permit Staff  
4700 River Road, 6th Floor, Unit 91  
Riverdale, MD 20737

## [Apply Online](#)

Regulatory Exemptions

Under the revised regulations, certain categories of modified plants are exempt from the regulations because they could otherwise have been developed through conventional breeding techniques and thus are unlikely to pose an increased plant pest risk compared to conventionally bred plants. These exemptions apply only to plants because the long history of plant breeding provides us extensive experience in safely managing associated plant pest risks. In addition, plants that have a plant-trait-mechanism of action combination that is the same as in a plant that has been determined by APHIS to be unlikely to pose a plant pest risk and therefore to be not regulated are exempt from the regulations

Developers can request a confirmation from APHIS that a modified plant qualifies for an exemption and is not subject to the regulations in 7 CFR part 340. This confirmation process replaces the preexisting “Am I Regulated?” (AIR) process. Previous AIR responses indicating nonregulated status of organisms are still considered valid exemptions from the new regulation for the particular requestor and specific plant(s).

- [Learn More About Regulatory Exemptions and Confirmations](#)
- [Learn More About the Revised Regulations](#)
- [Learn More About the Revised Regulations](#)

## Letter of No Permit Required

A permit is not required for the importation of interstate movement of most disarmed *Agrobacterium* strains or most *Drosophila melanogaster* developed using genetic engineering. In these instances, APHIS provides a “Letter of No Permit Required” to facilitate importation these organisms. Please refer to the guidance below for information on how to submit your request.

- [Letter of No Permit Required Submission Guide](#) (172.88 KB)
- [Submit a Request for a "Letter of No Permit Required"](#)

## Apply Online

On April 5, 2021, APHIS transitioned from ePermits to APHIS eFile. All applicants are required to use APHIS eFile to apply for permits for organisms developed using genetic engineering. Any applications submitted in the retired ePermits system through April 4, 2021, will complete processing in ePermits. Compliance reports related to these applications must also be submitted in ePermits. BRS will reject any applications submitted in ePermits on or after April 5, 2021.

- [Apply Online](#)
- [Learn More About APHIS eFile](#)

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