Biotechnology Regulatory Services

Stakeholder Meeting

November 18, 2021

Welcome

Alan Pearson

Assistant Deputy Administrator

Animal and Plant Health Inspection Service (APHIS)

Biotechnology Regulatory Services (BRS)

November 18, 2021

Agenda

1. BRS Quick Recap of FY 21 Focus for FY 22
2. Biotechnology Risk Assessment Programs Update
3. Compliance and Inspection Update
4. APHIS eFile Update
5. Q&A

6. International Engagement
7. Departmental Updates
8. Q&A
9. Closing Remarks
10. Break
11. APHIS eFile Breakout Session *(Optional)*

Deputy Administrator Update

Bernadette Juarez

Deputy Administrator

Animal and Plant Health Inspection Service (APHIS)

Biotechnology Regulatory Services (BRS)

November 18, 2021

FY2021 Rapid Recap

- Past

- Present

- Future

FY2022 USDA Priorities

- Addressing Climate Change via Climate Smart Agriculture and Forestry*

- Advancing Racial Justice, Equity and Opportunity

- Creating More and Better Market Opportunities

- Tackling Food and Nutrition Insecurity

- Making USDA a Great Place to Work for Everyone

FY2022 BRS Priorities

- Safe return to offices

- Continued implementation of revised regulations
  - Proposal to expand exemptions
  - Litigation

- Biotechnology Quality Management System (BQMS) Update

- Animal biotechnology

Biotechnology Risk Analysis Programs Update

Subray Hegde

Director, Biotechnology Risk Analysis Programs (BRAP)
Animal and Plant Health Inspection Service (APHIS)
Biotechnology Regulatory Services (BRS)
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FY21 Accomplishments

- APHIS BRS made determinations on six petitions

  - Monsanto insect (Lygus) protected cotton
  - Westhoff orange-colored petunia
  - Pioneer enhanced yield maize
  - Pioneer SPTA (seed production technology for Africa) maize
  - Agrivida phytase maize
  - Okanagan non-browning apple

Confirmation Requests

- Received 24 requests

- Completed 13 total and confirmed 7 (all posted to website)

- 11 remain in the queue

Authorizations
(October 1, 2020, through Sept 30, 2021)

- Processed 754 authorizations

  - 450 authorizations through ePermits
  - 304 authorizations in APHIS eFile

Regulatory Status Review (RSR) Guidance

- Published Draft RSR Guidance for Review

- September 28, 2021, webinar presentation to stakeholders on draft RSR guidance

  - 177 unique attendees and the recording of Q&A will be available soon on the APHIS website

Public Comments on the Draft RSR Guidance
(Comment period closed on October 25, 2021)

- Number of unique comments: 9

  - Requests for publication of the RSR risk evaluation model

  - Suggestion for handling PIPs

  - Concern that RSR is focused too broadly and will overregulate

  - Concern that RSR is focused too narrowly and will miss risk

  - Clarification about information/data requirement

  - Concern regarding handling of CBI

  - Clarification about NEPA analysis in RSR

Update on Confirmation Request (CR) Process

- Working to revise CR guidance

- Updating CR FAQs

- Tracking internal steps to monitor efficiency
  - Currently averaging 45 days to send a decision after receiving a sufficiently detailed request

Guidance on Permits

- Revising to reflect revised regulatory requirements and the capabilities of our new permitting system – APHIS eFile

- Developing an optional template for Standard Operating Procedures (SOP)
  - SOP replaces the design protocol requirement to guide developers with providing containment information, shipment, research, and field trial details

Supplemental Permit Conditions (SPCs) Updates

- **Updated to align with the revised regulation and improve clarity, such as:**

  - Regulated article -> modified organism, regulated organism or regulated material

  - References to renewals removed
    - "New authorization" used when appropriate for discussion of continuing a planted field trial

  - Removed variance references to align with revised regulatory shipping requirements

  - Responsible person(s) and their agents -> Permittee/Permit holder

SPC Updates

- Report name changes:

  - Planting Report -> Environmental Release Report

  - Planting unique ID -> Environmental Release ID

  - Field Test Report -> Final Environmental Release Report

FY22 Focus

- Develop a guidance for microbial permits

- Continue reviewing pending petitions, CRs, and RSRs

Questions? Comments?

Deshui Zhang (Permit and CR),
deshui.zhang@usda.gov; 301-851-3913

Suma Chakravarthy (RSR),
suma.chakravarthy@usda.gov; 301-851-3897

Martha Malapi-Wight (Microbial Permit),
martha.m.wight@usda.gov; 301-851-3874

FY 2021 Compliance and Inspection Updates

Douglas Grant

Director, Regulatory Operations Programs (ROP)

Phil Mason

Chief, Western Compliance Assurance Branch

Biotechnology Regulatory Services (BRS)

Animal and Plant Health Inspection Service (APHIS)
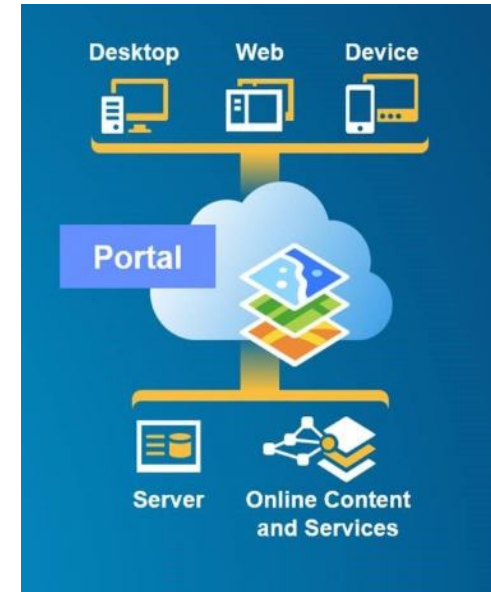
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FY 2021 ROP ConOps and Projects

- Carefully tracking authorizations in different permitting systems to ensure appropriate compliance oversight

- Reduced hand-offs and time-in-process for compliance determinations to improve timeliness of any necessary corrective action

- Engaged stakeholders to resolve issues and answer questions

FY 2021 ROP ConOps and Projects

- Continued virtual inspections during pandemic

  - Known as Monitoring and Evaluation Interviews (MEIs)

  - Document exchange of trial records and photos

  - Video conferencing technology for remote visualization

  - Remote sensing to support trial site compliance analysis
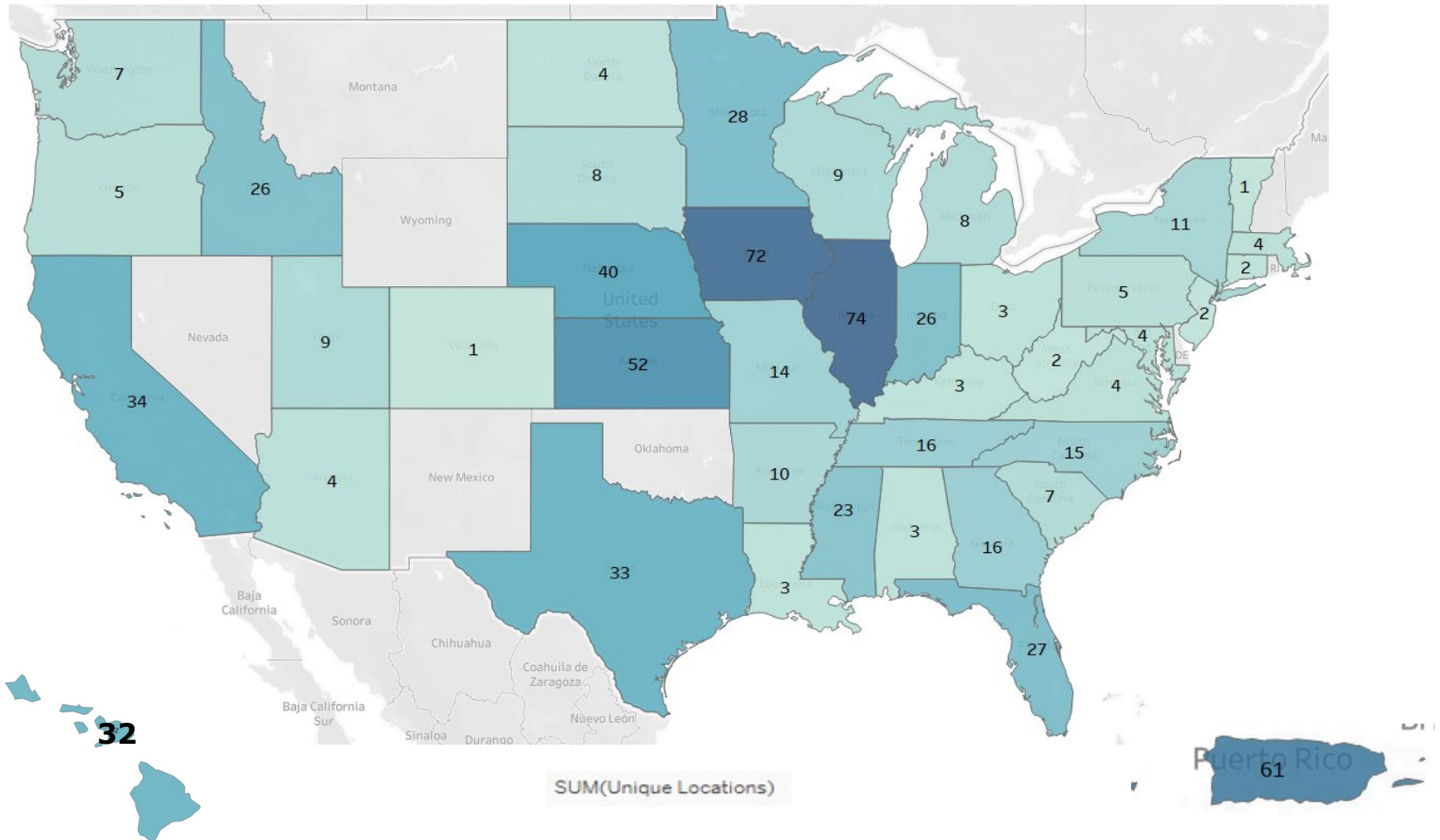
Use of Remote Sensing and GIS

- Analyze geospatial data gathered from applicants and inspections
  - Mapping GPS coordinates
- Remote Sensing
  - Select best image dates to support compliance inspections
  - Provides further context to assess observations from virtual inspections

FY 21 Conducted Inspections
Total = 708

% of Inspections Conducted By Organization

FY 19-21

FY	BRS	PPQ	State
19	68.5%	25.2%	6.3%
20	95.6%	3.9%	0.5%
21	86.4%	11.0%	2.6%

FY 21 BRS Inspections by Quarter

Quarter	New	Cumulative
1	165	165
2	97	262
3	158	420
4	288	708

Resumption of In-Person Inspections

- In-Person Inspections in FY 21:
  - 82 of 708 (11.6%)
    - BRS: 42
    - PPQ: 22
    - States: 18

- Resumed in Q3 after travel restrictions eased

- Focused on higher risk trials (PMPIs, species with higher likelihood of persistence, trials with compliance issues)

- Will continue using both virtual and in-person inspections to evaluate compliance in FY 2022

Compliance Inspection Outcomes

- Compliance Rates:
  - FY 20 – 95%
  - FY 21 – 98%

- Notices sent in FY 21:
  - Trial Compliant: 98.12%
  - Trial Non-compliant: 1.72%
  - Other outcomes: 0.16%

Compliance Trends

- Most Common Non-Compliances in FY 21:

  - Late or missing reports (PPR/FTR): 45

  - Failure to comply with Supplemental Permit Conditions: 17

  - Failure to comply with Standard Permit Conditions: 6

  - Release in areas or quantities not authorized: 8

  - Failure to timely obtain or maintain authorization: 8

  - Other: 32

  - Total: 116

FY 2022 ROP Projects

- Developing guide for submitting required reports and notices

- Integrate compliance database components into APHIS eFile

- Update BRS Inspection Manual to align with new worksheets, SPCs, and revised regulations

- GIS Dashboards to inform decision making

Contact BRS ROP Team

**Need support?
Questions?
Comments?**

- Nate Yates, Compliance Evaluation and Enforcement Branch
  nathaniel.j.yates@usda.gov; 240-499-6542

- Christie Bertone, Eastern Compliance Assurance Branch,
  christie.a.bertone@usda.gov; 919-855-7622

- Phil Mason, Western Compliance Assurance Branch,
  phillip.a.mason@usda.gov; 970-390-9000

BRSCompliance@usda.gov

Agenda

- FY2021 Updates
- FY2022 Enhancements Overview

- Breakout Session:
  - BRS Permitting Assistant Demo
  - FY2022 System Enhancements
  - Upcoming Location Requirements

FY2021 Updates

- On April 5, 2021, BRS transitioned all new applications to APHIS eFile system
  - ePermits remains open for compliance report submissions and accessing records

- Applicant Guides to APHIS eFile are available:
  - APHIS eFile: https://efile.aphis.usda.gov/
  - Help > Training

FY2021 Updates

- BRS implemented several system changes in accordance with revised 7 CFR part 340 regulations:

  - Notifications discontinued

  - Terminology aligned

  - Required information adjusted

  - Review process updated

FY2021 Updates

▪ BRS Permitting Assistant released

- Interactive tool improves navigating revised 7 CFR part 340 regulations

- Displays whether a permit is required based on user input

- Indicates *possible* eligibility for Exemption or option for Regulatory Status Review

FY2022 Enhancements Overview

- Exciting updates to APHIS eFile system are coming:

  - BRS application interface streamlined
  - PDF generation improvements
  - System improvements to process large data

- Late March 2022!

Thank You!

APHIS eFile Homepage:
https://efile.aphis.usda.gov/

BRS eFile Helpdesk:
BRS.eFile@usda.gov

USDA eAuthentication:
https://www.eauth.usda.gov/

International Collaboration

Jessica Mahalingappa

Associate Deputy Administrator

Animal and Plant Health Inspection Service (APHIS)

Biotechnology Regulatory Services (BRS)

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FY2021 Successes

- BRS hosted or participated in over 20 international engagements

- Collaborated with international organizations

- Bilaterals and trilaterals with Canada, Mexico, Korea, Spain, Portugal, UK, EU, and Brazil

- Developed an international strategy

International Strategy

Three main goals:

1. Provide assurance of the credibility of BRS' regulations and regulatory processes internationally

2. Build capacity in other countries for regulating agricultural organisms developed using genetic engineering

3. Promote harmonization in risk-based approaches to agricultural biotechnology regulatory systems globally

International Strategy

- Continue to engage with international regulators

- Continue to provide technical assistance to trade agencies to safeguard trade and minimize disruptions, as needed

- Continue to participate in engagements through international organizations
  - Organization for Economic Cooperation and Development (OECD)
  - Inter-American Institute for Cooperation on Agriculture (IICA)
  - Asia-Pacific Economic Cooperation (APEC)
  - World Trade Organization (WTO)

International Strategy

- Continue to engage internationally through bilateral and trilateral meetings
  - Canada/Mexico, Korea, and Japan

- Bolster international engagements by identifying additional economies to target for outreach

Thank You!

Questions?
Comments?
Feedback?

jessica.s.mahalingappa@usda.gov

Departmental Updates

Anastasia Bodnar

USDA Biotechnology Coordinator

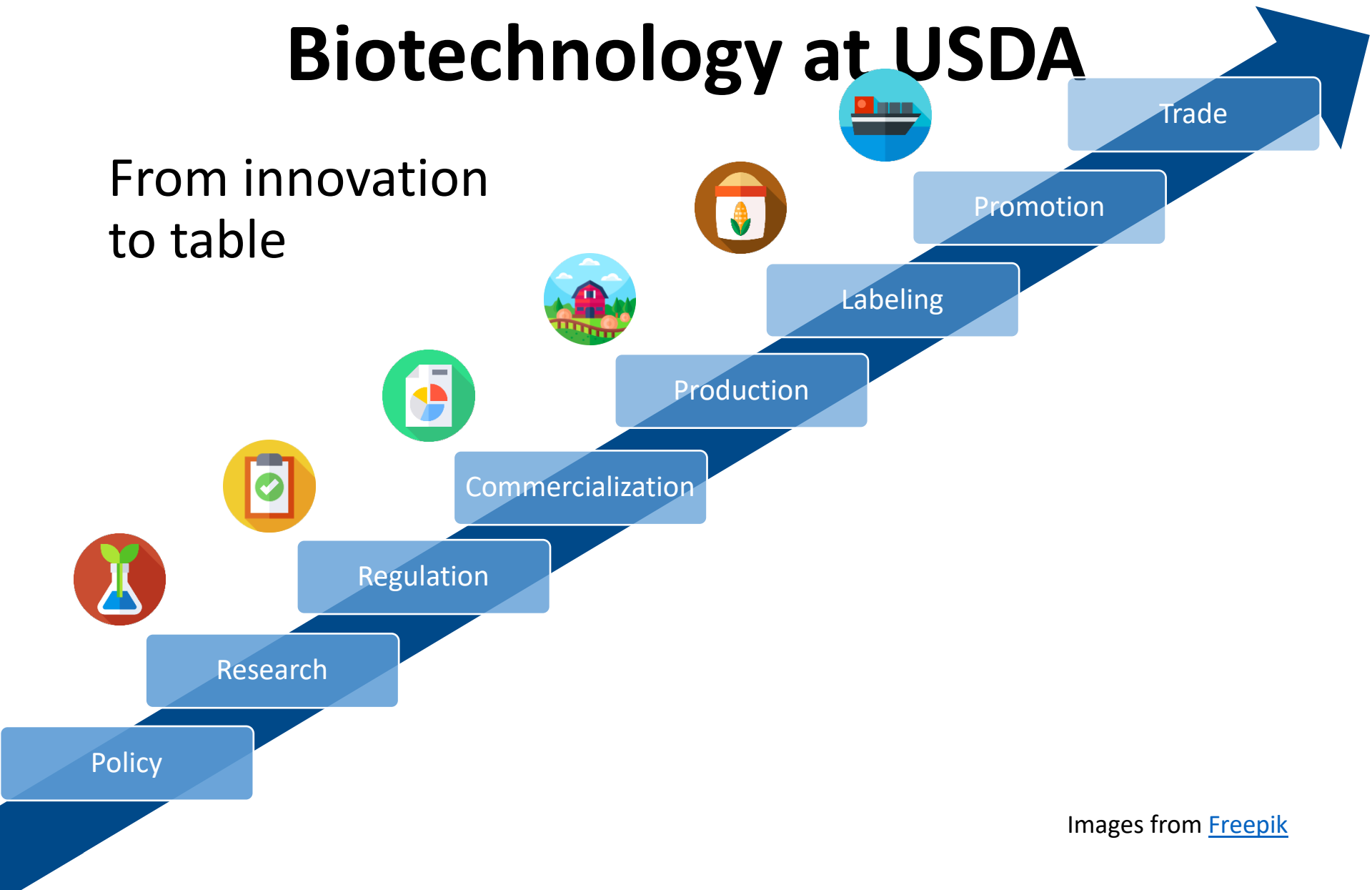U.S. Department of Agriculture

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U.S. Department of Agriculture

- 100,000 employees
- 4,500 locations
- 8 mission areas
- 29 agencies and offices

Learn about USDA

Biotechnology at USDA

From innovation to table

Policy

Research

Regulation

Commercialization

Production

Labeling

Promotion

Trade

Images from Freepik

Departmental Priorities in FY 2022

- Addressing Climate Change with Climate-Smart Agriculture and Forestry

- Advancing Racial Justice, Equity, and Opportunity

- Creating More and Better Market Opportunities

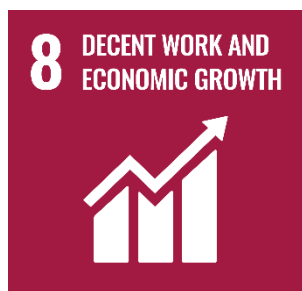- Tackling Food and Nutrition Insecurity

Sustainable Aviation Fuel (SAF) Grand Challenge

- Led by USDA, DOE, DOT

- Reduce cost, increase sustainability, expand production and use

- Meet 100% of U.S. aviation fuel demand by 2050

- USDA research in biomass feedstock genetics

Learn more about the government-wide Sustainable Aviation Fuels Grand Challenge

Coalition of Action for Sustainable Productivity Growth

- Initiated by the U.S. at the UN Food Systems Summit

- More efficient, productive, and sustainable agriculture and food systems

- 80 partners, including 14 countries

Learn about the Coalition for Sustainable Productivity Growth

Agriculture Innovation Mission (AIM) for Climate

- Joint initiative led by U.S. and UAE

- Climate-smart agricultural innovation
  - Increase investment
  - Enable technical discussions
  - Establish cooperation
- Over 80 partners, including 34 countries

Learn about AIM for Climate

Facilitation of Trade

- Lead agency: Foreign Agricultural Service (FAS)

- APEC High Level Policy Dialogue on Agricultural Biotechnology

- Topics for 2022:
  - Resource sharing
  - Communication efforts
  - Policy and regulatory frameworks

Learn about APEC HLPDAB

Research and Collaboration

- Lead mission area: Research, Education, and Economics (REE)

- USDA Plant Breeding Stakeholder Meeting

- Animal Biotechnology Workshops

- Ongoing research: Continuous flowering plants to feed astronauts

Chris Dardick, USDA researcher, evaluates a continuous flowering plum plant. Image by Stephen Ausmus.

National Bioengineered Food Disclosure Standard

- Lead agency: Agricultural Marketing Service (AMS)

- National standard for disclosing foods that are or may be bioengineered

- Mandatory compliance date is January 1, 2022

- Bioengineered foods are foods that:
  - contain genetic material modified through rDNA techniques and
  - could not otherwise be developed with conventional breeding or found in nature

Learn about the National Bioengineered Food Disclosure Standard

Closing Remarks

Alan Pearson

Assistant Deputy Administrator

Animal and Plant Health Inspection Service (APHIS)

Biotechnology Regulatory Services (BRS)

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Break

Resuming in 5 minutes

APHIS eFile Breakout Session

Miranda Wanex

Management Analyst

Animal and Plant Health Inspection Service (APHIS)

Biotechnology Regulatory Services (BRS)

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Breakout Agenda

- BRS Permitting Assistant Demo

- FY2022 System Enhancements

- Upcoming Location Requirements

BRS Permitting Assistant Demo

FY2022 System Enhancements

- Upcoming system update addresses:

  - Improving large application submission

  - PDF generation changes

  - XML improvements

  - Modernizing application and review interfaces

- Increased flexibility of application sizes and ease of use for all developers

FY2022 System Enhancements

- Improving large application submission

  - Improved system response for applications with large numbers of constructs and locations

  - Submit button moves application into submission queue

  - Applicants receive success email once application is submitted and updates are completed

FY2022 System Enhancements

- PDF generation changes

  - PDFs no longer generate in preview window

  - Applicants click a button to initiate downloadable preview
    - Time to generate varies depending on application size

  - PDF outputs improved throughout application process

FY2022 System Enhancements

- XML improvements

  - Upload area upgraded to modernized interface

  - 10 MB upload limit increased to 20 MB
    - *Estimated: 20 million characters in XML*

  - Implement descending upload sorting
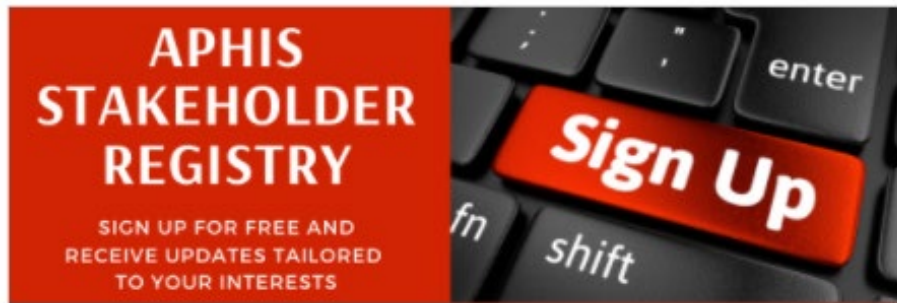
FY2022 System Enhancements

- Modernizing application and review interface

  - Web application interface upgraded to match newer PPQ/VS look and feel

  - Current functionality preserved with improvements

  - More streamlined internal review interface and system improvements to process large data for faster application turnaround

FY2022 System Enhancements

- Project completion currently targeted for **March 23, 2022**

- Existing applicants involved in acceptance testing of new features

- Contact BRS.eFile@usda.gov to participate

FY2022 System Enhancements

- Updates coming to applicant resources to match new interface

- More applicant training provided - dates will be announced to existing applicants and through BRS stakeholder registry

Upcoming Location Requirements

- Additional fields required starting <u>January 1, 2022</u>
  - Fields align with the revised 7 CFR part 340
  - Address fields required for <u>most</u> origins, all destinations, and all release locations
    - Street Address 1 / <LocationAddressLine1>
    - City / <LocationCity>
    - Zip / <LocationPostalCode>
  - Import permit origin locations require City
  - Provide northwest corner GPS coordinate if street address does not exist

Upcoming Location Requirements

- At least one Agent must be included with all locations, including origins

    - The following Agent fields are required:

        - Title / <Title>

        - First Name / <FirstName>

        - Last Name / <LastName>

        - Phone / <DayTelephone>

        - Email Address / <Email1>

- Applicants may request more time to adjust XML outputs