Welcome to the 2015

BRS Stakeholder Meeting!

November 18, 2015

Dick George, MC

APHIS Biotechnology Regulatory Services

Communications Branch Chief

Reflections on FY15 and a Look Forward to FY16

BRS Stakeholder Meeting, November 18, 2015

Michael Firko, Ph.D

APHIS Deputy Administrator

Biotechnology Regulatory Services

Brief History of U.S. Biotechnology Regulations

- 1970's – NIH Guidelines
- 1986 – "Coordinated Framework for Regulation of Biotechnology"
- 1987 – GE organisms that are plant pests (7 CFR part 340)
- 1993/1997 – 340 Notification authorizations created/expanded

APHIS BRS: Four Primary Operational Activities

- Answer Regulatory Status Inquiries
- Evaluate Applications / Issue Authorizations
- Compliance Review and Actions (e.*g.*, monitoring, inspections, enforcement)
- Consider Petitions for Non-Regulated Status

Am I Regulated ?

Completed Responses with incoming requests over the past five years posted on our web pages

- 2013: 6 Requests answered
- 2014: 3 Requests answered
- 2015 (so far): **10** Requests answered

Permitting

- Processed 90% of permits and notifications within the designated timeframes

Authorized Activities with Regulated Articles, 2014

		Import Only	Interstate Only	Release (Field Trial)	TOTAL
Notification	Received	322	396	436	1154
	Authorized	317	368	391	1076
Permit	Received	49	116	195	360
	Authorized	33	91	181	305

Authorized Activities with Regulated Articles (2014)

Number of Release Authorizations	Number or Release Sites	Number of Phenotypic Designations (crop-trait combination)
572	11,938	49,552

Permitting

- Despite the fact that we reviewed and authorized 11,938 release site locations (NEPA review, etc) via permit and notification…
- Only about one third were actually planted

Compliance

- Enhanced compliance program effectiveness by implementing a staff realignment to focus compliance efforts on inspections
- In 2014, increased inspections by ~ 5%, about 700 inspections
- Numbers similar for 2015, but…

Compliance

- Transition in Regulatory Analysis, field oversight and inspections
  - Hiring
- SPI (Business Process Improvement)
- GAO Engagement/Study
- OIG Audit

SPI (Signature Process Improvement)

Strategic Objective…

- Create a formalized process to effectively track, review and analyze planting and volunteer monitoring reports

Performance Goals…

- Create/Improve processes
- Increase utility of data
- Improve decision making to enhance compliance oversite

GAO Engagement

- Multiple USDA Agencies/Offices
- Completed “Exit Conference”
- Primary APHIS issues…
  - APHIS’ compliance program for field trials
  - GAO indicated support for a change of regulations to strengthen oversight

USDA-Office of the Inspector General (OIG): 2015 Audit

Published 10/1/15, 13 Recommendations, in summary:

1. Publish new regulations
2. Better oversight of outdoor plantings (*i.e.,* “environmental releases”)
3. Improve incident management
4. Consider compliance history when making decisions on permits and notifications
5. New IT system
6. Petition tracking system

APHIS' Response to OIG

- APHIS agrees with OIG's recommendations
- Three primary actions BRS is taking…
  1. New Regulations
  2. APHIS eFile (CARPOL initiative)
  3. SPI

Proposal to Require Permits

(as opposed to Notifications) for

Field Trials of Biotech Wheat

Current Status of Proposal

Federal Register Publication:

- "Changes to Requirements for Field Testing Regulated Genetically Engineered Wheat"
- Published 25 September 2015
- Comment Period Closed October 26
- Comments received…

Comments Received on Wheat/Permit Proposal

- 167 Submissions
- 11,088 Commenters
  - 11,029 seek ban/moratorium on field trials
    - But if authorize, most say do so under permit
  - 35 supportive, but strict permit conditions
  - 15 support continued use of notifications
  - 9 difficult to categorize

Comments Received on Wheat/Permit Proposal

Many comments indicating we did not do a good job of explaining why

So…

GE Organisms that Require a Permit for Outdoor Planting

- See Handout
- Plus…
  - Case-by-case
  - Large scale
  - Upon request

Number of GE Wheat Planting Authorizations and Entities

2014: **21** Notifications issued to **11** entities

- 6 companies
- 4 Universities
- 1 Federal Agency (USDA-ARS)

NOTE: a given authorization may have multiple sites/traits

Why Now?

- GAO study (Senator Tester)
- USDA Office of Inspector General (OIG) Audit, Findings and Recommendations
- New Regulations are at least a few years away (propose permits for all)
- Recent inspection findings
- Increase domestic/international confidence in biotech wheat

Why Wheat?

- Trade, OR and MT (2013 / 2014)
- Integrity of exports and domestic market
- Science… primarily dormancy
  - References available, see Subray

Permit vs. Notification
What does it mean ?

- Both constitute regulation
- Same application tool (ePermits)
- Both subject to inspection
- Both subject to same enforcement actions and fines
- Same regulatory goals, primarily…
  - minimize the likelihood of persistence in the environment following completion of the field trial

Notification: Regulatory Authority

- Minimal, performance standards listed in regs
  - Maintain identity/separation
  - No viable vector agent
  - Not persist in the environment
  - Volunteers should be managed
- APHIS can not specify any conditions
- APHIS can not mandate site-specific requirements
- Single report is required: “Field Test” within 6 months

Permits: Clarity & Collaboration

- Specific information requirements listed in the regulations (*7 CFR Part 340*)
  - Typically, similar information as submitted in Design Protocols
- APHIS works with applicant to create a set of permit conditions that work for both, *e.g.,*
  - Equipment cleaning if moved to nonregulated area
  - Reports
  - Disposal

Benefits

- Permits provide for better collaboration between APHIS and the responsible person
- Permits help both the permittee and APHIS collect data to employ risk-based confinement conditions

Petitions for non-regulated status: Completed in FY15

- FY15: completed eight petitions
- **118** total determinations of nonregulated status to date
- Of the 23 petitions for nonregulated status in-house in March 2012, only one remains
  - Freeze-Tolerant Eucalyptus

Creeping Bentgrass Petition

- 340 Petition withdrawn
  - Remains a regulated article
  - No longer on list of pending petitions
- 360 Petition (Request listing as Federal Noxious Weed, FNW)… Answered
  - APHIS will not list creeping bentgrass as a FNW)

Petitions for non-regulated status: Six (6) Currently in-house

- Three petitions
  - Eucalyptus, 2011 (EIS)
  - Increased Ear Biomass Maize, 2014
  - Herbicide Resistant Maize, 2015
- Three extensions, 2015
  - Herbicide Resistant Maize (out for review)
  - Two not yet complete for outside review

GE Plants with Nonregulated Status, 7 CFR part 340

- Alfalfa – HT, PQ
- Canola – HT, AP, PQ
- Corn – HT, IR, AP, PQ
- Cotton – HT, IR
- Papaya – VR
- Soybean – HT, IR, AP, PQ
- Sugar Beet – HT
- Rose – PQ
- Squash – VR
- Tobacco – PQ
- Apple – PQ
- Chicory – AP
- Flax – HT
- Plum – VR
- Potato – IR, VR, PQ, FR
- Rice – HT
- Tomato – PQ

Major Commercial Production
Minor Commercial Production
No Known Commercial Production

HT – Herbicide Tolerant
IR – Insect Resistant
VR – Virus Resistant
AP – Agronomic Properties
PQ – Product Quality
FR – Fungal Resistant

Looking Forward to 2016 (1 of 3)

- Implementing SPI
- Improve the condition development process for clarity and enforceability
- Enhance inspection and oversight processes

Looking Forward to 2016 (2 of 3)

- Complete Hiring strategy for risk assessment and regulatory oversight
- Delivering a final BRS Compliance Incident Response Plan

Looking Forward to 2016 (3 of 3)

- BRS conduct a higher percentage of inspections
- Complete five petitions (including extensions)
- Rulemaking (next presentation topic)

Cooperative Activities and Stakeholder Engagement

Sid Abel, APHIS Assistant Deputy Administrator for BRS

Michael Mendelsohn, Senior Regulatory Specialist,
Microbial Pesticides, EPA

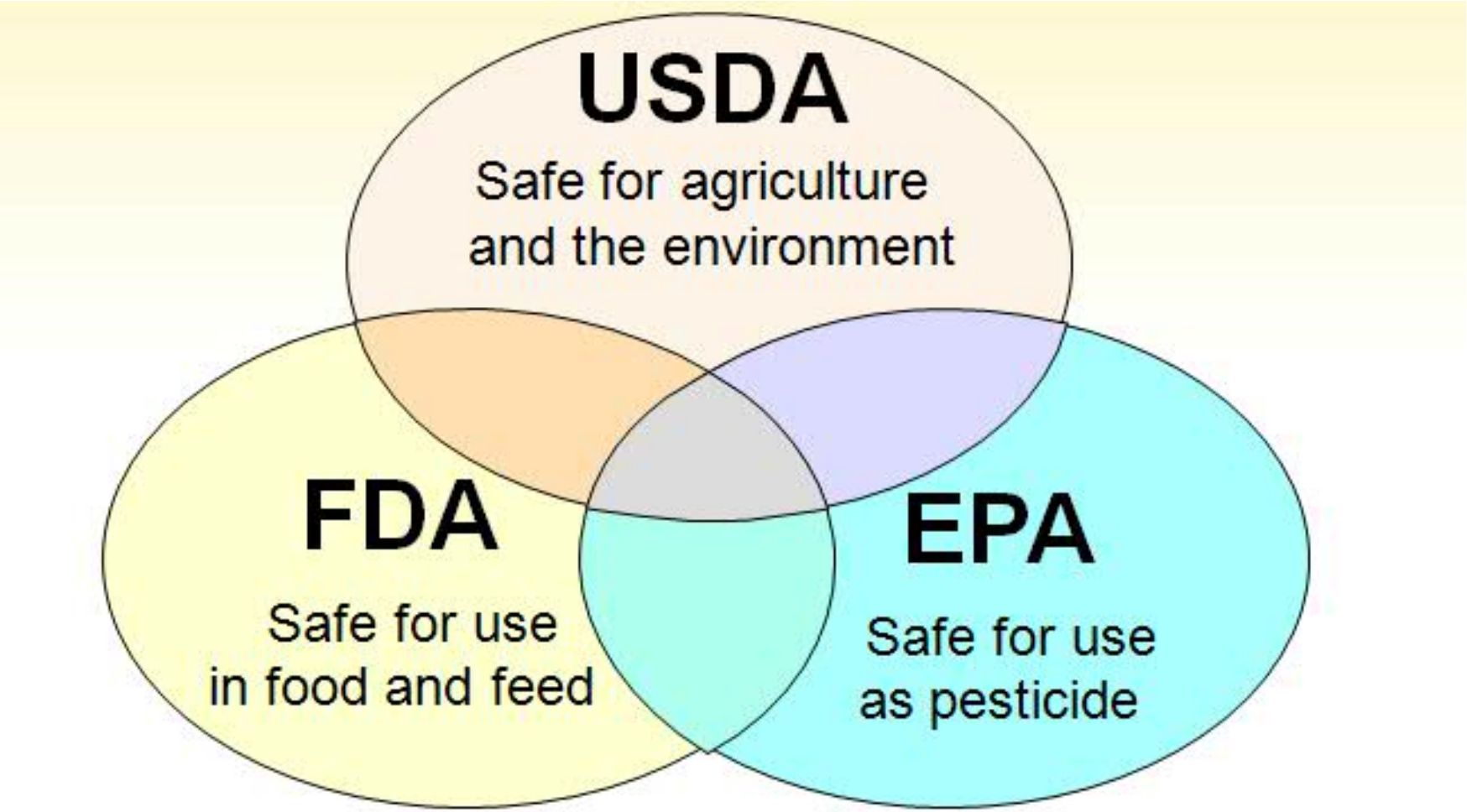
Robert Merker, Supervisor, Regulatory Group B
Office of Food Additive Safety,
Division of Biotechnology and GRAS Notice Review, FDA

Cooperative Activities

USDA's Biotechnology Regulatory Services (BRS) Stakeholder Meeting

Mike Mendelsohn, Senior Regulatory Specialist
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division

Federal Oversight of GE Crops with Pesticidal Traits



EPA works closely with USDA and FDA

1. Regulatory action coordination. Keep each other informed on specific actions and monthly interagency teleconferences. EPA/USDA/FDA information sharing MOU.
2. International outreach and coordination at FAO and OECD.
3. Incident coordination.
4. Small-scale testing of biotech microorganisms. USDA and EPA inform each other each time they receive applications to test biotech microorganisms.
5. USDA makes use of biopesticide and chemical herbicide risk assessments performed by EPA to support their plant pest risk assessments and NEPA compliance involving herbicide and insect resistant crops.
6. Coordination by EPA and USDA regarding weed resistance management related to herbicide resistant crops.

Office of Chemical Safety and Pollution Prevention

Biotechnology Resources

http://www2.epa.gov/regulation-biotechnology-under-tsca-and-fifra

Biotechnology Pesticide Resources

http://www2.epa.gov/pesticides/biopesticides

http://www2.epa.gov/regulation-biotechnology-under-tsca-and-fifra/overview-plant-incorporated-protectants

Biotechnology TSCA Resources

https://wcms.epa.gov/regulation-biotechnology-under-tsca-and-fifra/overview-biotechnology-under-tsca

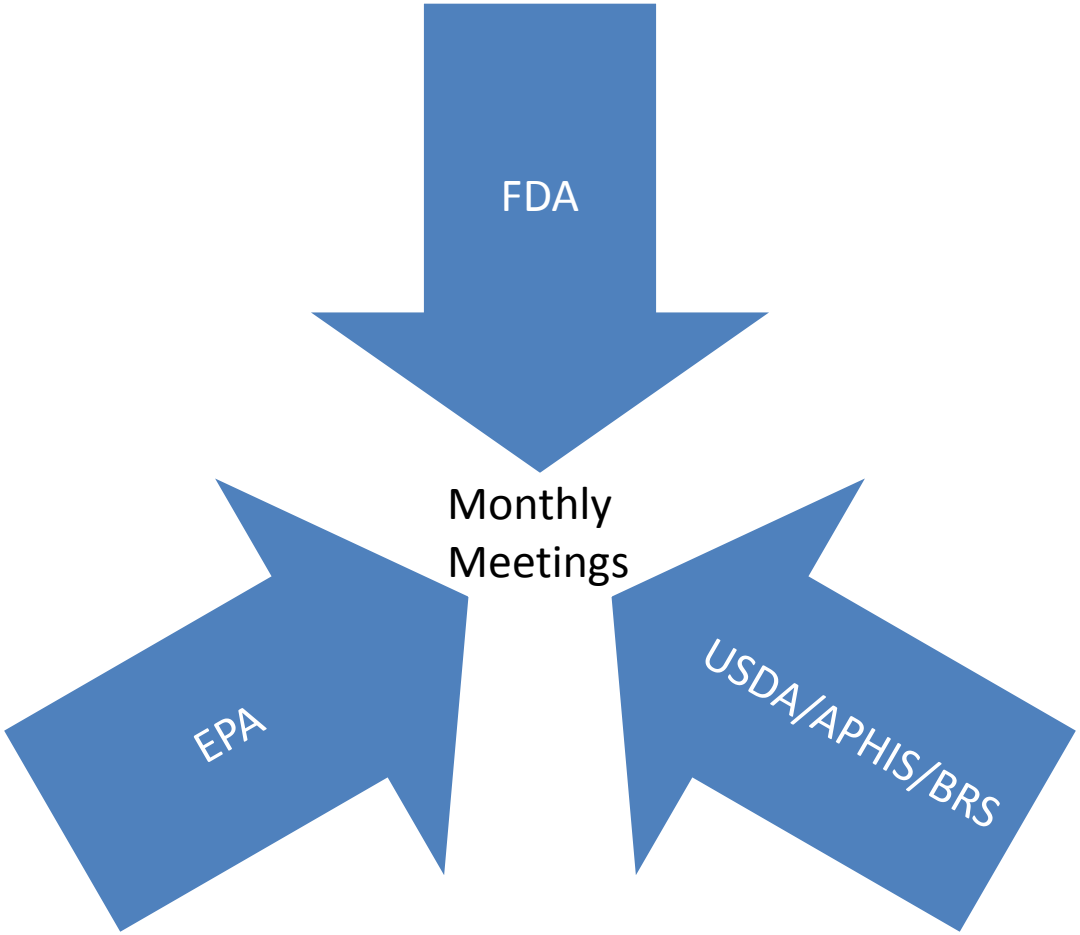
Microbial Products of Biotechnology; Final Regulation Under the Toxic Substances Control Act; Final Rule

40 CFR Parts 700, 720, 721, 723, and 725

Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms

FDA's Role in the Coordinated Framework and Interagency Communication

Communication and Coordination

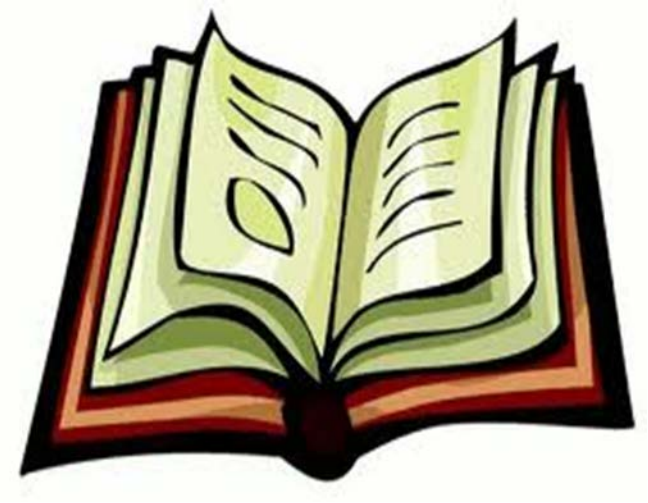


Consult with us

Tell us your story… about the new plant variety and why it is safe for food (and feed) use

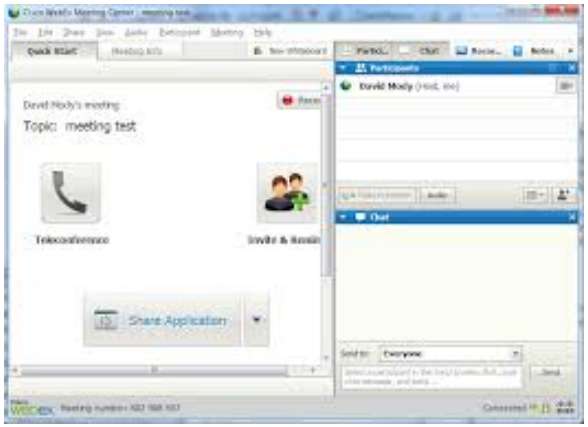
Consult early –

Avoid surprises



How to Interact with FDA

1. In Person
2. Teleconference
3. Computer Assisted Meeting (WebEx)



FDA regulates all Food and Feed

Contact Information

Contract Information	Consultation Lead Robert Merker (robert.merker@fda.hhs.gov)
	General questions: http://www.fda.gov/GEPlantFoods premarkt@fda.hhs.gov
	Early Food Safety Evaluations Carrie McMahon (carrie.mcmahon@fda.hhs.gov)

Biotechnology Regulatory Services

APHIS eFile Update

Janet Bucknall

APHIS Associate Deputy Administrator for BRS

Annual Stakeholder Meeting

November 18, 2015

The CARPOL Effort – An APHIS Enterprise Approach

(C)ertification

(A)ccreditation

(R)egistration

(P)ermitting

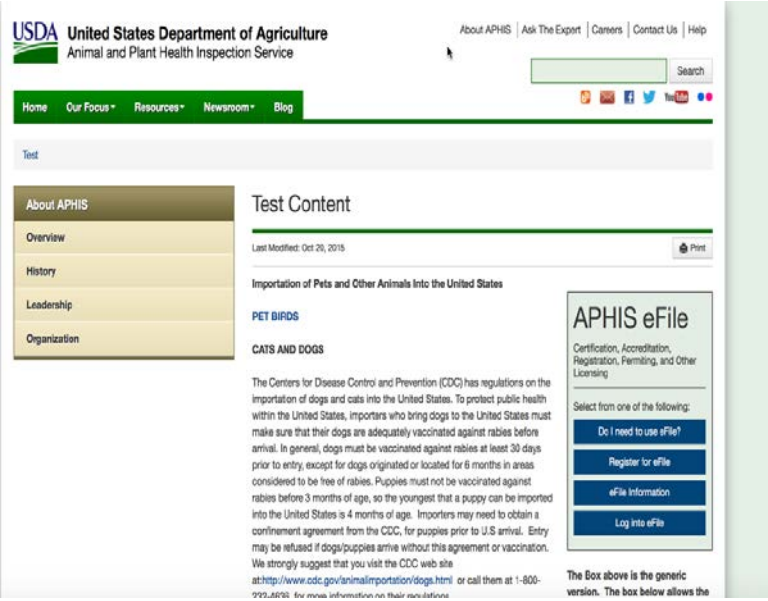
(O)ther (L)icensing

APHIS Systems

- 8 Legacy Applications
- 12 Feeder Systems
- 900,000 Authorizations Annually
- 30,000 Global Users

APHIS eFile

- Single electronic system
- Cloud based
- Salesforce1 Platform



BRS Permitting

- Under construction now
- User Acceptance Testing (UAT) expected early summer
- Implementation expected end of 2016

USDA-APHIS-BRS on the web:

http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology

Become a BRS Stakeholder:

Go to the link above and click on the red envelope on left side of the page

Questions?

Extensions

Leveraging 28 years of Experience To Increase Efficiency

John Turner

Director, Biotechnology Risks Analysis Programs

USDA APHIS BRS

Biotechnology Regulatory Services

2015 Stakeholder Meeting

November 18, 2015

2,4-D resistance?

Altered oil content?

Coleopteran resistance?

What do you think is the most frequently reviewed trait in the 115 petitions that we have deregulated?

Male sterile?

Drought tolerant?

Altered ripening?

Glyphosate resistance?

Top Traits in Petitions

1. Glufosinate resistance – 26 petitions!
2. Lepidopteran resistance – 25 petitions
3. Glyphosate resistance – 22 petitions
4. Coleopteran resistance – 11 petitions
5. Fruit ripening altered – 9 petitions
6. Virus resistance – 8 petitions

Which Plants have been most frequently reviewed in petitions?

1. Corn - 34 petitions
2. Soybean - 20 petitions
3. Cotton - 17 petitions
4. Tomato - 11 petitions
5. Rape/canola – 9 petitions
6. Potato - 7 petitions

- **APHIS spends a lot of time doing assessments for crops and traits that have already been assessed and found not to pose a plant pest risk**

- **Is there a way to leverage this previous work to expedite review of similar organisms without compromising risks to plant health and without a rule change?**

From the Regulations:

The Administrator may determine that a regulated article does not pose a potential for plant pest risk, and should therefore not be regulated under this part, based on the similarity of that organism to an antecedent organism.

A person may request that APHIS extend a determination of nonregulated status to other organisms. Such a request shall include information to establish the similarity of the antecedent organism and the regulated articles in question.

7 CFR 340.6 (e)

The Extension Project

- **BRS announced at our last stakeholder meeting in 2014 a project to explore the expanded use of petitions and to define a truly expedited process.**

- **We've since developed guidance for developers on what types of plants can qualify and information requirements.**

To be Eligible for Extensions

- **APHIS must have previously approved a petition or petitions with the same *mechanism of action(s)* in the same crop as in the extension request.**

or,

- **APHIS must have previously approved a petition with the same phenotype category in the same crop as in the extension request and has approved the same *mechanism of action* in some crop.**

We envision three categories of extensions:

1. Where a previously reviewed trait is introduced into different varieties of the same crop. For example, various apple varieties genetically engineered with the same non-browning trait as in one of the antecedent Arctic® apple events in “Golden Delicious’ and ‘Granny Smith’ varieties (10-161-01p).

We envision three categories of extensions:

2. Where traits previously reviewed separately in a particular crop are stacked into the same crop by introducing them together as a "molecular stack." For example, a stacked corn line is created by introducing both an *epsps* gene (previously reviewed in corn) and a *cry* gene from *Bacillus thuringiensis* (previously reviewed in corn). In this case there will be two or more antecedents.

We envision three categories of extensions:

3. Where phenotype categories have been reviewed previously in the crop but a mechanism of action new to the crop has been reviewed in another crop. For example, if the *hppd* gene which confers resistance to mesotrione herbicide is introduced in corn (*hppd* was previously reviewed in soybean and many herbicide resistant corn lines have been reviewed). In this case there will be two or more antecedents.

Data Requirements

- A complete description of the genotype and phenotype of the regulated article(s). This includes a description of the following:
  - Genetic modifications in the regulated article(s) under consideration.
  - Function and donor organisms for any inserted genetic material.
  - Transformation vector.
  - Mechanism of action of the genetic modification.

Data Requirements

- A molecular characterization of the regulated article.
- A complete concise written narrative comparison and summary table of the regulated article and the antecedent(s).
- Information on the phenotypic expression describing differences between the regulated article and the antecedent organism(s).
- The petition number(s) of the determinations from which this extension is requested.

Time for Completion of Extensions

- Timelines for review may become longer as the similarity to antecedents decreases. In our case examples similarity decreases from case 1 to 3.

- Previous NEPA (National Environmental Policy Act) analyses may not be sufficient and additional analyses may be required. This may increase the total time for extensions.

- APHIS believes that in most cases meeting one of the three criteria, review will be completed in 8 months or less.

Important Concepts

- There may be one or more antecedents.
- Developers requesting extensions may rely on antecedents in petitions from other developers.
- NEPA considerations are to some extent independent of considerations of whether something qualifies as an extension.
  - In some cases NEPA will involve only a new FONSI.
  - In other cases, a new environmental assessment will need to be prepared.
- Field data may not be required.
- We encourage developers who are considering extensions to come and talk to us.

The Extension Project Committee

- Virginia (Ginny) Boulais – Chair
- Donna Lalli
- Neil Hoffman
- Chessa Huff-Woodard
- John Turner

Executive Champion - Janet Bucknall

Questions?

7 CFR Part 340 Proposed Rule:

Our Current Thinking

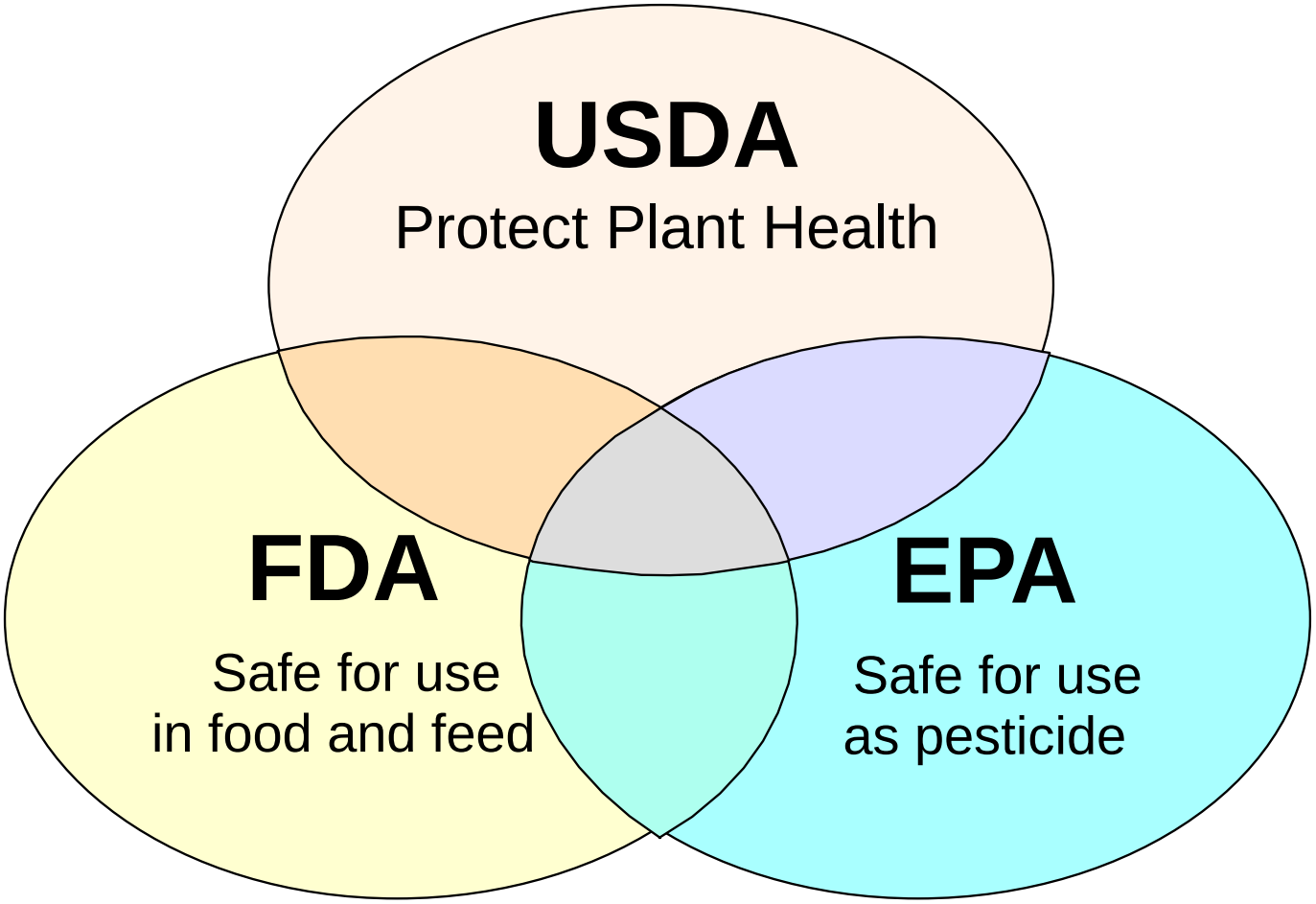
BRS Stakeholder Meeting, November 18, 2015

Michael Firko, Ph.D

APHIS Deputy Administrator

Biotechnology Regulatory Services

Regulation Under the Coordinated Framework



Coordinated Framework Concepts

- The risks of GE organisms are not fundamentally different from risks posed by non-GE organisms with similar traits.
- Regulation should be science-based and conducted on a case-by-case basis.
- The existing laws provide adequate authority.
- Agencies should stick to their statutory authority

New Regulations

USDA's "Topline Messaging"

- USDA's biotech regs have protected…
- Science is changing
- Regulations are from 1987 (with a few tweaks)
- Plant Protection Act of 2000
- Focus on risk
- Move from "Regulate first/analyze later" to…
- Regulatory Relief

New Regulations

This is our CURRENT THINKING

- Where are we?
  - Webinars, 221K
  - NOI in December, 2015
  - Weed Risk Assessment (WRA) tool
  - Completed several WRAs
  - Developing PR concepts… publish PR next summer

New Regulations

This is our CURRENT THINKING

- Regs written 1987 (PPA)… 28 yrs of learning
- Statutory Authority
- Regulatory Relief
- New trigger/definition
- Mere involvement of a PP does not confer risk

Current 7 CFR 340

- Regulated article:
  - ✓ If the organism has been altered or produced through genetic engineering (rDNA techniques)

AND

  - ✓ If there is a possibility that the GE organism could be a plant pest, i.e.,
    - The organism was produced using plant pests (donor, recipient, or vector agent is a plant pest) ***or***
    - There is otherwise a reason to believe that the organism is a plant pest

New Regulations

This is our CURRENT THINKING

- Regulate ONLY w/documented risk
- From “Regulate First/analyze later” to “Analyze first/regulate when risk can be documented ”
- Regulation will be Risk-based
- Review vs. Regulate (What comes in?)

New Regulations

This is our CURRENT THINKING

- Umbrella
- Precision breeding
- What comes “in”?
- Trade/Foreign trading partners

Questions ?