

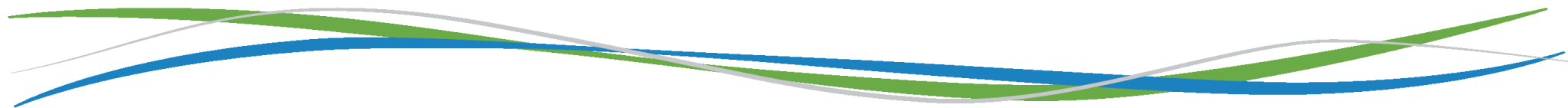
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The Status and Future of Biopesticides

Charles “Billy” Smith, Acting Director
Biopesticides and Pollution Prevention Division (BPPD)
Office of Pesticide Programs (OPP)
Office of Chemical Safety and Pollution Prevention (OCSP)





Charles “Billy” Smith

- Has been with the Office of Pesticide Programs since 2004.
- Currently the Acting Director of the Biopesticides and Pollution Prevention Division.
 - Charged with overseeing the Registration and Registration Review for all biopesticides.
- Prior to joining BPPD, served 4 years as the Deputy Director of the Pesticide Re-evaluation Division (PRD) leading the conventional pesticide Registration Review program.
- Before joining PRD, spent 12 years in the Health Effects Divisions serving as the acting Deputy Director, as a Branch Chief, and as an exposure/risk assessor.
- Extensive experience in the interpretation of exposure data, conduct of risk assessment, and the development of exposure and risk assessment policy.
- Significant experience related to risk management decisions, leading organizations, and working with multidisciplinary technical teams.



Biopesticides and Pollution Prevention Division

- Our Mission – To protect human health and the environment by ensuring the availability of properly regulated biopesticides, and encouraging sustainable pollution prevention practices
- Division houses both regulatory and risk assessment functions
 - BPD – focuses on biochemicals
 - MPB – focuses on microbials
 - RAB – performs risk assessments for biochemicals and microbials
 - ETB – focuses on emerging technologies
 - ESB - Pesticide Environmental Stewardship Program and Center for Integrated Pest Management
- Currently about 65 staff





Goals

- Provide a background on biopesticides and BPPD
- Discuss BPPD's current workload
- Discuss BPPD's process improvement and digital transformation work
- Discuss BPPD's stakeholder and international engagement
- Biopesticide outlook for the future



Biopesticides in the U.S.

- Microbial pesticides
 - Microorganisms that produce a pesticidal effect
- Plant Incorporated Protectants (PIPs)
 - Pesticidal substances that plants produce and the genetic material that has been added to the plant
 - EPA regulates the protein and its genetic material, but not the plant itself.
- Biochemical Pesticides
 - Are naturally occurring chemicals or are synthetically derived equivalents;
 - Have a history of exposure to humans and the environment demonstrating minimal toxicity, or in the case of synthetically derived biochemical pesticides, are equivalent to a naturally occurring chemical that has such a history; and
 - Have a nontoxic mode of action to the target pest(s)



Benefits of Biopesticides

- Generally pose fewer risks compared to other types of pesticides
- Low environmental persistence leading to reduced potential for exposure
- Can be target specific
- When used as part of IPM program, can decrease use of conventional pesticides
- When used in rotation with conventional pesticides, can reduce incidence of resistance development
- Often require reduced restricted entry interval and have no pre-harvest interval – greater flexibility for growers
- May address minor crop or limited pest control needs that are not addressed by conventional pesticides



BPPD Current Workload

Registration

- New AIs: ~40
- New Uses: ~35
- Other PRIA Actions: ~250
- Non-PRIA (working to reduce backlog, redistributing work to utilize new staff/resources)

Registration Review

- 3 proposed interim decisions
- 13 interim decisions
- Working on developing workplans for next round





BPPD Current Workload Cont.

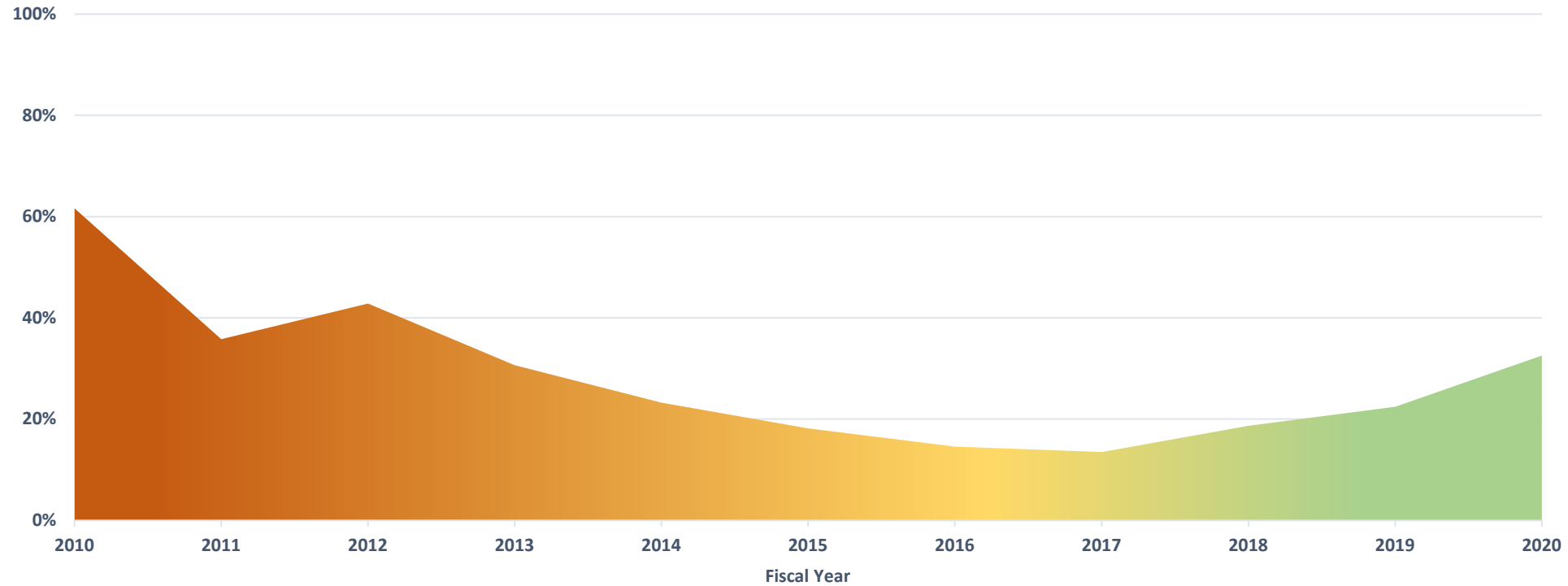
Other Work

- 25(b) ANPRM
 - Considering whether regulatory/policy changes are needed to improve the exemption provisions for pesticides that may be considered minimum risk
- PIPs Exemption, Final Rule
 - Proposed Exemption for “Plant-incorporated protectants based on sexually compatible plants created through biotechnology”
- Biostimulants Guidance
 - Provide certainty and transparency for the growing area of plant biostimulants
- Insect Resistance Management Proposed New Framework for Bt Corn Lepidopteran Pests





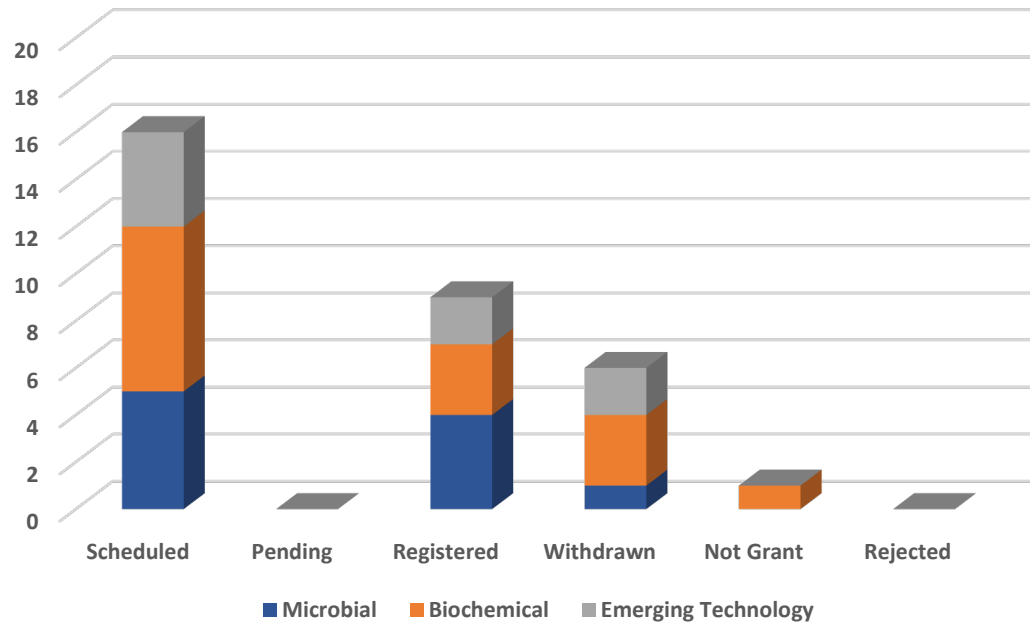
BPPD Renegotiation Rate For PRIA Actions



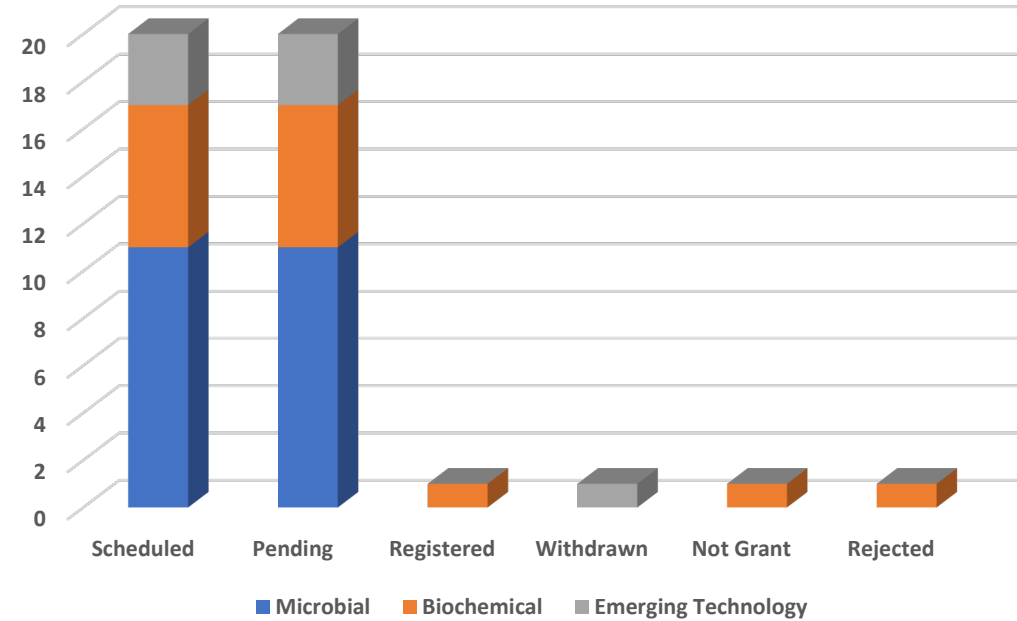


FY20 and FY21 New Active Ingredient Decisions

FY2020 New Biopesticide Active Ingredient Decisions



FY2021 New Biopesticide Active Ingredient Decisions



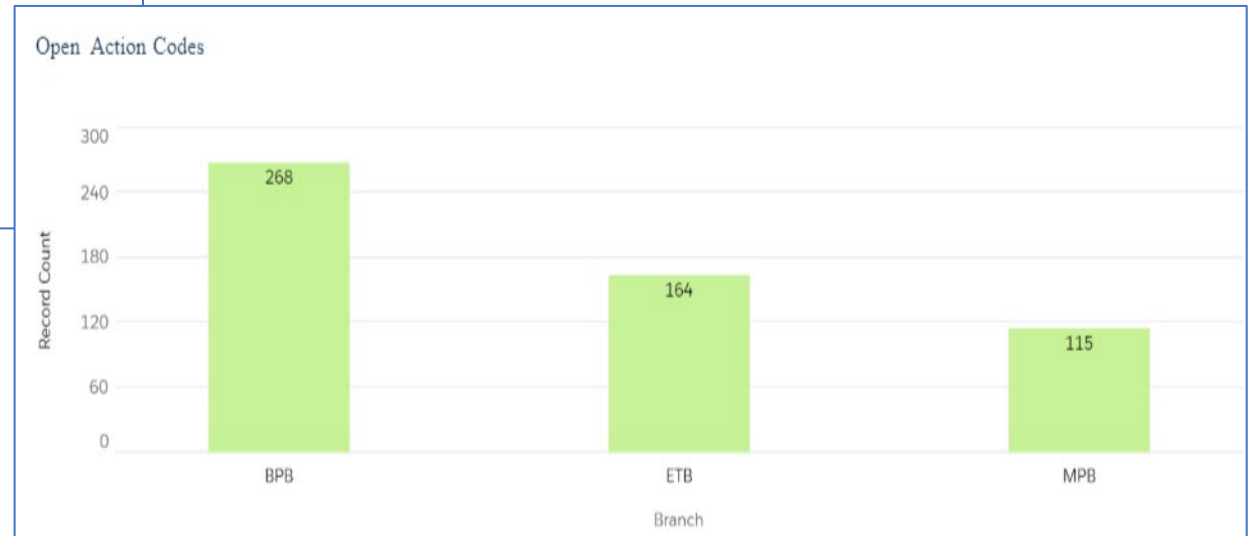
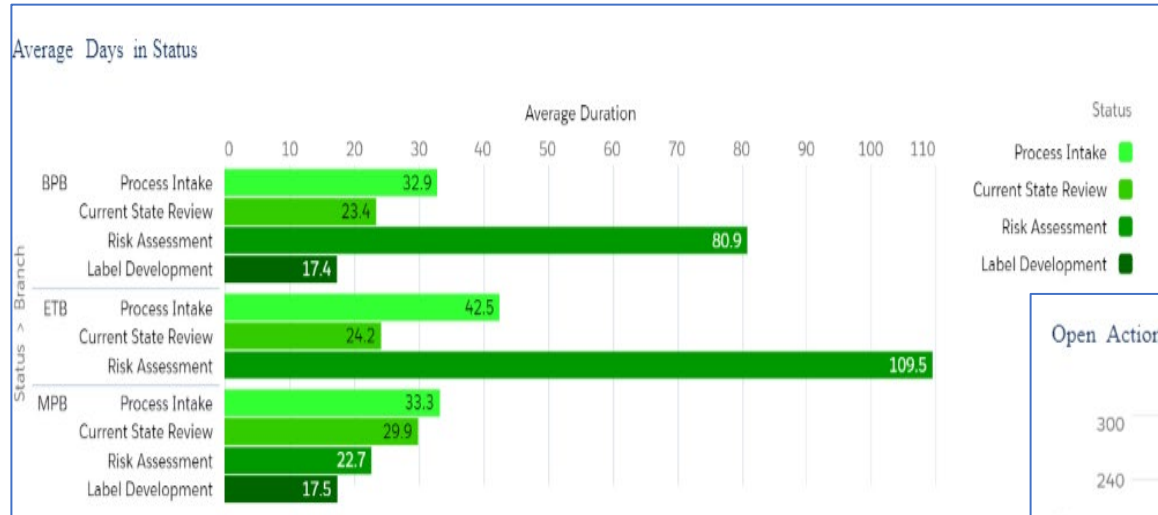


Digital Transformation (Salesforce)

- Implemented use of Salesforce in Fall 2020
 - Improved tracking and reporting capabilities
- Adopting EPA Lean Management System (ELMS) new AI process in Salesforce
 - Focus on process and areas that can be streamlined/improved
- Also working to pilot Registration Review chemicals in Salesforce this fiscal year
 - Focus on entire workplan development and mapping out the Registration Review process



Digital Transformation (Salesforce)





Other Process Improvement

- Biochemical Classification Committee “re-work”
 - Bringing in experts across OPP to determine biochemical classification decisions
- SOP development
 - Risk assessment expectations under common PRIA codes
 - Eco review/assessment SOP
- Risk assessment template development



Stakeholder and International Engagement

- Work with our biopesticide registrant community, Biological Products Industry Alliance, Crop Life America
- OECD Participation
 - Chair of Expert Working Group on Biopesticides
 - Working Party on Harmonization on the Regulatory Oversight of Biotechnology Products
 - Working Party on Safety of Novel Foods and Feeds (Participates with FDA regarding food and feed safety biotechnology issues)
 - Working Party on Pesticides (Expert Group on RNAi)
- Co-chair of the Microbials and Bees Subgroup within the International Commission on Plant-Pollinator Relationships (ICP-PR) Bee Protection Group
- International engagement for workshops, meetings, and capacity building related to biotech issues
- Pesticide Program Dialogue Committee (PPDC) Resistance Management Workgroup
- IPM Webinars
 - Focus on educational and practical strategies for establishing and improving integrated pest management programs in facilities and environments





Future of Biopesticides

- Continued surge in biopesticide applications
 - Averaging 20-30 new active ingredient applications per year
- Continued focus on consistent science around biochemicals
 - Working with Health Effects Division and Ecological Fate and Effects Division
- Emerging technologies and innovations in biotech are advancing in ways presenting policy and assessment challenges:
 - GE mosquitoes
 - Gene editing (e.g., CRISPR)
 - PIPs Rule
- Biostimulants Guidance
- Minimum Risk Pesticides





Questions?

