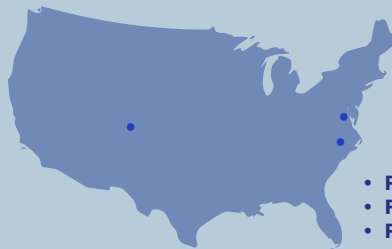**APHIS Biotechnology in Numbers**

Biotechnology

Through the Biotechnology Regulatory Services (BRS) program, the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) protects against risks to U.S. plant health by overseeing the safe import, interstate movement, and environmental release/field testing of certain organisms developed using genetic engineering. APHIS coordinates these responsibilities along with the other Federal agencies as part of the Federal Coordinated Framework for the Regulation of Biotechnology.

$15.9M
BUDGET

89
EMPLOYEES

WHERE WE WORK

- Riverdale, MD (APHIS Headquarters)
- Fort Collins, CO
- Raleigh, NC

FY 2021 Highlights

Fully implemented USDA's revised biotechnology regulations, which streamline and modernize our system, providing over **$8 million** in annual cost savings

Completed **6** petitions for nonregulated status, bringing the total number of determinations to **135**

Responded to **13** requests for confirmation that a plant met the criteria for exemption from regulation, resulting in **6** letters confirming exemption, issued in an average of **44** days from receiving a complete request

With APHIS' Plant Protection and Quarantine (PPQ) and States, performed more than **700** inspections of authorized field trials involving organisms developed using genetic engineering, with a **98%** rate of compliance

Processed over **750** authorizations in **48** States for nearly **100** different species of organisms for the movement or field testing of organisms developed using genetic engineering

Fully implemented APHIS eFile, processing over **300** authorizations in APHIS' new online permitting system

Published an Advanced Notice of Proposed Rulemaking for regulatory oversight of certain animals developed using genetic engineering, receiving over **51,000** written comments and conducting **68** one-on-one outreach meetings

Delivered more than **20** presentations to international stakeholders representing **9** countries to offer technical information and build capacity abroad for regulating biotechnology

Managed **16** Freedom of Information Act (FOIA) requests and released over **184,000** pages of records under FOIA, upholding our commitment to the public and transparency about biotechnology regulatory activities

Provided over **$74,000** in cooperative funding to universities and other partners for critical biotechnology work, including State inspections and protecting natural plant heritage

www.aphis.usda.gov/biotechnology

BIOTECHNOLOGY REGULATORY SERVICES

APHIS eFILE PROGRAM UPDATES

On April 5, 2021, the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) transitioned from ePermits to APHIS eFile. All applicants must 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. As of April 5, 2021, APHIS' Biotechnology Regulatory Services (BRS) no longer accepts applications submitted in ePermits.

FY21 Updates

- APHIS eFile fully released on April 5, 2021
- System aligned to updated 7 CFR part 340
- BRS Permitting Assistant available to public

Coming March 23, 2022

- Updated BRS application interface
- Enhanced PDF production
- Improved handling of large permit applications

CREATE YOUR ACCOUNT TODAY

- Visit efile.aphis.usda.gov.
- Register with your eAuthentication account.
- Submit your first application!

Contact Us
✉ efile.communications@usda.gov

ABOUT APHIS eFILE

The new APHIS eFile system allows applicants to submit APHIS form 2000 electronically—permits for the importation, interstate movement, and environmental release of organisms developed through genetic engineering that are plant pests or that pose plausible plant pest risks.

APHIS eFILE FEATURES

- **Applicant Portal**
  Personalized Applicant Portal provides easy and quick navigation.
- **Organization Accounts**
  Shared accounts enable team collaboration and management of applications.
- **Previously Submitted Constructs**
  Add construct records from previous applications.
- **Chatter**
  Communicate with APHIS reviewers online.
- **Permitting Assistant**
  Navigate revised 7 CFR part 340 regulations.
- **Revising Applications**
  Correct submissions easily.

APHIS eFILE
Required Fields for Location Records

*Bold indicates information required in the revised regulations

Movement	Origin Location	Origin + Destination Location	Destination Location	Environmental Release Location
Import	• Location Name • Country • **City** • **At Least 1 Agent***		• Location Name • Country • State • County • **Street Address** • **City** • **Zip Code** • Previously Inspected by APHIS • At Least 1 Material Record • **At Least 1 Agent***	
Interstate Movement	• Location Name • Country • State • County • **Street Address** • **City** • **Zip Code** • **At Least 1 Agent***	• Location Name • Country • State • County • **Street Address** • **City** • **Zip Code** • Previously Inspected by APHIS • At Least 1 Material Record • **At Least 1 Agent***	• Location Name • Country • State • County • **Street Address** • **City** • **Zip Code** • Previously Inspected by APHIS • At Least 1 Material Record • **At Least 1 Agent***	
Interstate Movement + Environmental Release	• Location Name • Country • State • County • **Street Address** • **City** • **Zip Code** • **At Least 1 Agent***	• Location Name • Country • State • County • **Street Address** • **City** • **Zip Code** • Previously Inspected by APHIS • At Least 1 Material Record • **At Least 1 Agent***	• Location Name • Country • State • County • **Street Address** • **City** • **Zip Code** • Previously Inspected by APHIS • At Least 1 Material Record • **At Least 1 Agent***	• Location Name • Country • State • County • **Street Address** • **City** • **Zip Code** • Location Unique ID • Number of Proposed Releases • Number of Acres • Critical Habitat Involved? • Release Site History • At Least 4 GPS Coordinate Sets • **At Least 1 Agent***
Release				• Location Name • Country • State • County • **Street Address** • **City** • **Zip Code** • Location Unique ID • Number of Proposed Releases • Number of Acres • Critical Habitat Involved? • Release Site History • At Least 4 GPS Coordinate Sets • **At Least 1 Agent***

*Title, First Name, Last Name, Phone Number, and Email Address are minimally required for Location Agents