


# EXHIBIT 1



# **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 13, 2023**

# AGENDA

- Welcoming Remarks/Ground Rules
- OPP Organizational Chart and Staffing Update
- PRIA 5 Summary/Implementation
- IT Development Update
- FY'23 Fees Collected Mid-year
- FY'23 Mid-year PRIA Metrics
- FY'23 Mid-year Non-PRIA Fast Metrics/Division Updates
- Registration Review Update
- Wrap-Up/Next Meeting Dates



## Office of Pesticide Programs

Edward Messina, Director  
*Vacant*, Deputy Director, Management  
Michael Goodis, Deputy Director, Programs  
**Monique Perron**, Senior Science Advisor

**Endocrine Disruptor  
Screening Program**

### Antimicrobials Division

Anita Pease, Director  
Kristen Willis, (Acting) Deputy Director  
Lisa Christ, Associate Director

### Biopesticides and Pollution Prevention Division

**Madison Le**, Director  
Frank Ellis, (Acting) Deputy Director

### Registration Division

**Charles "Billy" Smith**, Director  
Daniel Rosenblatt, Deputy Director  
Catherine Aubee, Assoc. Director

### Pesticide Re-evaluation Division

Elissa Reaves, 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, (Acting) Director  
Amy Blankenship, (Acting) Deputy Dir.  
Brian Anderson, Assoc. Director

### Biological and Economic Analysis Division

**Anne Overstreet**, Director  
Neil Anderson, Deputy Director



# PRIA 5 and Appropriations

- **PRIA - Increase in fees and funding for OPP (+\$11m for maintenance; +\$6m for registration)**
- **FY23 appropriations - \$11m increase, targeted at ESA**
- Omnibus - October 1, 2026, deadline extension (IDs with measures to reduce)
- Bi-lingual Labeling for Pesticides
- ESA Guidance to Registrants
- Renegotiation Provisions for submissions
- Grants for Farmworker Organizations
- Testing Protocols for Devices
- Vector Expedited Review Voucher program
- Pesticide Surveillance Program
- Audit of OPP Processes and IT Upgrades
- Government Shutdown Provisions
- Reports to Congress
- <https://www.congress.gov/bill/117th-congress/house-bill/2617/text> (CTRL F "pesticide")



## **PRIA 5 Implementation**

- Maintenance fees were re invoiced to be reflective of the PRIA 5 collection target and the maintenance fee webpage has been updated;
- OPP's internal tracking systems (OPPIN, Salesforce) are being updated to include PRIA 5 information;



## **PRIA 5 Implementation**

- PRIA fee table, primary/secondary table, and refund table webpages were updated in February;
- Interpretations discussions are being wrapped up, as are revisions to the Fee Determination Decision Tree;
- Fee Determination Decision Tree, category specific pages, and the PRIA Interpretations pages will be updated to be reflective of PRIA 5 category descriptions and fees once Interpretations are finalized;



# PRIA 5 Implementation- FY 2023 Due Dates

- **June:**
  - Seek stakeholder input on ways to make bi-lingual labeling accessible to farmworkers;
  - Post to a single webpage guidance related to risk assessment, risk mitigation, benefits, assessment, and cost-benefit balancing, as well as hyperlinks to resources (e.g., pesticides exempt from registration under section 25(b))
- **September:**
  - Issue ESA guidance to registrants for outdoor uses of new active ingredients, registration review cases
- **December:**
  - Establish VERV program
  - Issue ESA guidance to registrants for new outdoor uses of registered active ingredients
  - Establish grant program to develop training curricula
  - IT Update deliverables
  - Issue process assessment contract





## **PRIA Process Changes- Coding and Recoding**

- EPA will develop and implement a process to determine the appropriate fee category(ies) in order to assist applicants and prevent unnecessary payment of fees for multiple categories for a single application;
- Final PRIA category cannot be changed, without providing the information to the applicant, after completion of the preliminary technical screen.



## **PRIA Process Changes- Renegotiations**

- If EPA cannot meet a decision review time period, EPA will notify the applicant in writing of the reason and the additional time needed to make a decision;
- Decision timeframes can be extended if:
  - There is new or additional data or information from the applicant that is necessary for the EPA to make a decision on the application that cannot be made available within the original time period;
  - A public comment period associated with an application generates significant comments which cannot be addressed within the original decision timeframe;
- Once a decision review time period is missed or extended, EPA shall make any action on the application a priority.



# PRIA Process Changes- Preliminary Tech Screen

- By completion date of preliminary technical screen, EPA must:
  - Make reduced risk determinations;
  - Grant or deny any data waiver requests submitted with an application;
  - Verify and validate the accuracy of the fee category selected by the applicant;
  - Notify the applicant in writing, if a new fee category is needed and calculate the new decision timeframe for the action based on the original submission date.



# IT Upgrades

- Not later than 1 year after date of enactment (by December 2023), EPA shall establish an information technology system that:
  - Includes all registering divisions in OPP;
  - Provides a real-time, accurate tracking system for all regulatory submissions;
  - Provides applicants confidential, real-time, accessible information on the status and progress of their regulatory submissions; and
  - Updates the electronic submission portal:
    - To ensure that label reviews are limited to current label changes, to the maximum extent practicable;
    - To automate, to the extent practicable, minor, low risk regulatory actions; and
    - To allow self-certification of certain regulatory actions as determined by EPA.



## EPA IT Update

- The Mission Support contract for EPA's IT modernization effort has been awarded;
- EPA is now finalizing the task orders that will operationalize the contract including management of the contract, infrastructure, and new development. This phase is expected to take 90 days with work to expand the Digital Transformation estimated to begin in Q3, 2023.
- Reviewing PRIA 5 to ensure meeting statutory requirements related to IT development within the larger Digital Transformation scope.



## Digital Label Updates

- The eCSF builder pilot is open and able to accept formulation statements as standardized PDFs (37 received to date)
- OPPEL builder pilot is available for pilot participants to test and provide feedback
- Currently building an international coalition of fellow regulators for digital label harmonization
- Working with industry and fellow regulatory agencies to develop a phased developed plan for a fully digitized label



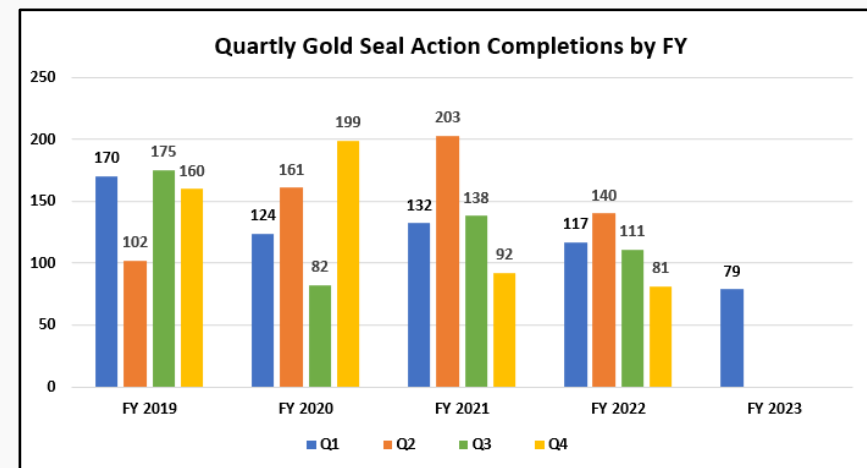
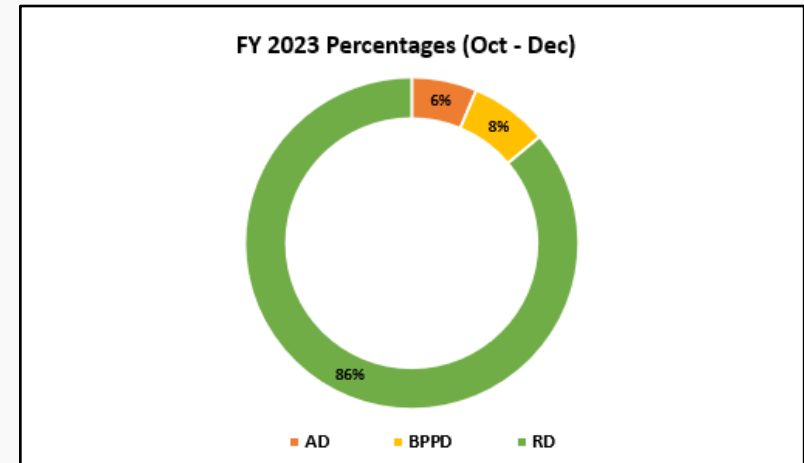
## Front End Processing Delays

- EPA has identified that starting as far back as mid-October of 2022, some PRIA actions were delayed during the front-end process
  - Milestone 1 emails were being sent out for these affected actions but Milestone 2 emails were not going out until January as fixes and work-arounds were implemented
  - Some delayed actions are still going through contractor review
- As a result of these issues, EPA will be examining all parts of the front-end workflow to identify any efficiencies or weaknesses in the process



# Gold Seal Status Update

- It is a priority of the Agency to resolve the front end processing issues as quickly as possible so Gold Seal letters can be issued.
- At this time we cannot provide a timeline on when we will start issuing letters again.
- Registrants are encouraged to send a list with the EPA Registration Numbers of their submitted actions to [goldsealletters@epa.gov](mailto:goldsealletters@epa.gov) or Shanta Adeeb at [adeeb.shanta@epa.gov](mailto:adeeb.shanta@epa.gov).







# FY'23 Fees Collected Mid-Year

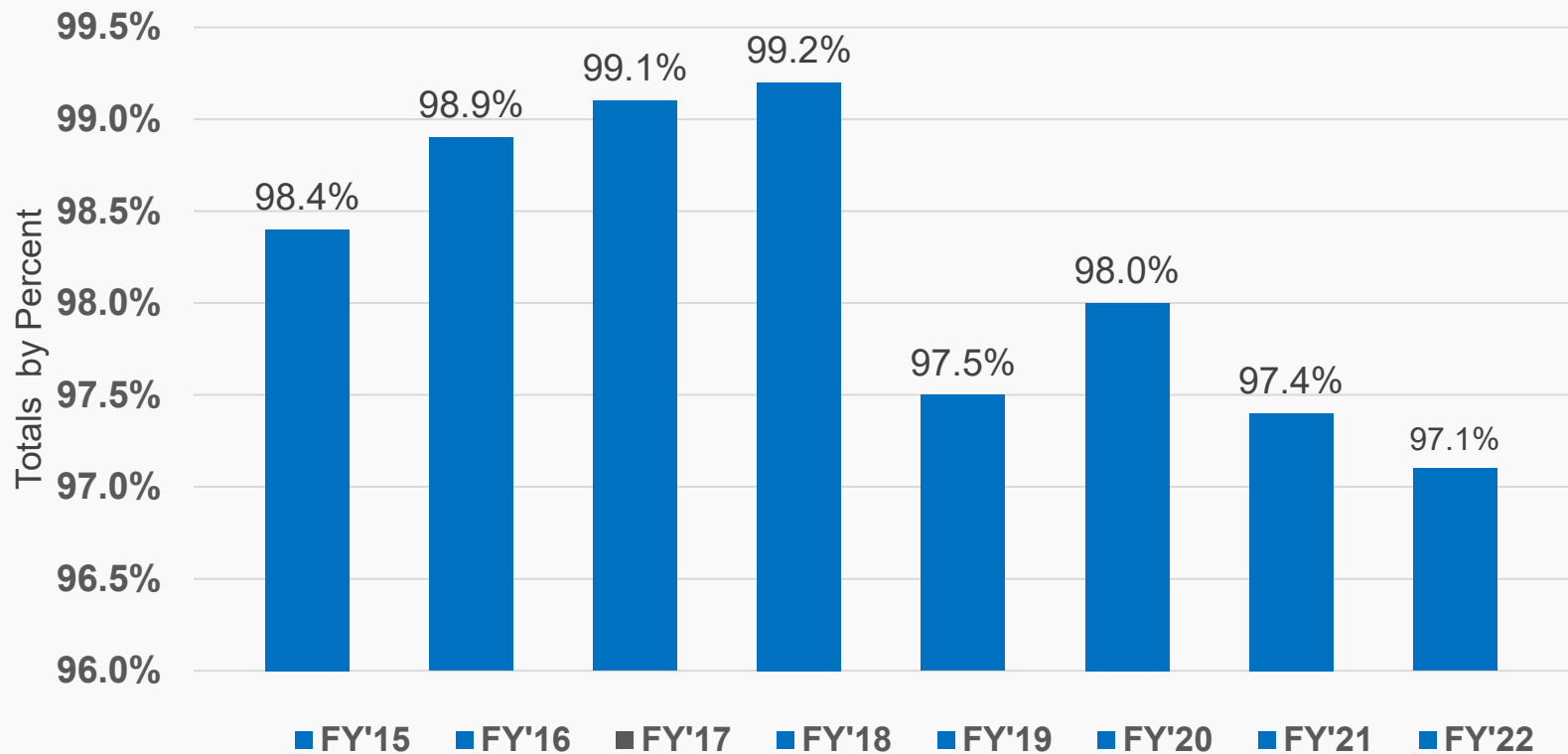


**PRIA Fees: \$12.4M**

**Maintenance Fees: \$38.1M**



# FY'22 OPP On-Time Completion Rates- Goodbye!



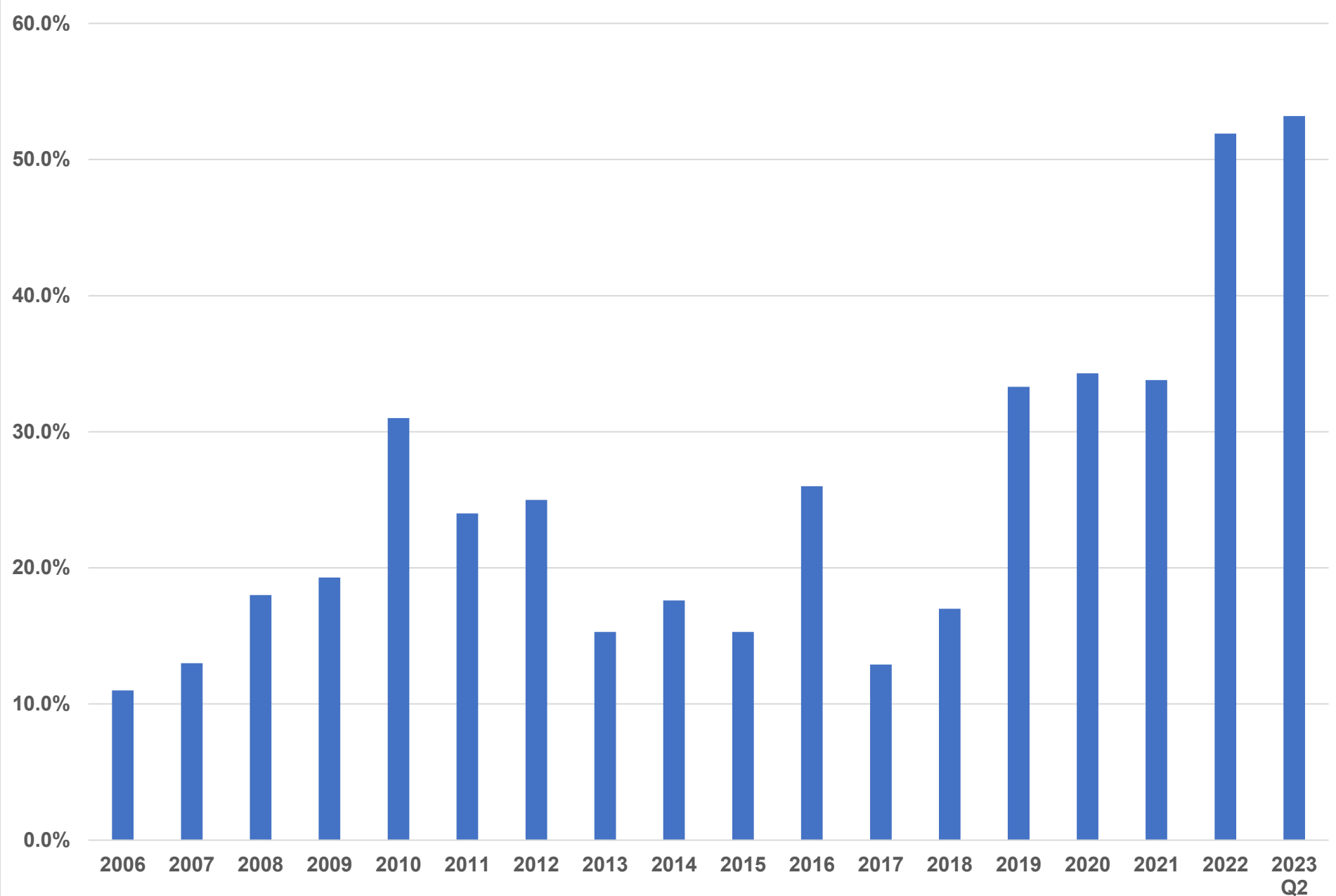


## Historical % of Completed PRIA Decisions with Renegotiated Due Dates

FY	Antimicrobials	Biopesticides	Conventionals	Misc.	Inerts
2015	44/319 = 13.8%	28/154 = 18.2%	229/960 = 23.8%	2/622 = 0.3%	18/56 = 32.1%
2016	31/350 = 8.9%	22/151 = 14.6%	254/977 = 26.0%	2/643 = 0.3%	21/49 = 42.9%
2017	26/338 = 7.7%	22/163 = 13.5%	197/937 = 21.0%	0/544 = 0%	16/42 = 38.1%
2018	6/328 = 1.8%	40/214 = 18.7%	310/1044 = 29.7%	2/578 = 0.3%	16/35 = 45.7%
2019	82/391 = 21.0%	46/205 = 22.5%	541/854 = 63.4%	3/611 = 0.5%	24/34 = 70.6%
2020	48/514 = 9.3%	56/172 = 32.5%	667/1094 = 60.9%	32/582 = 5.4%	16/23 = 69.5%
2021	84/640 = 13.1%	79/164 = 48.1%	673/1054 = 63.8%	19/659 = 2.8%	9/39 = 23.0%
2022	296/492 = 60.1%	96/200 = 48.0%	657/927 = 70.8%	71/539 = 13.1%	29/52 = 55.7%
2023, Q2	104/190 = 54.7%	33/72 = 45.8%	293/461 = 63.6%	14/110 = 12.7%	11/22 = 50.0%

# PRIA Renegotiation Rates for Completed Actions

## FY2004 to **FY2023** Mid-Year, Q2 Baseline





## **PRIA 5 Renegotiation Criteria**

- EPA and applicant may mutually agree to extend a decision time review period if--
  - There is new or additional data or information from the applicant that is necessary for EPA to make a decision on the application that cannot be made available within the original decision time review period, or
  - A public comment period associated with the application generates significant comments that cannot be addressed within the original decision time review period

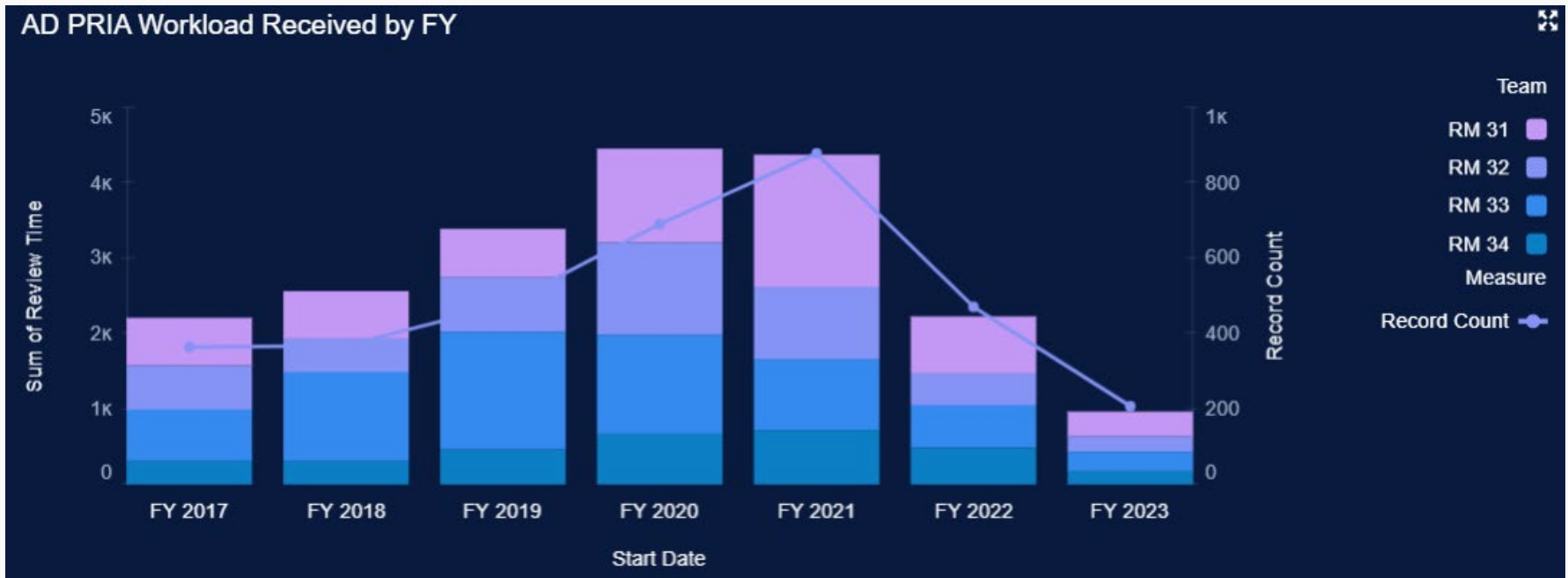


## **PRIA Renegotiation Reporting Requirements/ New Metrics to Be Developed**

- Reporting requirements
  - Dates of any renegotiations and dates to which action is renegotiated
  - Reason(s) for renegotiation
- Overall decision review timeframe to complete action by PRIA category and activity
  - Degree to which original timeframe is exceeded

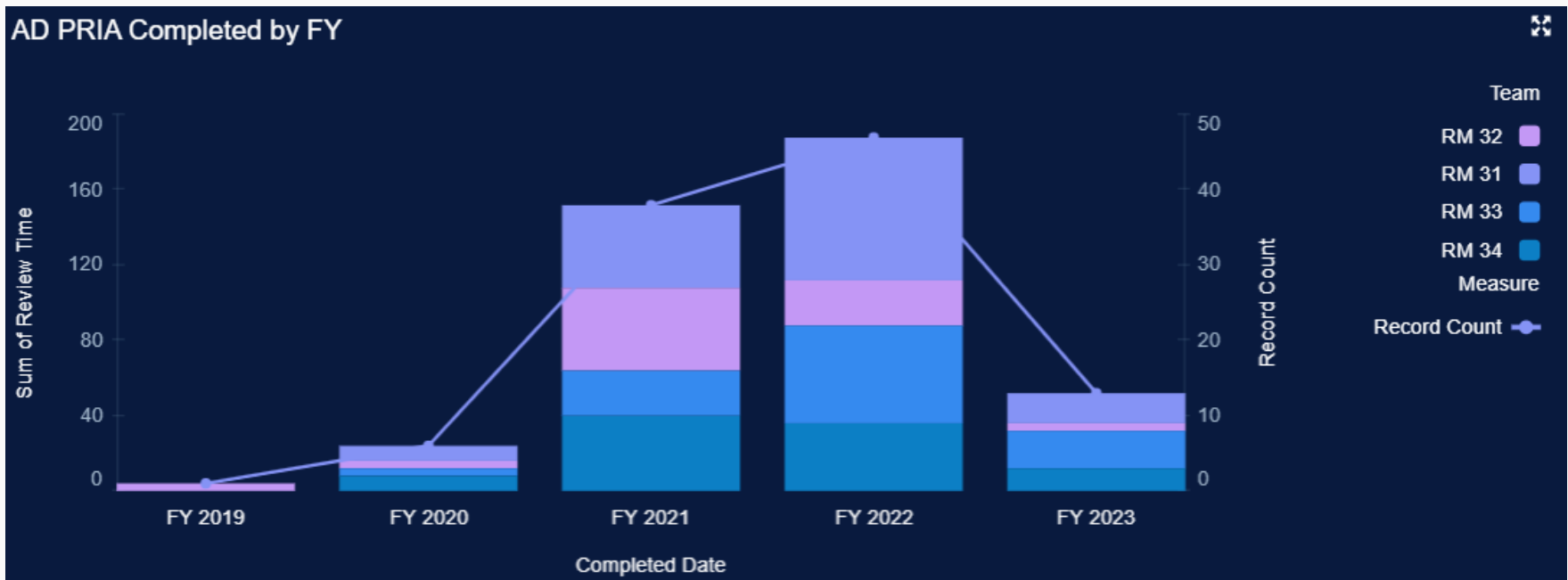


# AD PRIA Received FY17-FY23





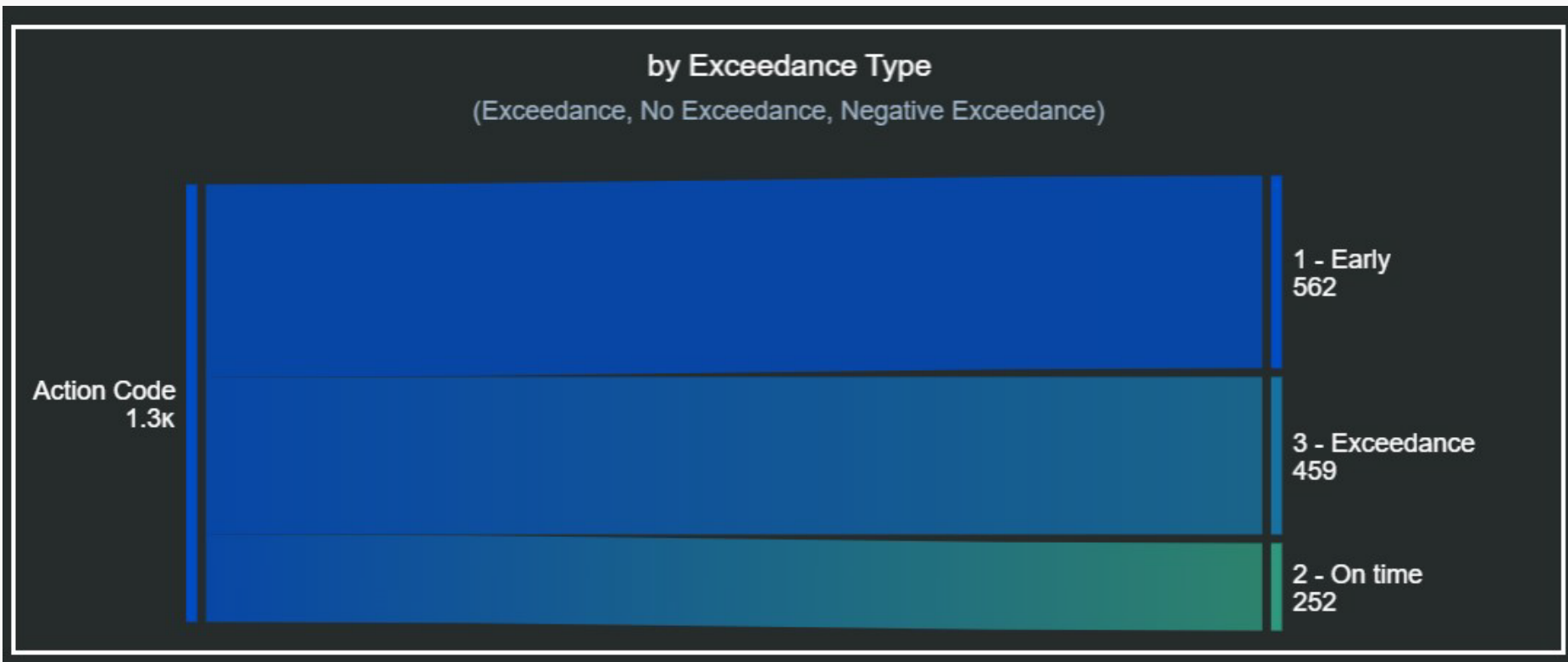
# AD PRIA Completed FY17-FY23







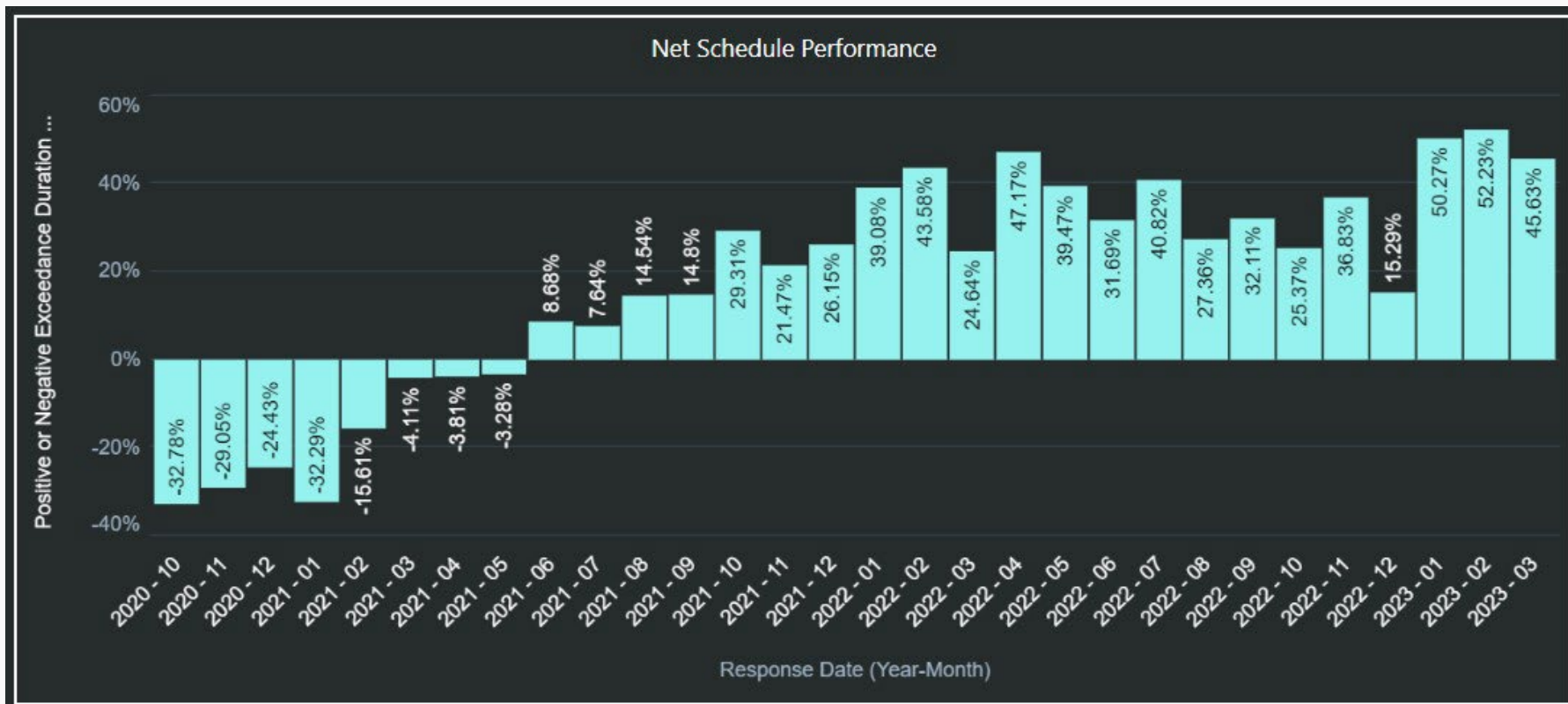
## AD Net Schedule Performance FY21-FY23



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



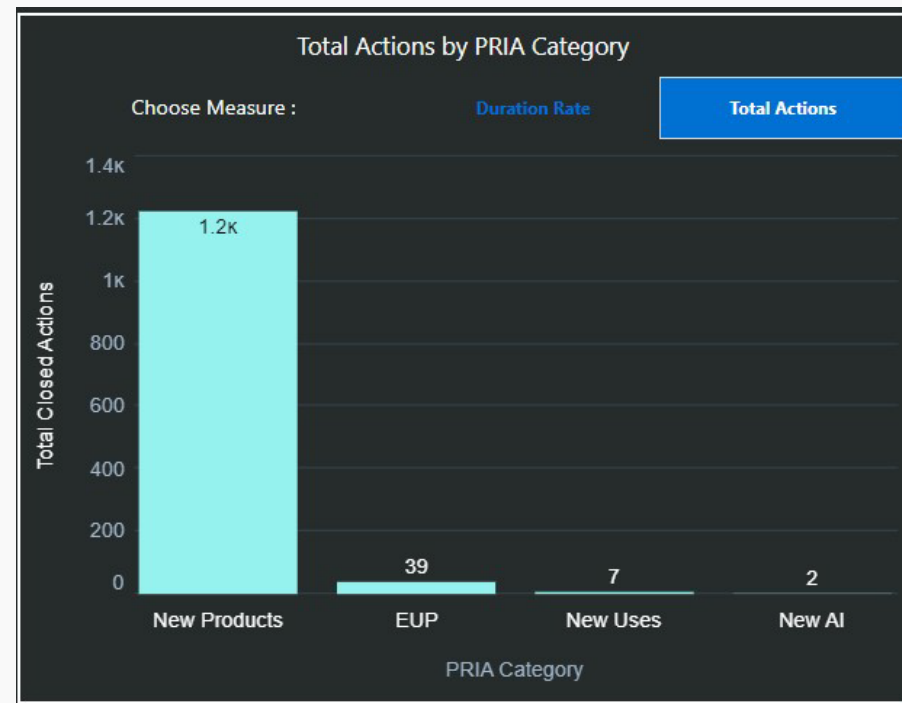
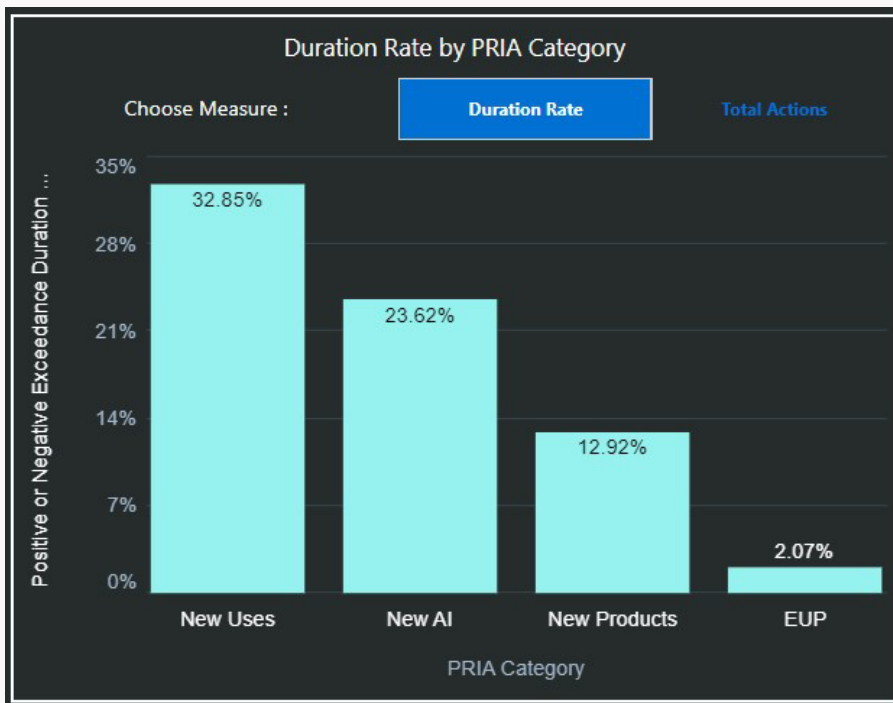
# AD Net Schedule Performance FY21-FY23



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



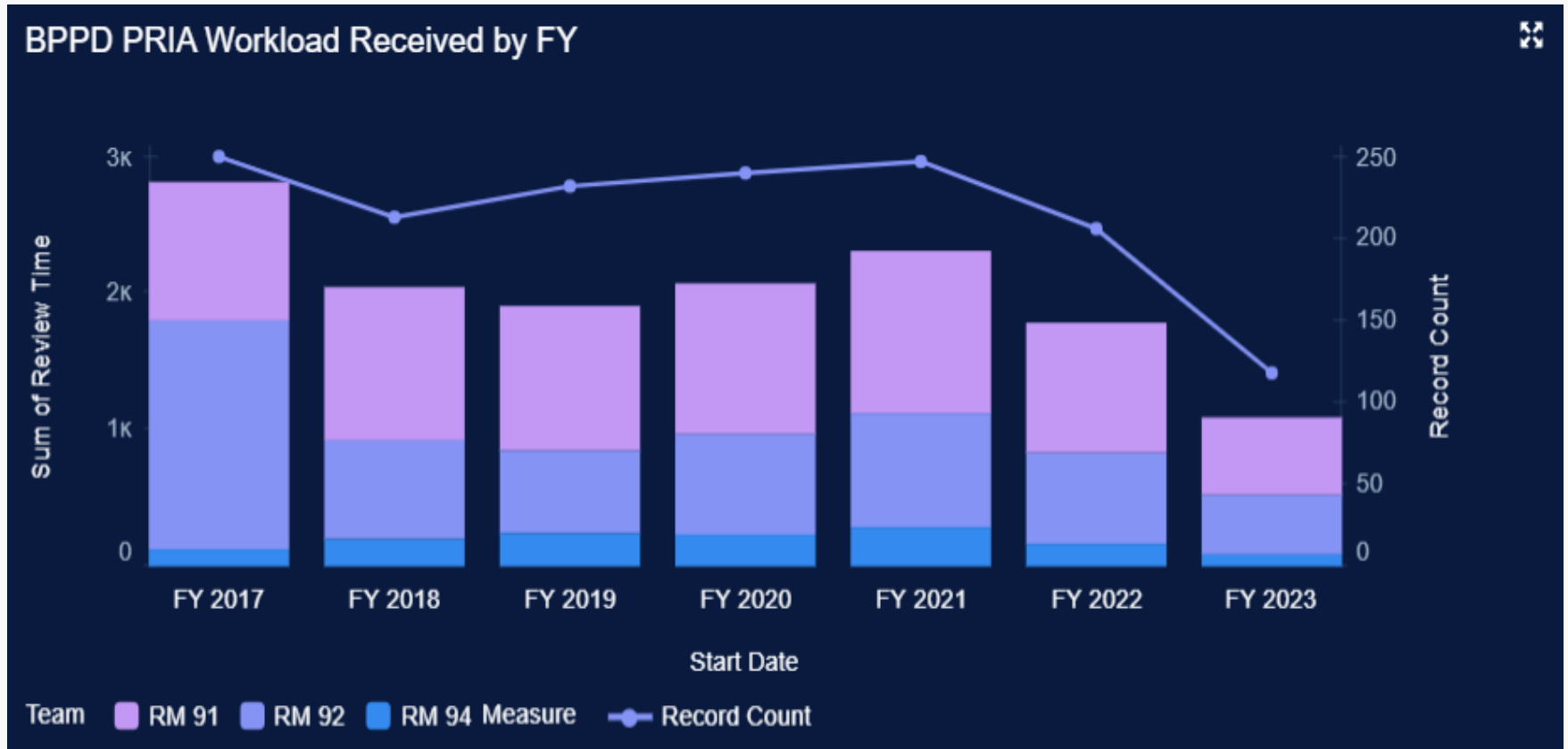
# AD Net Schedule Performance FY21-FY23



\*Represents percent of time original PRIA dates were exceeded and total completed actions during that time period.

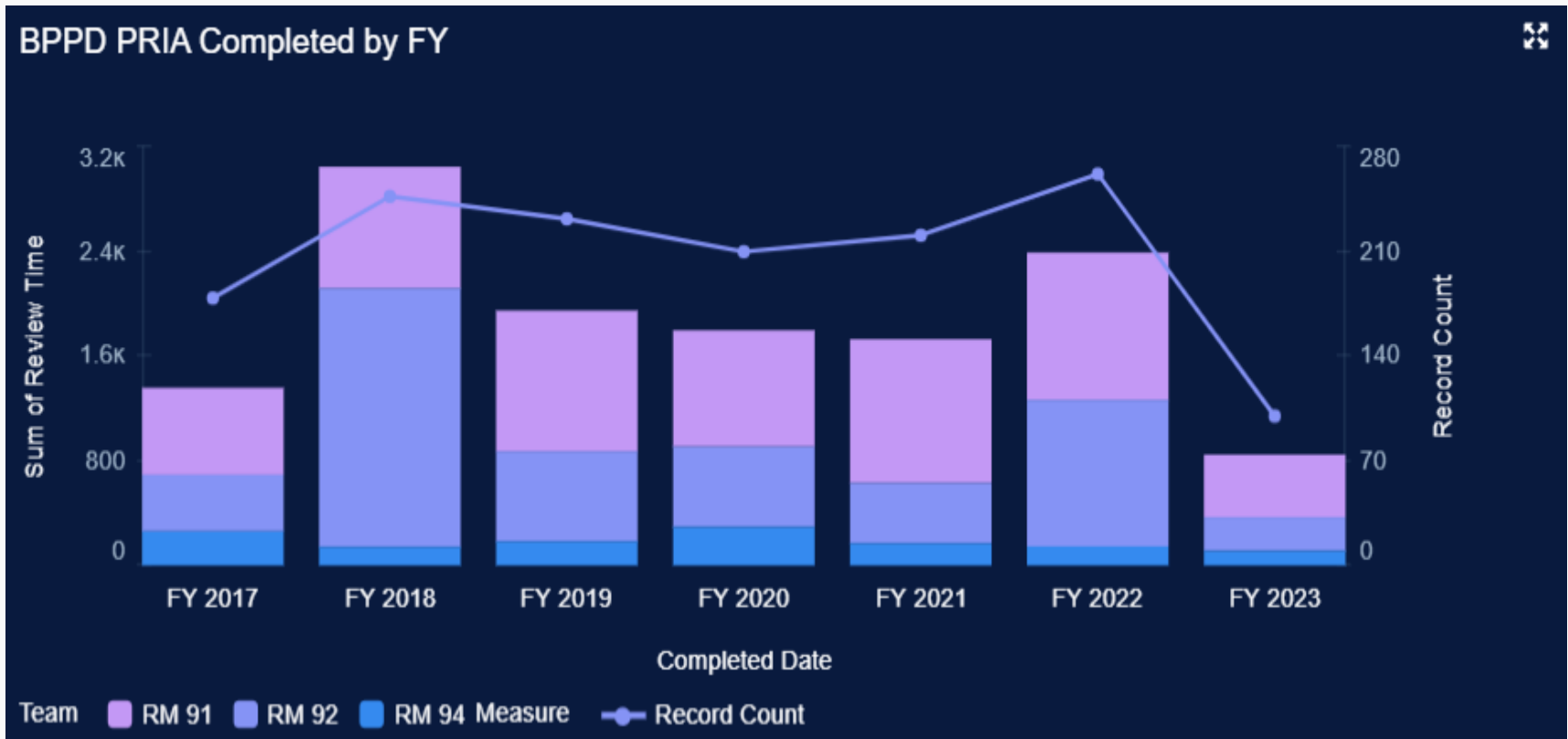


# BPPD PRIA Received FY17-FY23





# BPPD PRIA Completed FY17-FY23





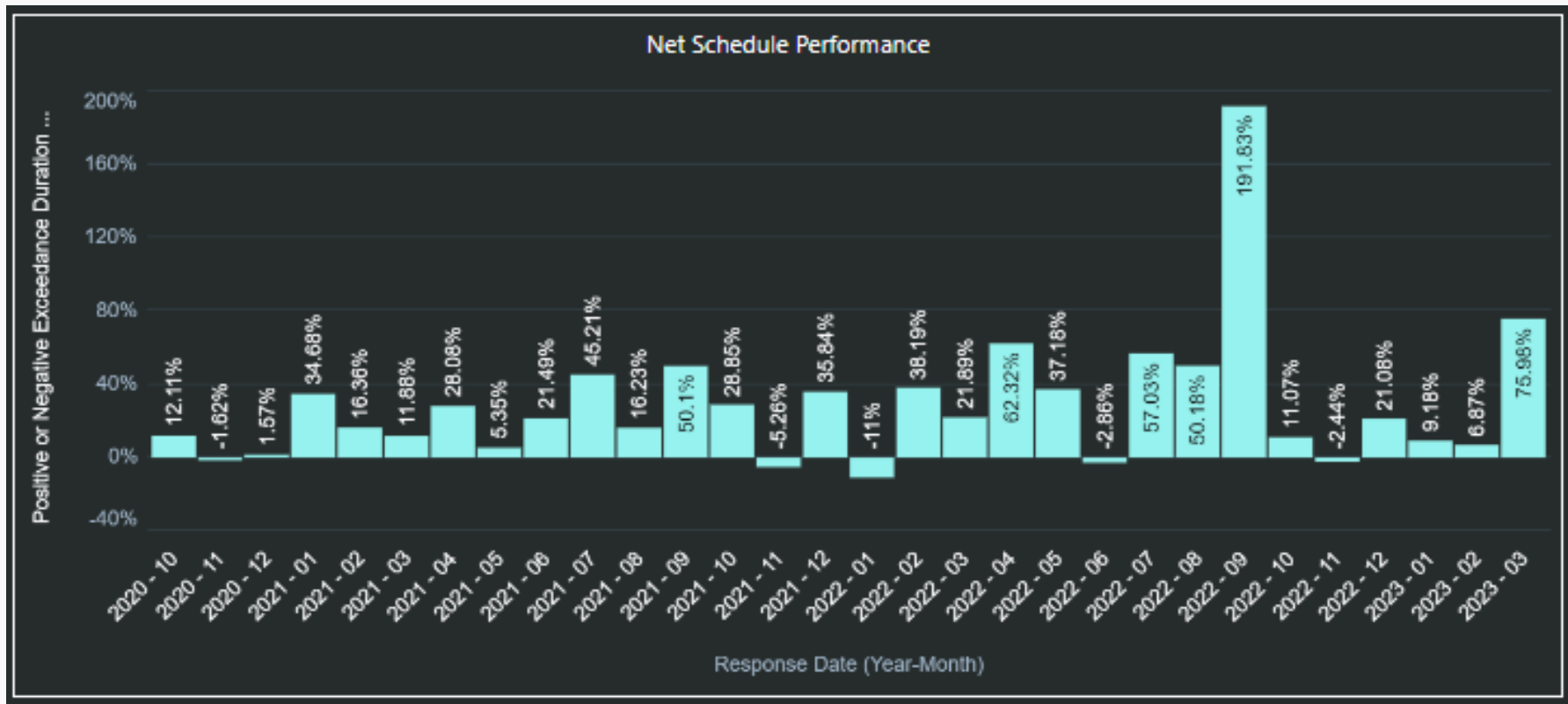
## BPPD Net Schedule Performance FY21-FY23



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



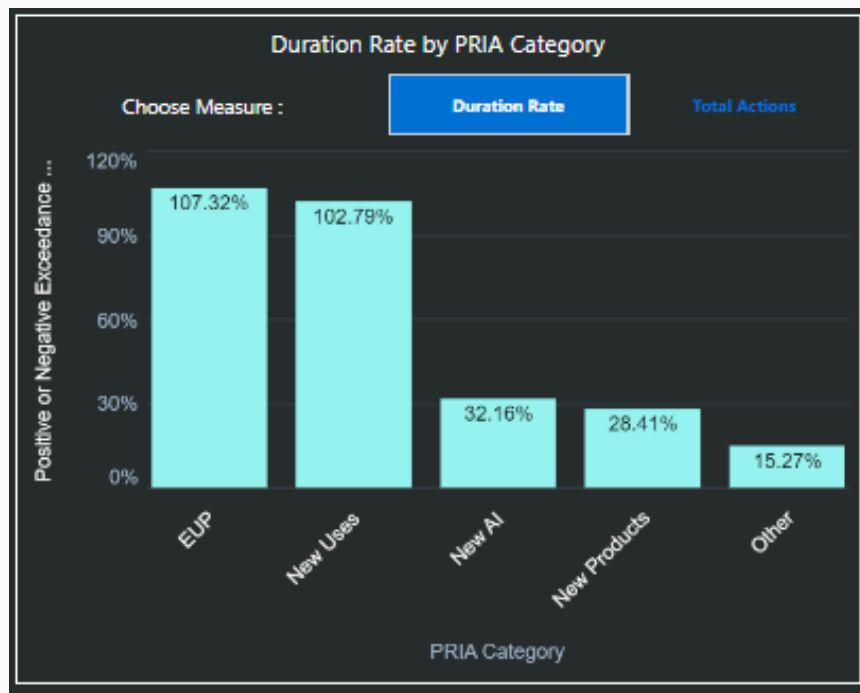
# BPPD Net Schedule Performance FY21-FY23



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



## BPPD Net Schedule Performance FY21-FY23



\*Represents percent of time original PRIA dates were exceeded and total completed actions during that time period.





# 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

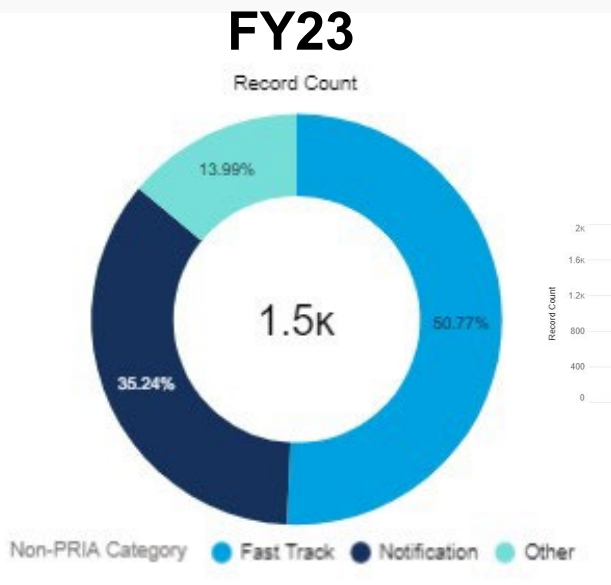


# Antimicrobials Division- Non-PRIA Backlog Proposal for Amendments

- 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 Salesforce Non-PRIA Completions (as of 4/10/23)



### Completed FY18-FY23

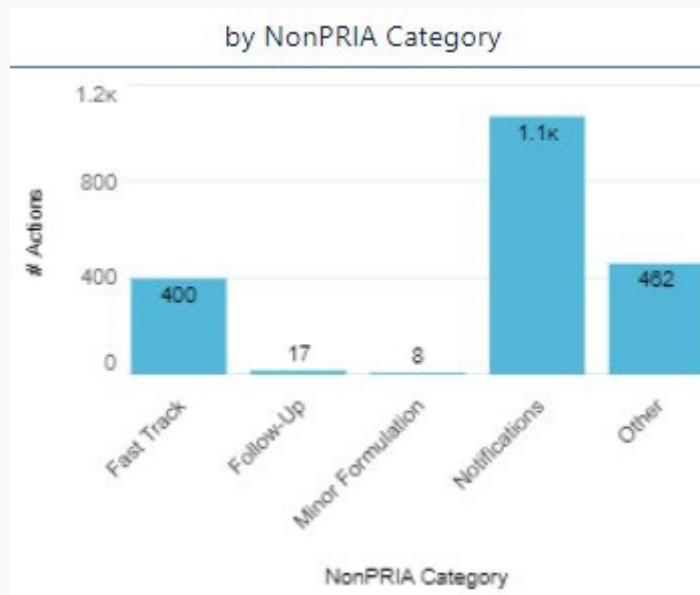


Note: ~70% of the FY23 completions are due to the mass closeout for cancelled products

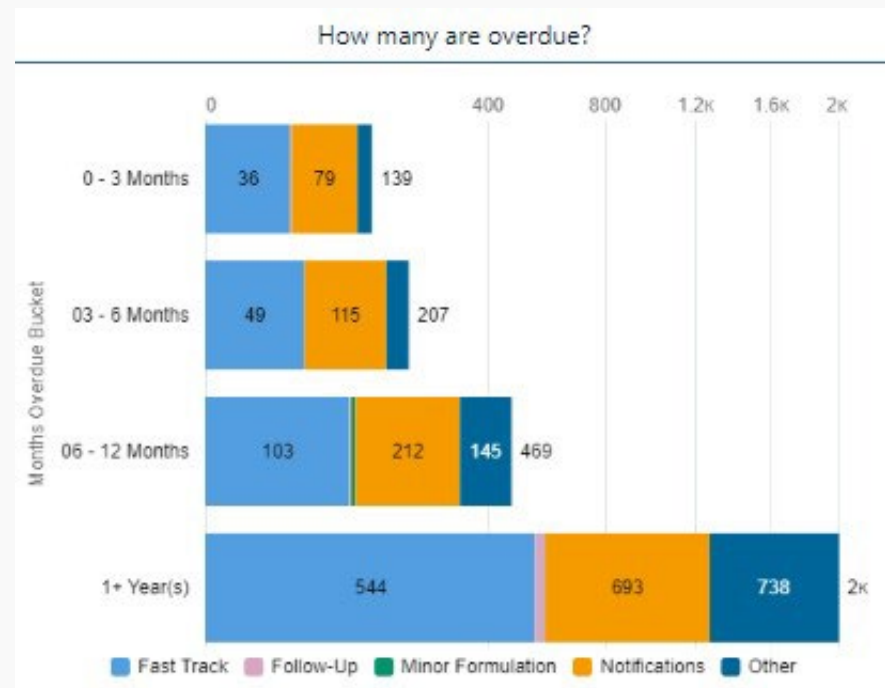


# AD Salesforce Non-PRIA “Backlog” (as of 4/10/23)

**Actions received FY22-FY23**

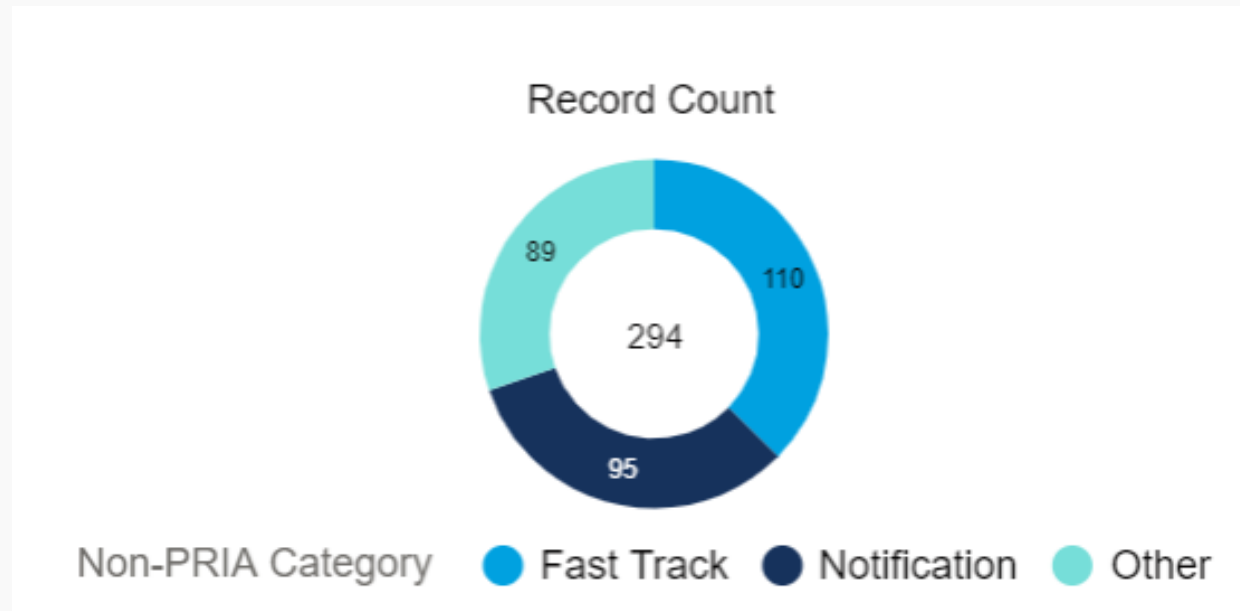


**Overdue actions FY18-FY23**



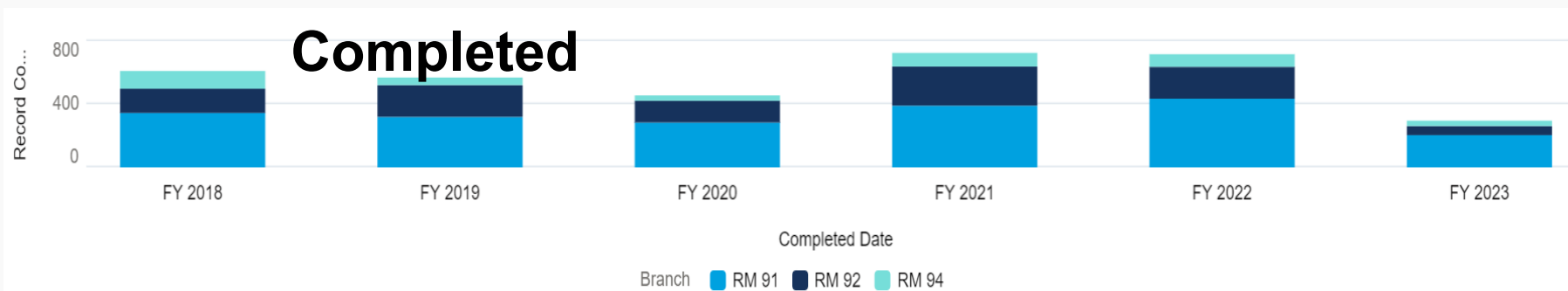


# BPPD Salesforce Non-PRIA FY23 Completions (as of 4/5/23)



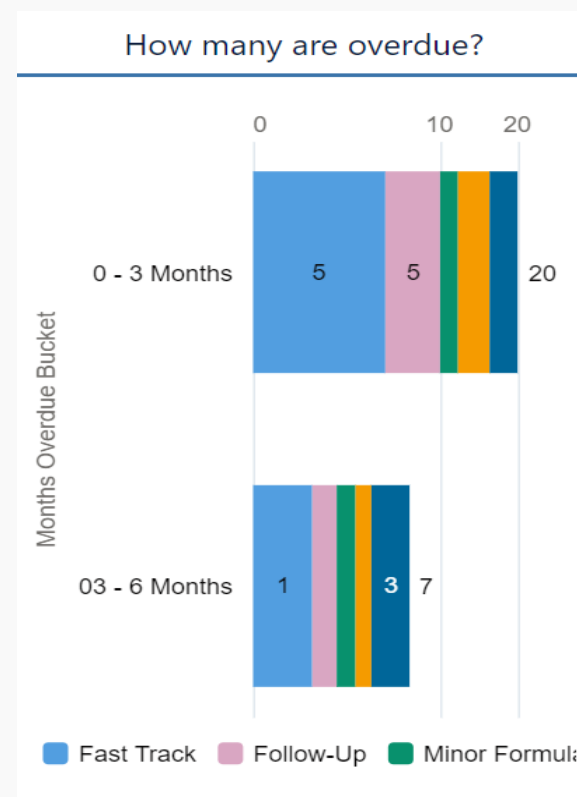
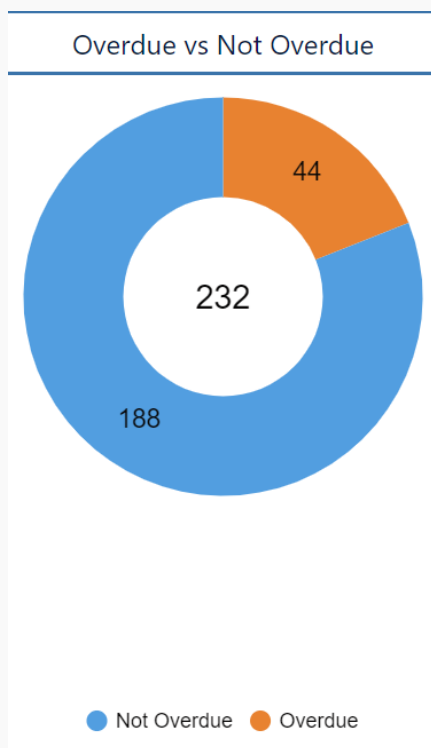


# BPPD Salesforce Non-PRIA FY17-FY23 (as of 4/5/23)





# BPPD Salesforce Non-PRIA “Backlog” FY17-FY23 (as of 4/5/23)





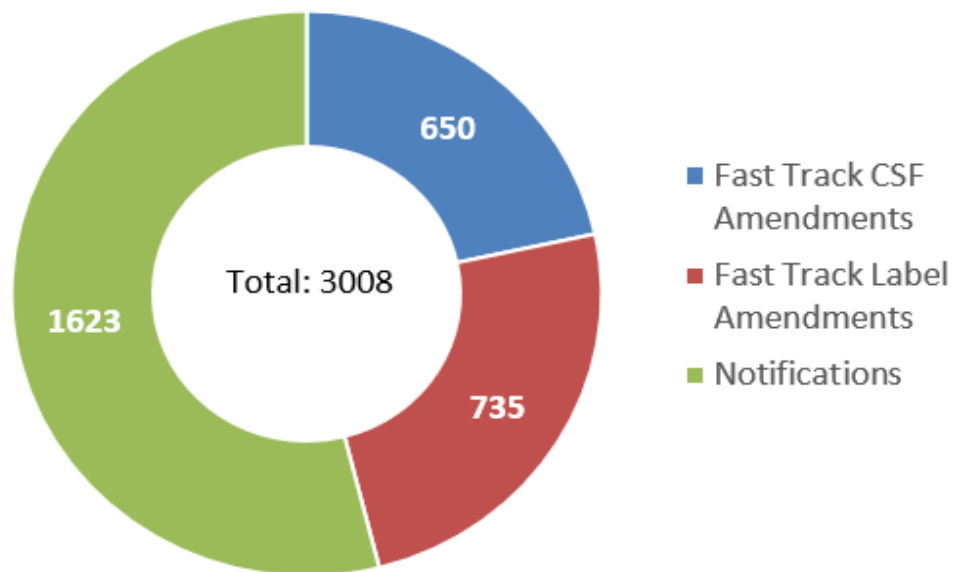
# RD Non-PRIA FY23 Mid-year Completions

- Through mid-year FY 2023, RD completed:
  - **341** Fast Track Label and CSF Amendments
  - **568** Notifications (labels and CSFs)
  - **50** Minor Formulation Amendments
  - **8** Section 18s (excluding 4 withdrawn and 1 amendment)
  - **133** SLNs past 90 days





## Registration Division FY17-FY23 Pending Fast Track and Notification Decisions



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



## 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.
- About 10% or close to 175 actions were able to be withdrawn and removed from the backlog.
- RD is next piloting a project with some of the larger companies to complete a similar effort.
- RD combines similar type non-PRIA actions on the same product (such as 2 CSF actions) whenever possible as standard practice. While some registrants have asked if they can help us do this proactively, we are limited by our outdated IT infrastructure and there is no way to do this without creating additional resource burdens.



## Continued..

- Additionally, RD is reviewing the backlog to identify old actions that are no longer needed or valid and do some data cleanup to prepare us for Salesforce transition, as well as help RD staff focus on items that are truly needed from the backlog.
- RD may consider doing the same as AD to close out old notifications without staff review.
- RD encourages registrants to reach out to the product's PM if there are actions that they no longer need and can be withdraw.
- While RD has been balancing increasing numbers of PRIAs and other commitments while keeping the total number of non-PRIAs reviewed each year constant, it is not enough to keep up with the volume of new submissions and the non-PRIAs backlog.



## Bobcat Team for CSF Actions

- The goal of the Bobcat Team is to work on more recent CSF actions and help with industry concerns over supply chain issues for inerts. The team is focused on completing CSF notifications and non-PRIA CSF amendments submitted in 2020 and 2021.
- The team attends weekly CITAB office hours where they come prepared to ask any product chemistry questions found during their review. This allows for timely input from product chemists regarding non-PRIA CSF actions.
- The bobcat team number for quarter 2 completions was ~168 actions.
- The Bobcat team has also been combining actions outside of the 2020 and 2021 time period, when possible.



# Pesticide Registration Review

- In 2007, an amendment to FIFRA formalized a requirement that EPA review each registered pesticide at least every fifteen years – this is what we call registration review.
- The FY2023 Omnibus Bill provided a four-year extension for the registration review deadline for the pesticides registered before October 1, 2007.
- The deadline for the completion of registration review final decisions is now October 1, 2026.
- The Bill requires interim decisions (IDs) to include “measures to reduce the effect of the [pesticide]” on listed species and designated critical habitats if EPA has not “made effects determinations or completed any necessary consultation under [ESA Section 7(a)(2)].”
- EPA affirms its aggressive plan to review all remaining pesticide cases and issue decisions to protect humans, endangered species, and the environment, while providing pesticide users with predictability about the legal status of pesticides in registration review.
- New Pesticide Registration Review Schedule located here:  
<https://www.epa.gov/pesticide-reevaluation/upcoming-registration-review-actions>



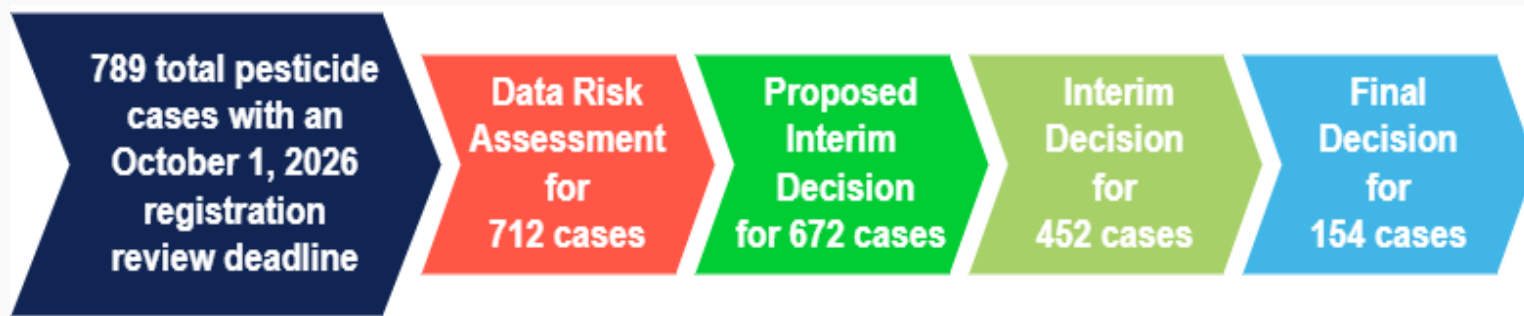
# Pesticide Registration Review Progress

- There are 789 cases with a registration review deadline before October 1, 2026. EPA has:
  - Completed 712 draft risk assessments (90% of total number of cases), evaluating the potential for human health and ecological effects of a pesticide
  - Completed 672 proposed interim or proposed final decisions (85% of total number of cases)
    - which present EPA's responses to public comment on draft risk assessments and which propose label mitigations and/or restrictions so that a pesticide product can continue to be used safely
  - Issued 452 interim decisions (57% of total number of cases)
    - which explain any changes to what had been proposed, respond to significant public comments, and require registrants to submit any product label amendments needed to protect human health and the environment



# Pesticide Registration Review Progress

- Issued 154 final decisions (20% of total number of cases),
  - which document proposed changes, respond to significant public comments, and require registrants to submit product label amendments needed to protect human health and the environment
- Of the 606 interim or final decisions, 140 cases resulted in cancellation of some or all uses (18% of total number of cases).





# PRIA Points of Contact

- Steve Schaible, Senior Advisor, PRIA Coordinator:  
[schaible.stephen@epa.gov](mailto:schaible.stephen@epa.gov)
- OPP Ombudsperson Mailbox  
[pesticidequestions@epa.gov](mailto:pesticidequestions@epa.gov)
- RD Ombudsman:  
[OPP\\_RD\\_Ombudsman@epa.gov](mailto:OPP_RD_Ombudsman@epa.gov)
- BPPD:  
[BPPDQuestions@epa.gov](mailto:BPPDQuestions@epa.gov)
- AD Ombudsman:  
[pesticidequestions@epa.gov](mailto:pesticidequestions@epa.gov)





# Thank You!