USDA
United States Department of Agriculture

Biotechnology Regulatory Services

Annual Stakeholder Meeting

November 7, 2018

Meeting Begins At 10:00 AM EST

BRS Reflections on FY18

A Look Forward to FY19

BRS Stakeholder Meeting, November 07, 2018

Michael Firko, Ph.D

APHIS Deputy Administrator

Biotechnology Regulatory Services

FY 18 Primary BRS Accomplishments & Progress

Next 9 Slides

Authorized Activities with Regulated Articles, FY18

Number of Release Authorizations	Number of Release Sites	Number of unique Phenotypic Designations (crop-trait combination, all activities)
387	4,553	14,856

Petitions for Deregulation

Two deregulation petitions completed

- Bayer dual herbicide resistant cotton
  - ✓ 332 days (Path I target 395 days)
- Nuseed Americas Inc. improved omega-3 canola
  - ✓ 370 days (Path II target, 463 days)

Plus one already completed this FY

- Texas A&M ultralow gossypol cotton
  - ✓ 362 days (Path II target, 463 days)

Am I Regulated ?

"Does my GE organism meet the definition of a regulated article under *7 CFR part 340*?"

- FY 16: 13
- FY 17: 14
- FY 18: **14** (plus 2 answered so far in FY 19)

Inquiries under review: 5 (all received since July)

SDN Am I Regulated Requests (2011-2018)

Site Directed Nuclease	Number of Inquires	Number Pending	Number of Responses *
Meganuclease	4	0	4
Zinc Finger	1	0	1
TALEN	9	0	9
CRISPR	11	2	9
TOTAL	25	2	23

* All Responses = Not Regulated. This year: our first SDN 2/3

Permit Application: Genetically Engineered Citrus Tristeza Virus (CTV) for Biological Control of Citrus Greening Disease

Published dEIS & dPRA

- 51 comments
- New paper on transmission

USDA / EPA / FDA

Horizon Scanning System

- NAS recommendation *("Preparing for Future Products of Biotechnology")*
- Details will be provided by Sally McCammon at 11:20
- Beta release available at https://www.futurebioengineeredproducts.org

USDA / EPA / FDA

Biotechnology Unified Web Portal

- Single point of entry for regulatory information on products of biotechnology
- Goal – modern, user-friendly tool for assisting developers, especially small developers, navigate the regulatory system
- NAS recommendation
- Set of global pages describing the regulatory system with links to more details hosted by EPA, FDA and USDA
- Query tools for questions from one or more of the three regulatory agencies
- Launch anticipated in near future

APHIS eFile

- Afternoon session
- Transition ePermits → APHIS eFile
- Relationship between change in system and change in regulations

340 (7 CFR part 340)

- Withdrew Proposed Rule (PR) for revisions to 340
- Published Notice of Intent (NOI) for programmatic Environmental Impact Statement (pEIS)
  - 35 comments
- Preparing new PR, draft pEIS, Regulatory Impact Analysis (RIA)

Looking Forward to 2019

340, 340, 340

Our No. 1 Strategic Initiative

- Publish:
  - Proposed Rule
  - Draft pEIS
  - Draft RIA
  - More to say about 340 as my final topic today

Looking Forward to 2019

Current Petitions for Non-Regulated status: 5

1. ArborGen Freeze Tolerant Eucalyptus
   - Pending FWS decision on whether to enter consultation
2. Verdecca Increased Yield Soybean
   - Draft PPRA and EA in preparation
3. BASF Canola
   - Draft PPRA and EA in preparation

4-5. Two petitions received recently

- Completeness reviews underway

Looking Forward to 2019

Issue Permit for Florida-wide release of GE CTV as a Biological Control Agent of Citrus Greening Disease




340 Outreach

- 17 Universities
- NGOs & Thought Leaders
- Small & Large Biotechnology Developers
- Industry Groups
- Commodity Groups
- Grain Trade, Value Chain
- Tribes
- State Departments of Agriculture
- EPA, FDA, USTR, other USDA Agencies
- 50+ Countries

340 Conceptual Framework

- Starts with Secretary Perdue's statement on Plant Breeding Innovation
- Flow Chart


thank you
danke
рахмат
謝謝
ngiyabonga
teşekkür ederim
gracias
merci
obrigado
bedankt
dziękuję
sukriya
kop khun krap
go raibh maith agat
mochchakkeram
tapadh leat
спасибо
Баярлалаа
dank je
grazie
arigatô
takk
dakujem
terima kasih
감사합니다
мерси
ευχαριστώ
mersi
barka
welalin
tack
spas
kia ora
faafetai lava
vinaka
blagodaram
спасибі
misaotra
matondo
paldies
grazzi
mahalo
хвала
asante
manana
obrigada
murakoze
tenki
kiitos
dankie
nanni
nandri
dhanyavad
mauruuru
hvala
köszönöm
gràçie
bayarlalaa
enkosi
dankon
aćiū
akun
djiere dieuf
tau
дякую
mamnun
chokrane
chnorakaloutioun
gratias ago
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sobodi
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didi madloba
najis tuke
kam sah hamnida
rahmat
ありがとう
tanemirt
rahmet
diolch
dhanyavadagalu
shukriya
mercé
trugarez
xièxie
তোমাকে ধন্যবাদ

USDA
United States Department of Agriculture

International Outreach

November 7, 2018

Ibrahim Shaqir
Associate Deputy Administrator for International and Emerging Issues
USDA APHIS Biotechnology Regulatory Services

Approach to International Collaboration

Protect Plant Health

Support International Trade

Training and Outreach

2018 BRS International Activities

- Foreign Government Capacity Building
- Bilateral and Trilateral Working Groups
- Global Collaboration
- Support for International Trade

Visitors to Washington, DC

(FY2018 total visitors = 86 from 9 different countries)

Diverse visitors:

- **Parliamentarians and local legislators**
- **Government regulatory officials**
- **Scientists**
- **Importers of seed, grain, etc.**
- **Journalists**

International Courses and Meetings
(163 participants from 26 countries)

Workshops, courses, and meetings:

- **Michigan State University**
- **University of Missouri-Columbia**
- **National Defense University**
- **China Agricultural University**

Frequent Questions

- Do Americans eat food derived from GE crops?
- How do APHIS, EPA, and FDA coordinate roles?
- What resources are needed to implement a system?
- What is your regulatory approach for new plant breeding techniques (e.g., gene editing)?
- What is government's role in co-existence in ag production?

Biotechnology Trilateral Technical Working Group

Topics:

- Approvals, Consultations, etc.
- Seminars (e.g., Synthetic Biology)
- International Organizations
- Chestnut blight resistant trees

USA – China Technical Working Group (2018)

- Regulatory updates
- Public outreach and education
- Regulatory approaches for plant breeding innovations

- Citrus Greening - UF Indian River Research and Education Center, Fort Pierce, FL

New Breeding Innovation and Genome Editing in OECD

Organisation for Economic Co-operation and Development

OECD Technical Biotechnology Working Groups

- Food/Feed (US FDA chairs)
- Environment (APHIS-BRS chairs)
  - Biology consensus documents, etc.
  - http://www.oecd.org/science/biotrack/

Conference on Genome Editing Applications in Agriculture: Implications for Health, Environment and Regulation

June 28-29, 2018

- Ken Ash, Director of the Trade and Agriculture Directorate: policies must be “fit-for-purpose” and international cooperation can mitigate problems before they arise.

- Three topic areas with speakers and a panel discussion
  1. Animal and plant applications
  2. Risk and safety considerations
  3. Regulatory aspects

OECD
BETTER POLICIES FOR BETTER LIVES

BRS International Outreach

United States Department of Agriculture

Foreign Agricultural Service

International Policy Engagement - Precision Breeding

Paul Spencer

Paul.Spencer@fas.usda.gov

Director

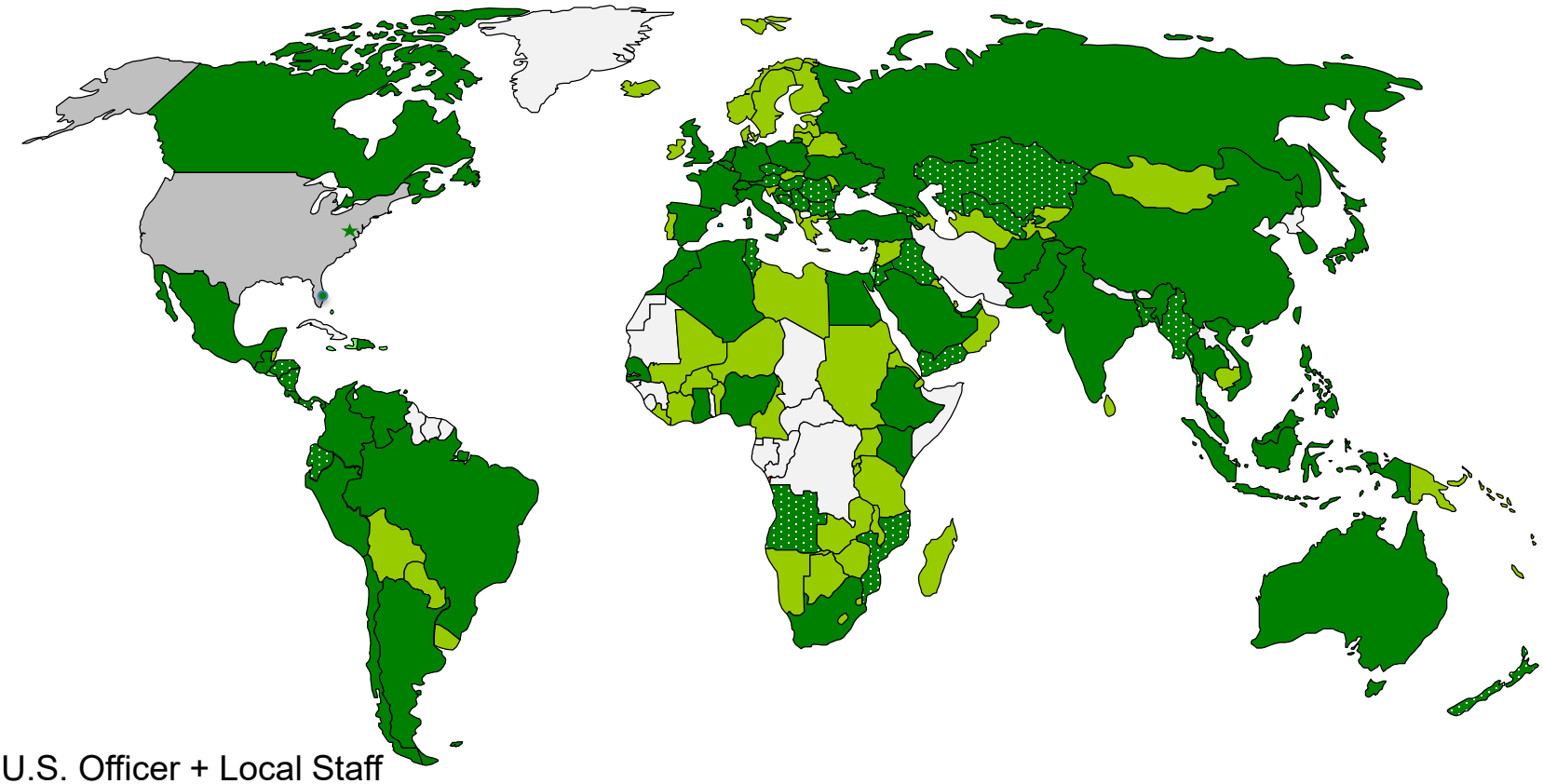
New Technologies and Production Methods Division

Foreign Agricultural Service USDA

United States Department of Agriculture

Foreign Agricultural Service

FAS Worldwide



U.S. Officer + Local Staff

Local Staff Only

Covered Regionally

96 Offices (Posts)
Covering 170 countries

Trade and Innovation Linkages

- Innovation = U.S. Competitive Advantage
- Foreign market ‘signals’ are influential
- Foreign Acceptance Requires U.S. Government Advocacy
- Seeking Regulatory Compatibility

International Engagement

FY 2018 USDA Efforts

- Collected data on country policies
- Defined main policy risk
- Started engagement based on:
  - Secretary's March Policy statement on Plant Breeding Innovation
  - Multilateral cooperation

USDA United States Department of Agriculture

Foreign Agricultural Service

Global Regulatory Status

Norway: Proposed; foreign DNA insertion regulated; case-by-case tiered approach – notification, expedited, standard review

Canada: Not regulated unless product identified as novel

Europe: European Court of Justice ruling genome editing techniques must be regulated as GMOs

China, Korea: Issue still being debated; no formal guidance

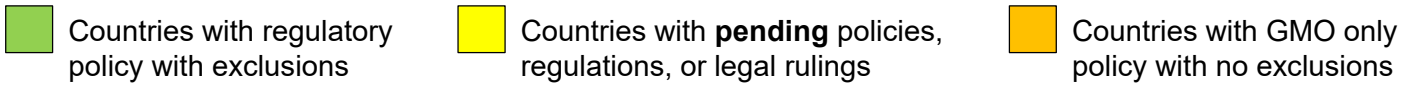
United States: developing new rule; for plants – USDA 'Am I Regulated?' letters, March 28 Statement; FDA & EPA under review

Israel: Foreign DNA insertions regulated

Philippines, Japan: Under consideration; Foreign DNA insertions likely to be regulated as GMO

Argentina, Brazil, Chile, Colombia: Case by case approaches; foreign DNA insertions generally regulated as GMO

Australia: Under review; possibly regulated whenever when templates involved; case-by-case review



Court of European Justice (ECJ) Decision

What it says

- Genome editing is subject to the GMO directive
- Member states may regulate conventional mutagenesis products
- [the European Commission is studying how to implement ruling]

Implications

- Emboldens anti-technology groups
- Negatively impacts global agricultural innovation and food security
- Expands potential for trade conflict between EU and its trading partners

USDA response

- Secretary Perdue statement, July 27th
- "Global regulatory treatment… has strategic innovation and trade implications for U.S. agriculture"
- Redouble efforts to work with partners globally

Looking Ahead

FY 2019 USDA International Approach

- Continue building coalitions
- Limit influence of European Court of Justice decision
- Develop communication themes

Recent International Engagement

International Statement on Agricultural Applications of Precision Biotechnology

WTO Members Support Policy Approaches to Enable Innovation in Agriculture

WASHINGTON, Nov. 2, 2018 – U.S. Secretary of Agriculture Sonny Perdue today announced that the United States has joined with 12 other nations to support policies that enable agricultural innovation, including genome editing. The International Statement on Agricultural Applications of Precision Biotechnology was released in Geneva at the World Trade Organization (WTO) Committee on the Application of Sanitary and Phytosanitary Measures.

Press Release
Release No. 0239.18

Contact: USDA Press
Email: press@oc.usda.gov

"Precision biotechnologies such as genome editing hold great promise for both farmers and consumers around the world. These tools can play a critical role in helping farmers address many of the production challenges they face while improving the quality and nutritional value of foods available to consumers worldwide," said Perdue.

Conclusions

- Conflating genome editing with ‘GMO’ remains the biggest policy challenge
- Strong trade linkages = need for regulatory compatibility
- Many countries off to a good start (but EU a challenge)
- USDA is advocating internationally

APHIS-BRS Biotechnology Research and Scientific Engagement

November 7, 2018

Sally McCammon
Science Advisor
Biotechnology Regulatory Services

Presentation Outline

- Context
- Policy
- USDA-APHIS-BRS Research Priorities
- USDA-NIFA and USDA-ARS
- NASEM
- Partnering
- Engagement
- Informal

Context

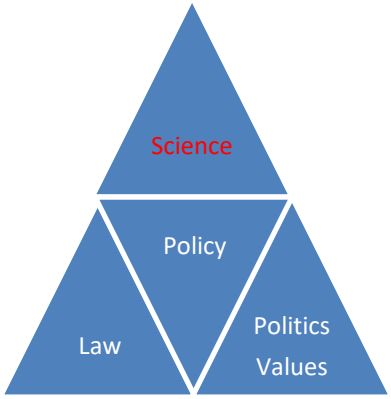
The Law

- Codifies protection goals
  - Protect against pests and diseases, weeds, pesticides, etc.
  - Regulations implement

Science

- Data and information
- Most aspects of evaluation and management

Policies- use of risk assessment and decisions, management



Policy

TASK FORCE ON AGRICULTURE AND RURAL PROSPERITY

Call to Action #4: Harnessing Technological Innovation

Stream-lined, **science-based** Regulatory Policy for Biotechnology

- Coordinate Federal regulation of biotech products
- Coordinate Interagency action through the Office of Science and Technology Policy
  - ✓ Small and mid-sized innovators
  - ✓ Protect consumers
- Expedite Commercialization of Biotech Products

APHIS-BRS Research Priorities

ANNUALLY IN AUGUST

- Weediness
- Gene Drives
- Comparison of sources o genomic variation
- RNAi
- Comparison of
  - potential unintended effects

USDA NIFA and ARS

- **National Institutes of Food and Agriculture**
- **Biotechnology Risk Assessment Research Grants (BRARG)**
  - REQUEST FOR APPLICATIONS
    - December 21, 2017
    - APHIS-BRS, EPA, FDA, ARS, NIFA
  - REVIEWER PANEL
  - WORKSHOP May 22, 2018

REQUEST FOR APPLICATIONS: ADDRESS ONE OF THE FOLLOWING

- **Management Practices to Minimize Environmental Risk**
- **Methods to Monitor and Understand the Dispersal**
- **Gene Transfer to Domesticated and Wild Relatives**
- **Environmental Impacts of GE relative to Non-GE Organisms in the Context of Production Systems**
- **Other Research Topics**

2002 FARM BILL (Section 7210)

GRANT PROGRAM:

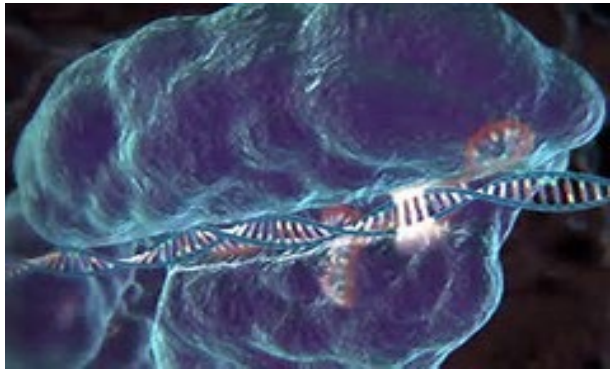
- provide the necessary funding for **environmental assessment research** concerning the introduction of genetically engineered animals, plants, and microorganisms into the environment.

AUTHORIZATION OF APPROPRIATIONS.—

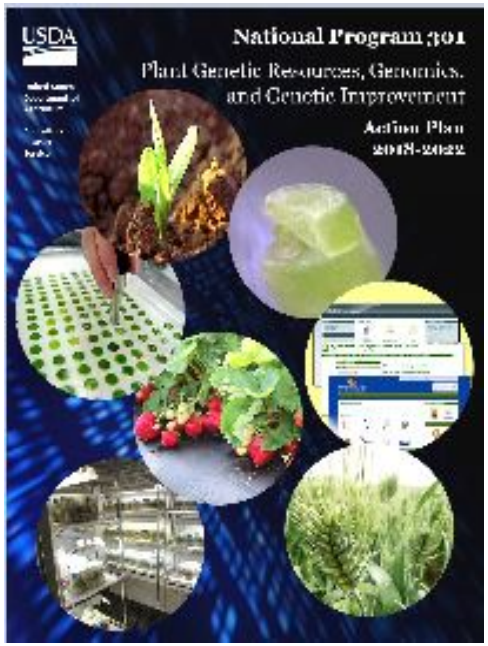
2) **WITHHOLDINGS FROM BIOTECHNOLOGY OUTLAYS** for research on biotechnology, at least **2 percent** for research on biotechnology risk assessment.

BRARG

In 2018, thirty-five (35) proposals were submitted to the BRARG program with awards of $5.4 M made for nine research and one conference proposals.



Agriculture Research Service



Action Plan: National Program 301: **Plant Genetic Resources, Genomics & Genetic Improvement** 2018-2022

Crop biotechnology risk assessment…

Identify and reduce unintended effects of biotechnological improvement on crop plants, agricultural production, and the environment

https://www.ars.usda.gov/ARSUserFiles/np301/NP%20301%20Action%20Plan%202018-2022%20FINAL.pdf

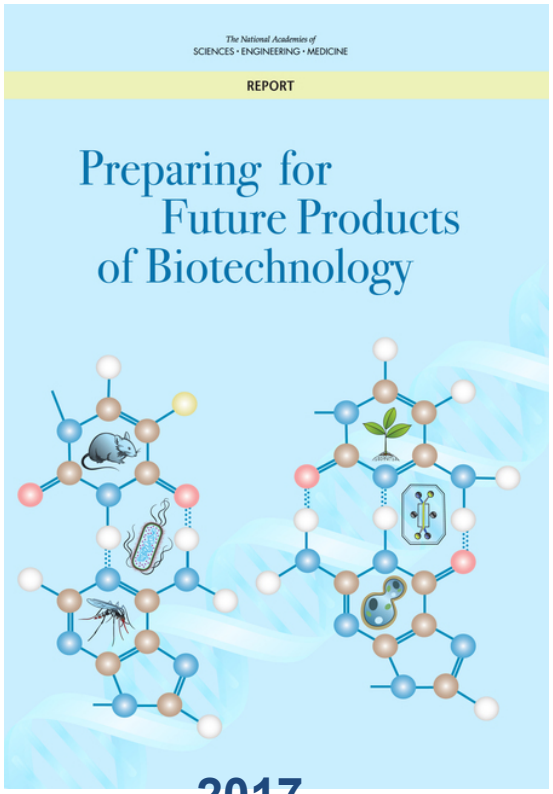
APHIS SCIENCE COMMITTEE

APHIS-ARS Science Symposium

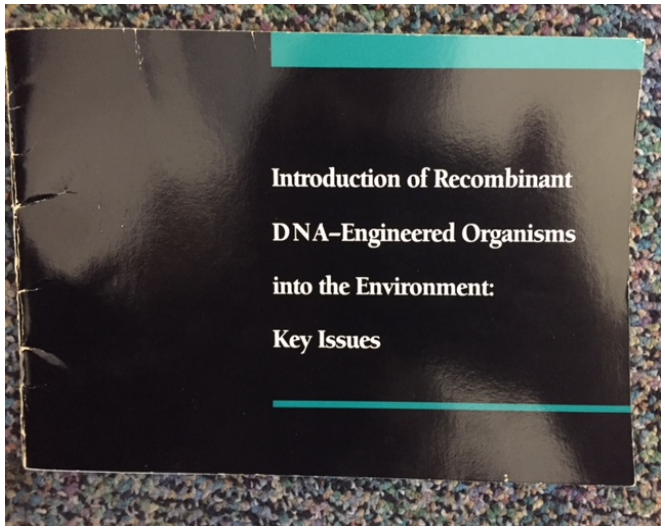
August, 2018

- Enhancing cross-agency communication for addressing scientific problems and engaging with policy-makers and stakeholders
- Identifying innovative solutions and technologies for enhanced preparedness and prevention
- Best practices in preparing for and preventing potential emergencies and for responding to dynamic critical research needs

NASEM Authoritative Scientific Reports



2017

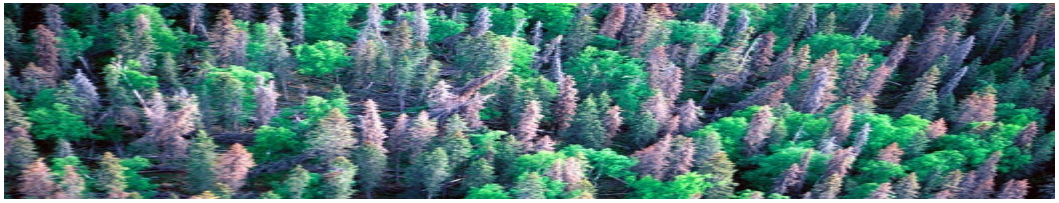


1987

2016

The Potential for Biotechnology to Address Forest Health

- NASEM
- Interagency funded study
- December - publically available
- International Union of Forest Research Organizations Workshop August 2018
- AAAS meeting in DC on Presidents' Day weekend (Feb 16-18, 2019)



http://dels.nas.edu/Study-In-Progress/Potential-Biotechnology-Address/DELS-BANR-16-0

PARTNERING

Horizon Scanning System

Follow up to March 2017 NASEM report

September 2017, APHIS cooperative agreement

Environmental Law Institute (ELI)

- design and development of a horizon scanning system for future biotechnology products consistent with the NASEM report.

Alpha version for review and comment

Complete Beta testing of the website with a select group

https://www.futurebioengineeredproducts.org

Weed Science Society of America

WSSA and Interagency Engagement
Weed Science 60(sp1):1-1. 2012
https://doi.org/10.1614/WS-D-12-10001.1
Introduction to the Special Issue of *Weed Science* on Herbicide Resistance Management
Weed Science 60(sp1):2-30. 2012

https://doi.org/10.1614/WS-D-11-00206.1
Herbicide Resistance: Toward an Understanding of Resistance Development and the Impact of Herbicide-Resistant Crops

Weed Science Society of America

- **WSSA Herbicide Resistance Education Committee** and USDA OPMP and EPA
- **2018 grant-Actions** to further address herbicide resistance.
- planning team meetings on Oct 16 at the EPA and on Oct 25-28 in Guelph.
- Two open access articles --HR regional Listening Sessions in Weed Technology Vol. 32(4) (https://www.cambridge.org/core/journals/weed-technology)
- **National forum** to include additional agencies and stakeholders

Engagement

Organization for Economic Cooperation and Development (OECD)

Technical Working Groups and Biotechnology Risk Assessment

-Biology, trait and composition documents

-Emerging Issues-e.g. LLP

-Workshops and Conferences on New Plant Breeding Techniques, Genome Editing Applications in Agriculture and Next Generation Sequencing

Specialty Crops Regulatory Assistance

2018 'Nuts and Bolts of Biotech Regulations' Workshop (October 3-5, 2018)

Small and large companies, academics, and other potential developers

USDA-APHIS, FDA, and EPA

Case studies

- American Chestnut
- Golden Rice
- Hypo-allergenic peanut

facilitating technological innovation of safe crops

Guidance for New Users to the Petition Process

Informal

- BRS Science Journal Club
- 4 AAAS Fellows
- On Sight Presentations
- Outreach on 340
- Webinars – Canada and Mexico

Tree of Knowledge circa 1490

Thank You!

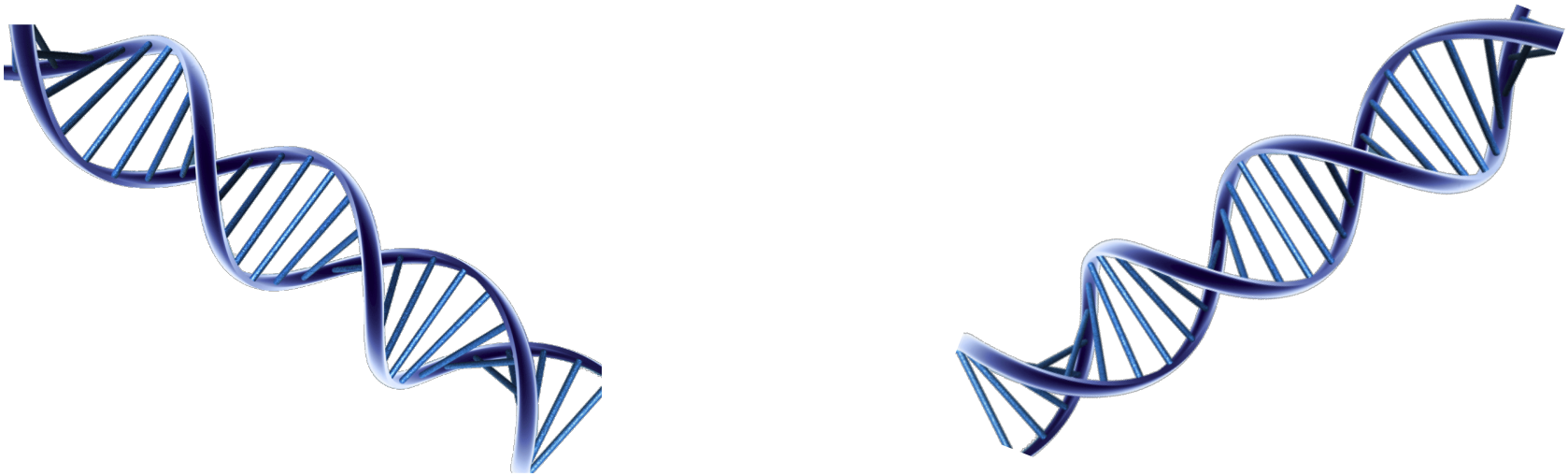
USDA-APHIS-BRS
Am I Regulated (AIR) Process: Implementations of Business Process Improvements

November 07, 2018

Bill Doley, BRS Government Relations Specialist

Benefits of the AIR Process

Reduces the frequency of organisms that are not regulated articles from entering the regulatory system.



The Am I Regulated (AIR) Process

- A developer who would like agency analysis and confirmation that their GE organism does not meet the definition of a regulated article is encouraged to send a letter of inquiry to USDA-APHIS-BRS.

- Instructions for voluntarily submitting “Am I Regulated?” inquiries can be found on the BRS website.

The Am I Regulated (AIR) Process

- After BRS responds to the inquiry, both the inquiry and the response are posted on the BRS website.
  - Since July 2011, BRS has responded to 70 “Am I Regulated?” inquiries.
  - Some of these inquiries and responses relate to the so-called new plant breeding techniques (NPBTs).

Posted AIR Inquiry / Response Sets – Screenshot

Regulated Article Letters of Inquiry

Data Updated: July 13 2018

Print

Search

Download

Show 25 entries

Date	Institution	Description	Documents
7/12/2018	Iowa State University	Genome Edited Maize Developed with CRISPR/Cas technology	View Letters
5/18/2018	University of Georgia	Soybean Engineered for Transposon Mutagenesis that uses Trans-acting siRNA	View Letters

www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated

AIR Legal Analysis

- Does the GE organism meet the definition of a regulated article?

1. Is it altered or produced through genetic engineering?

AND

2. Is the donor, vector or recipient a plant pest?

AIR Responses by Category

AIR Responses	AIR Category
31	No Plant Pest Components
25	Site Directed Nucleases (SDN) [1]
6	Null Segregants
3	Nonviable Material [2]
1	Not an Organism
1	Not Genetically Engineered
3	Regulated Article
70	**Total**

[1] = Some SDN inquiries utilized plant pest components as donor, a plant pest vector (*Agrobacterium*) and/or a plant pest vector agent (TALEN).

[2] = The organism is a regulated article; however, these requests relate to the movement of *non-viable plant parts*.

The AIR Business Process Improvement (BPI) Project

- Purpose of the AIR BPI Project:
  - Make response times more predictable for developers.
  - Reduce the variance in response times.
  - Ensure our responses are more consistent from a technical and policy standpoint.

FY 2018 Improvements to the AIR Process (1)

- Revised Standard Operating Procedures (Nov 2017)
  - New templates and checklists for various steps in the AIR process.
- AIR Triage Review Committee (Nov 2017)
  - Small team to identify any new scientific or policy issues early in the AIR process.

FY 2018 Improvements to the AIR Process (2)

- Improved Guidance for Developers (Sept 2018)
  - Reduction in delays due to Confidential Business Information (CBI) issues.
  - Reduction in delays due to requests for additional information.

Improved AIR Response Time

Data Set	Timeframe	Sample Size	Response Time (months)	
Control Phase	Jun 2017 - Aug 2018	N=11	Mean	3.5
			STD	1.5
BPI Data	2014 - 2016	N=24	Mean	7.9
			STD	4.4

FY 2019 Improvements to the AIR Process

- Improved AIR Website (Nov/Dec 2018)
  - New columns will allow searches by species, transformation method, genetic alteration and phenotype.

U.S. FOOD & DRUG ADMINISTRATION

Agricultural Biotechnology Education and Outreach Initiative

Update of Activities

November 7, 2018

Appropriations Language

A total of $4.5 million has been appropriated for this initiative

P.L. 115-31, Consolidated Appropriations Act, 2017

- "*Provided further, That of the total amount made available under this heading, $3,000,000 shall be used by the Commissioner of Food and Drugs, in coordination with the Secretary of Agriculture, for consumer outreach and education regarding agricultural biotechnology and biotechnology derived food products and animal feed, including through publication and distribution of science-based educational information on the environmental, nutritional, food safety, economic, and humanitarian impacts of such biotechnology, food products, and feed:...*"

Agencies involved

- FDA has established an interagency Steering Committee, which includes experts from FDA, USDA and EPA.
- The Steering Committee helps guide decisions on the Initiative.

Formative Research

We are conducting formative research to inform and guide the formulation of effective communication concepts and materials.

- Literature review
- Public comments
- Audience analysis
- Social listening
- Focus groups

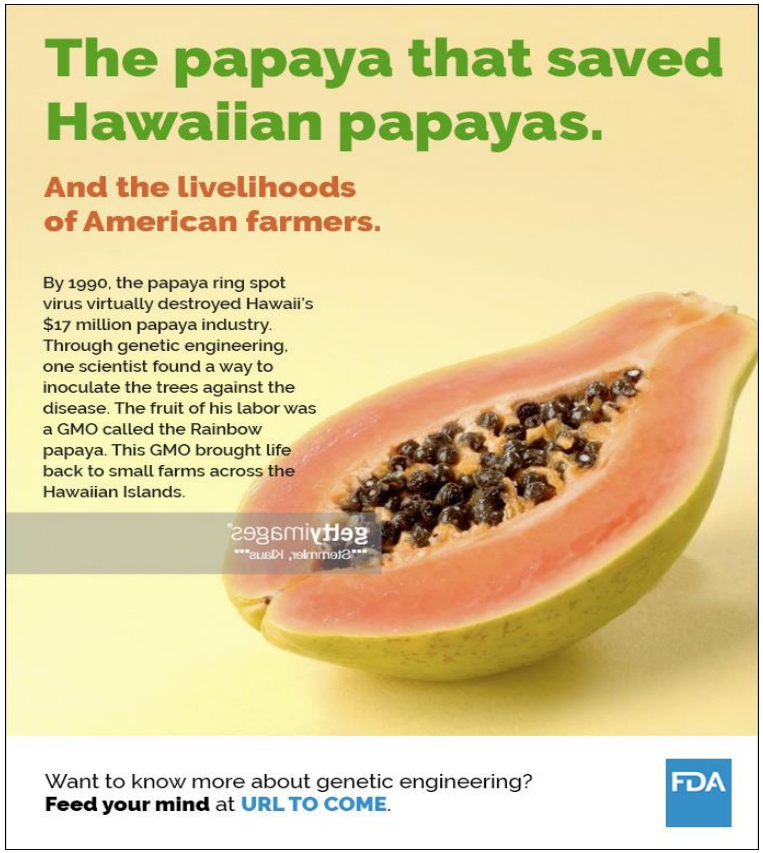
Public Listening Sessions

- Public meetings were held Nov. 7 and 14, 2017, in Charlotte, NC, and San Francisco, CA, respectively.
- Comments in person and through docket
  - Commenters included consumers, advocacy groups, farmers, academia and industry.

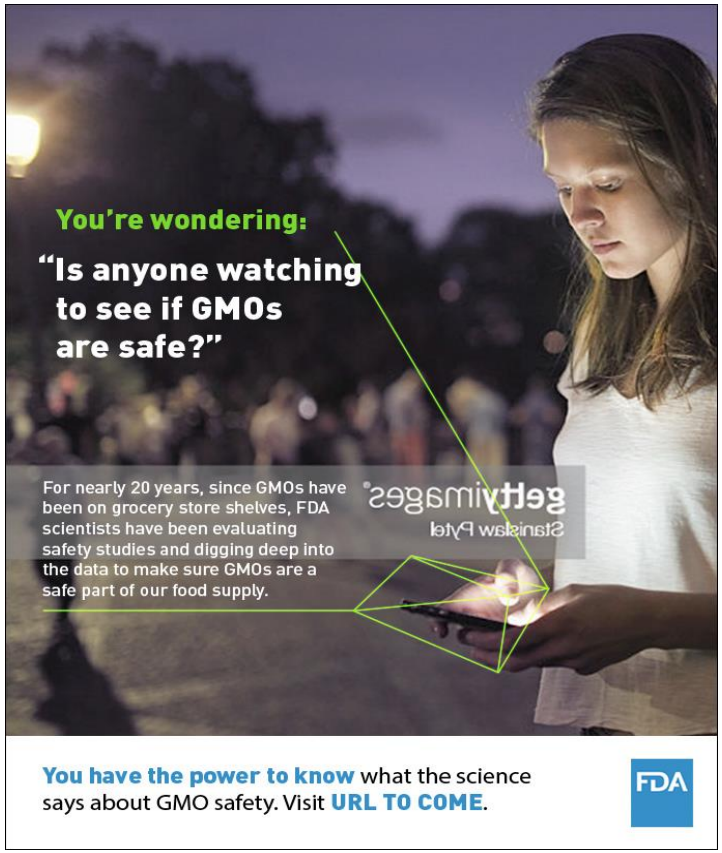
Next Steps

- Develop draft educational materials
- Test draft materials in another wave of focus groups
- Revise educational materials and conduct evaluation of materials
- Finalize materials and implement the initiative
- **Tentative initiative launch date: Fall 2019**

Knowledge



Empowerment



Initiative Webpage

- FDA has created a webpage (Agricultural Biotechnology Education and Outreach Initiative) under the "Resources for You" section of FDA's website where stakeholders can keep abreast of the initiative.
- We plan to update this page as the initiative proceeds.

Questions?

APHIS eFile:

"A Sneak Peek"

BRS Stakeholder Meeting
November 7, 2018

Welcome

Laura Lewandowski, Chief, Digital Services Support Office – MRP IT

Agenda

Modernizing APHIS Permitting

Learn Why APHIS is Transitioning Permitting Systems

APHIS eFile Demo

A Preview of the APHIS eFile Customer Portal and BRS Applications

Demo Q&A

Question and Answer Session Following the Demonstration

Preparing for APHIS eFile

Learn How APHIS Will Transition From ePermits to APHIS eFile

Modernizing APHIS Permitting

Mark Davidson, DVM, Deputy Administrator – MRPBS
Doug Nash, Assistant Deputy Administrator – MRPBS

Where We're Coming From: ePermits

Why does ePermits have to go away?

- Built on Outdated technology (Cold Fusion)
- Increased Maintenance Costs
- Lack of Flexibility
- Scalability Issues
- Embrace Digital Transformation in Federal Government

Where We're Going in Spring 2019: APHIS eFile BRS Release

IMPROVED CUSTOMER EXPERIENCE

Newer, More Flexible and Intuitive User Interface

Reduced Submission Times

Improved Collaboration

Increased System Reliability

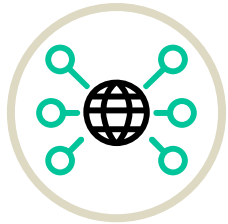
SUSTAINABLE IT PATH

Easier to Maintain and Update

Better Data Management

Modern Infrastructure

SUPPORTING ONEUSDA



System Architecture for Enterprise (APHIS CARPOL)

USDA Embracing Salesforce

The Journey:
APHIS Modernization Initiative

USDA is the "Lighthouse" or Pilot Agency for the New Centers of Excellence (CoE) Approach to IT Modernization

Five Centers of Excellence	Addressed by APHIS eFile
IT Infrastructure Optimization	✓
Cloud Adoption	✓
Customer Experience	✓
Data Analytics	
Contact Centers	

APHIS eFile Demo

Monica Galli, Senior Regulatory Specialist, Biotechnology Regulatory Service
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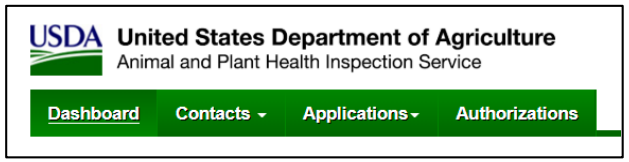
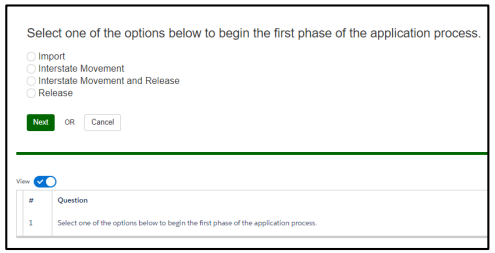
BRS Applicant Experience

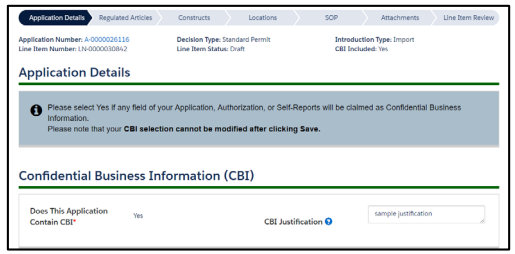
#1: Navigation



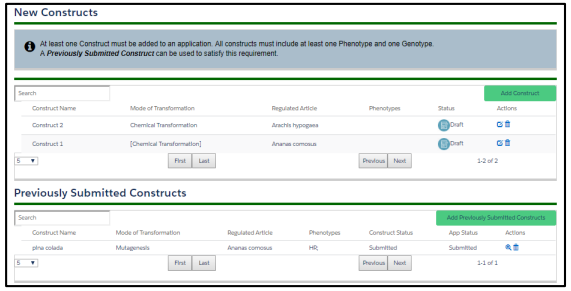
#2: New Application



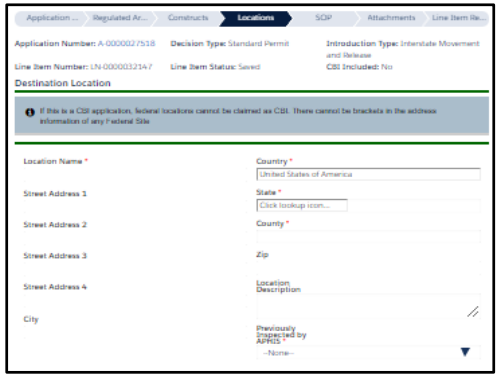
#3: Application Details and CBI



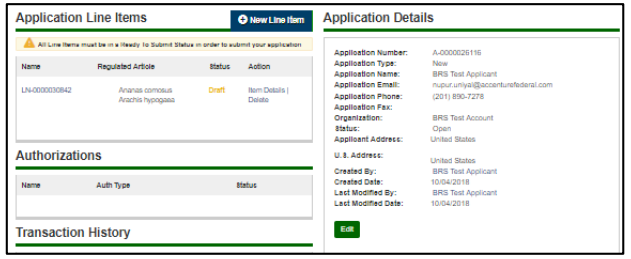
#4: Regulated Articles and Constructs



#5: Locations



#6: Application Review Page



Full Scope of the BRS Initial Release for APHIS eFile

At BRS Go-Live, APHIS eFile will also include:

- Applicant Dashboards
- Application Cloning
- Amendments & Renewals
- Self-Reports
- XML Uploads

Demo Q&A

Monica Galli, Senior Regulatory Specialist, Biotechnology Regulatory Services
Ashok Anant, eFile Product Owner, Digital Services Support Office – MRP IT
Chris Holby, Project Manager, Accenture Federal Services

Preparing for APHIS eFile

Monica Galli, Senior Regulatory Specialist, Biotechnology Regulatory Services
Ashok Anant, eFile Product Owner, Digital Services Support Office – MRP IT

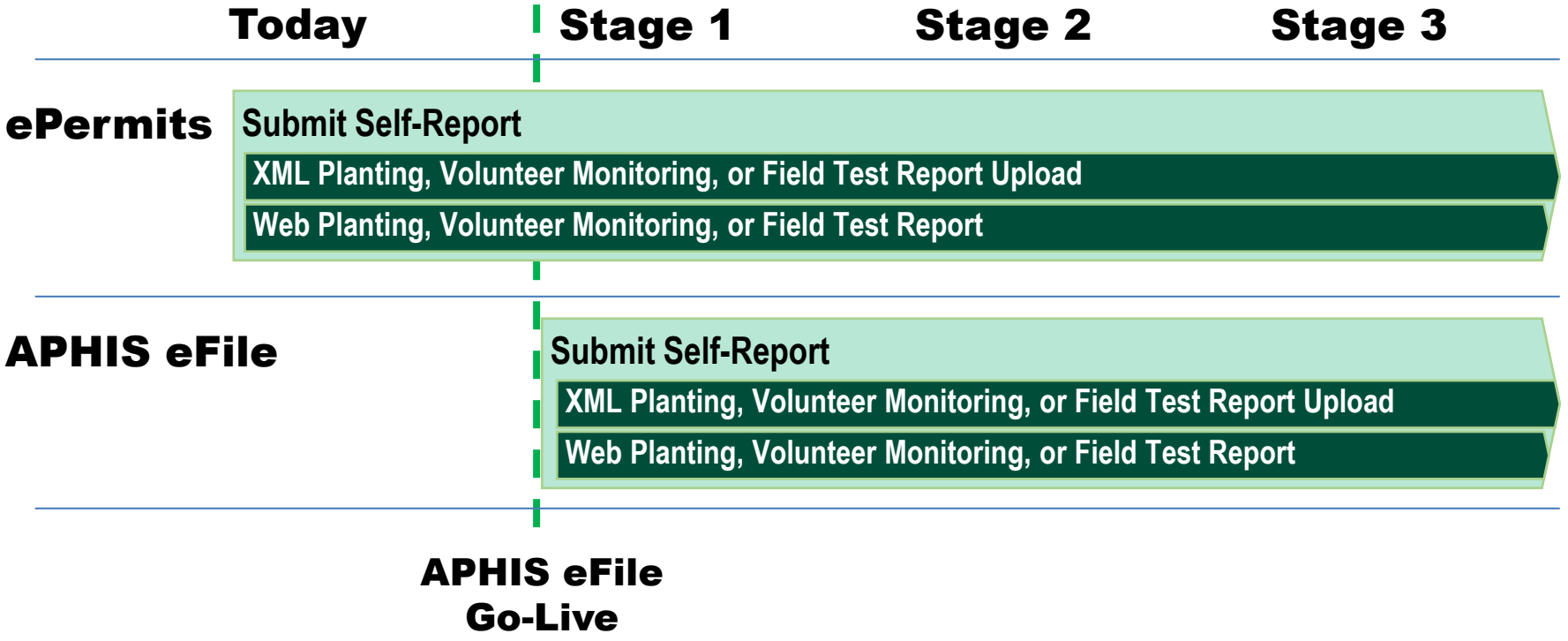
BRS ePermits Transition Plan

BRS is developing guidance to minimize confusion and disruption during the transition from ePermits to APHIS eFile, which will occur in three stages. BRS will inform BRS applicants of movement between stages. The following slides illustrate guidance for each stage.

What you use ePermits for today will in part determine how you'll use APHIS eFile later.

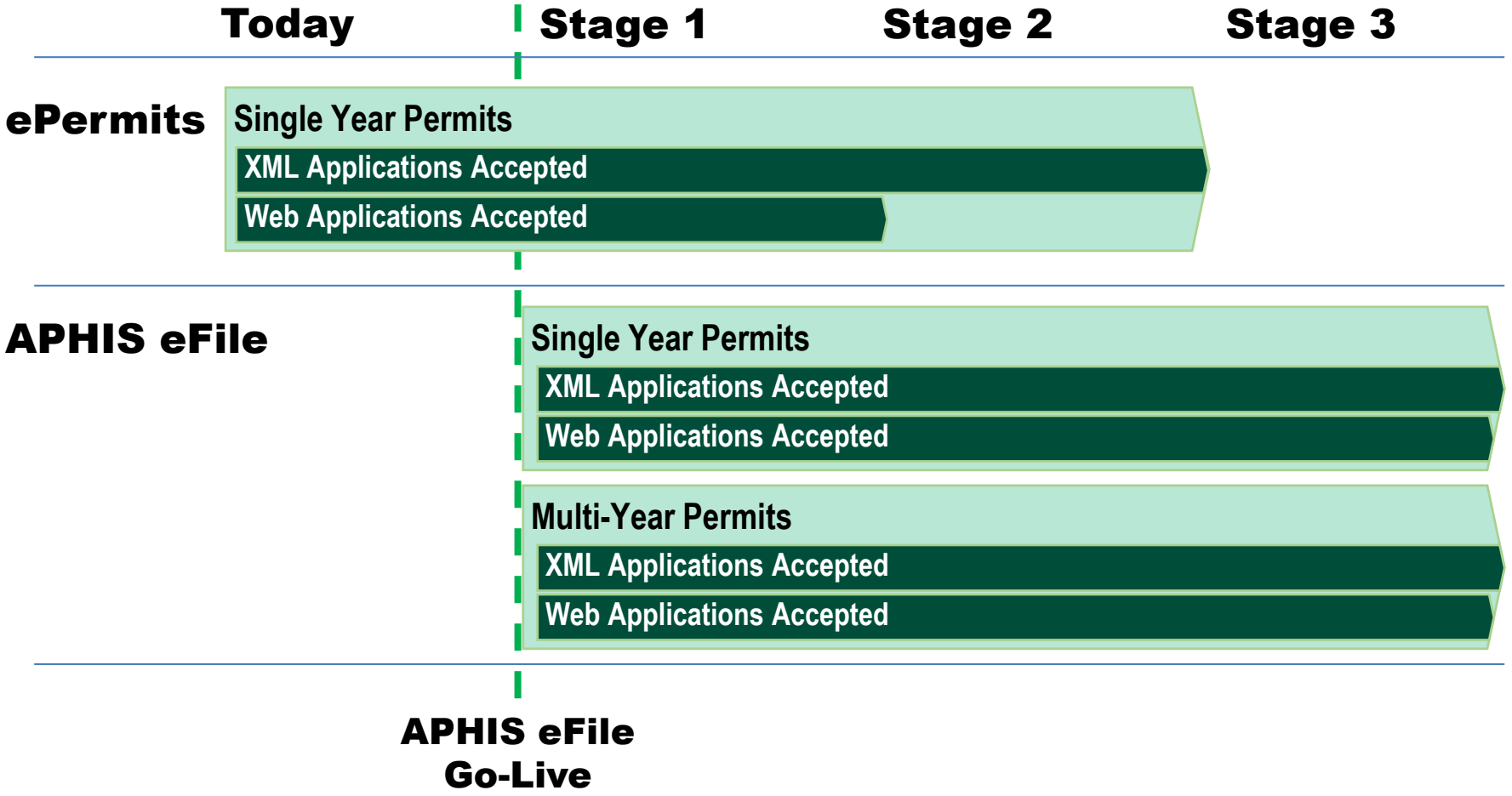
- Self-Reporting
- New Permit Applications
  - *Single and Multi-Year Permits*
  - *Web and XML applications*
- Permit Renewals
- Permit Amendments

ePermits Transition Plan for BRS Permit Holders – Reporting Requirements



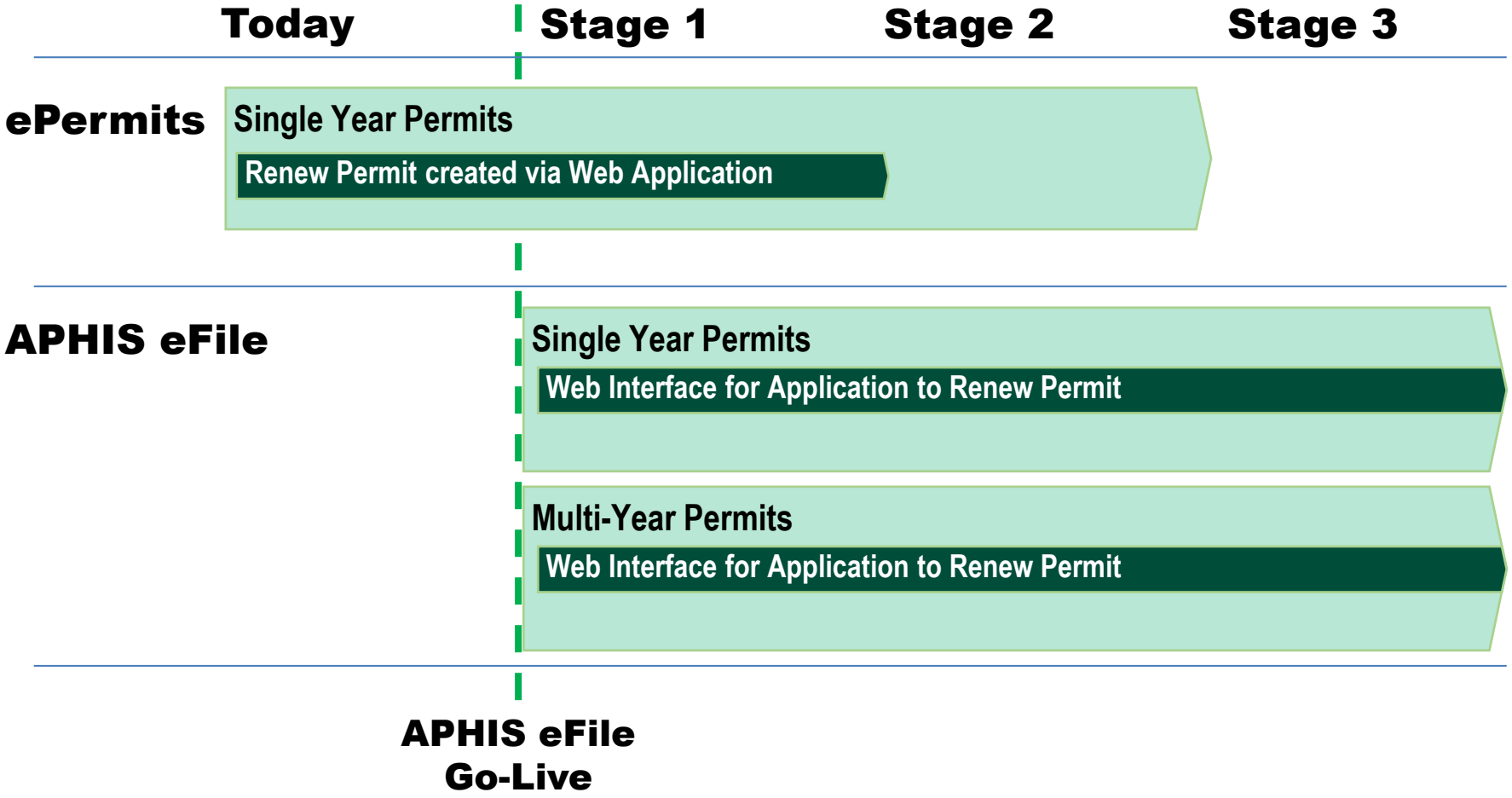
BRS will accept self-reports on a permit **in the system that the permit was originally issued**

ePermits Transition Plan for BRS Applicants – New Permit Applications



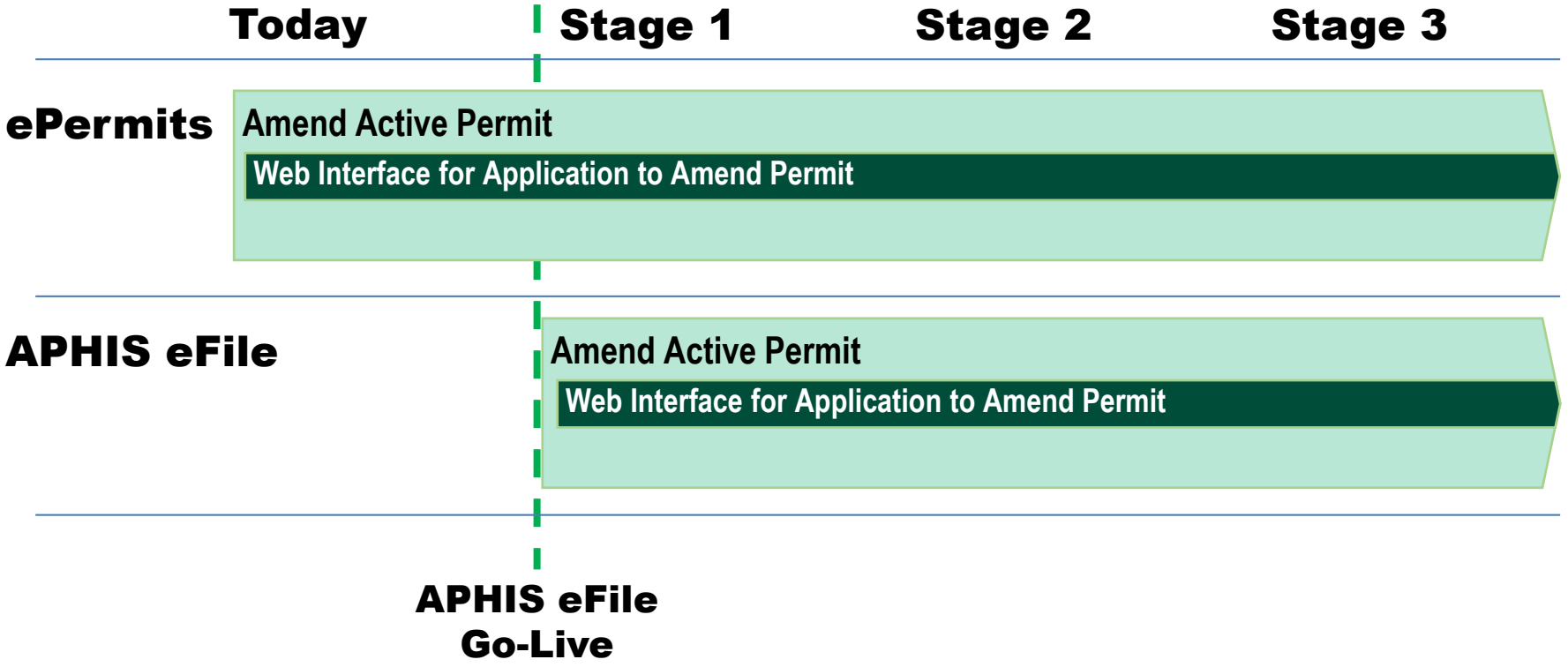
BRS will no longer issue any new permits in ePermits at stage 3 and **APHIS eFile** will be **the only way** to submit **all new permit applications**

ePermits Transition Plan for BRS Permit Holders – Permit Renewal Applications



BRS **strongly recommends** that applicants **submit new permit requests in APHIS eFile** rather than permit renewals in ePermits

ePermits Transition Plan for BRS Permit Holders – Amended Permit Applications



BRS will accept permit amendment requests **in the system that the permit was originally issued**

Scope of Future Releases for APHIS eFile

How will APHIS eFile **grow** to meet APHIS' needs?

- Organizational Applicant
- Usability enhancements based on your feedback
- PPQ Permitting Release
- VS Permitting Release
- Building to meet APHIS' other customer-facing functions over time:
  - Certifications
  - Accreditations
  - Registration (AC Annual Reporting is live)
  - Other Licensing

Getting Up to Speed with APHIS eFile

What resources will be available to help applicants learn the new system?

Webinars

FAQs

User guides

Preparing for APHIS eFile Q&A

Monica Galli, Senior Regulatory Specialist, Biotechnology Regulatory Services
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Chris Holby, Project Manager, Accenture Federal Services

THANK YOU!

Questions? Reach out to us at eFile.Communications@aphis.usda.gov