



# Updates from the EPA Registration Division

**NPIRS Conference  
April 24, 2024**

**Dan Rosenblatt; Deputy Division Director**



# Agenda

- Resources – Staffing and Funding
- EPA/OPP's priorities
- PRIA 5 Projects and Requirements
- Workflow charts and Metrics – PRIA
- Non-PRIA Activities
- Contacts Pages



## 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) Assc. 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

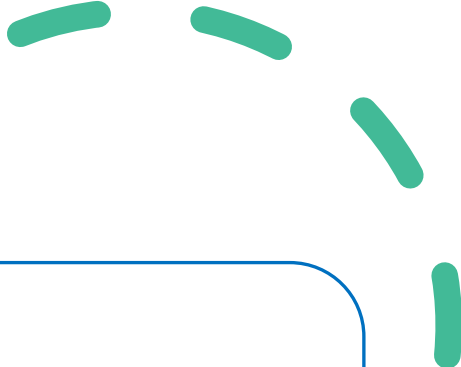
### Environmental Fate and Effects Division

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

### Biological and Economic Analysis Division

Anne Overstreet, Director  
Neil Anderson, Deputy Director

**RD IO**  
Charles "Billy" Smith, Director  
Dan Rosenblatt, Deputy Director  
**Jenn Saunders, Acting Associate Director**  
Kable Davis, Senior Advisor  
Anthony Britten, Senior Advisor  
Paul DiSalvo, Senior Advisor



**IVB1**  
**Jackie Herrick, Acting Branch Chief**  
**Scott Campbell; Acting PM3**  
Beth Fertich; PM4  
Kevin Ulrich, Sr Entomologist  
9 Staff

**IVB2**  
Ideliz Negron-Encarnacion; Branch Chief  
Tamica Cain; PM10  
Michael Walsh; PM11  
Debra Rate; SRS  
8 Staff  
**Staff Vacancies: 2**

**IVB3**  
Dee Colby, Branch Chief  
Venus Eagle; PM1  
Mel Bridges; PM7  
Gene Benbow, SRS  
8 Staff  
**Staff Vacancies: 1**

**FB**  
Cynthia Giles-Parker; Branch Chief  
**Vacant; PM21**  
Kristy Crews; PM22  
**Jeana Hansel; Acting SRS**  
8 Staff  
**Staff Vacancies: 1**

**FHB**  
Nate Mellor; Branch Chief  
Shaja Joyner; PM20  
Heather McFarley; PM24  
Aswathy Balan; SRS  
8 Staff  
**Staff Vacancies: 1**

**HB**  
Lindsay Roe; Branch Chief  
Mindy Ondish; PM23  
Emily Schmid; PM25  
**Vacant; SRS**  
8 Staff  
**Staff Vacancies: 1**

**MUERB**  
Eric Bohnenblust; Branch Chief  
Nancy Fitz; Minor Use Lead  
Jen Gaines; SRS  
5 Staff  
**Staff Vacancies: 1**

**ISB**  
Rachel Holloman; Branch Chief  
Raderrio Wilkins, Front-End Lead  
5 Staff  
**Staff Vacancies: 1**

**CITAB**  
Kerry Leifer; Branch Chief  
**Ian Blackwell: Acting Acute Tox Lead**  
Mathur Shyam; Product Chem Lead  
Evisabel Craig; Inerts  
16 Staff  
**Staff Vacancies: 2**

# RD Org Chart March 2024



# OPP/RD Staffing Updates

- New Staff/Positions
  - Ideliz Negron-Encarnacion, IVB2 BC
  - Rachel Holloman, Permanent transfer to BC ISB
  - Nate Mellor, FHB BC
  - Jen Gaines, SRS MUERB
  - Kevin Ulrich, Transfer to Senior Entomologist
  - Cassandra Luna and Elizabeth Danon, IVB3
  - Jenna Wiegand, HB
  - Eric Ingram and Laura Rademacher, IVB1
  - Hector Escobar, FHB
- Details-In
  - Jenn Saunders, Acting Associate Director
  - Jackie Herrick, Acting IVB1 BC (February through May)
  - Scott Campbell, Acting PM3
  - Kendra Brown, ISB
- Details-Out/Departures
  - Catherine Aubee, Detail to the EDSP Program
  - Julie Breeden-Alemi (Detail Special Assistant in OCSPPIO)
  - Virna Stillwaugh, Departure



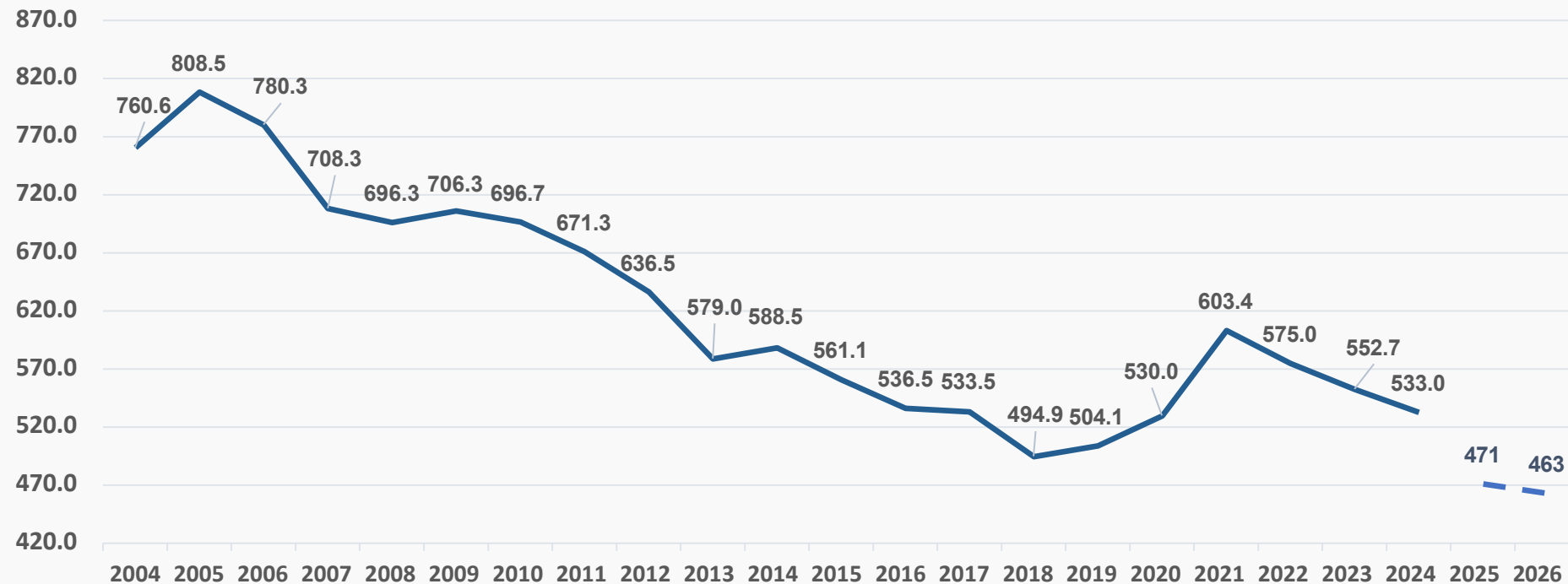


## Office Level Priorities

- 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 (People, Processes, and Technology)

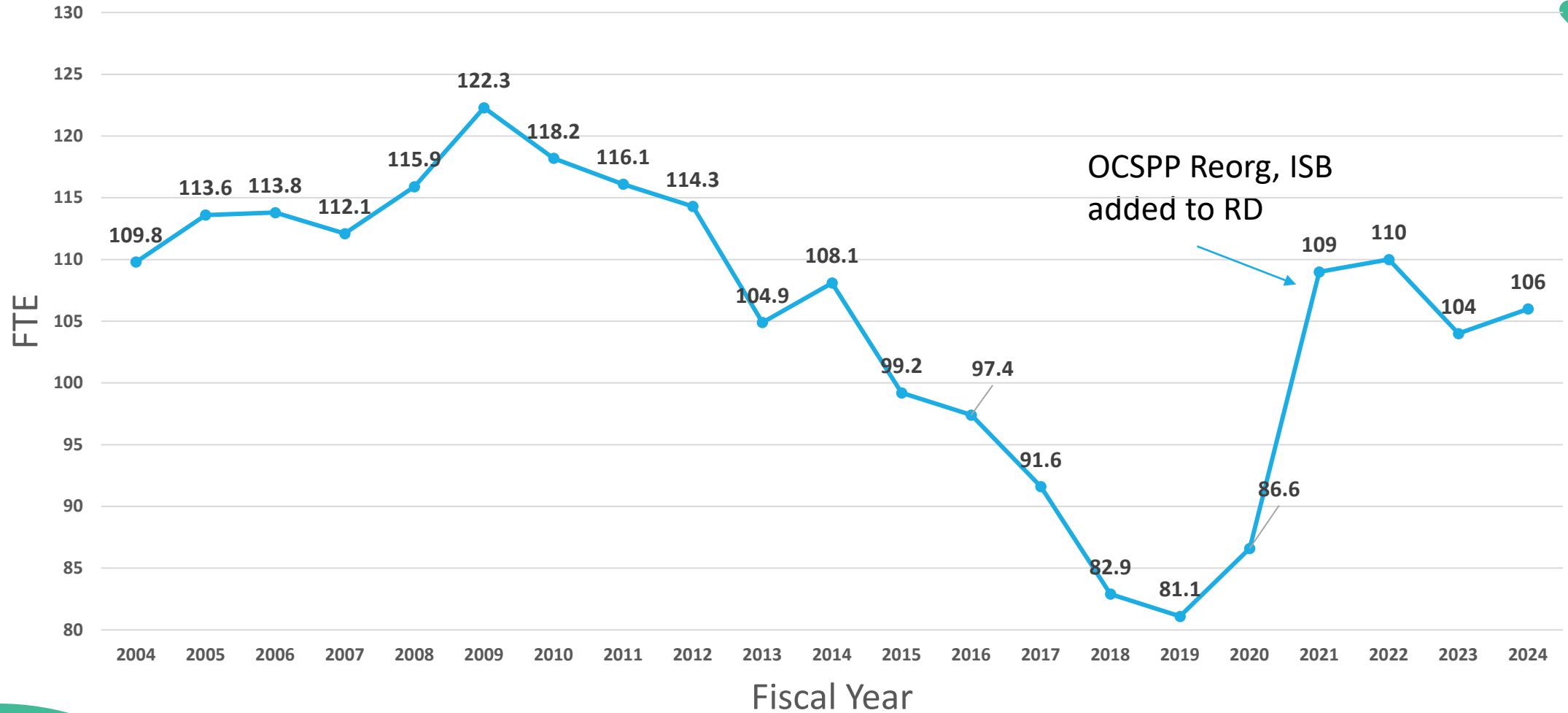


# EOY Total FTE Usage Assuming FTE Cuts and Holding Current Contract Spending Constant



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 for RD from FY 2004 - FY 2024



Note: 2021 – 2023 includes ISB FTEs (currently 7)  
Green line represents RD ideal structure







## 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.
- 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.

# PRIA 5 Implementation

- OPP PRIA 5 accomplishments and upcoming activities can be found: <https://www.epa.gov/pria-fees/pria-5-implementation>
  - In June 2023, EPA posted a centralized webpage for guidance and pesticide-related links. Over 1,000 guidance documents relating to pesticide regulation are included on this page. [View the webpage](#)
  - ESA guidance (for conventional and biopesticides) developed and issued for new active ingredient registrations and active ingredients going through registration review
  - ESA draft guidance for new uses of registered active ingredients developed and put out for public comment
  - Implemented new framework for renegotiation of PRIA applications
  - Bi-lingual labeling outreach
    - To State partners regarding bi-lingual labeling implementation
    - To a broad array of stakeholders regarding making bi-lingual labels accessible to farmworkers
  - Successfully migrated all divisions within OPP into the Salesforce platform
    - External facing view into the workflow is anticipated for end of calendar year 2024





## 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](https://www.epa.gov/pria-fees/pria-5-implementation)
- PRIA annual report



## Updated Milestone Webpage

Initial communication to an applicant regarding their pesticide application comes from the Pesticide Submission Portal (PSP) in EPA's Central Data Exchange, and notifies the applicant that their application has been successfully transmitted from the portal to OPP.

### 7 Milestones

1. Application receipt date; receipt number assigned.
2. Payment completed (waiver review completed, if applicable); PRIA category(ies) and PRIA start and due dates provided (including pre-decisional determination due date, if applicable); product manager contact information provided.
3. Risk manager contact information provided; technical screen task initiated.
4. 45/90-day technical screen completed; full science review begins.
5. Science review completed.
6. Pre-decisional determination date reached (if applicable); public participation process initiated (if applicable).
7. Regulatory decision completed

<https://www.epa.gov/pria-fees/automated-email-milestone-tracking-pria-actions>

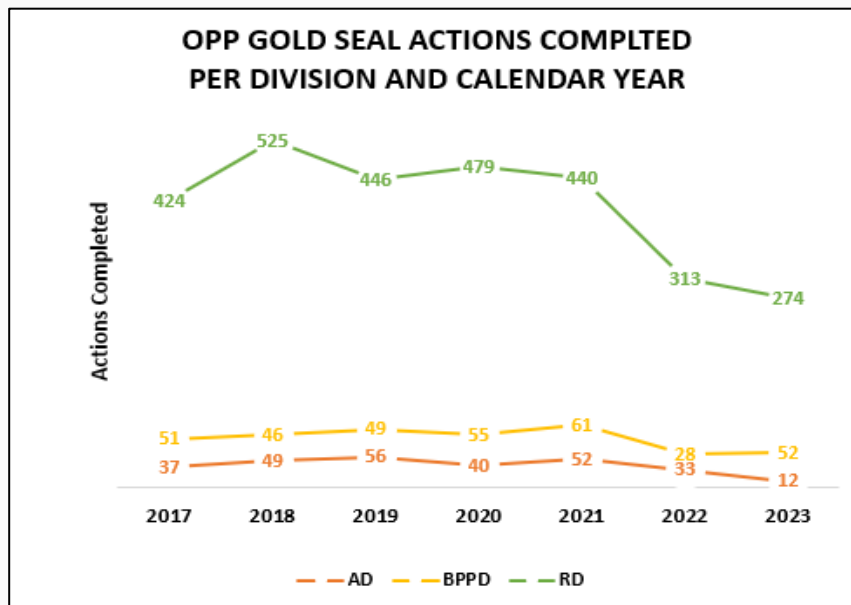
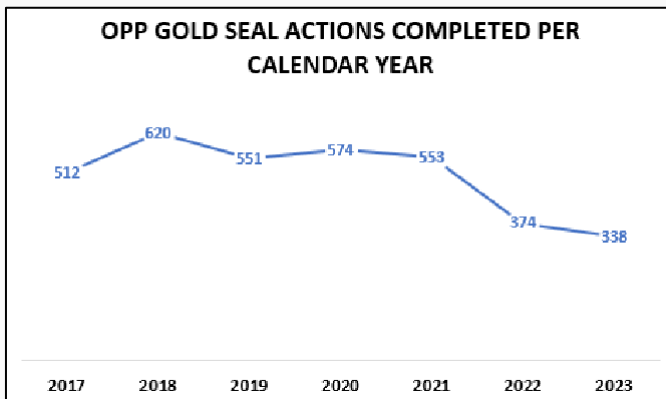


## Status of Front-End Processing

- 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



# Gold Seal Status Update



- Starting February 1, 2024, AD, BPPD, and RD will each fully process their own Gold Seal letters.
- General Gold Seal questions as well as questions about Gold Seal actions submitted *before* February 1, 2024, should be emailed to Shanta Adeeb at [adeeb.shanta@epa.gov](mailto:adeeb.shanta@epa.gov).
- Questions about Gold Seal actions submitted *after* February 1, 2024, should be directed to the PM/TL for that specific product.
- AD, BPPD, and RD Contact information can be found at <https://www.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-regulatory-divisions-ad-bppd-prd-rd>.



## PRIA Actions

- For fee for service applications, in FY 23:
  - EPA received ~1,600 actions
  - EPA completed almost 1,700 actions
  - 30% of applications were completed in statutory timeframes
- ESA effects determinations are being factored in for certain types of actions (e.g., new a.i.s), which adds additional time to the EPA review;
- In accordance with PRIA 5 requirements which limited the scenarios under which EPA could extend the PRIA decision timeframe, EPA implemented process changes which have greatly reduced the incidence of renegotiation.
- Pivot from reporting “on-time” completion rate (on or before the original due date or renegotiated due date) to “completed in statutory decision time frame” and “average days exceedance”

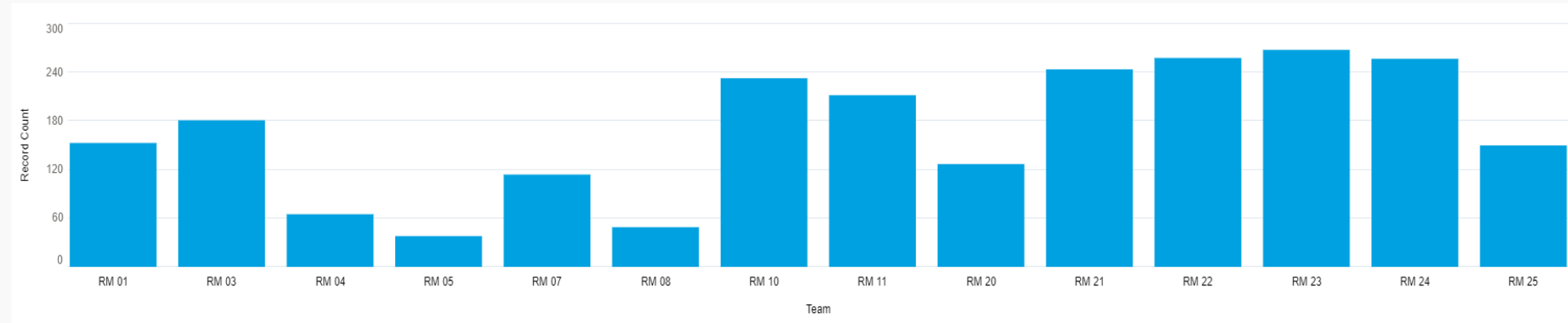
# FY23 RD Highlights

- RD completed ~800 PRIA actions:
  - 3 new active ingredient decisions (plus 1 withdrawal)
  - Over 110 new uses, including new uses on simazine, cyclaniliprole, fluridone, transfluthrin, ethalfluralin (first conventional use on hemp), bromethalin and flupyradifurone.
  - 600 PRIA new products and amendments
  - 40 inert actions (30 food, 10 non-food)
- RD completed ~2,000 non-PRIA actions (i.e., 1,300 98-10 notifications; ~600 Fast Track Amendments)
- Responded to 23 S18s addressing critical pests, including to control avian malaria, invasive coconut rhinoceros beetle, etc.
- Over 620 product chem reviews, over 500 acute toxicity reviews, almost 50 efficacy reviews, and 12 CRP reviews completed
- Seresto incident and regulatory work
- 10,574 submissions processed via PSP with 1,440 via Sales Force

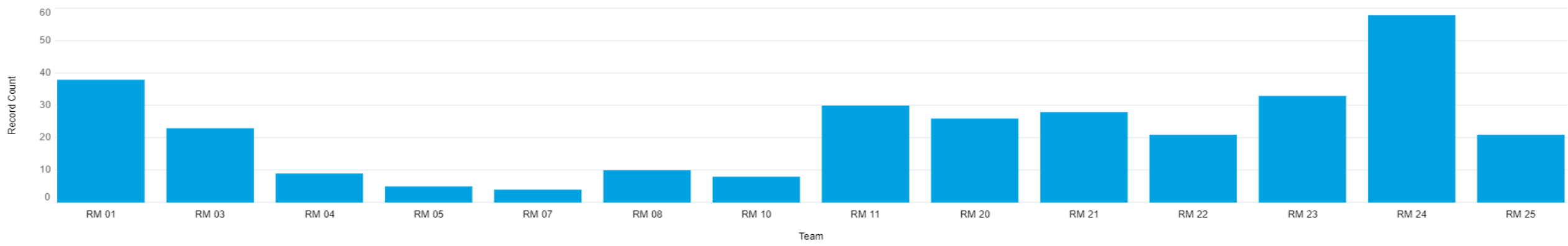




## RD Pending PRIA as of 4/16/24



## RD FY24 Closed PRIA as of 4/16/24



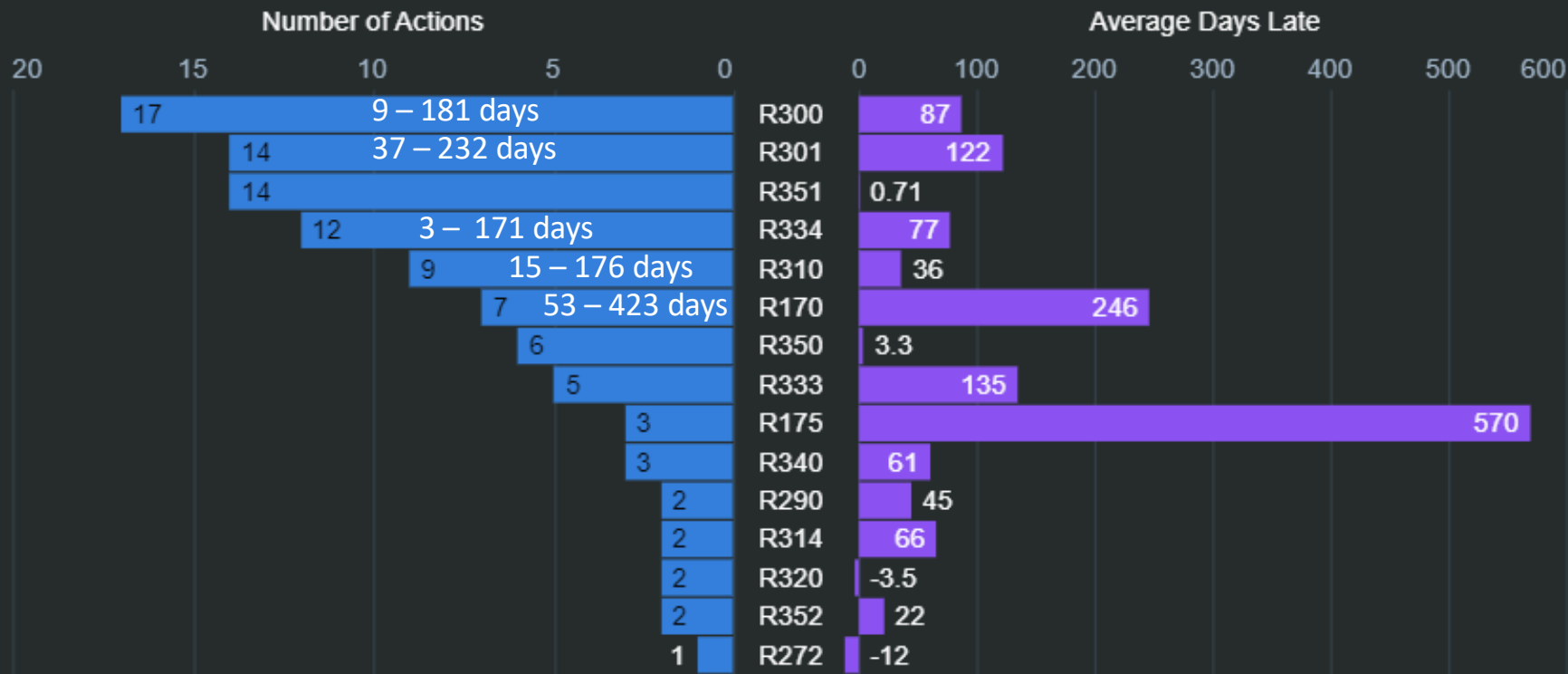


## Average Days Late Trend by Action Code

(All Closed Actions)

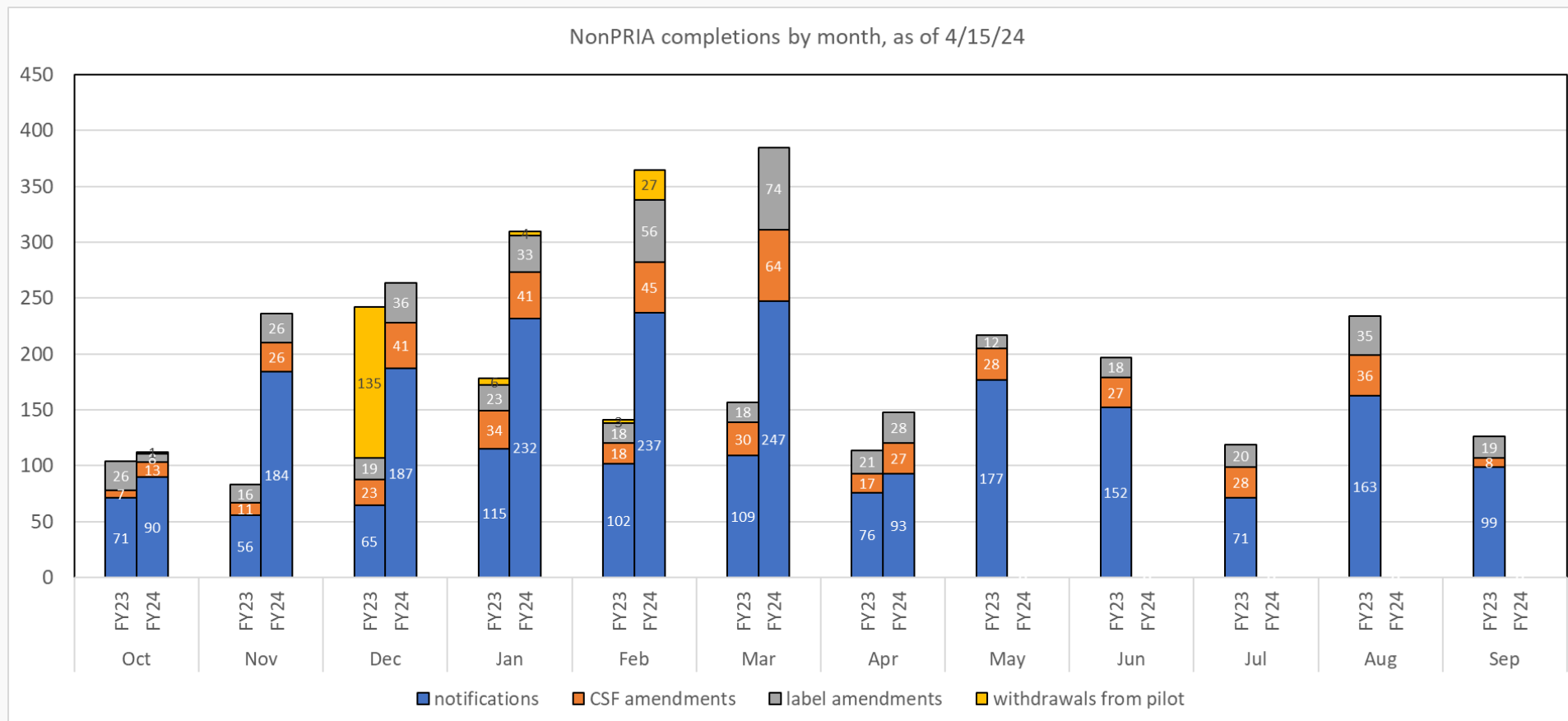
Sort By:

Action Code	# Actions	Avg Days Late
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# RD Non-PRIA Strategy Initiative





# 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



## 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)
- <https://www.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-registration-division#io>