Biotechnology Regulatory Services
Stakeholder Meeting Agenda

Check-in begins at 12:30 pm	
Welcome	**Doug McKalip** *Acting Communications Branch Chief*
Introduction	**Greg Ibach** *Under Secretary, USDA Marketing and Regulatory Programs*
BRS Update *Overview of BRS activities for FY 2019, and a look ahead to FY 2020 priorities and status of the SECURE Rule*	**Bernadette Juarez** *BRS Deputy Administrator*
Overview of Administration Biotechnology Activities *Status update on implementation of Executive Order 13874, highlights of biotechnology education and outreach efforts, and a summary of current trade topics impacting innovation*	**Fan-Li Chou** *Biotechnology Coordinator, USDA Office of the Chief Economist*
Oversight Update *Status update on FY19 compliance activities, including wheat incident response*	**Doug Grant** *Branch Chief, BRS Regulatory Operations Program*
APHIS eFile Update *Status update on the APHIS eFile pilot and next steps*	**Ibrahim Shaqir** *Management Analyst*
Confidential Business Information Review *Review on how to submit CBI*	**Maxine Ball** *Management Analyst*
Summary, Wrap-Up, and Mingling	**Doug McKalip** *Acting Communication Branch Chief*

USDA

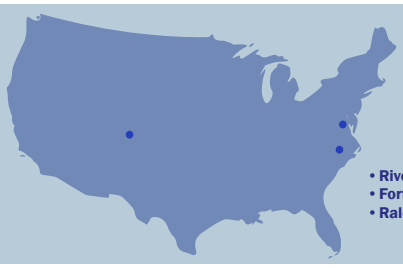
United States Department of Agriculture

Biotechnology

Through the Biotechnology Regulatory Services 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 genetically engineered (GE) organisms. APHIS coordinates these responsibilities along with the other designated Federal agencies as part of the Federal Coordinated Framework for the Regulation of Biotechnology.

$19M
BUDGET

82
EMPLOYEES



WHERE WE WORK

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

2019 Highlights

- Provided **$870,000** in cooperative funding to universities and other partners for critical biotechnology work, including State inspections, risk assessments, and protecting natural plant heritage
- With APHIS Plant Protection and Quarantine and States, conducted more than **600** safety inspections of authorized GE field trials to protect other crops
- Completed **53** virtual inspections of GE field trials
- Held **3** meetings or workshops for our stakeholders and regulated community to share information and guidance helping them understand how to follow our regulatory processes
- Completed **3** petitions for deregulation within time targets, bringing the cumulative number of deregulated products to **132**
- Delivered presentations to over **100** visitors representing **12** countries to offer technical information and build capacity abroad for regulating biotechnology
- Processed **1,486** permits and notifications for the import, interstate movement, or environmental release of regulated GE products
- Authorized **10,027** locations and **3,283** sites in **51** U.S. States and territories for the movement or field testing of GE products
- Converted **670,000** pages of notification and permit records from paper to electronic versions, allowing faster response to requests for FOIA (Freedom of Information Act) and administrative records

www.aphis.usda.gov/biotechnology

APHIS eFile Update

BRS Stakeholder Meeting

December 5, 2019

EFILE PROGRAM UPDATES

The BRS eFile team continues to **prioritize user experience** as it updates and improves the eFile system based on real-world feedback. Input from pilot participants has led to improvements in the XML schema and previously submitted constructs. As the pilot expands at the end of 2019 and into 2020, BRS and the regulated community will continue to collaborate to create a better online permitting experience.

eFile by the numbers…

76	Feedback items received
7	Applications' data available on BRS website [1]
4	Notifications acknowledged
1	Permit pending

JOIN THE EXPANDED EFILE PILOT!

Pilot Applicants…

- Can request multi-year permits
- Use the new organizational access feature
- Provide input so that BRS can improve the system

Join the eFile Pilot Today!

1. Request a PDF application from efile.communications@usda.gov
2. Complete the application then email it to efile.communications@usda.gov

STAKEHOLDERS OFTEN ASK:

Where can I access application data from eFile?

› The BRS Permits' Check Status page on aphis.usda.gov[1]

Who can apply to join the expanded pilot?

› Any applicants that have received at least one permit from BRS in ePermits

When will BRS fully switch to eFile?

› BRS will provide an updated full-release timeline in early Summer 2020

[1] https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/sa_permits/ct_status

For additional assistance, please email BRS at eFile.Communications@usda.gov.

USDA

Company Letterhead

CBI Copy

Each page should denote that the document contains CBI

Bernadette Juarez
APHIS Deputy Administrator
Biotechnology Regulatory Services
4700 River Rd, Unit 98 Riverdale,
MD 20737

Contains Confidential Business Information

Dear Ms. Juarez,

The following example document demonstrates proper formatting and composition of submissions containing Confidential Business Information (CBI) to Biotechnology Regulatory Services. Arranging content in this way ensures clarity and protection for an institution's CBI data.

This sentence gives background on the purpose of the communication without disclosing novel business methods, practices, or data. This sentence names and describes specific genotypes, phenotypes, donor organisms, gene names, gene descriptions and transformation methods to provide BRS with context needed for a decision or response. Square brackets should surround the CBI data to denote its sensitivity.

Publically available information is not eligible to be claimed as CBI. However, [trade secrets and information that is commercially valuable] may be claimed with the proper justification. This justification letter should be submitted along with the request, and should detail each category of information that was claimed, without revealing the data itself. A CBI deleted copy of the document should also be provided along with the submission. **CBI** **CBI**

For example, if [Gene ABC] is CBI and used in transformation of the organism, [Gene ABC] should be surrounded by brackets and not visible anywhere in the CBI deleted copy of the document. In the justification document, a submitter may describe why disclosure of genomic information is competitively or financially harmful without revealing the actual information that was enclosed in square brackets. **CBI, CBI**

For proper formatting of CBI Deleted or No CBI materials, please see the following pages.

Sincerely,

Your Name
Your Title
Your Address
Your Phone
Your Email

Please provide contact information for BRS to use in a response. This cannot be claimed as CBI.

Company Letterhead

CBI Deleted Copy

Each page should denote that the copy is CBI-Deleted

Bernadette Juarez
APHIS Deputy Administrator
Biotechnology Regulatory Services
4700 River Rd, Unit 98 Riverdale,
MD 20737

Confidential Business Information Deleted

Dear Ms. Juarez,

The following example document demonstrates proper formatting and composition of CBI Deleted documents that must be included with CBI submissions to Biotechnology Regulatory Services. This document should be identical to the confidential copy, but have all CBI replaced with blank space.

This sentence gives background on the purpose of the communication without disclosing novel business methods, practices, or data. This sentence names and describes specific genotypes, phenotypes, donor organisms, gene names, gene descriptions and transformation methods to provide BRS with context needed for a decision or response. Square brackets should surround the CBI data to denote its sensitivity.

Publically available information is not eligible to be claimed as CBI. However, [ ] may be claimed with the proper justification. This justification letter should be submitted along with the request, and should detail each category of information that was claimed, without revealing the data itself. A CBI deleted copy of the document should also be provided along with the submission.

CBI-Deleted
CBI-Deleted

For example, if [ ] is CBI and used in transformation of the organism, [ ] should be surrounded by brackets and not visible anywhere in the CBI deleted copy of the document. In the justification document, a submitter may describe why disclosure of genomic information is competitively or financially harmful without revealing the actual information that was enclosed in square brackets.

CBI-Deleted, CBI-Deleted

For proper formatting of CBI documents, please see the previous page. A No CBI example follows.

Sincerely,

Your Name
Your Title
Your Address
Your Phone
Your Email

Contact information may not be claimed as CBI, but is often protected by FOIA as Personally Identifiable Information.

Company Letterhead

No CBI

Heading is optional if first page clearly denotes No CBI

Bernadette Juarez
APHIS Deputy Administrator
Biotechnology Regulatory Services
4700 River Rd, Unit 98 Riverdale,
MD 20737

Does Not Contain Confidential Business Information

Dear Ms. Juarez,

The following example document demonstrates proper formatting and composition of submissions that do not contain Confidential Business Information to Biotechnology Regulatory Services. Arranging content in this way ensures clarity that the document does not contain sensitive CBI data.

This sentence gives background on the purpose of the communication without disclosing novel business methods, practices, or data. This sentence names and describes information (that the institution does not consider financially harmful) to provide BRS with context needed for a decision or response. Square brackets should not be included anywhere in the document.

No information in this document should be considered CBI. A justification document is not required with the submission, and no CBI-deleted copy is necessary.

For example, if Gene ABC is not considered to be novel, proprietary, or secret, Gene ABC should not be surrounded by brackets. Regardless of whether a document is marked as containing CBI, BRS and APHIS FOIA routinely allow submitters to conduct a "Second Bite of the Apple" review prior to any public disclosure of the materials. Submitters have a second opportunity to review the document for justifiable claims of CBI at that time.

For proper formatting of CBI and CBI-deleted documents, please see the previous pages.

Sincerely,

Your Name
Your Title
Your Address
Your Phone
Your Email

Despite No CBI in the document, contact info may still be protected under FOIA as Personally Identifiable Information.