



PRIA Coalition Quarterly Stakeholder Meeting



**Steve Schaible, OPP PRIA Coordinator
U.S. Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs**

April 18, 2024

AGENDA

- Welcoming Remarks/Ground Rules
- OPP Organizational Chart, Budget, and Hiring Update
- Front End Update
- PRIA 5 Implementation
- Antimicrobial Devices Test Standards Update
- Bilingual Labeling Update
- Data Evaluation Record (DER) Process Update
- IT Update
- FY'24 Fees Collected to Date
- FY'24 PRIA and non-PRIA Metrics
- Registration Review Update
- Wrap-Up/Next Meeting Dates



Office of Pesticide Programs

Edward Messina, Director
Leo Gueriguian, Deputy Director, Management
Michael Goodis, Deputy Director, Programs
Monique Perron, Senior Science Advisor

**Endocrine Disruptor
Screening Program**
Catherine Aubee,
(Acting) Senior Advisor

Antimicrobials Division

Anita Pease, Director
Kristen Willis, Deputy Director
Elizabeth Donovan, (Acting) Assc. Director

Biopesticides and Pollution Prevention Division

Madison Le, Director
Shannon Borges, Deputy Director

Registration Division

Charles "Billy" Smith, Director
Daniel Rosenblatt, Deputy Director
Jennifer Saunders, (Acting) Assoc. Director

Pesticide Re-evaluation Division

Tim Kiely, Acting Director
Tim Kiely, Deputy Director

Health Effects Division

Dana Vogel, Director
Donald Wilbur, Deputy Director
Greg Akerman, Associate Director

Environmental Fate and Effects Division

Jan Matuszko, Director
Amy Blankenship, Deputy Dir.
Brian Anderson, Assoc. Director

Biological and Economic Analysis Division

Anne Overstreet, Director
Neil Anderson, Deputy Director



Priorities

- PRIA 5 Implementation
- Registration and Registration Review
- ESA Efficiencies and Progress on our ESA Obligations
- Implementation of Agency Priorities
 - Environmental Justice
 - Climate Change
- Advancing State of the Art Science
 - PFAS – EDSP – NAMs
- Rule-Making, Guidance, Litigation, OIG, and Petition Responses
- Increasing Resources and IT Improvements
- Employee Experience/Organizational Development /Process (GP2W) (People, Processes, and Technology)



Appropriations

- PRIA minimum appropriations level: **\$166,000,000**
- FY 2023 Final budget: **\$138,646,000**
- FY 2024 Final budget (projection): **\$132,464,000**
- FY 2025 President's budget: **\$175,027,000**
 - STAG: \$14,027,000
 - EPM: \$150,000,000
 - S&T: \$11,000,000



FY24 Appropriations and Fee Collection Impact

- For FY24, the Presidents' Budget requested ~**\$170.6 million** from Congress for the pesticide programs at EPA.
- Congress only provided overall funding of ~**\$133 million** through these appropriations.
 - OPP has not yet received an Operating Plan, so these are tentative estimates
- This funding level is almost **\$38 million** below the FY24 President's Budget request, **\$33 million** below the minimum appropriation level in PRIA 5 and represents a cut of **\$6 million** from the FY23 Congressionally enacted appropriations.
- This cut is significant to our programs
 - For context, this \$6 million decrease in funding represents approximately 30 FTEs (federal employees) or contractor equivalents for the year.
- Additionally, projected FY24 PRIA fee collections are significantly less than anticipated (~**\$4 million**).
 - FY23 collections were also over \$2M lower than projected.
- The significant decrease in resources negatively impact our programs' ability to manage the workload and subsequently time to complete actions will worsen.

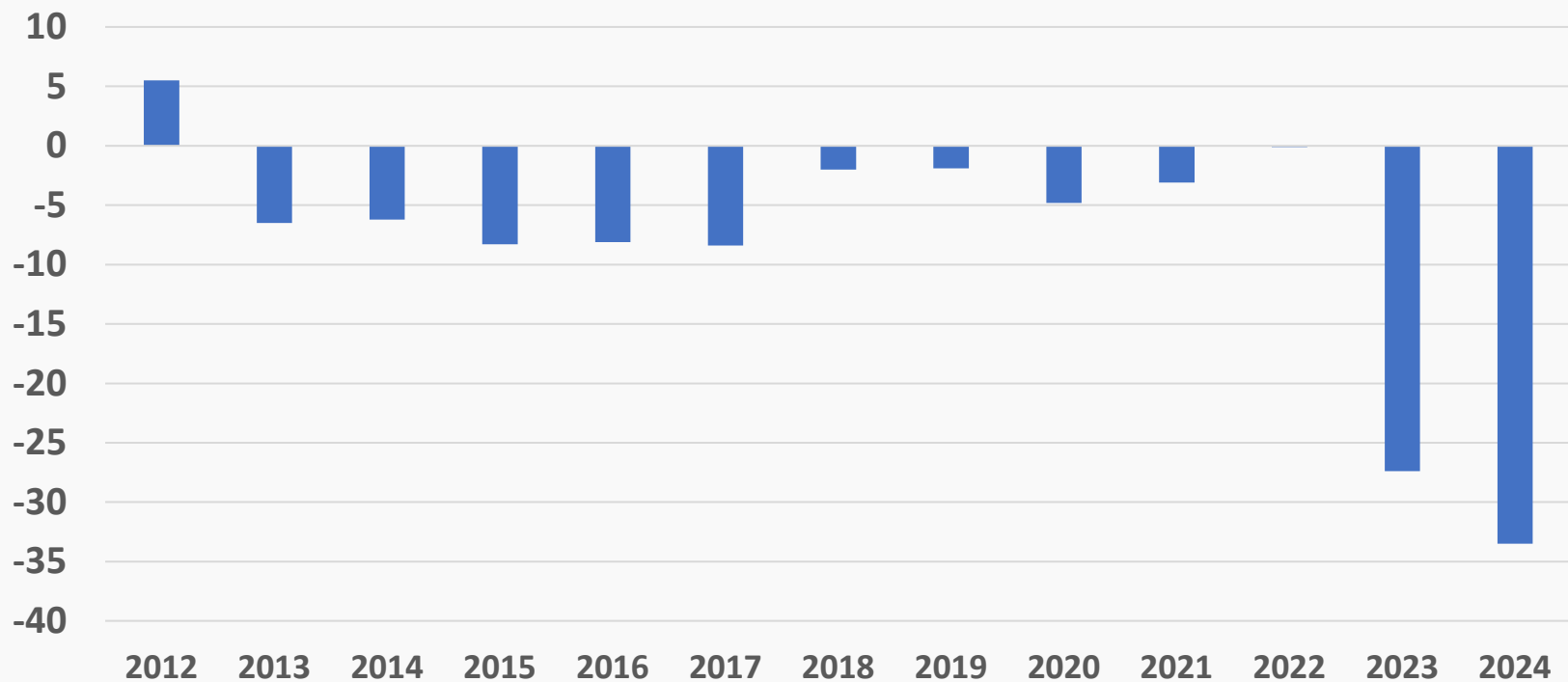


Budget- Minimum Appropriation Level

- PRIA 5 raised the minimum appropriation level necessary for EPA to collect pesticide registration service fees from \$128.3 million (the FY 2012 appropriations level for pesticide programs) to \$166 million.
- The increase is for EPA to improve performance on review timeframes for fee and non-fee applications, and to support incremental increase in EPA's ability to meet its Endangered Species Act obligations in EPA regulatory decisions.
- This trigger is meant to maintain the balance between fees and appropriations as far as funding pesticide activities and is an indication of the level of funding Congress believes EPA needs to operate the pesticide programs.



Amount Funding (\$Million) Below Minimum Appropriation Level (FY 2012 - FY 2024)



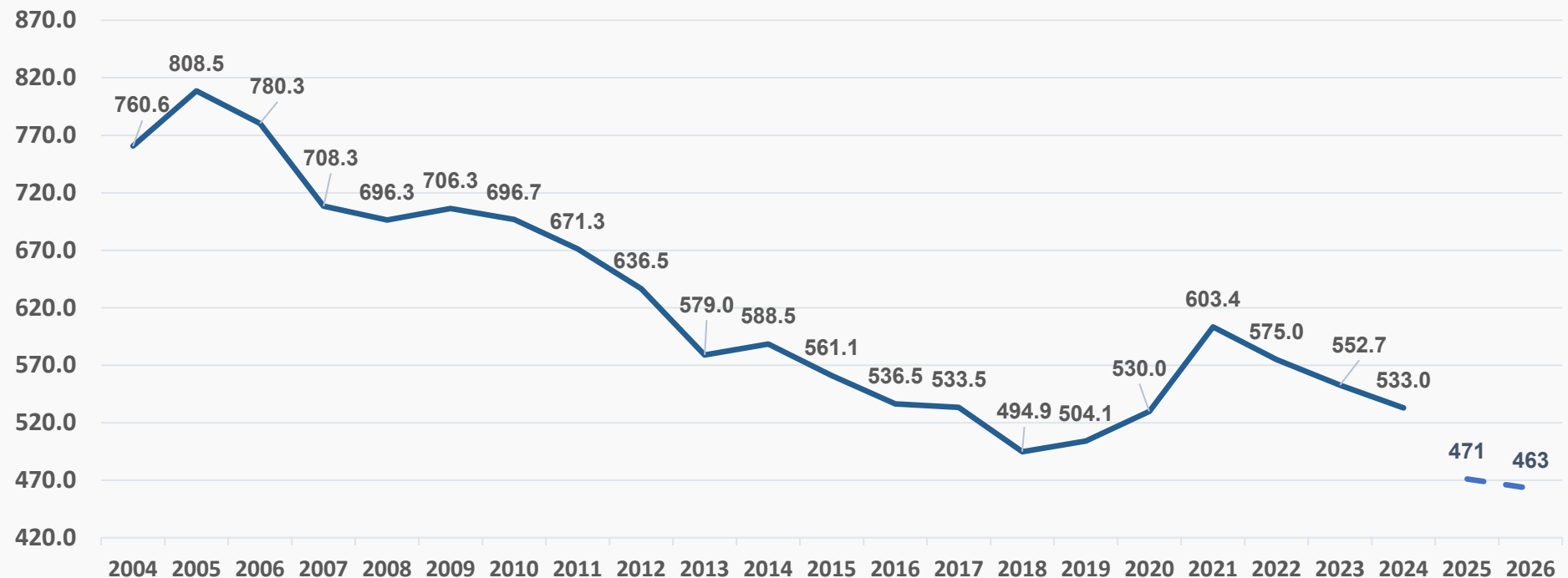


Hiring Update

- Overall if FY24, EPA has continued to face challenges in hiring and keeping up with attrition.
- Status of new hiring activity (excludes details):
 - OPP has hired 19 new people in FY24
 - OPP has experienced a loss of 21 people in FY24
- Because of budget constraints, EPA will likely need to reduce hiring this year.
- EPA is pursuing process improvements aimed at decreasing the time it takes EPA to hire new staff.



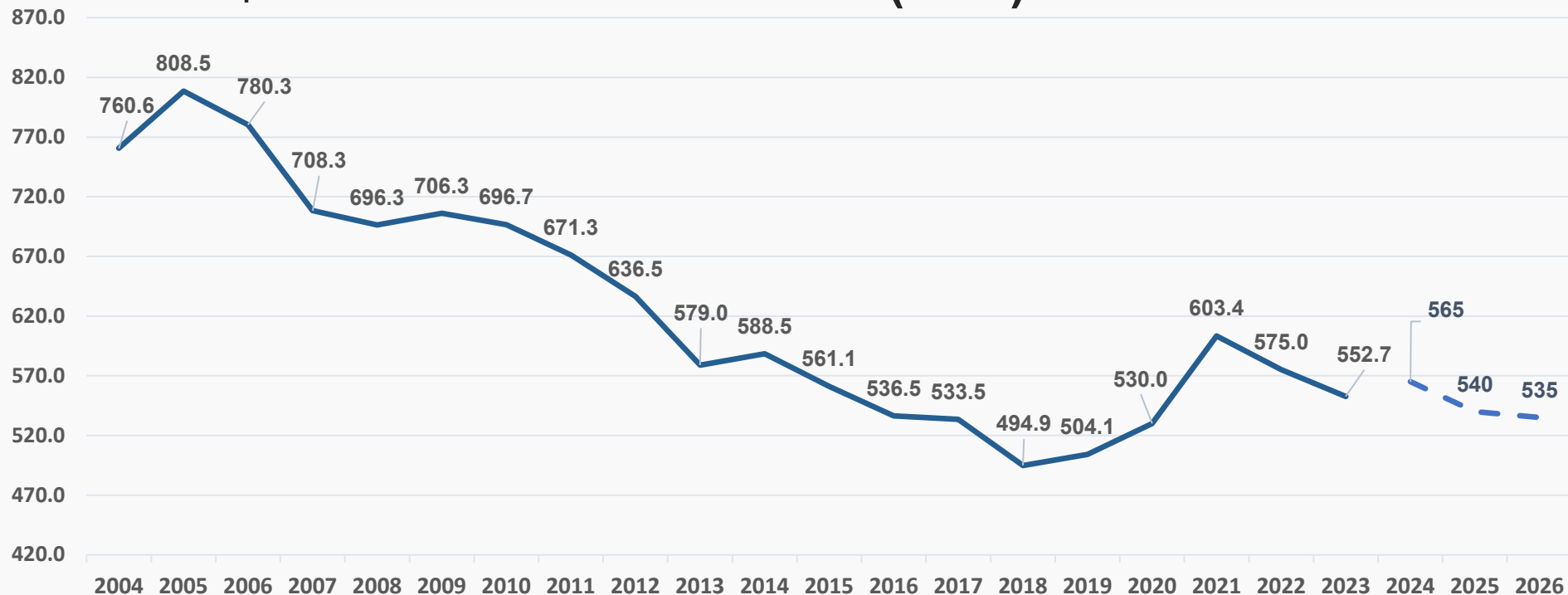
EOY Total FTE Usage Assuming FTE Cuts and Holding Current Contract Spending Constant



95 FTE deducted from the OCSPP Program funding levels to normalize the data to reflect OCSPP Reorganization and those FTE being moved to OPS.



EOY Total FTE Usage Assuming FTE Cuts and \$34M Contract Reduction (40%) from FY24-FY26



95 FTE deducted from the OCSPP Program funding levels to normalize the data to reflect OCSPP Reorganization and those FTE being moved to OPS.

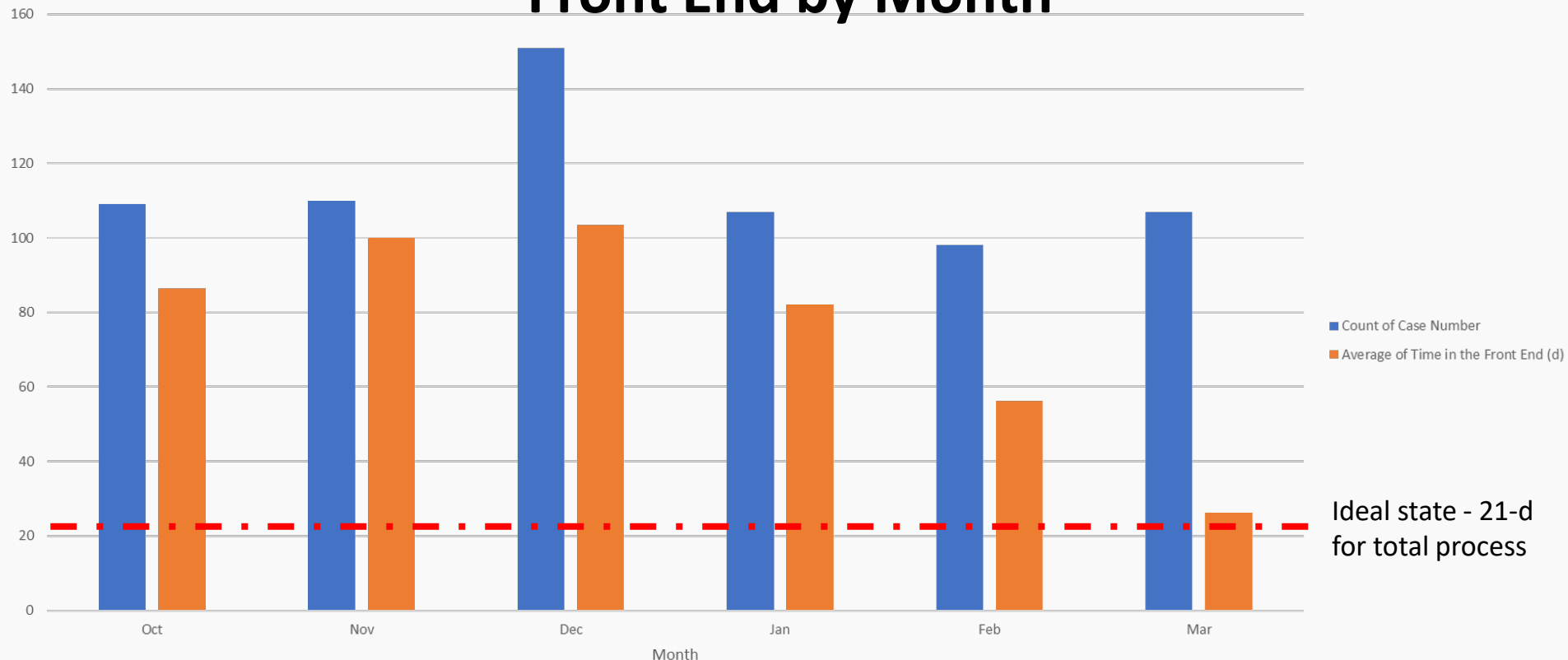


Status of Front-End Processing

- EPA is no longer in a backlog status for front-end processing
 - Front-end is operating under a “normal” number of actions
- 21-day screen from contractors is taking additional time for PRIA actions
 - Occurs after in-processing by ISB
 - Inerts clearance and data entry most important;
 - RD SWAT team performed 21-days screens for their PRIA actions themselves
- Note – Non-PRIA actions go directly from ISB to the PMs and do not receive a 21-day screen
- Bottom line – Will take some time until the impacts of the front-end backlog are completely mitigated



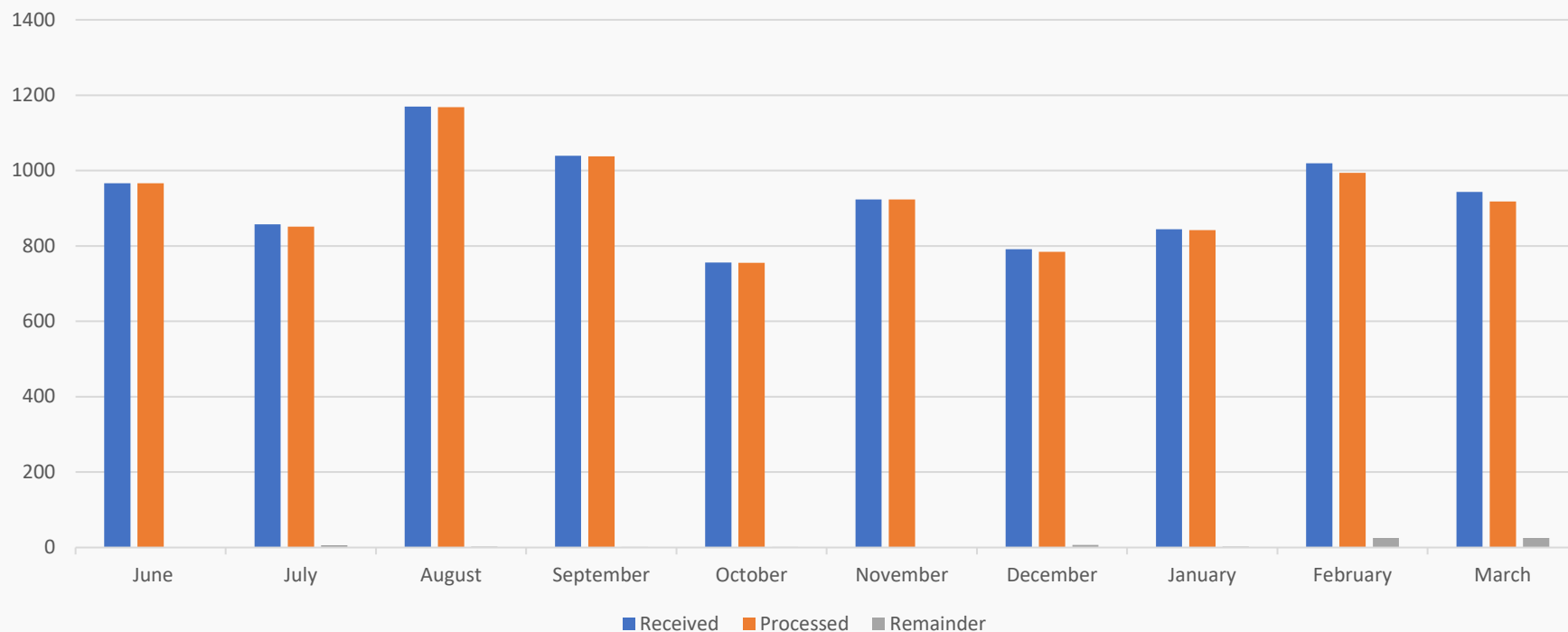
Number of PRIA Actions and Average Time in Front End by Month





Status of Front-End Processing

June 2023-March 2024 Monthly Front End Processing





PRIA 5 Implementation- FY24 Activities

- Training Set-aside:
 - Utilizing an existing Office of Water grant to inventory and consolidate existing training
 - Establish grant program with the third party entities identified in PRIA 5 to develop training curricula
- Workforce and Process Assessment Contracts
 - Utilizing an existing OMS contract for both activities
- PRIA 5 process changes implementation
- Non-PRIA backlog reduction and review timeframes for new actions
- Farmworker and Health Clinician Cooperative Agreements
- Bi-lingual labeling implementation
- DER process implementation
- IT Update deliverables
- EPA webpage on PRIA 5 Implementation: <https://www.epa.gov/pria-fees/pria-5-implementation>
- PRIA annual report



Antimicrobial Devices Test Methods Set-Aside

- PRIA 5 provided up to \$500K per year FY23-27 “... To develop efficacy test methods for antimicrobial pesticide devices making public health claims”
- EPA OPP in collaboration with the Office of Research and Development has been developing a workplan and putting in place a contract mechanism to support this work.
 - All ORD FTE support has been and will be provided in-kind
- In FY23:
 - Defined our priorities for test method development
 - Our initial focus will be on testing for photocatalytic devices intended to treat infectious aerosols
 - Surveyed available test methods that have been developed (or are being developed) by voluntary consensus standards (VCS) bodies.
- In FY24:
 - Conducting market research to select devices for testing
 - Preparing necessary ORD quality assurance documentation
 - Plan to conduct initial bioaerosol testing



Bilingual Labeling: Coordination at EPA/OPP

- OPP Interdivisional Spanish Labeling Workgroup
- Formed subgroups to address the various provisions of PRIA 5
 - Accessibility Subgroup – evaluating public feedback
 - Communications Subgroup – developing a website
 - Tracking Subgroup - investigating internal systems and processes to develop a plan for tracking
 - Spanish Translation Guide Subgroup - evaluating public feedback



Stakeholder Engagement and Outreach

- Presented bilingual labeling charge questions regarding farmworker access to the NEJAC – 3/30/23
- SFIREG Meetings – 4/17/23, 9/18/23, 12/5/23, & 4/15/24
- Quarterly Farmworker Advocacy Stakeholder Calls – 4/17/23 & 8/3/23
- CLA RISE Conference – 4/19/23, 4/20/23, & 4/17/24
- AAPCO WPS Committee Meeting – 4/20/23
- OCSPP/OECA/Regions Monthly Call – 4/26/23
- OCSPP Regional WPS Quarterly Calls – 5/2/23 & 10/31/23
- PPDC Meetings – 5/31/23 & 11/16/23
- OCSPP/OECA National Pesticide Manager Meeting – 6/6/23
- Bilingual Pesticide Labeling National Webinar – 6/15/23
- Call with State Lead Agencies – 7/6/23
- PRIA Coalition and NASDA Virtual Workshop – 7/20/23
- Call with PRIA Coalition and Industry Representatives – 9/6/23
- Call with the TPPC's Executive Committee – 9/20/23
- U.S., Mexico and Canada Technical Working Group on Pesticides – 11/7/23
- Focus Groups with Farmworkers in R9 – 12/5/23, 1/17/24, 2/6/24, & 2/12/24
- Quarterly PRIA Coalition Calls – 1/18/24 & 4/18/24



Planned Stakeholder Engagement and Outreach FY24

- Update the PRIA 5 Website with bilingual labeling information and Q&As from various stakeholder engagements and webinars
- Coordinate with CLA and hold webinar on Q&As with registrants
- Conduct focus groups with Region 9 and farmworkers on accessibility
- Plan to hold discussion with various stakeholders on the tracking of bilingual labeling (tracking plan due Dec 2024)
- Plan to hold discussion with various stakeholders on the accessibility plan throughout FY24 and FY25 (accessibility plan due Dec 2025)



Data Evaluation Record (DER) Update

- PRIA 5 directed EPA to develop a process for sharing of EPA data evaluation records (DERS) at the time of the regulatory decision.
- EPA developed a process using Go Anywhere to share DERs with applicants, and provided training to registrants on using the tool.
- Implementation of this process began in January 2024.



PRIA 5 IT Update Requirements

- PRIA 5 requires EPA to establish an IT system that:
 - Includes all registering divisions in the Office of Pesticide Programs;
 - Provides a real-time, accurate tracking system for all regulatory submissions to the Office of Pesticide Programs;
 - Provides a real-time, accessible information that provides each applicant; confidential, online access to the status and progress of the regulatory submissions of the applicant;
 - Updates the electronic submission portal:
 - To ensure label reviews are limited to current label changes, to the maximum extent practicable;
 - To automate, to the extent practicable, minor, low risk regulatory actions;
 - To allow self-certification of certain regulatory actions, as determined by EPA;
- 5% fee increase in FY25 tied to first two deliverables



IT Update

- In FY 2023, EPA successfully migrated all divisions within OPP into the new IT system for electronic submission and application tracking;
 - Conventional registration
 - Registration Review for PRD, AD, and BEAD
 - DCI generation module
- Both registration and reevaluation workflows are now fully in the new IT system;
- In FY 2024, EPA will:
 - Continue to enhance workflows in the internal IT systems for receipt and review of applications;
 - Continue outreach to pesticide registrants regarding development of a customer portal to allow applicants to view EPA progress of review of their applications (some delay)
 - Data Management Solutions (some delay)



Major Projects: In Flight and Coming Soon

Historical Data Migration
Completion for RD

Data Management: Start All
Over!

Physical Infrastructure
Replacement

Document Repository
Modernization/Replacement

New Submission and
Communication Portal
Design and Build

Digital Forms, CSFs, Labels

DCI Modules for Issuance,
Communications, Data
Analysis

Enhancements to
Registration and Registration
Review Workflows

CY2024 ROADMAP

DCI OVERHAUL	MIGRATION 2	INFRASTRUCTURE	PORTAL	CONTINUOUS IMPROVEMENT
DCI Form DCI Communication DCI Tracking	Completed Cases from 2016-Date of Migration Close non-migrated cases up to DOM	Underlying physical and information technology devices Outdated and malfunctioning, causes severe disruption	Initial design session held December '23 Design sessions with internal and external Q1 Requirements Gathering Q2/Q3 Initial deployment Q3/Q4... project completion mid '25	Internal work on People and Process – what can we improve on, streamline, make life easier? Minor enhancements to UI/UX to make navigation easier, reduce errors, enhance engagement



Digital Label, Customer Experience and CSF Projects

- Digital label
 - Ongoing Stakeholder Engagement
 - Keep the good from past work
 - Move focus away from building
 - Iterative Steps Forward
 - Proof of Concept with Caliper Content Services in Progress
 - Future Label Data Submission Module
- Customer Experience
 - “New Portal”
 - Submission experience, Application Experience
 - Workflow Experience for OPP
 - Data, Data, Data (in and out!)
- “e-CSF”
 - Current Module Enhancements
 - Expected end of March
 - Future Module in New Portal
 - Data focused long term
 - Validations short term
 - Reduce resource inputs from contracts and rework for OPP/Registrants



FY'24 Fees Collected as of 4/12/24



PRIA Fees: \$11.4M

Maintenance Fees: \$42.2M



PRIA and Non-PRIA Actions

- For fee for service applications, at FY 24 midyear:
 - EPA received 761 PRIA actions
 - EPA completed 449 actions
 - 79% of those actions were completed late (outside of statutory decision time periods)
- For non-fee for service actions (fast track amendments and notifications), at FY24 mid-year:
 - EPA received 1,189 actions
 - EPA completed 2,333 actions



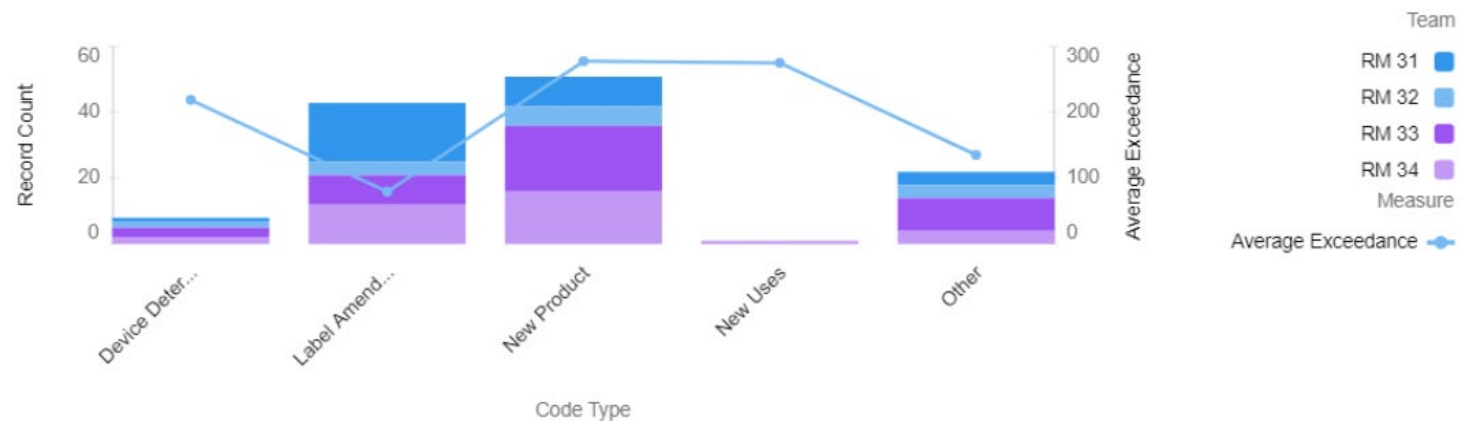
OPP Salesforce Metrics Demo



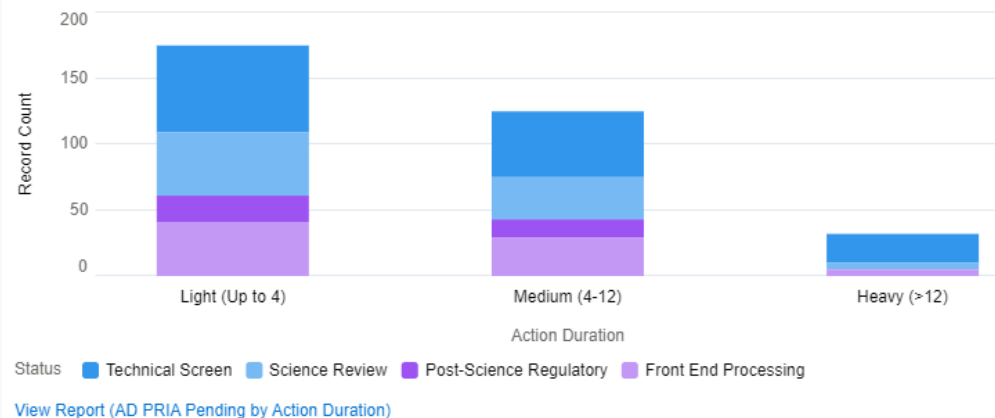
AD PRIA Completed and Pending FY24

(as of 4/16/24)

AD PRIA Completed FY24



AD PRIA Pending by Action Duration





Antimicrobials Division- Non-PRIA Efforts

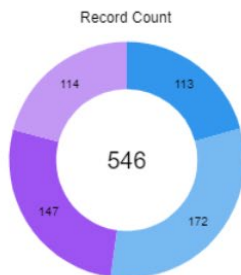
- We previously reported the [June 29th, 2023](#) close out all notifications submitted before 10/1/2022 (~2000 actions)
- AD is currently working on an amendment prioritization and consolidation effort
 - As a reminder we started the effort with a list of ~4,000 non-PRIA amendments in backlog status.
 - Inclusive of fast-track amendments (including minor formulation amendments and non-PRIA label and CSF amendments)
 - Goal was to contact all 550+ companies with backlogged actions to ask for (1) a list of actions that could be withdrawn and (2) a priority list (max 10)
 - AD has contacted all companies and has received responses back from ~46% of the companies.
 - To date, 785 actions have been withdrawn and 83 actions were identified as being previously completed but not closed out properly and the agency record was corrected.
 - We are working on completing actions from the priority lists and on a first come first serve basis for other non-PRIA actions as much as possible
 - At this time, we cannot commit to expediting non-PRIA submissions unless there is a very specific urgent need that you can document.
 - If that is the case, please send us your rationale so it can be shared with the appropriate PM and regulatory team to determine if the particular action can be prioritized.



AD Salesforce Non-PRIA Pending and Completions

AD All Pending Notifications

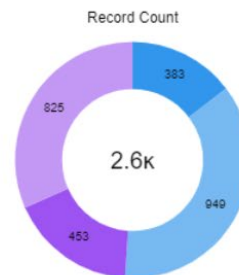
332



[View Report \(AD All Pending Notifications\)](#)

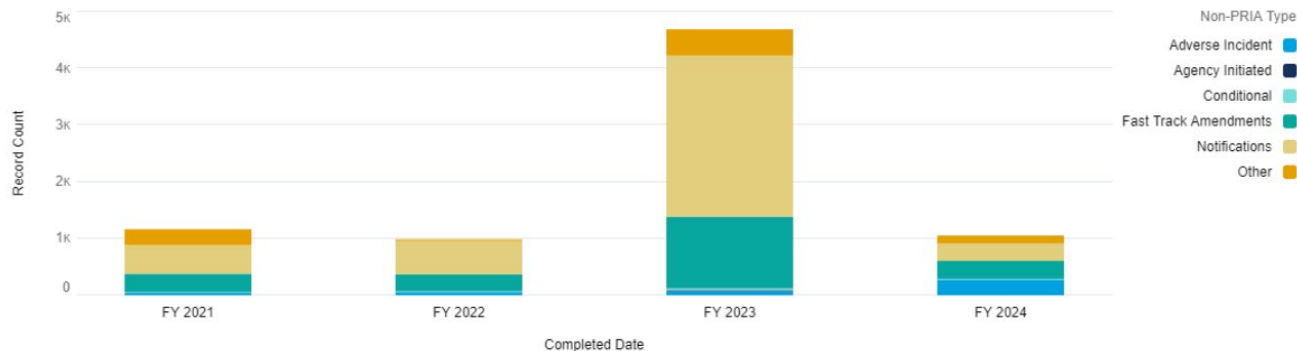
AD All Pending Fast Track Amendments

300, 302, 307, 362



[View Report \(AD All Pending Fast Track Amendments\)](#)

Pending



Completed
FY21-FY24

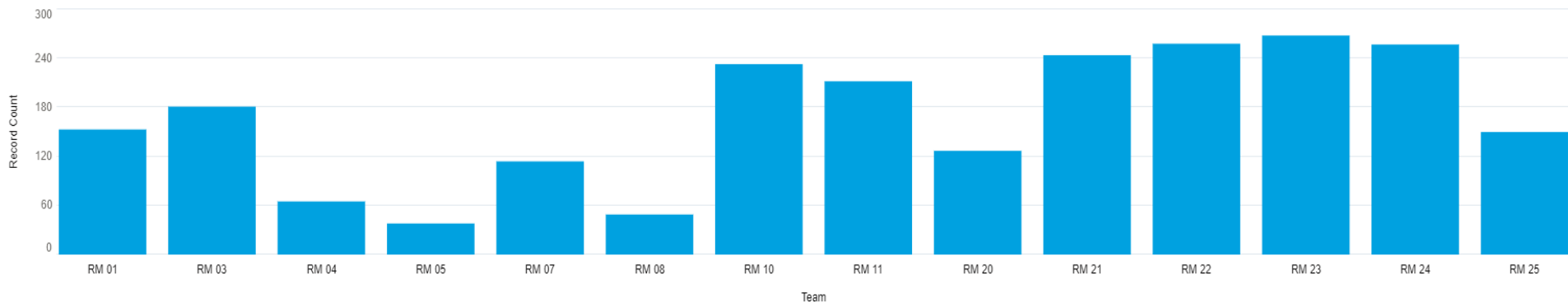


AD Process Improvements

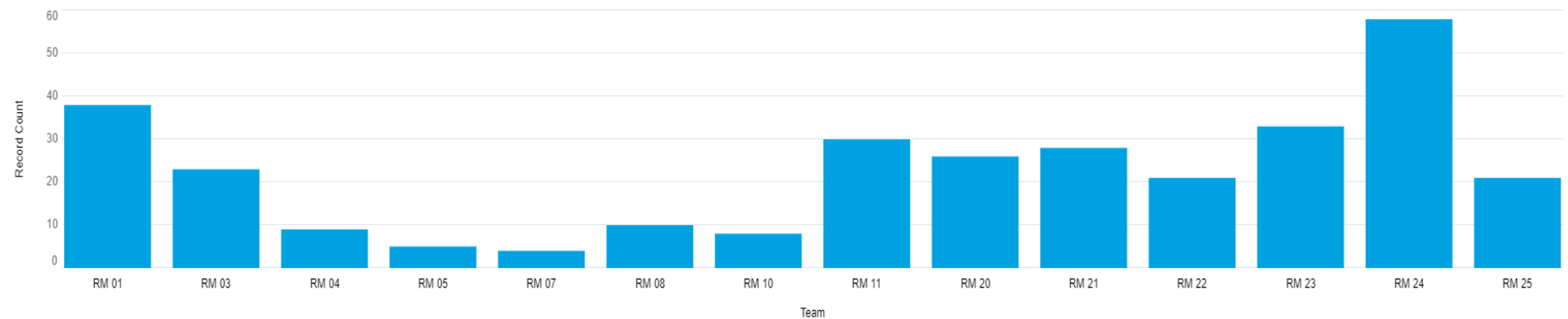
- Other Non-PRIA efforts
 - We are in the process of scheduling some non-PRIA stand down half days to focus on completion of these actions.
 - Already implemented non-PRIA power hours and non-PRIA March madness!
 - Considering implementation of partial review pilot for FTAs (similar to RD effort)
- Annotated label pilot and roll out
 - In FY'23 we started a pilot program to streamline our PRIA label review process across regulatory and science disciplines.
 - Goal was to allow concurrent review by all disciplines with a single annotated label delivered back to the registrant rather than separate comments from all disciplines.
 - We are in the process of rolling this out to the entire division after a successful pilot.
- Response/Rebuttal table for label reviews
 - We have developed a table format to provide registrants that will help both the science and regulatory teams within AD respond to label comments clearly and efficiently and document decisions in a consistent manner.
 - The Rebuttal Table is intended to be used only when the registrant does not agree with or is seeking clarification to Agency comments.



RD Pending PRIA as of 4/16/24



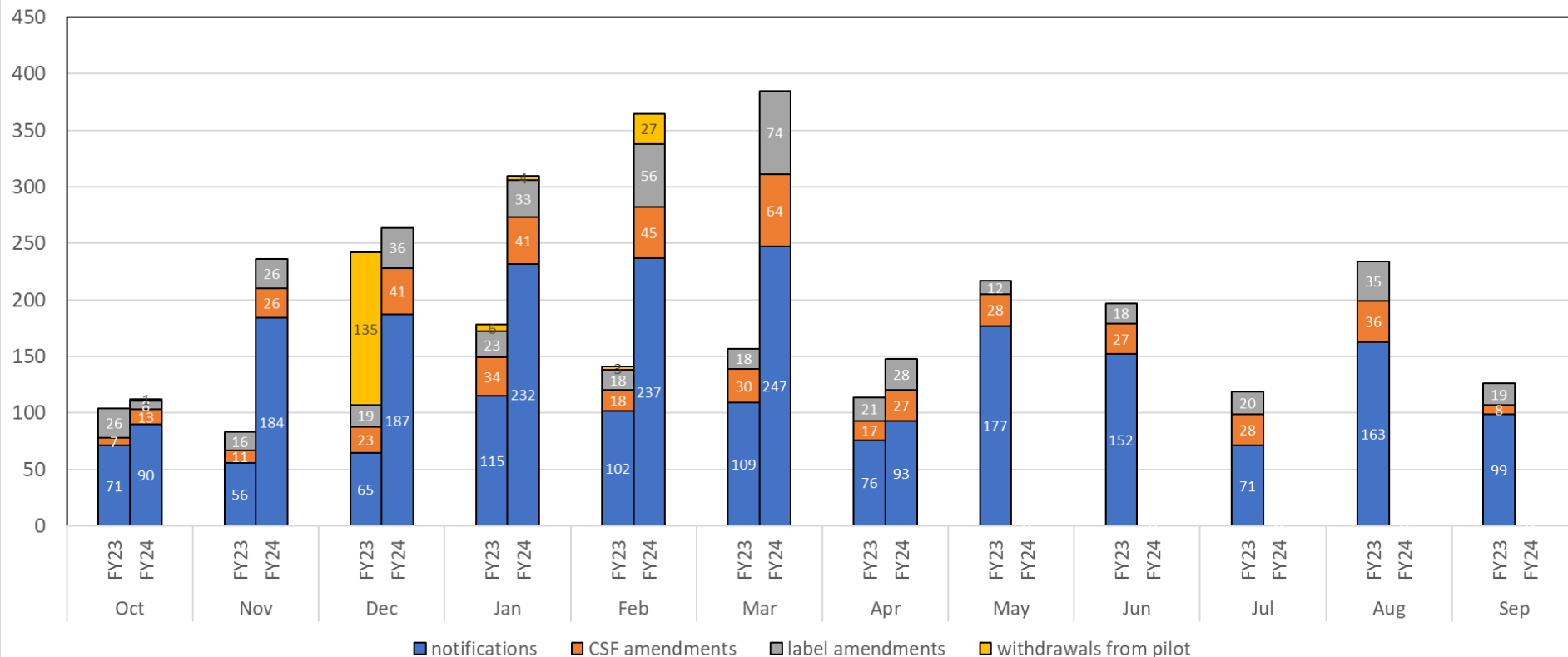
RD FY24 Closed PRIA as of 4/16/24





RD Non-PRIA Strategy Initiative

NonPRIA completions by month, as of 4/15/24





RD Process Improvement Efforts

- What's new
 - Launched a process to review only the new parts of nonPRIA label amendments (~20% of label amendments completed in February-April have used this process)
 - Created a living list of registrant contacts
 - Developed internal guidance and external talking points on how to reduce the number of rounds of label review
 - Launched a PRIA coding team pilot
- What's next
 - Re-analyze the reasons for notification rejections for actions submitted since the release of the document listing common reasons for rejections
 - Develop and implement new 98-1 for product chemistry self-certification
 - Draft tentatively complete by end of this month
 - Develop common rejection issues and best practices for product chemistry submissions
 - Make Me Too/Substantially Similar submissions easier/quicker
 - Develop external best practices for "Me Too/Substantially Similar" submissions
 - Ensure RD consistency in evaluation of these submissions



BPPD PRIA Workload and Challenges FY24

- BPPD has 78 pending new active ingredients (AIs)
 - For context, BPPD typically receives ~20 new AIs per year; already received this amount for first half of FY24
 - Additional 55 pending new products, 75 other PRIA actions and 250 non-PRIA
- BPPD staffing is down to 64 FTEs with more pending retirements/separations by end of year and very little, if any ability to backfill due to resource challenges
 - One risk management branch has fewer than 5 staff; contract budget covers less than half of actual needs for DERs
- Due to significant cuts to EPA's OPP FY24 budget, lower staffing levels and increased workload, BPPD anticipates significant delays in completing PRIA actions
 - For example, PRIA timeframe for new biopesticide AIs range from 13 to 19 months; on average, it is taking BPPD between 36 to 42 months to complete new AI
- Despite resource challenges, so far this year BPPD has completed 71 PRIA actions, including 5 new AI decisions
 - In FY23, BPPD completed 18 new AIs; likely will less this year due to staffing and resource limitations
- BPPD is also continuing to make process improvements to gain efficiencies, where possible
 - Prioritizing work
 - Contributing to cross-divisional efforts
 - Meeting with stakeholders to identify issues and implement efficiencies
 - Investigating streamlined approaches to ESA
 - Continue to avoid building up a non-PRIA backlog



Registration Review

- The FY 2023 omnibus set a new deadline of October 1, 2026, for completing the first round of registration review;
- There are 789 registration review cases due by October 1, 2026- 726 cases carried forward and 63 new active ingredients registered after FY 2007 with registration review due dates that fall before October 2026;
- Of the 789, through midyear FY24 there were
 - 718 cases (or 91%) for which draft risk assessments are completed (71 remain)
 - 616 cases (or 78%) for which final or interim decisions are completed (173 remain)



Wrap-Up/Next Meeting Date

- FY 24 quarterly stakeholder meetings
 - July 18, 2024
 - November 21, 2024



PRIA Points of Contact

- Steve Schaible, Senior Advisor, PRIA Coordinator:
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- OPP Ombudsperson Mailbox
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- BPPD:
BPPDQuestions@epa.gov
- AD Ombudsman:
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Thank You!