PRIA 5 Workshop

April 19, 2023

Marriott Marquis, Washington, DC

and Zoom

Welcome

Megan Provost

President, RISE, and Chair, PRIA Coalition

Rick Keigwin

Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention (OCSPP), Environmental Protection Agency (EPA)

PRIA Coalition

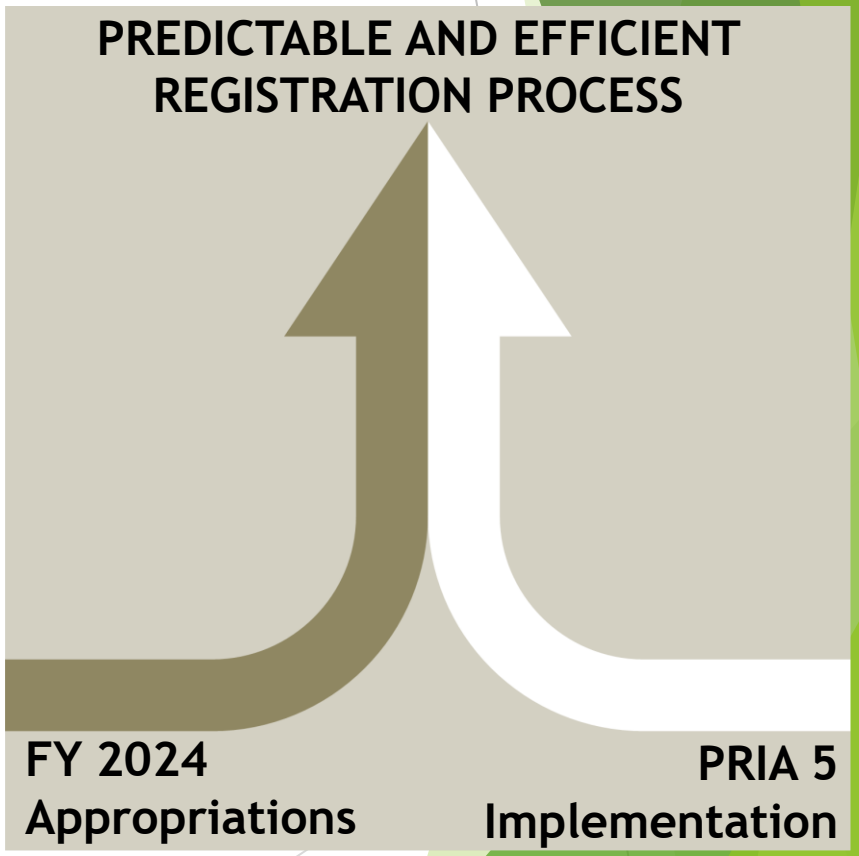
- Coalition Members:
  - American Chemistry Council's Center for Biocide Chemistries
  - Animal Health Institute
  - Biological Products Industry Alliance
  - CropLife America
  - Council of Producers & Distributors of Agrotechnology
  - Household & Commercial Products Association
  - ISSA, The Worldwide Cleaning Industry Association
  - RISE (Responsible Industry for a Sound Environment)

Pesticide Registration Improvement Act (PRIA)

- First authorized in 2004
  - PRIA was reauthorized by the Pesticide Registration Improvement Renewal Act of 2007, the Pesticide Registration Improvement Extension Act of 2012, and Pesticide Registration Improvement Act Extension of 2018
- Under PRIA: Companies must pay service fees according to the category of the registration action
- EPA must meet registration decision review time periods, which result in a more predictable evaluation process for companies
- Shorter decision review periods are provided for reduced-risk registration applications

Our Approach: Appropriations and Implementation

- Work to increase annual appropriations for OPP
- Implement our PRIA 5 reauthorization bill that includes adequate resources for OPP, along with significant process improvements and efficiencies



PRIA Appropriations

- FY 2022 Funding: $129.367 million
- FY 2023 Funding: $140.457 million
  - Industry Request: $163 million
  - President's Budget: $138.341 million
  - House-Passed Funding: $158.675 million
  - Senate Draft Funding: $140.841 million
- FY 2024 Process Underway
  - **Industry Request: minimum of $166 million**
  - President's Budget: $172.18 million
- *PRIA Funding Trigger:*
  - *PRIA 4: $128.3 million*
  - ***PRIA 5: $166 million***

Overview of PRIA 5

Laurie Flanagan

Vice President, DC Legislative & Regulatory Services, and Coordinator, PRIA Coalition

PRIA 5 Addresses All PRIA Coalition Priorities

- Clean reauthorization free of extraneous policy issues
- Ensuring that EPA has the resources it needs to meet deadlines for both PRIA and non-PRIA actions, but also ensuring that there is more EPA predictability (accountability) around deadlines
- Create a mechanism to ensure that non-PRIA actions are processed in a timely manner and that current backlog is addressed
- Prioritize process improvements, efficiencies, and consistency among reviewers and registering divisions
- Ensuring that OPP user-fee based operations can continue during a government shutdown

PRIA 5 Funding:
A 30% Overall Increase in OPP Funding

- An additional $17 million in industry fees
  - Total of $67 million from industry
  - Up from the current $51 million
- A goal of an additional $37 million in additional federal appropriations
  - Total of $166 million from appropriations
  - Up from the current $128 million

PRIA 5 Funding: *Maintenance & Registration Fees*

Maintenance Fees = $42 million annually

- Up from the $31 million
- The caps will be as follows:
  - $172,200 for large businesses with 50 products or less;
  - $277,200 for large business with more than 50 products;
  - $105,000 for small businesses with 50 products or less;
  - $184,800 for small businesses with more than 50 products
- The per product fee is $4,875
- Average cap increase of $47,000
- Move all set asides to come from maintenance fees (Section 4 funds) to provide greater certainty and transparency of funding, rather than some from registration fees (Section 33 funds)
- Effective retroactively to October 1, 2022 (FY2023), supplemental invoices issued

Registration Fees = Estimated $26 million

- Up from the current $20 million
- In general, 30% increase for each fee category
- Registration fees will increase by 5%:
  - On October 1, 2024 (or after) IF EPA has begun to implement an information technology system and includes all registering divisions and provides a real-time, accurate tracking system for all regulatory submissions OPP
  - On October 1, 2026 (or after), IF EPA has begun to implement the appropriate process improvements identified in the third-party audit outlined below
- Continues the prohibition on tolerance fees
- Effective 60 days after enactment (February 27, 2023)

PRIA 5 Funding:
New Maintenance Fee Set Asides

- Create a set aside for processing registrant submissions not covered by a PRIA code and to clear the current backlog at 1/8 of the total maintenance fee fund (roughly $5.25 million per year)
- $500,000 set aside for EPA staff education and training to be conducted cooperatively through land grant institutions in partnership with HBCUs, 1890 institutions, or other minority-serving institutions
- $500,000 set aside for Vector Expedited Review Voucher (VERV) to incentivize development of new insect disease vector control methods, with any unused funds returning to general maintenance fee fund
- $500,000 set aside to begin development of public health performance standards for antimicrobial devices
- $500,000 set aside for education and training of clinicians
- $500,000 set aside to support the interagency agreement between EPA and CDC/NIOSH related to the SENSOR Pesticide Program, with a goal of increasing the number of participating states and/or improving the reporting of existing participants
- $350,000 set aside for grant writing technical assistance

PRIA 5 Funding:
Continued Maintenance Fee Set Asides

- Increase worker protection activities to an average of $1,500,000 per year (previously funded at 1/17 Pesticide Registration Fund, but not less than $1,000,000 per year)
- Pesticide Education Safety Program (continued at $500,000 per year)
- Partnership grants (continued at $500,000 per year)
- Good Laboratory Practices (GLP) inspections (continued at $500,000 per year)

PRIA 5 Funding:
Eliminated Maintenance Fee Set Asides

- Efficacy guidelines for public health pests (previously funded at $500,000 per year)
- Fast track and inert review set aside (previously funding at 1/8 to 1/9 of maintenance fees)

PRIA 5 Fee Charts:
*Highlights from **Registration Division** (Tables 1-6)*

- RD PRIA Technical Team (AHI, CLA, HCPA and RISE) compared average completion times to decision review times for all R and I codes
- Technical assistance from RD: time estimates for contractor review, FR notice, public comments process, and ESA
- For new outdoor AIs only, time increased 50% for ESA review
  - No time increase for ESA review where guidance is lacking, e.g., new indoor AIs, new uses, EUPs
- For several categories added 1 to 3 months for public participation process and or FR publication
- EPA must release DERs for all studies to applicant by end of decision review time

PRIA 5 Fee Charts:
*Highlights from **Registration Division** (Tables 1-6)*

Major changes to categories:

- Table 1: new R126: seed treatment active ingredient; accommodate changes from 2018 guidance
- Table 2: new R276, R277: new seed treatment uses; accommodate changes from 2018 guidance
- Table 3: new R281, R282: import tolerances using APEC protocol
- Table 4: new R361, R362: more combinations of multiple active ingredients and multiple target pests

PRIA 5 Fee Charts:
*Highlights from **Registration Division** (Tables 1-6)*

- Table 4: new R363: splits out repack of MUP as EUP from repack of EUP as MUP (R331)
- Table 5: amendments: no significant changes
- Table 6: new R278: Review protocol for companion animal safety study
- Table 6: new R279: Comparative product determination for reduced risk submission (voluntary)
- Table 6: delete R370: move cancer reassessment to Table 19

PRIA 5 Fee Charts:
ESA Footnote *(throughout charts)*

ESA footnote added to several PRIA codes:

- If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

PRIA 5 Fee Charts:
*Highlights from **Inerts/Miscellaneous***

- Table 18: new I017: add new source or safener
- Table 18: new I018: add one compound to commodity inert list
- Table 19: revised M001: regarding HSRB, adding “currently registered”
- Table 19: new M012: Certificate of Establishment
- Table 19: new M013: Cancer reassessment, combines R370 and A571
- Table 19: new M014: Pre-application nano-particle determination

PRIA 5 Fee Charts:
*Highlights from **Antimicrobial Division** (Tables 7-10)*

- Table 7 (New Active Ingredients):
  - Adjustment of fees for Non-Food Use and Indirect Food Use; Extension of most review timelines for public process
- Table 8 (New Uses):
  - Extension of most review timelines for public process
- Table 9 (New Products & Amendments):
  - Cancer Risk Reassessment moved to MISC codes
  - New End Use Products and Amendments adding new public health organisms—codes divided by 9/10 (vs former 25) organisms
  - Extended review time for A565, New MUP generic data package
- Table 10 (Experimental Use Permits and Other Actions):
  - Removes data review for devices making pesticidal claims from A522
  - New code for efficacy similarity determination

PRIA 5 Fee Charts:
*Highlights from **BPPD** (Tables 11-16)*

- All fees increased by 30%
- Table 11: Combine B610/B611, B600/B12, B613/B580/B590 because they require the same level of effort or were rarely being used and some timeframes were adjusted to accommodate public participation, science committees, ESA, and possibility of deficiency corrections (10-day and 75-day). Add explanatory text to B600 and B610 descriptions.
- Table 12: Combine B630/B642/B643, B640/B631, B644/B650 because they require the same level of effort or were rarely being used and some timeframes were adjusted to accommodate public participation, science committees, ESA, and possibility of deficiency corrections (10-day and 75-day). Add explanatory text to B630, B640, B644 and B645 descriptions.
- Table 13: Discontinue B652 and B671 (unused categories). Combine B674/B675 and update description. Combine B673/B676 and update description. Add two months to all categories except B674 recognize complexity. (Note: Added 2 months timing is consistent across all divisions.)

PRIA 5 Fee Charts:
*Highlights from **BPPD** (Tables 11-16)*

- Table 14: No change
- Table 15: Add explanatory text to B720/B721 descriptions.
- Table 16: Add explanatory text to B682 description. Add two new categories for pre-application conditional ruling on a non-food use determination and biochemical classification determination.
- Table 17: PIPS
- Table 19: M009 Includes EPA confirmation of eligibility for exemption for plant-incorporated protectants

PRIA 5 Fee Charts:
*Highlights from **BPPD** (Tables 17 - PIPs)*

- General
  - Renamed “Biopesticides Division — Emerging Technologies Pesticides”
  - Deleted duplicative categories and clarified others
  - SAP is now standalone option category (triggered as needed)
- Timeline Increase
  - EUPs: **+3 months**
  - New active ingredients: **+4 months**
  - Standalone tolerance exemption categories (more realistic and consistent)
  - ESA 50% timeline increase “footnote” may be applicable for these categories:
  - B780, B800, B820, B870, B880, B883, B884, B890, B922, B923, B924, B926 and B928
  - Applicant to negotiate at pre-submission stage

PRIA 5 Fee Charts:
*Highlights from **BPPD** (Tables 17 - PIPs)*

- New Categories (Driven by new emerging technologies)
  - Category for Biotechnology Notifications – EUP Determination
  - Categories for Genetically Engineered Animals Intended for Use as a Pesticide
  - Categories for Exogenous Applications of RNA to Elicit the RNA interference Pathway in Pests
  - Generic (non-PIP) amendment categories
    - EUP and registration amendments
    - Needed to cover amendments to new RNA and GE animal categories
    - Could also cover future emerging technology categories
      - If subsequently added in future reauthorizations of PRIA
  - M009 Non-FIFRA Regulated determinations
    - Adjust interpretation language to allow for PIP exemption determinations under the rule

PRIA 5 Process Improvements: *Renegotiation Rates*

- Specify allowable reasons for renegotiation of PRIA timelines:
  - If there is new or additional data or information from the applicant that is necessary for EPA to make a decision
  - If a public comment period generates significant comments that cannot be addressed within the original decision time
- New timeframes must be agreed to by the registrant and the Director of OPP
- EPA must provide the registrant a written letter that outlines the justification for why the additional time is needed and the number of days needed to allow EPA to make a regulatory decision
- During the 45-or 90-day technical screens, EPA shall verify and validate the accuracy of the PRIA fee category selected by the registrant
  - EPA must verify any PRIA fee category change in writing
  - If a new PRIA fee category is needed, the PRIA due date shall be calculated based on the original submission date
  - EPA shall develop a process to prevent double payment registration fees
  - EPA shall determine if a submission meets with qualifications for reduced risk
  - EPA shall to the extent practicable grant or deny data waiver requests
- EPA must continue to prioritize the action if EPA misses a PRIA deadline

PRIA 5 Process Improvements:
Registrant Submissions Not Covered by a PRIA Code

- Convert the maintenance fee set aside for inerts into a set aside to address registrant submissions not covered by a PRIA code (non-PRIA actions)
- EPA must seek stakeholder input and publish a plan to address the backlog and the expected annual workload for actions not covered by a PRIA code
- Additional reporting, audit and metric requirements related to these submissions

PRIA 5 Process Improvements:
Third-Party Audit

- EPA shall issue a competitive bid for an independent a third-party audit of the Agency's processes and performance and to make recommended process improvements. The audit must be completed within 2 years (December 29,2024) and must address, at a minimum, the following:
  - The 21-day content screen
  - The 45/90 day technical screen
  - Performance, processes, and progress towards reducing renegotiation rates and the average length or renegotiations
  - Performance, processes, and progress towards eliminating the backlog of registrant submissions not covered by a PRIA code
  - Performance, processes, and progress towards ensuring that all registrant submissions not covered by a PRIA code are completed by the deadlines specified in PRN 98-10: Notifications, Non-Notifications and Minor Formulation Amendments (October 22, 1998, and as amended) and as described in subsections (c)(3)(B) and 18(h) of section 3
  - Compliance with the statute's provisions related to renegotiations and registrant submissions not covered by a PRIA code
  - Information technology systems
  - Recommended improvements to employee training
  - Performance, progress, and processes in completing registration review
  - Other appropriate issues, such as submissions by inert suppliers and fast-track amendments

PRIA 5 Process Improvements: *IT Dashboards*

- Within one year (December 29, 2023) EPA shall create an **IT system** that:
  - Covers all registering divisions in OPP
  - Provides a real-time, accurate tracking system for all regulatory submissions to OPP
  - Provides a real-time, registrant-accessible dashboard that allows registrants to access the progress of their regulatory submissions online
  - Updates the Pesticide Submission Portal to ensure that label reviews are limited to current label changes, automate non-substantive changes, and allow for self-certification for certain actions

PRIA 5 Process Improvements: *Annual Reports*

- Eliminate unnecessary or unhelpful metrics in **Annual Report** from 67 to key metrics:
  - Information on each **PRIA action**, including the action code, the application date, the original decision due date, the dates of any renegotiations and the renegotiated due dates if applicable, the reasons for each renegotiation if applicable, the decision completion date if action has been completed, the status of action, and the reason for any denial or do not grant decision if applicable
  - Information on each **registrant submission not covered by a PRIA code**, including the application date, the type of regulatory action, the status of action, the reason for rejection if applicable, and the completion date if applicable
  - Information on the **screening processes**, including the number of applications successfully passing each type of screen, the number of applications that failed each type of screen, and the number of applications resulting in a rejection
  - Information on **Agency staffing**, including the number of new hires and personnel departures by each OPP division, the number of full time equivalent (FTE) by OPP division, the number of FTEs working on registration review activities, and the number of FTEs working registrant submissions not covered by a PRIA code
  - Maintain some metrics requested by the NGOs

PRIA 5 Process Improvements: *Endangered Species Act*

- EPA shall develop through notice and comment, guidance to registrants regarding analysis necessary to support the review of outdoor uses of pesticide products under the Endangered Species Act
  - Within 9 months of enactment (September 29, 2023) for new active ingredients or any registration review decision proposed for 1 or more outdoor uses
  - Within 1 year of enactment (December 29, 2023) for new out-door uses of a registered pesticide
  - Within 3 years of enactment (December 29, 2025) for antimicrobial pesticide products

PRIA 5 Additions: *Miscellaneous Additions*

- Add certificates of establishment (which serve as proof for pesticide exporters that the product is manufactured at an EPA-registered facility) to Gold Seal letters

- Specify that fee-based activities shall continue in the event of a government shutdown to the maximum extent practicable

PRIA 5 Additions: *Bilingual Label Requirements*

- A phase in of electronic Spanish labels via scannable technology or other electronic methods readily accessible on the product label
  - Only parts of the label contained in the **EPA Spanish Translation Guide for Pesticide Labeling**
- Phased in as follows:
  - Restricted use pesticides (RUPs) within **three years** (by December 29, 2025)
  - Non-RUP products that are designated as Toxicity Category 1 within **three years** (by December 29, 2025) for agricultural products and within **four years** (by December 29, 2026) for non-agricultural products
  - Non-RUP products that are designated as Toxicity Category 2 within **five years** (by December 29, 2027) for agricultural products and within **six years** (by December 29, 2028) for non-agricultural products
  - All other products within **eight years** (by December 29, 2030)
- Registrants of antimicrobial and non-agricultural use products may comply with the bilingual labeling requirement by providing la link to the safety data sheets (SDS) in Spanish (SDS option not available for non-agricultural RUPs)
- EPA shall seek stakeholder input on ways to make bilingual labels available to farm workers and implement a plan with in 3 years (by December 29, 2025)
- After the initial implementation dates, changes to label translations will be made the earlier of
  - The next time the end-product label is changed or amended as released for shipment
  - Within one year of publication of updates to EPA's Spanish Label Translation Guide for agricultural-use pesticide products
  - Within two years of publication of the updates to EPA's Spanish Label Translation Guide for non-agricultural use pesticide products
- The labeling will be done through non-notification
- EPA must consult with the states regarding implementation

PRIA 5 Additions: *Regulatory Information and Resources*

- Direct EPA to post on the Agency's website, aggregated on a single webpage, all EPA guidance pertaining to risk assessment, risk mitigation, benefits assessments, and cost-benefit balancing

- Direct EPA to post on the Agency's website, aggregated on a single webpage, links to resources, including organic farming (national list of allowed and prohibited substances); biopesticides and 25(b) minimum risk pesticides; integrated pest management (IPM) principles, and technical assistance for implementation of IPM

- These websites shall be posted by within 6 months of enactment (June 27, 2023)

PRIA 5 Summary

- A 30% increase in overall funding for OPP
- Coupled with policy and process changes that will:
  - Reduce the high rate of renegotiated PRIA actions
  - Increase the predictability of review timelines
  - Drive an enhanced culture of accountability within EPA's Office of Pesticide Programs (OPP)
  - Establish a process for addressing the non-PRIA backlog in a timely manner
  - Eliminate the ability for EPA to assign two PRIA codes (i.e., fees) to one regulatory submission (i.e., no double dipping)
  - Leverage self certification, where possible, for low-risk regulatory actions
  - Increase the accountability of the Agency to deliver the PRIA annual reports
  - Provide real time access by registrants to EPA tracking of completed and pending PRIA actions

Questions re: Overview of PRIA 5

Laurie Flanagan

Vice President, DC Legislative & Regulatory Services, and Coordinator, PRIA Coalition

Early Implementation of PRIA 5: Resources, IT, and Timelines

Laurie Flanagan

Vice President, DC Legislative & Regulatory Services, and Coordinator, PRIA Coalition

Ed Messina

Director, Office of Pesticide Programs (OPP), EPA

Hamaad Syed

Chief Digital Officer, OCSPP, EPA

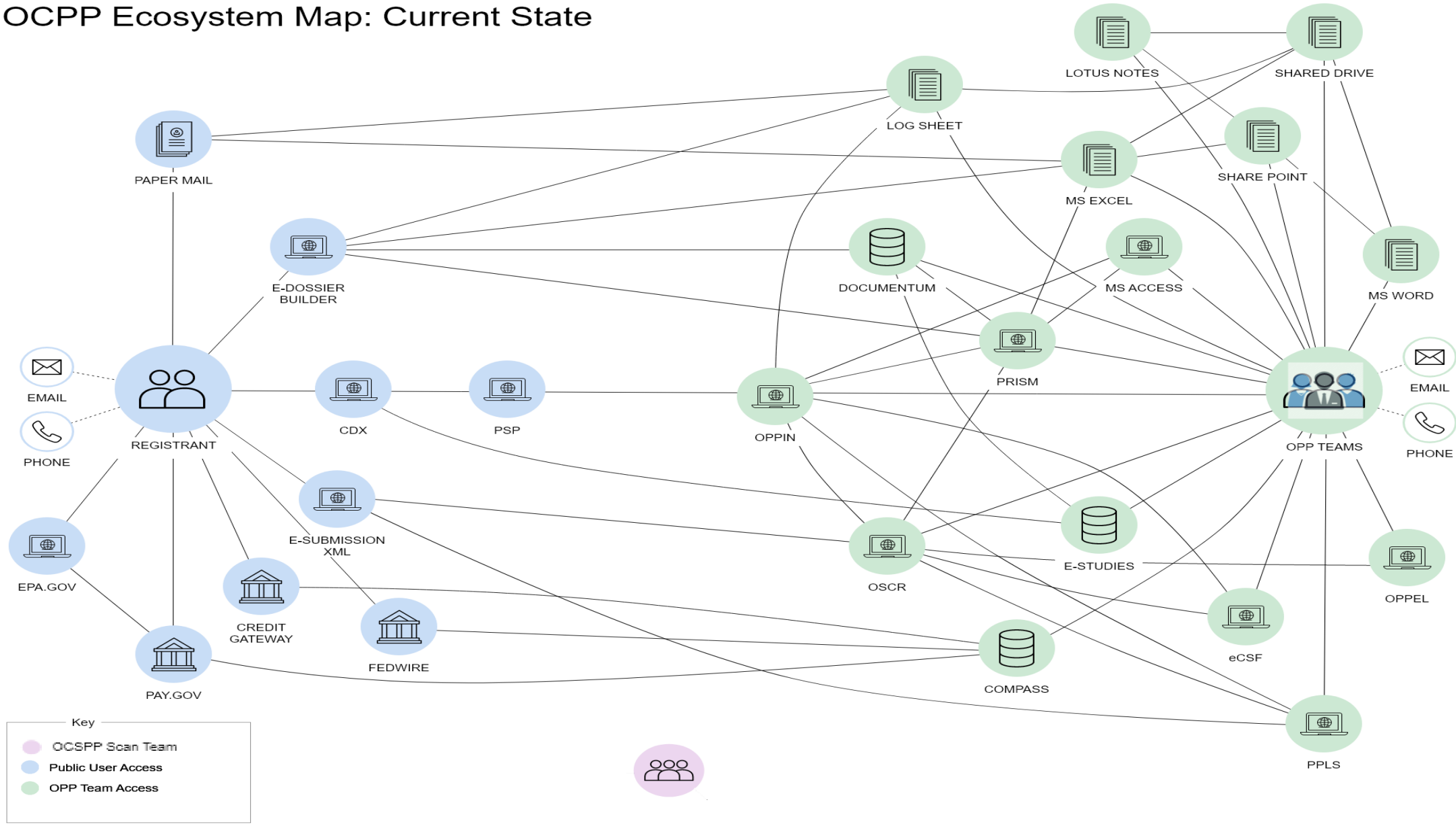
Transforming OCSPP's Mission Through Digitalization

October 2022

Once upon a time…. (As Was)

- Expanding Mission
- Fewer Resources
- Paper-based and E-mail-based Workflow
- Aging custom-built data systems
- Difficult to support remote work

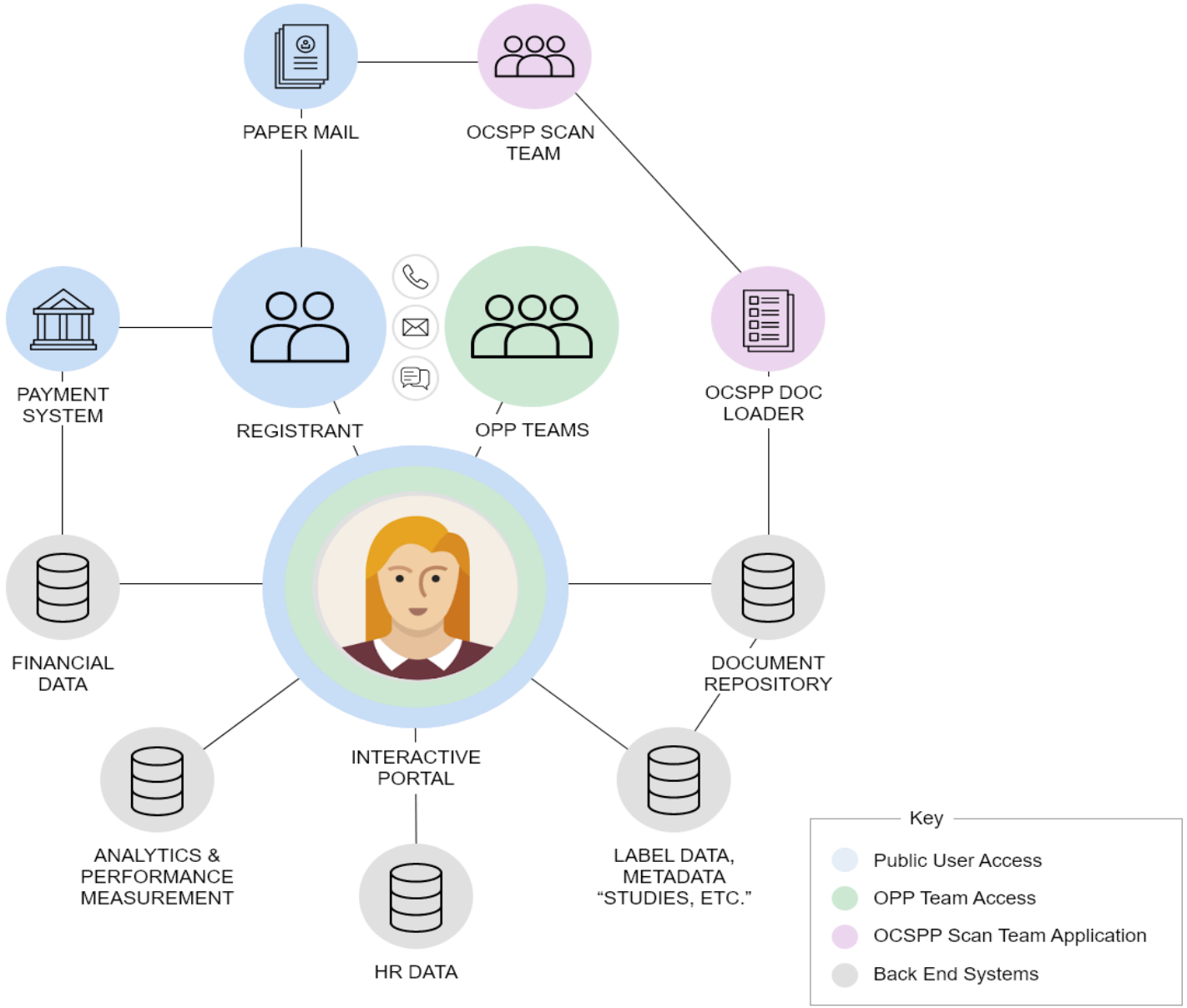
OCPP Ecosystem Map: Current State



Today…. (As Is)

- Platform-Based (Reuse and Compliance)
- Industry-Leading Capabilities (Buy not Build)
- Configure Out of the Box (No Code)
- Human-Centered (Workforce and Stakeholders)
- Reduced Time to Value
- Iterative and Agile
- 3/7 Divisions Live in OPP
- Obtaining Return on Investment

OCSPP Ecosystem Map: Future State



Vision…. (To Be)

Prepare the Soil

- Enterprise Support
- Trusted Data
- Insights for Actions
- Scale for Improved ROI

Seed New Capabilities

- Artificial Intelligence
- Machine learning
- Improved Customer Experience (Pizza Tracker)
- Self-Service
- Bi-Directional Communication
- Hybrid Work Ready

Harvest Sustainably

- Automation
- Sharing Data Across Agency/Govt
- Internet of Things
- Geographic Information Systems
- Predictive Analytics

Implementation Plan

Build the Foundation

PHASE 01

ISB, BPPD & AD

- → Registration workflow management (PRIA & non-PRIA)
- → Workload visibility
- → Reporting

- Cloud-based
- Case hierarchy
- Agile development
- DevOps security
- Finance Central

Enhance & Expand

PHASE 02

All OPP, OPS, and NCD

- → Registration Review
- → Intake processing
- → Risk management
- → Reviews & assessments

- Dashboards & metrics
- Digitized, curated document library
- e-signatures
- Process automation

Integrate & Engage

PHASE 03

Remainder of OCSPP And Industry

- → EPA workgroup management
- → Interagency coordination
- → Stakeholder management

- Interactive registrant portal
- Integrate or retire systems
- 360-degree view of data

Innovate & Predict

PHASE 04

Public & External Stakeholders

- Predictive modeling
- Advanced analytics
- AI/Robotic process automation
- Mobile app

LIGHTHOUSE VISION

- Empowered workforce
- Customer enlightenment
- Transparent processes
- Curated information
- Modern technology

People → Process → Technology

Questions re: Early Implementation of PRIA 5: Resources, IT, and Timelines

Laurie Flanagan

Vice President, DC Legislative & Regulatory Services, and Coordinator, PRIA Coalition

Ed Messina

Director, Office of Pesticide Programs (OPP), EPA

Hamaad Syed

Chief Digital Officer, OCSPP, EPA

Renegotiation Rates in PRIA 5

Jim Jones, President, JJones Environment, and Consultant, Household & Commercial Products Association

Ray McAllister, Founder, RSM Consulting, and Consultant, CropLife America

Anita Pease, Director, Antimicrobials Division, OPP, EPA

Billy Smith, Director, Biopesticides and Pollution Prevention Division, OPP, EPA

Dan Rosenblatt, Acting Director, Registration Division, OPP, EPA

FIFRA Section 33(f)(5)(B) - extension

(B) EXTENSION BY NEGOTIATION OR MUTUAL AGREEMENT.— The Administrator, acting solely through the Director of the Office of Pesticide Programs, and the applicant may mutually agree, in writing, to extend a decision time review period under this subsection if—

(i) there is new or additional data or information from the applicant that is necessary for the Administrator to make a decision on the application that cannot be made available within the original decision time review period; or

(ii) a public comment period associated with the application generates significant comments that cannot be addressed within the original decision time review period.

FIFRA Section 33(f)(5)(B) - priority

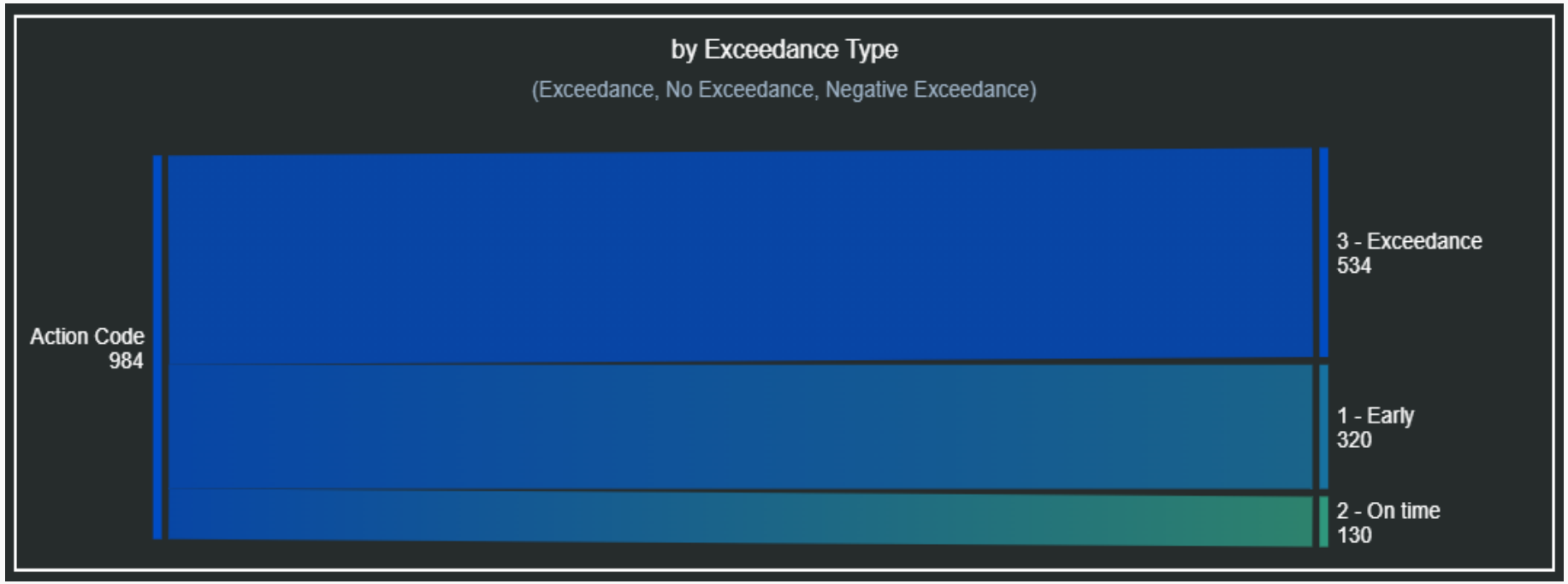
(C) PRIORITY.— Once a decision time review period for a covered action described in subsection (b)(3)(B) is missed or extended, the Administrator shall make any action on the application a priority.

Future of PRIA Metrics

- New focus on total time to complete action
  - Compared to PRIA date

- Real time metrics are already available for A codes, B codes, and M codes from Salesforce
  - Simple exceedance vs. no exceedance (on-time/early)
  - Average days exceeded
  - Percent of time exceeded
    - 100% exceedance on a 4 month action = 8 months total
  - Can breakdown by program, division, type of action, individual PRIA codes

Net Schedule Performance FY22-FY23
A Codes, B Codes, and M Codes



*Represents completion of PRIA actions relative to original PRIA date.

Net Schedule Performance FY22-FY23
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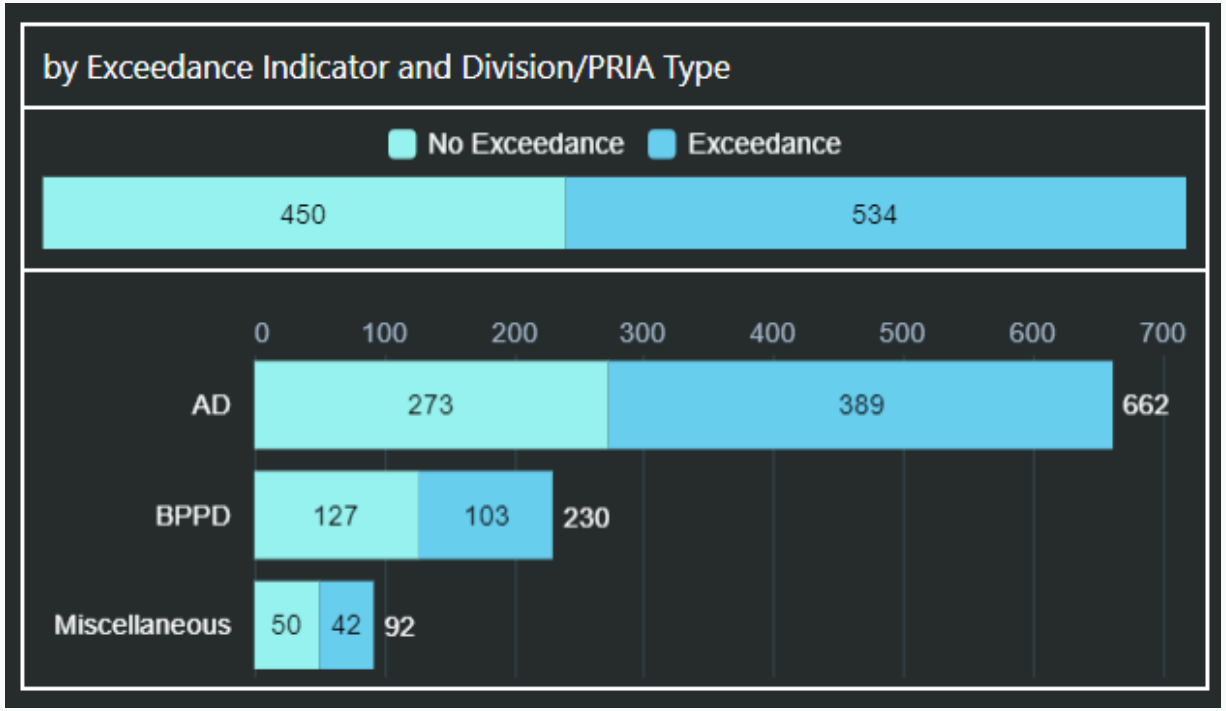

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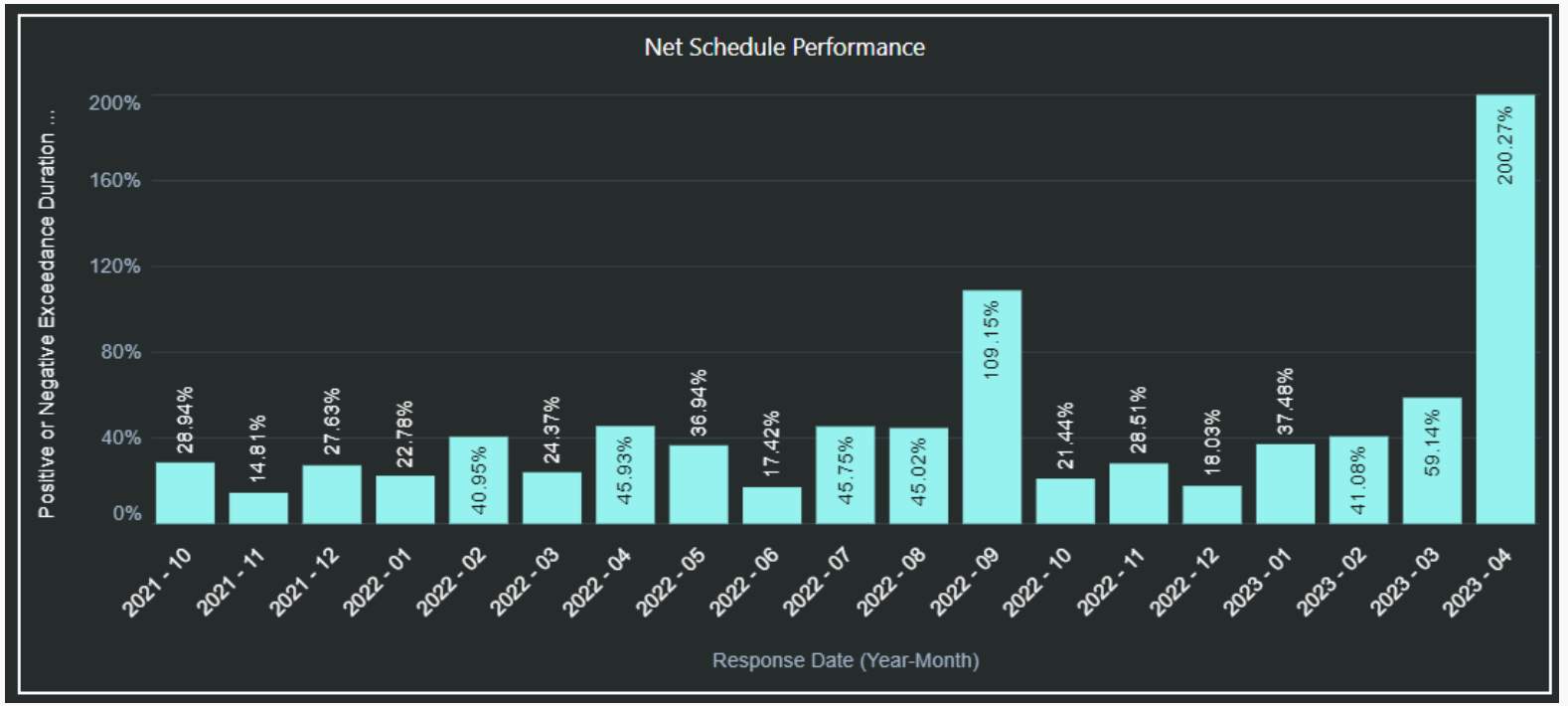
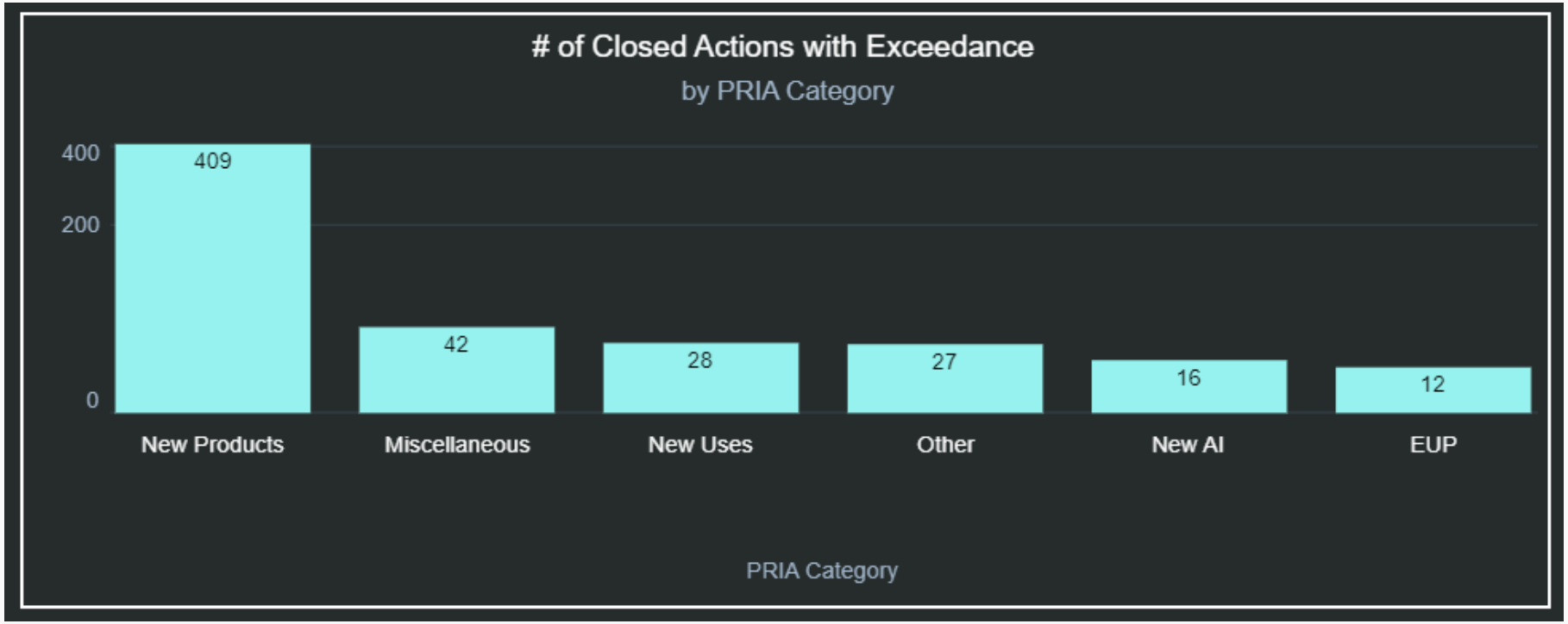
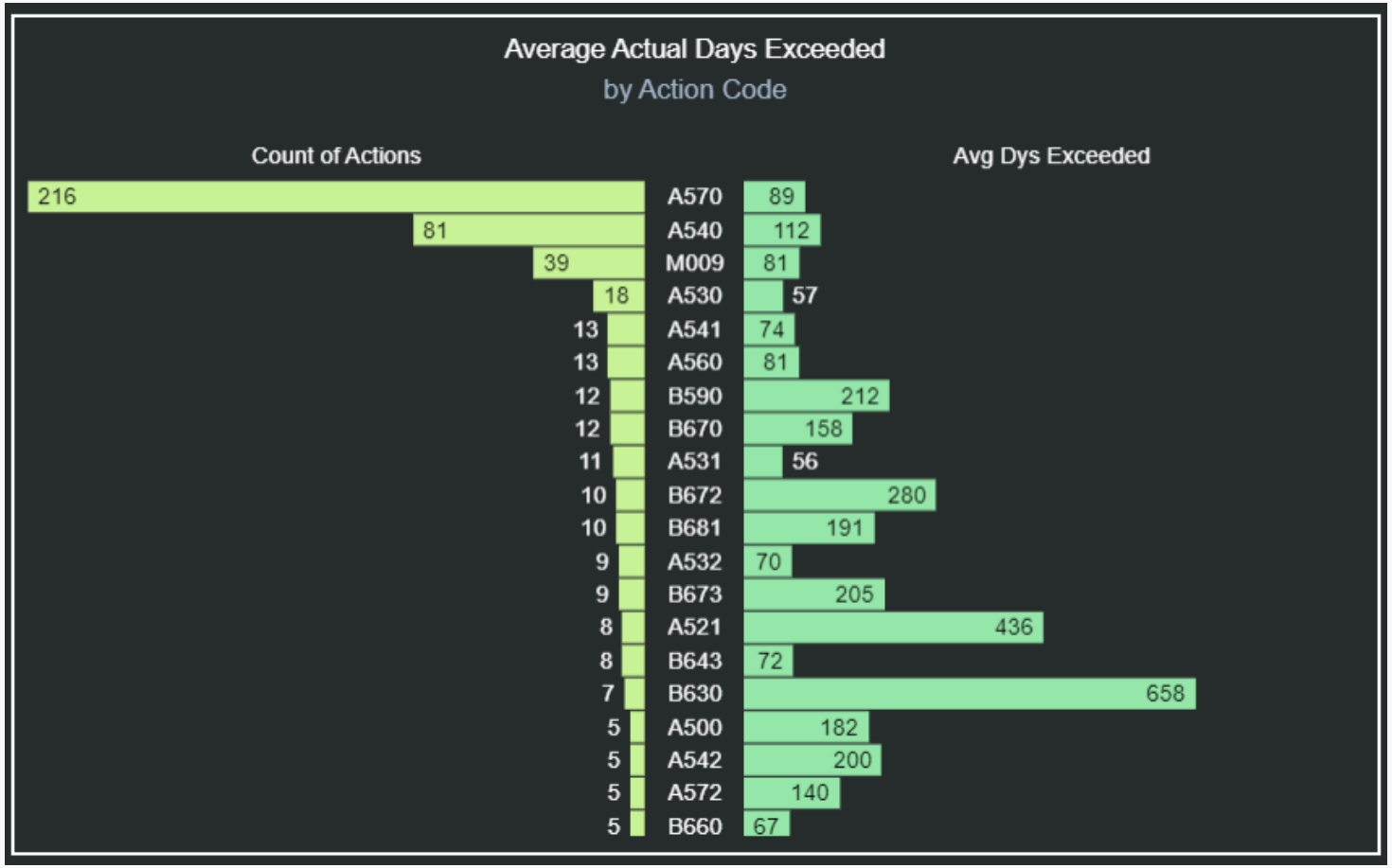


*Represents percent of time original PRIA dates were exceeded across all actions per month.

Net Schedule Performance FY22-FY23 by Type of Action



Net Schedule Performance FY22-FY23 by Code

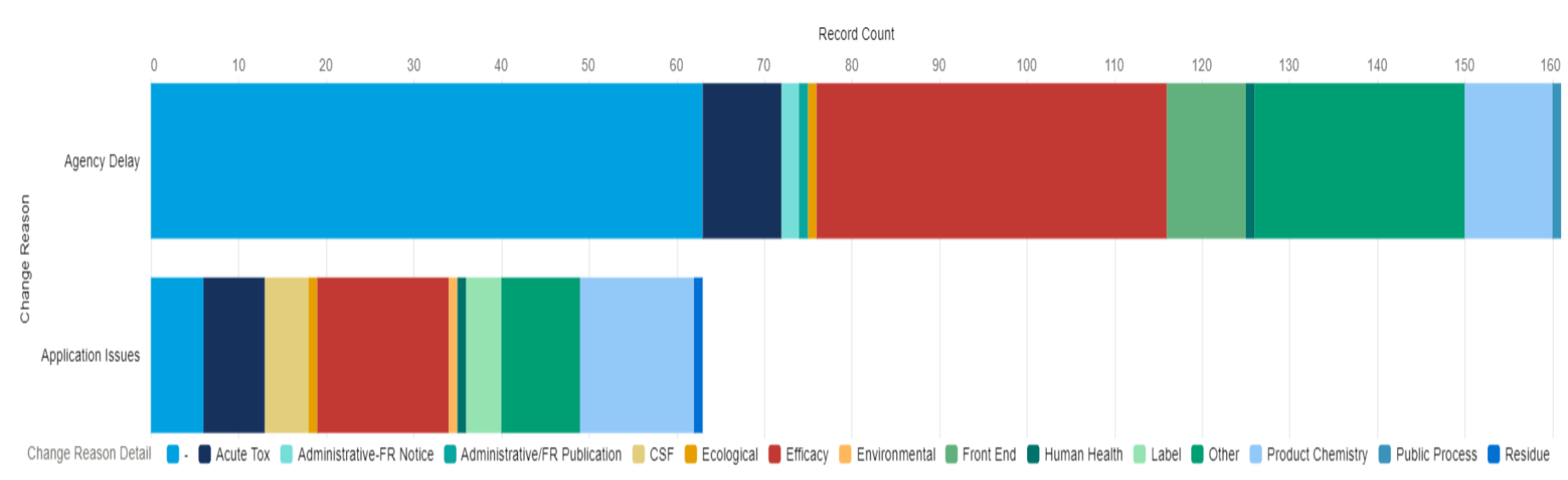


Future of Renegotiations

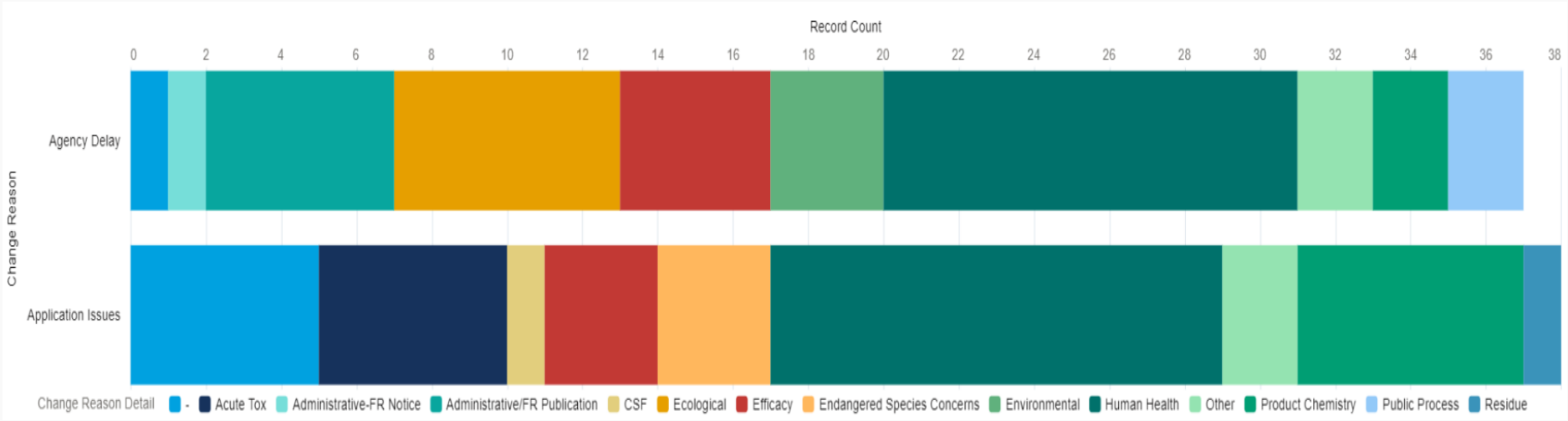
- AD/BPPD have been tracking renegotiation reasons in Salesforce (e.g., acute tox, eco data, human health data)
  - Split into agency delays vs. application issues
  - For agency delays, this reporting will likely change to focus on “Late PRIA” reasons

- How to represent “Late PRIAs” and provide industry insights into completion timelines for “Late PRIAs”
  - Considering something for internal tracking purposes like “Projected completion date”
    - Would get wrapped into Salesforce with potential to be included in external dashboard

Renegotiation Reasons – AD FY23



Renegotiation Reasons – BPPD FY23



Future of Renegotiations and Impacts of PRIA V

- PRIA V Renegotiation Process Improvements
  - New or additional data is needed
    - Agreement externally on the definition of “data”
  - Significant public comments received
  - One time ESA increase (pending completion of guidance)

- If renegotiating under the three reasons above
  - Establish a new PRIA due date, wouldn’t be reflected in reporting as a “Late PRIA”

- To the extent practicable, grant/deny waivers during technical screen
  - Developing internal guidance

Questions re: Renegotiation Rates in PRIA 5

Jim Jones, President, JJones Environment, and Consultant, Household & Commercial Products Association

Ray McAllister, Founder, RSM Consulting, and Consultant, CropLife America

Anita Pease, Director, Antimicrobials Division, OPP, EPA

Billy Smith, Director, Biopesticides and Pollution Prevention Division, OPP, EPA

Dan Rosenblatt, Acting Director, Registration Division, OPP, EPA

Break

Please return to your seat by 10:40 am

Non-PRIA Actions in PRIA 5

Anastasia Swearingen, Senior Director of Chemical Products and Technology, American Chemistry Council's Center for Biocide Chemistries

Scott Rawlins, Consultant, Council of Producers & Distributors of Agrotechnology

Anita Pease, Director, Antimicrobials Division, OPP, EPA

Billy Smith, Director, Biopesticides and Pollution Prevention Division, OPP, EPA

Dan Rosenblatt, Acting Director, Registration Division, OPP, EPA

What are Non-PRIA Actions?

Center for Biocide Chemistries

- Actions not covered by a PRIA decision review time period and service fee
- Examples:
  - Notifications & minor formulation amendments (see PRN 98-10)
  - Fast Track Amendments and label amendments with no data review
  - EPA-initiated amendments (e.g. complying with reg review decision)
  - Submission of sub-registrant/supplemental distributor label
  - 6(a)2 evaluations

Importance of Non-PRIA Actions

Center for Biocide Chemistries

- Non-PRIA actions ***are not less important*** to registrants than PRIA submissions
- Many non-PRIA actions are business critical
- Delays in non-PRIA action reviews can cause significant delays in bringing products to market (months/years)
- Not all non-PRIA actions can be combined with a PRIA action or submitted under a PRIA code for a dedicated timeline

PRIA V and Non-PRIA Actions

Center for Biocide Chemistries

- Create a set aside for processing non-PRIA actions and to clear the current backlog at 1/8 of the total maintenance fee fund (roughly $5.25 million per year)
- EPA must seek stakeholder input and publish a plan to address the backlog and the expected annual workload for actions not covered by a PRIA code
- Additional reporting, audit and metric requirements related to these submissions

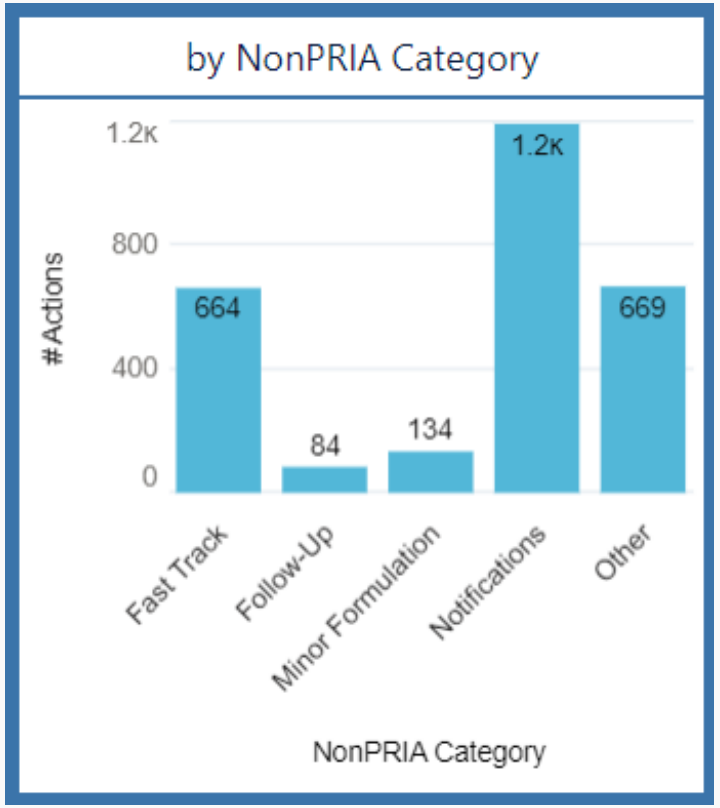
Antimicrobials Division- Non-PRIA Backlog Proposal for Notifications

- AD is planning to close out all notifications submitted before 10/1/2022:
  - This includes ABN, CSF and label notifications
  - Will result in > 2,000 notifications being closed and ~196 in AD backlog
  - Upon request, AD will create a company specific report of the actions closed out.
    - Reach out to the appropriate PM for a list.
  - The closed notifications will not be given Agency letters or have the labels entered on PPLS.
  - The states were informed of the close out plan and were supportive of our decision. An example of the report was provided to states for comments. The states will be given a list of submissions affected by this proposal.
- Notifications and other non-PRIA actions (e.g., fast-track, 6(a)2) for cancelled products have been closed out
- Anticipated Next Steps:
  - Development of communication materials for close out
  - Closeout target in May-June 2023

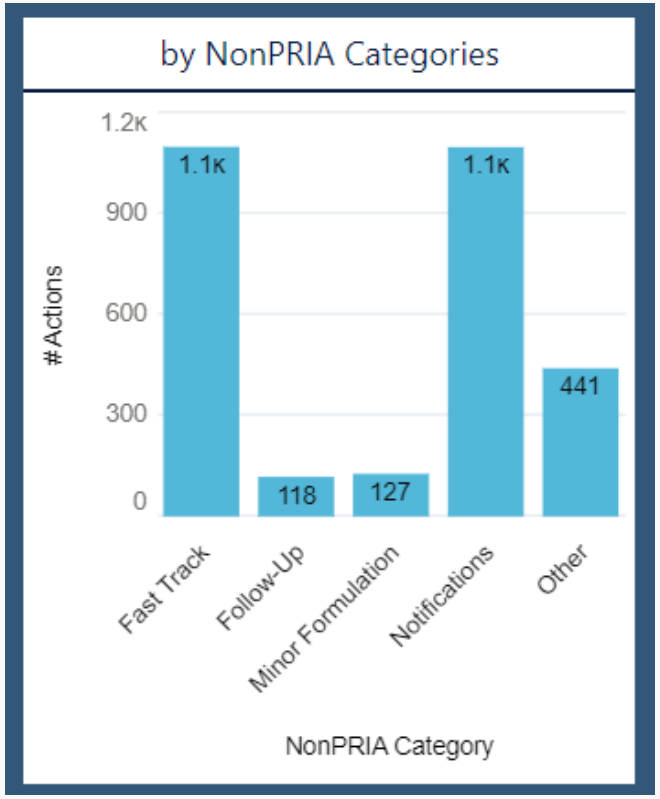
Antimicrobials Division- Non-PRIA Backlog Proposal for Amendments

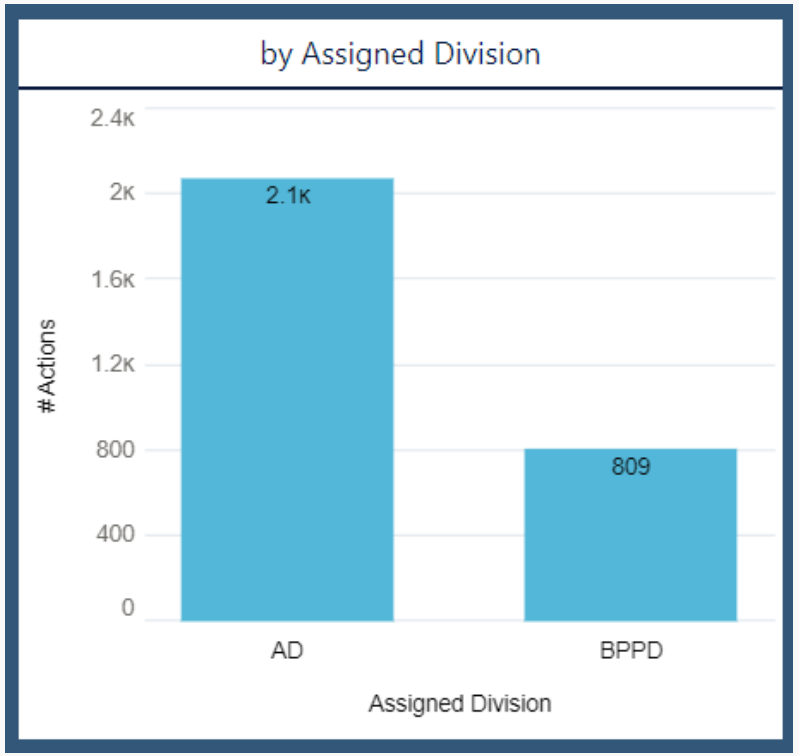
- AD plans to provide each company with a list of open, backlogged non-PRIA amendments.
  - This includes fast-track amendments (including minor formulation amendments and non-PRIA label amendments)
- There are currently ~4,000 non-PRIA amendments in backlog status.
  - AD will ask companies to identify non-PRIA amendments that can be withdrawn.
  - After those actions are withdrawn the Agency will contact the registrants requesting they provide highest priority actions.
- AD will initiate this process after the notification closeout is complete with a target of summer 2023.

AD/BPPD Salesforce Non-PRIA Received FY22-23

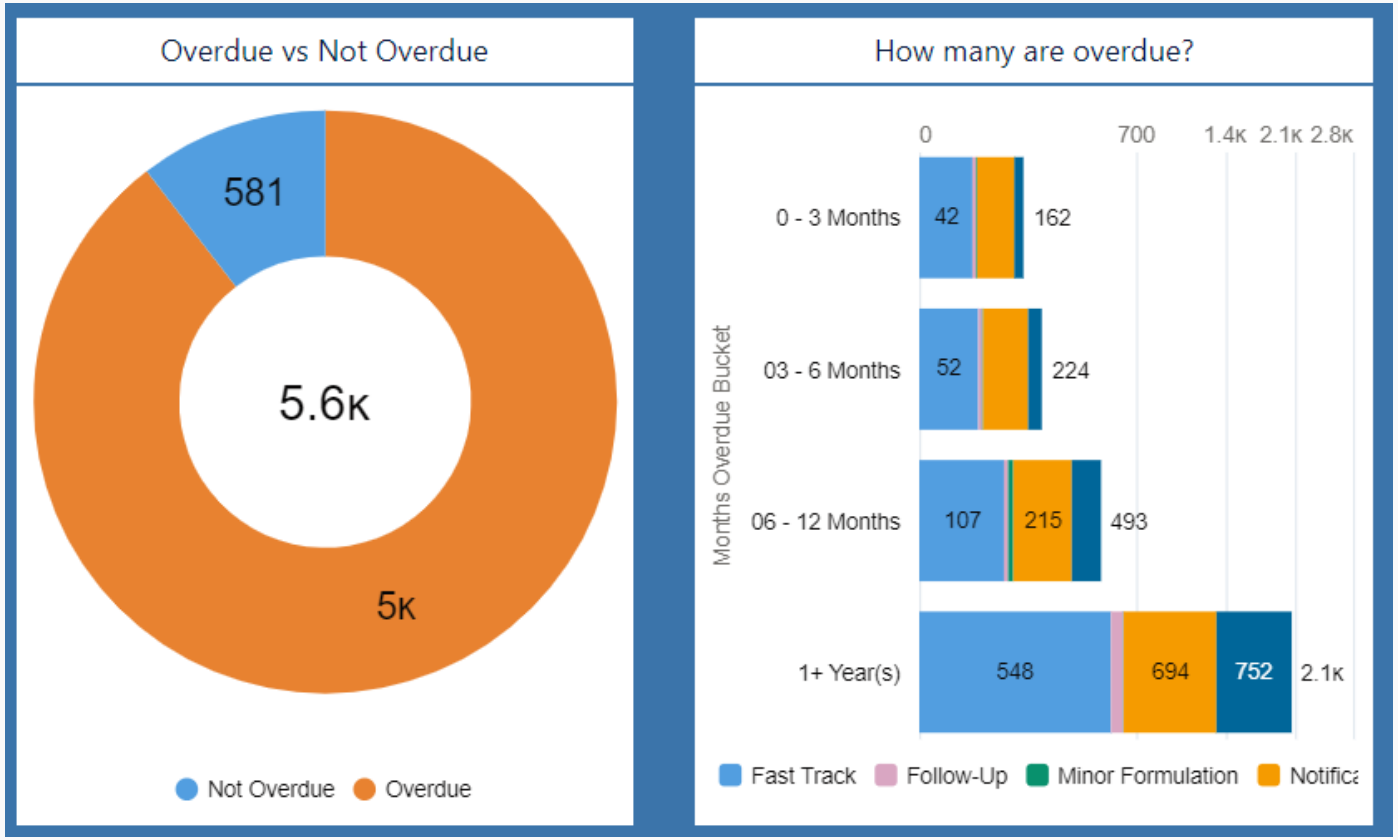


AD/BPPD Salesforce Non-PRIA Completions FY22-23





AD/BPPD Salesforce Non-PRIA Overdue (5 year Summary)



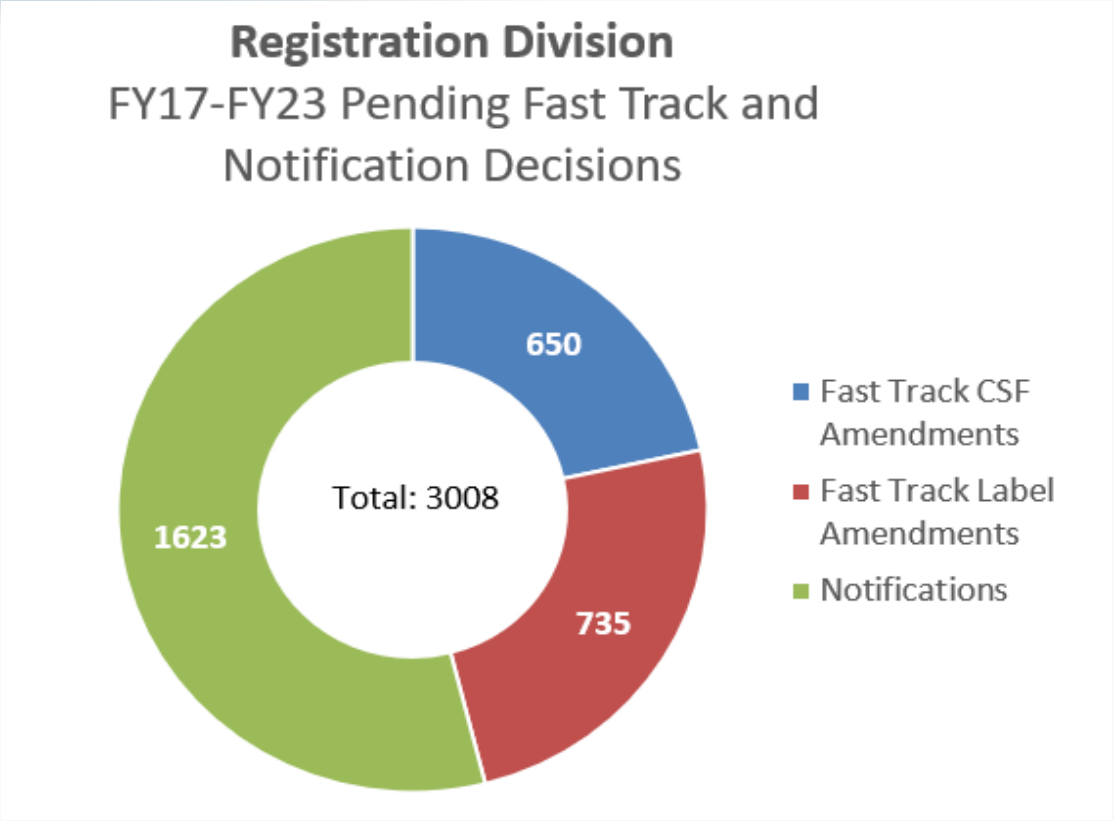


Chart above excludes “hanging receipts” awaiting assignment of decision # and action code.

RD Non-PRIA Submissions and Initiatives

- RD worked with CPDA on a pilot project to have over a dozen CPDA-member companies review their non-PRIA actions list and identify those that were no longer needed.
  - RD is next piloting a project with some of the larger companies to complete a similar effort
- RD reviewing the backlog to identify old actions that are no longer needed or valid
  - Data cleanup to prepare for Salesforce transition
- RD will consider AD's proposals to close out old notifications and prioritize/close out amendments
  - No easy way to facilitate this given current IT infrastructure does not easily facilitate this without creating additional resource burdens
  - RD rollout in Salesforce will allow for further consideration and potential implementation of these efforts

Questions re: Non-PRIA Actions in PRIA 5

Anastasia Swearingen, Senior Director of Chemical Products and Technology, American Chemistry Council's Center for Biocide Chemistries

Scott Rawlins, Consultant, Council of Producers & Distributors of Agrotechnology

Anita Pease, Director, Antimicrobials Division, OPP, EPA

Billy Smith, Director, Biopesticides and Pollution Prevention Division, OPP, EPA

Dan Rosenblatt, Acting Director, Registration Division, OPP, EPA

Bilingual Labeling

Kristen Spotz

Senior Director of Regulatory Affairs, RISE

Elissa Reaves

Director, Pesticide Re-evaluation Division, OPP, EPA

Bilingual Labeling: The Requirements

- A phase in of electronic Spanish labels via scannable technology or other electronic methods readily accessible on the product label
  - Only parts of the label contained in the EPA *Spanish Translation Guide for Pesticide Labeling*
- Registrants of antimicrobial and non-agricultural use products may comply with the bilingual labeling requirement by providing a link to the safety data sheets (SDS) in Spanish
  - SDS option not available for non-agricultural RUPs
- The labeling will be done through non-notification

Bilingual Labeling: The EPA *Spanish Translation Guide*

- *Spanish Translation Guide for Pesticide Labeling* (STGPL) was published by EPA in October 2019
- Only parts of the label contained in the EPA Spanish Translation Guide for Pesticide Labeling must be translated under PRIA 5, including:
  - First aid and precautionary statements label language
  - Signal words
  - Misuse statements
  - Storage and pesticide container disposal instructions
  - Personal Protection Equipment (PPE) label statements
  - Worker Protection Standard (WPS) agricultural use requirements language
- Available at: https://www.epa.gov/sites/default/files/2019-10/documents/spanish-translation-guide-for-pesticide-labeling.10.10.19.pdf

Bilingual Labeling: The Timelines

- Spanish labeling provisions are phased in as follows:
  - Restricted use pesticides (RUPs) within three years (by December 29, 2025)
  - Non-RUP products that are designated as Toxicity Category 1 within three years (by December 29, 2025) for agricultural products and within four years (by December 29, 2026) for non-agricultural products
  - Non-RUP products that are designated as Toxicity Category 2 within five years (by December 29, 2027) for agricultural products and within six years (by December 29, 2028) for non-agricultural products
  - All other products within eight years (by December 29, 2030)
- After the initial implementation dates, changes to label translations will be made the earlier of:
  - The next time the end-product label is changed or amended as released for shipment
  - Within one year of publication of updates to EPA's *Spanish Label Translation Guide* for agricultural-use pesticide products
  - Within two years of publication of the updates to EPA's *Spanish Label Translation Guide* for non-agricultural use pesticide products

Bilingual Labeling: Enforcement

- There are no bilingual labeling-specific enforcement provisions in PRIA 5
- Any violations would be subject to general FIFRA penalty provisions (7 U.S. Code §136l – Penalties), which state:
    a) Civil penalties
        1. In general: Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of this subchapter may be assessed a civil penalty by the Administrator of not more than $5,000 for each offense.

Bilingual Labeling: Coordination/Outreach

- EPA shall seek stakeholder input on ways to make bilingual labels available to farm workers and implement a plan with in 3 years (by December 29, 2025)
- EPA must consult with the states regarding implementation

Bilingual Labels - Requirements

- PRIA 5 amended FIFRA requiring Spanish language translation for sections of the end-use pesticide product labels where translation is available in the EPA Spanish Translation Guide.
  - The Guide will serve as a resource for pesticide registrants as they translate sections of the label.
- The Spanish language translation must appear on the product container or a link to such translation via scannable technology or other electronic methods readily accessible on the product label.

Bilingual Labels - Exceptions

- Antimicrobial pesticide products and non-agricultural/non-RUP pesticide products may, in lieu of including a translation or a link to the label translation, provide a link to the safety data sheets (SDS) in Spanish via scannable technology or other electronic methods readily accessible on the product label.

Bilingual Labels – Deadlines

- Restricted Use Pesticides (RUPs) – 3 years (Dec 2025)
- Agricultural Non-RUPS:
  - Acute Toxicity Category I – 3 years (Dec 2025)
  - Acute Toxicity Category II – 5 years (Dec 2027)
- Antimicrobials and non-agricultural:
  - Acute Toxicity Category I – 4 years (Dec 2026)
  - Acute Toxicity Category II – 6 years (Dec 2028)
- All other products – 8 years (Dec 2030)
- Other label timing provisions for when the Spanish Translation Guide is updated.

Translation Guide

- Sections of the Translation Guide
  - Keep out of reach of children
  - Restricted use pesticide (RUP)
  - Signal word
  - First aid
  - Precautionary statements
  - Personal protective equipment (PPE)
  - Misuse statement
  - Storage and disposal
  - Example label language
    - Agricultural use requirements
    - Precautionary statements
- The Spanish Translation Guide is located at: https://www.epa.gov/pesticide-labels/spanish-translation-guide-pesticide-labeling

Signal Word

English	Spanish
Caution	Precaución
Warning	Aviso
Danger	Peligro
Danger - Poison	Peligro - Veneno

First Aid

Ingestion

Ingestion treatment for acute oral toxicity categories 1, 2, and 3. Not required for category 4 – may use statements below.	
English	Spanish
First Aid	Primeros Auxilios
If swallowed:	Si se ingiere:
- Call a poison control center or doctor immediately for treatment advice.	- Llame de inmediato a un centro de control de envenenamientos o a un médico para consejo de tratamiento.
- Have person sip a glass of water if able to swallow.	- Si la persona puede tragar, haga que beba un vaso de agua lentamente.
- Do not induce vomiting unless told to by a poison control center or doctor.	- No induzca el vómito a menos que así se lo indique un centro de control de envenenamientos o un médico.
- Do not give anything to an unconscious person.	- No administre nada por boca a una persona que haya perdido el conocimiento.

Bilingual Labels – Implementation

- Label changes made through non-notification.
  - A change may be made to a pesticide label without notifying EPA.
- EPA shall cooperate and consult with State lead agencies for pesticide regulation to implement bilingual labeling.
- EPA to seek stakeholder input on ways to make bilingual labeling accessible to farmworkers – 180 days (June 2023).
- EPA shall develop and implement, and make publicly available, a plan for tracking the adoption of the bilingual labeling – 2 years (Dec 2024).
- EPA shall implement a plan to ensure that farmworkers have access to the bilingual labeling – 3 years (Dec 2025).

Non-notification Process

- Non-notifications are amendments that can be done on pesticide labels that are not required to have prior approval from OPP.
  - 40 CFR 152.46(b) provides examples for non-notifications.
  - Bilingual label language may be on any product without notification. The foreign text must be a true and accurate translation of the English text. Note: Both language versions of the labeling must appear on a container. Foreign text may be used on all or part of the labeling.
  - Non-notifications are not tracked by OPP.
- PRIA 5 ensures consistency for bilingual language for health and safety portions of labels with the use of the Spanish Translation Guide.
- PRIA 5 requires a tracking element for bilingual language labels.

Current Status - Stakeholder Engagement

- Presented bilingual labeling charge questions regarding farmworker access to the NEJAC – 3/30/23
- SFIREG Meeting – 4/17/23
- Quarterly Farmworker Advocacy Stakeholder Call – 4/17/23
- CLA RISE Conference – 4/19/23 & 4/20/23
- WPS Committee Meeting – 4/20/23
- OCSPP/OECA/Regions Monthly Call – 4/26/23
- PPDC Meeting – 5/31/23
- National Webinar

Bilingual Labels – Accessibility

- Seek stakeholder input on ways to make bilingual labeling accessible to farmworkers.
  - Define/Identify farmworkers
  - Define accessibility – what does it look like for farmworkers?
  - How can we determine the bilingual labels are accessible to farmworkers?
  - What works – past, present, future?
  - What type of technology do you think will help?

Spanish Labeling: Coordination at OPP

- Current OPP workgroup members:
  - Linda Arrington – PRD
  - Susan Bartow – PRD
  - Derek Berwald – BEAD
  - Joseph Daniels – AD
  - Tiffany Green – PRD
  - Jocelyn Hospital – PRD
  - Karen Milians – EFED
  - Briana Otte – BEAD
  - Shannon Rebersak – OGC
  - Ana Rivera-Lupiañez – PRD
  - Sergio Santiago – BEAD
  - Carolyn Schroeder – PRD
  - Stephen Smearman – BEAD
  - Monica Thapa – BPPD

Questions re: Bilingual Labeling

Kristen Spotz

Senior Director of Regulatory Affairs, RISE

Elissa Reaves

Director, Pesticide Re-evaluation Division, OPP, EPA

Open Discussion and Q&A

Megan Provost

President, RISE, and Chair, PRIA Coalition

Laurie Flanagan

Vice President, DC Legislative & Regulatory Services, and Coordinator, PRIA Coalition

Ed Messina

Director, Office of Pesticide Programs (OPP), EPA

PRIA 5 Resources

Visit https://www.pestfacts.org/pria-resources