

PRIA Coalition Quarterly Stakeholder Meeting

**U.S. Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs**

November 21, 2024

AGENDA

- Welcoming Remarks/Ground Rules
- OPP Organizational Chart
- Divisional Process Improvements
- IT Update
- FY'24 Fees Collected
- PRIA 5 Implementation
- Bilingual Labeling Update
- FY24 Maintenance Fee Invoicing
- Data Evaluation Record (DER) Process Update
- Registration Review Update
- Wrap-Up/Next Meeting Dates

Office of Pesticide Programs

Edward Messina, Director
Leo Gueriguian, Deputy Director, Management
Elizabeth Vizard, Deputy Director, Programs
Monique Perron, Senior Science Advisor
Catherine Aubee, Senior Advisor (EDSP)
Susan Jennings, Senior Advisor for Public Health

Endocrine Disruptor
Screening Program

Antimicrobials Division

Anita Pease, Director
Kristen Willis, Deputy Director
Elizabeth Donovan,
Associate 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

Anne Overstreet, Director
Tim Kiely, Deputy Director

Health Effects Division

Dana Vogel, Director
Currently vacant, Deputy Director
Greg Akerman, Associate Director

Environmental Fate and Effects Division

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

Biological and Economic Analysis Division

Donald Wilbur, Director
Neil Anderson, Deputy Director

Pesticide Program Dialogue Committee (PPDC)

- EPA held the fall meeting for the PPDC on November 13-14, 2024
- OPP updates typically included in the PRIA Coalition quarterly meeting slides (e.g., priorities, resources, FY24 accomplishments) were presented as part of Ed Messina's OPP Overview presentation on the first day
- The slides for that presentation are found on the following webpage, in the link for Session 1:
 - <https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/pesticide-program-dialogue-committee-16>

RD FY25 Priorities

- New AIs: 16 pending with 8-10 projected for completion in FY25
- New Uses
- “Other” PRIA
 - AT/PC common deficiencies list - POSTED
 - Assigning AT/PC as received and developing SF “science” analytics
 - Draft 98-1 for product chemistry self-certification out for public comment
- Non-PRIAs: clear notifications, keep up with new notifications, focus on FTs
 - Determine if there will be a change to our current alternate AI source CSF approach process
 - Continue work on the revision of 98-10
- Policy work, including but not limited to
 - Pollinator data
 - ESA support and implementation
 - Development of Pet incident SOP in response to OIG
 - Implementation of AMR framework, including IDPREW formation
- ISB process Improvements

Communicating Common Submission Deficiencies

- Update to [common notification rejection reasons](#) posted in October
- New list of [common product chemistry and acute toxicity study deficiencies](#) posted in October
- PRN 11-3 screen
 - [PRN 11-3](#) describes both the recommended and the required procedures for submitting FIFRA and FFDCA data
 - Most common deficiencies related to the 11-3 screen
 - Failure to include one of the two statements related to data confidentiality (required under 40 CFR 158.33; see pages 6-10 of PRN 11-3)
 - Failure to sign statement of data confidentiality (required under 40 CFR 158.33; see pages 6-10 of PRN 11-3)
 - Failure to include one of the three statements related to compliance with GLP on page 3 of all studies signed and dated by the study sponsor, the study submitter, and the study director (required under 40 CFR 160; see page 19 of PRN 11-3)
 - Failure to include a title page for the study (see example on page 17 of PRN 11-3)

Updating PRN 98-10

- PRN 98-10 describes actions that fall under notifications, non-notifications, or accelerated minor formulation changes.
- In 2017, EPA released a draft revised version of 98-10 but never finalized it.
- In 2025, we hope to release a new draft revised version of 98-10 for public comment.
- While this new draft will consider the 2017 draft and comments received on it, we intend to consider different approaches for revisions, including maintaining CSF notifications and determining if other actions might fall under non-notification.
- Stakeholders have shown interest in discussing their thoughts on 98-10 with OPP; we've met with four registrant groups and the POM committee this month.

CSF Formatting Considerations

- RD has been approving CSFs where each new active ingredient source with a different purity is on its own alternate CSF.
 - This has resulted in some huge CSF records (100s of alternates!), particularly for products with multiple active ingredients.
- CLA/RISE proposed a different formatting scheme to allow for active ingredient sources with different purities to be on the same alternate CSF, with the goal of reducing the number of alternate CSFs needed for a product.
- RD has worked with AD and we are currently considering this proposal and looking for ways to streamline it even further.
- We plan to follow up in the near future with a draft revised formatting scheme for discussion.

FY25 ISB Process Improvements

- Develop a listing of ISB/ITRMD/contractor Front-End Processing responsibilities with vulnerabilities/challenges
- Update guidance/SOP for fee waivers
- Update guidance/SOP for company transfers
- Update guidance/SOP for company contacts
- Continue implementing ISB process improvement to get Maintenances Fees
- Work to Digitize Jackets
- Targeted LEAN/continuous improvement projects to address recent challenges
- Payment processing/verification –update guidance/SOP

AD FY'25 Priorities

- New Als: 4 pending with 1-2 projected for completion in FY25
- New Uses: 5 pending
- “Other” PRIA
 - Track and provide list of common reasons for 75-day letters
 - Collaborate with RD on streamlining review of CSFs
 - Provide monthly SF metrics to stakeholders
- Non-PRIAs: Continue working to reduce the notification and FTA backlog
 - Continue Non-PRIA amendment consolidation and prioritization effort and streamlined review of FTAs
 - Proposed Administrative Withdrawal of Certain Antimicrobial and Biopesticidal Non-coded PRIA Submissions FRN (actions older than Jan. 1st, 2017)
 - Collaborate with RD on revision of 98-10
- Reg review
 - Publication of the EtO ID (Est. January 2025)
 - Formaldehyde

AD FY'25 Priorities Continued

- Policy work, including but not limited to
 - Posting of draft FRN with clarifications on pesticidal devices (Est. Q2 FY'25)
 - ESA guidance for registrants (Est. Q1 FY'25)
 - Continued work on ESA workplan
 - Risk assessment model updates
 - Efficacy
 - Finalization of the virucidal guidance for sanitizers (Completed Oct. 2024)
 - Posting of draft minimum testing requirements for chemical air treatment (Q2-3 FY25)
 - Posting of draft minimum testing requirements for treated filters (Q2-3 FY25)
 - Post Antimicrobial Performance Evaluation Program (APEP) final strategy (Q3 FY25)
 - PPDC suggested revisions to the Emerging Viral Pathogens (EVP) guidance (Q2 FY25)
 - Post guidance and method for towelettes for public comment in collaboration with BEAD. Pending comments, post final guidance/method (Q1 and Q4 FY25)
 - Continue work on PRIA set aside for devices (ongoing)

Common AD Acute Toxicity PRIA Deficiencies

In addition to the list of [common product chemistry and acute toxicity study deficiencies](#) posted in October which includes issues from AD, we also complied to the top 3 acute tox and chemistry deficiencies specific to AD.

AD's top three deficiencies for Acute Toxicity data requirements which result in a 10-day technical screen failure and/or 75-day data deficiency letter:

- The applications fail to either include a cited product or cite more than one product for a similarity claim. Proposed product is not identical/substantially similar to the cited product.
- The applications fail to address all [acute toxicity 870 data requirements](#) (acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, eye/skin irritation, and dermal sensitization) or cite very old studies that do not meet the current test guidelines and GLP-compliant requirements.
- The test substance, purity, pH, etc. in the submitted acute toxicity studies is inconsistent with information provided in the application data package, such as, the proposed Confidential Statement of Formula (CSF), the name of the proposed product, and/or draft label.

Common AD Product Chemistry PRIA Deficiencies

AD's top three deficiencies for Product Chemistry data requirements which results in a 10-day technical screen failure and/or 75-day data deficiency letter:

- Not all chemistry guideline studies are addressed (including group A and B), and the data matrix needs to list the correct MRIDs.
- Proposed product is not identical/substantially similar to the cited product.
- CSF Issues:
 - Uncleared inerts, trade names not included in the EPA internal database.
 - Inaccurate certified limits and lack of a justification for non-standard limits.
 - Data submitted does not match information listed on the CSFs (Boxes 7, 8 and 9, i.e., pH, density, and flash point).

AD Process Improvements

AD has taken a multipronged approach to implementing efficiencies for both non-PRIAs and PRIAs

- **Significant Non-Coded PRIA efforts**

- Partial review pilot for FTAs on July 1, 2024 (applicable to actions submitted after January 1, 2023)
 - Registrants should submit a label with the changes highlighted.
- Notification closeout in 2023
- Planned administrative withdrawal of certain Antimicrobial Non-coded PRIA Submissions FRN (actions older than Jan. 1st, 2017)
- Amendment prioritization (initiated 2023)
 - Fast-track amendments (including minor formulation amendments and non-PRIA label and CSF amendments)
 - AD has contacted all companies with backlogged FTAs and received responses back from ~46% of the companies.
 - Companies identified 315 priority actions.
 - 29 were determined to be reg review actions and will be managed through the reg review process.
 - 38 actions were submitted before 2017 and the team will reach out separately about those actions.
 - AD has completed **43%** of the of the remaining priority actions.
- Amendment consolidation
 - Approximately 1,200 actions were identified as no longer needed and withdrawn and 83 actions were identified as being previously completed but not closed out properly and the agency record was corrected.
- Non-PRIA stand down days/afternoons

- **PRIA**

- **Annotated label roll out**

- In FY'24 we rolled out the annotated label process to streamline PRIA label reviews across regulatory and science divisions.
 - Labels are reviewed concurrent review by all disciplines with a single annotated label delivered back to the registrant rather than separate comments from all disciplines.

- **Best practices presentations** for submitting a package (<https://www.epa.gov/pesticides/antimicrobial-division-presentations>)

BPPD Priorities for FY25

- In FY25, BPPD will focus on implementation and reducing PRIA backlog
- Microbial pesticides
 - Science reviews for microbial pesticides are back on track (i.e., anticipate to start meeting PRIA timeframes by end FY25)
 - Anticipate to complete science reviews for all new AIs (~ 9 new AIs) and new products/uses/amendments (~15 PRIA actions) currently in the queue that are due in FY25 and prior
 - Also anticipate to complete science reviews for new products/uses/amendments received in the first 6 months of FY25
 - Post Science: Anticipate to complete regulatory actions/decisions within ~ 5 to 6 months for new AIs and ~1 o 2 months for PRIA amendments/new products
- Biochemical pesticides
 - Anticipate to complete science reviews for all new AIs due in FY24 and prior (~9 new AIs)
 - Due to resource challenges, anticipate science reviews for new AIs due in FY25 will be delayed about 12-18 months (~13 new AIs in queue); exploring staff cross training and additional program efficiencies to reduce delays
 - Apply targeted approach for clearing backlog of new products/uses/amendments (~115 PRIA actions in queue)
 - Post Science: Anticipate to complete regulatory actions within ~ 5-6 months for new AIs and 1-2 months for PRIA amendments/new products/new uses
- Emerging technology pesticides
 - Anticipate to complete 13 new AIs by end FY25
 - Complete majority of new AIs with PRIA dates due in FY24 and prior
 - Due to resource challenges, anticipate new AIs with PRIA dates due in FY25 will be delayed 6-8 months; exploring staff cross training and additional program efficiencies to reduce delays

BPPD Efficiency Efforts

- Data Evaluation Record (DER) templates:
 - Tier 1 tests, Series 830, 850, and 870: [Study Profile Templates | US EPA](#)
 - Microbial pesticides: [OECD Data Evaluation Record Templates | US EPA](#)
- Technical screening public checklist for biochemical/microbial pesticides
 - [BPPD Internal Application Checklists | US EPA](#)
 - Most recently updated checklist: [technical-screen-for-applications-containing-microbial-ais.docx](#)
 - In process of updating these checklists and remove outdated checklists in next few months
- Close out application deficiencies via faster/alternative methods
- Develop rulemakings and/or guidance to expand exemptions or streamline testing/data needs (e.g., biostimulant rule, small scale testing, biotech notifications, PIPs testing/data guidance)
- Publish Emerging Technology Pre-Submission Meeting Guidance on the Web
- Cross-training BPPD staff to optimize throughput (and build capacity)
- Exploring additional training and engagement opportunities with external stakeholders for additional efficiency efforts

Digital Transformation Update

- New Portal and Customer Experience
 - Two-way interaction between OPP and external stakeholder
 - Modern submission and application tracking experience
- e-CSF and e-label Projects
 - e-label workshop with Caliper to build on previous projects
- DCI Modules; create, send, receive, track progress
 - Interact with the case via an automated workflow
 - Automated response pathways for registrants
- CRM Analytics
 - Modern performance metrics identifying needs and opportunities across OPP to both internal and external stakeholders



Major Transformational Projects



Documentum Replacement

Target for Completion
9/2025

Project Timeline of 12
Months

Alternatives Analysis
Complete

Kick-off and Scoping
Completed October 2024

Three Phases: Planning,
Deployment, Migration

OCSPP strategy



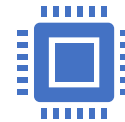
Data Management Solution

Interdependent with Document
Repository Project

Interdependent with
Infrastructure Project

Holistic plan to deal with legacy
software and Data Solution

Critical to transforming workflows
and allowing for data-centric
approach to documents, risk
assessments, e-label and e-CSF



INFRASTRUCTURE

Underlying physical and
information technology
devices

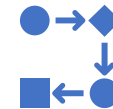
Legacy Apps: PRISM,
OPPIN DE, OPPIN Query,
etc. are all on prem

Interdependent on Data
Management/Documents

12+ Months

Move to Cloud Solution

Build Business
Capabilities in
Salesforce



PORTAL

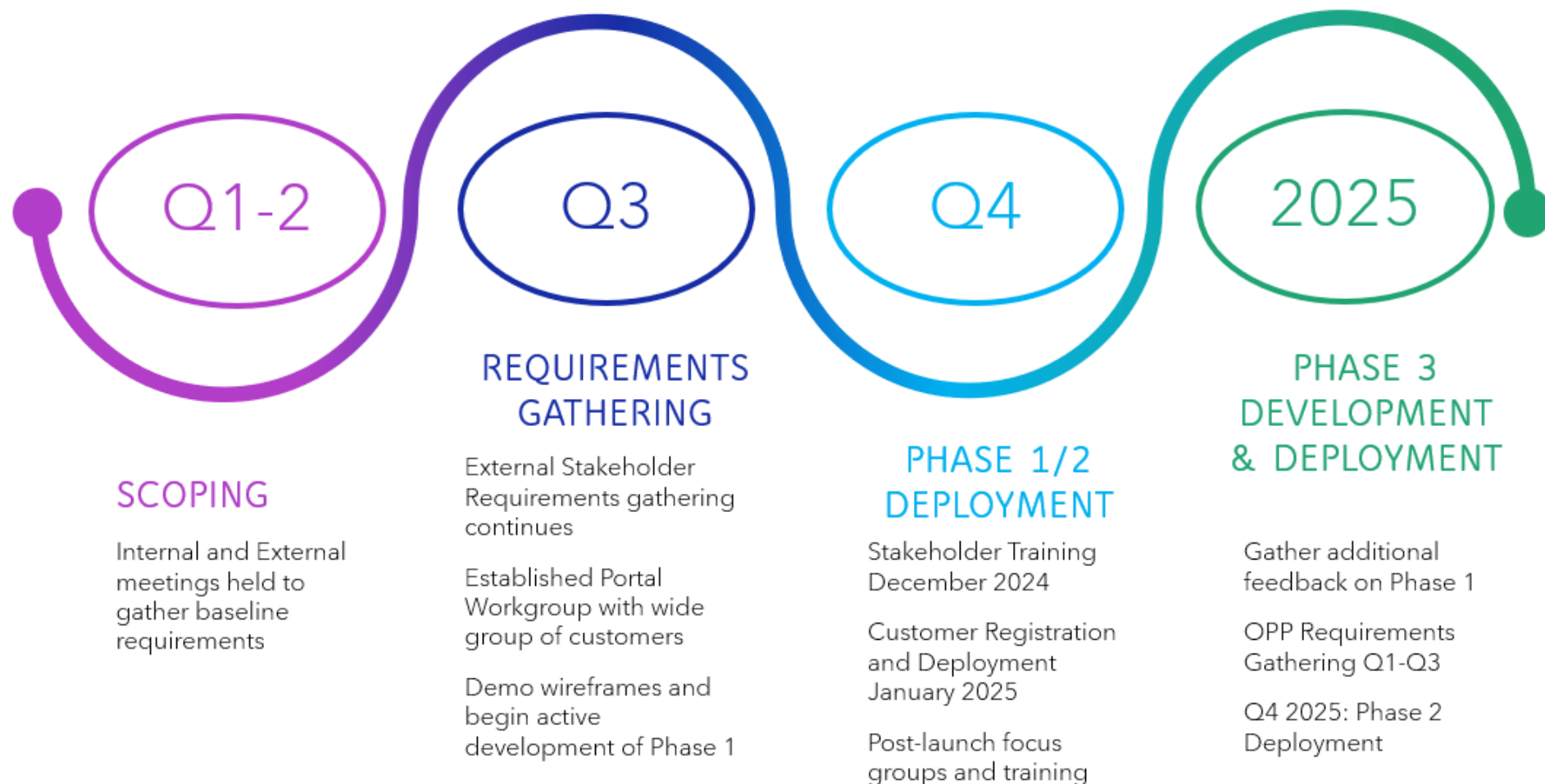
Phase 1 Deployment
December 2024:
Registrants Log In

Phase 2 Deployment
January and TBD 2025:
Registrant Dashboards

Phase 3 Deployments
TBD Late 2025:
Submissions (high
dependence on other
projects)

APPLICATION EXPERIENCE PROJECT ROADMAP

PHASE 1: DEPLOY APPLICATION/CASE MANAGEMENT DASHBOARD
PHASE 3: DEPLOY END TO END APPLICATION EXPERIENCE





FY'24 Fees Collected



PRIA Fees: \$18.4M

Maintenance Fees: \$44.5M

PRIA 5 Implementation - FY 24 Activities

- EPA webpage on PRIA 5 Implementation: <https://www.epa.gov/pria-fees/pria-5-implementation>
- FY 2023 PRIA Annual Report issued
- Non-PRIA backlog reduction and review timeframes for new actions
- IT modernization efforts
- Bilingual labeling implementation- FAQs, implementation plan, outreach
- Vector Expedited Review Voucher (VERV) Program
- DER process implementation

Pesticide Registration Improvement Act (PRIA) 5 Implementation - FY 24 Activities

- Set-aside to develop and administer training to EPA staff and registrants
 - Developing grant program to compete and award in FY25
 - Contract funded to administer training in interim
- Continuation of existing cooperative agreements including Pesticide Safety Education Program cooperative agreement and a new partnership grant for the National Pesticide Information Center
- New set-asides for farmworker training, health care clinician training and grant technical assistance cooperative agreements
 - Requested stakeholder input on program design for both farmworker and health care provider training grant programs
- Third-party audit of business processes and workforce assessment; contract in review, anticipated award for FY25

Bilingual Labeling – Implementation

- Label changes to be 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 farm workers – 180 days (June 2023) **complete**;
- EPA shall develop and implement, and make publicly available, a plan for tracking the adoption of the bilingual labeling – 2 years (Dec 2024) **on schedule**;
- EPA shall implement a plan to ensure that farm workers have access to the bilingual labeling – 3 years (Dec 2025) **in progress**

Bilingual Labeling - Coordination at EPA/OPP

- OPP interdivisional Spanish Labeling Workgroup
- EPA formed subgroups to address the various provisions of PRIA 5
 - Accessibility Subgroup – evaluating public feedback and NEJAC recommendations
 - Communications Subgroup – working on additional FAQs for the EPA website
 - Bilingual labeling website - <https://www.epa.gov/pesticide-labels/bilingual-labeling>
 - FAQs - <https://www.epa.gov/pesticide-labels/bilingual-labeling-questions-answers>
 - Tracking Subgroup – finalizing the draft tracking proposal for review
 - Spanish Translation Guide Subgroup – evaluated public feedback and drafted an updated version that is in internal review
- Coordinating with EPA/OPP registering divisions on implementation issues (e.g., QR codes, supplemental distributor labeling)

FY24-FY25 Stakeholder Engagement and Outreach

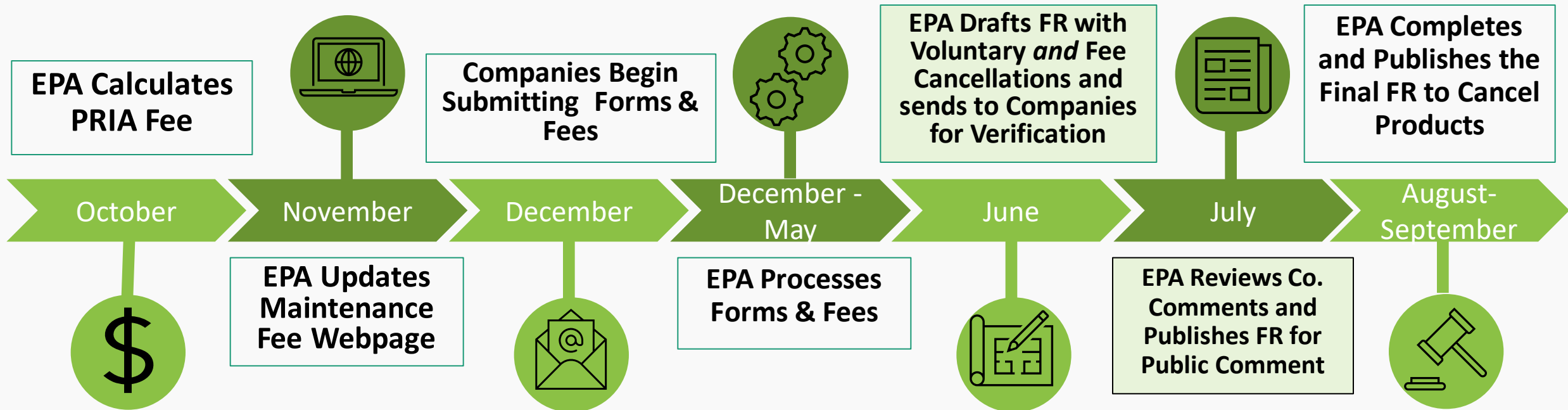
- Quarterly PRIA Coalition Calls – 7/18/24 & 11/21/24
- PREP Courses – Week of 8/5/24
- CDPR Meeting – 8/22/24
- SFIREG Meetings – 8/27/24, 9/16/24, 9/17/24, 11/14/24 & 11/19/24
- OCSPP Regional Division Director Call – 9/12/24
- OCSPP/OECA/Regional Monthly Call - 9/18/24
- PRIA Coalition Meeting – 9/26/24
- Quarterly Farmworker Advocacy Stakeholder Calls – 10/2/24
- AAPCO Worker Safety Committee Meeting – 10/16/24
- RISE Advocacy Webinar on Bilingual Labeling - 10/31/24

FY24- FY25 Planned Stakeholder Engagement and Outreach

- NEJAC provided responses to the bilingual labeling charge questions (May 2024) – **completed – preparing for 6 months update to NEJAC**
- Update the PRIA 5 Website with bilingual labeling information and Q&As from various stakeholder engagements and webinars (August 2024) – **completed**
 - Update Q&As with additional questions from various stakeholders (Nov 2024) – **in progress**
- Coordinate with CLA and hold webinar on Q&As with registrants (October 2024) - **completed**
 - The webinar is intended to answer registrants' questions about bilingual labeling
- Plan to track the adoption of bilingual labeling (Dec 2024) – **on schedule**
 - PRN and ICR will be posted for public comment
- Plan to hold discussion with various stakeholders on the accessibility plan throughout FY25 (accessibility plan due Dec 2025)

New Maintenance Fee Process for FY25

New Process



Changes were made to the June – July Steps in FY24

Data Evaluation Record (DER) Update

- OCSPP is now making all previously released via FOIA DERS available and searchable by key word (i.e. chemical ID; registration number) via ChemView at www.chemviewepa.gov
- This is different than the PRIA requirement of sending DERs to the MRID study owners on which the DER is based.
- The FOIA released DERs are available at chemviewepa.gov
 - Click on Advanced Search
 - The PC Code number can be entered under Chemical Information
 - The MRID can be entered under Document Information
 - Then just click Generate Results
- EPA is exploring if there would efficiencies for new DERs to be distributed through Chemview as well.

OPP FY24 Registration Highlights

- Over **12,000** submissions received (includes resubmission to existing actions)
- Over **5,800** PRIA and non-PRIA actions received via Portal
- ~**8,700** PRIA and non-PRIA actions completed (**1,458** PRIA [including **428** gold seal letters], **7,229** non-PRIA)
- Over **16,200** actions currently pending (**2,200** PRIA, **14,000** non-PRIA)
- Registered **20** new biopesticide active ingredients; Proposed **2** new conventional and **1** new antimicrobial active ingredients
- PRIA/non-PRIA performance dashboards are being shared with Coalition via email

Pesticide Registration Review

- The FY 2023 omnibus set a new deadline of October 1, 2026, for completing the first phase of registration review.
- There are 789 registration review cases due by October 1, 2026 - 726 cases registered prior to FY 2007 that 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 September 2024 there were:
 - 719 cases (or 91%) for which draft risk assessments are completed (70 remain).
 - 626 cases (or 79%) for which final or interim decisions are completed (163 remain).



Wrap-Up/Next Meeting Date

- FY25 quarterly meetings to be scheduled shortly

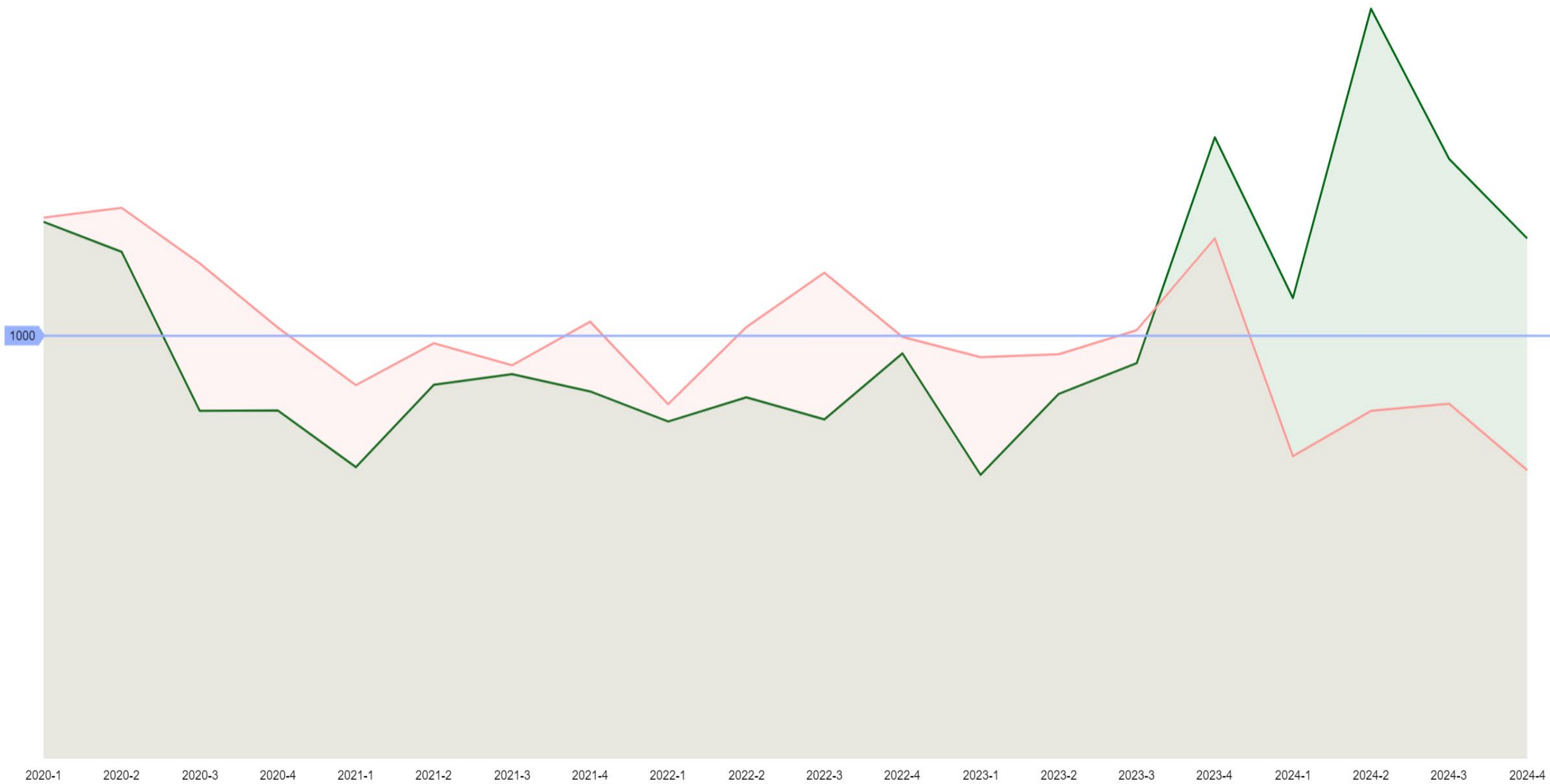
PRIA Points of Contact

- PRIA Coordinator:
schaible.stephen@epa.gov, murasaki.seiichi@epa.gov
- OPP Ombudsperson Mailbox
pesticidequestions@epa.gov
- RD Ombudsman:
OPP_RD_Ombudsman@epa.gov
- BPPD:
BPPDQuestions@epa.gov
- AD Ombudsman:
pesticidequestions@epa.gov

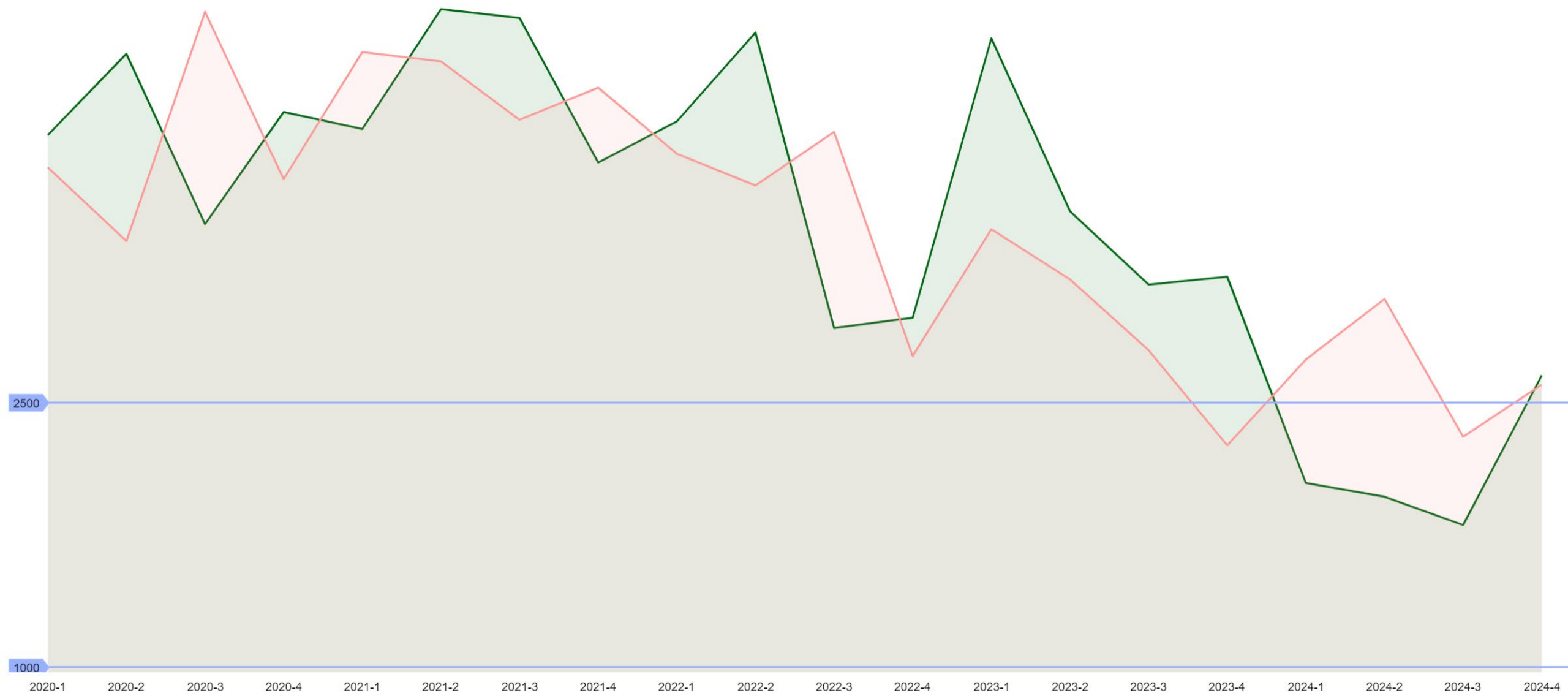
Thank You!

Appendix

Non-PRIA Notifications and Amendments Closed vs Received by FQ



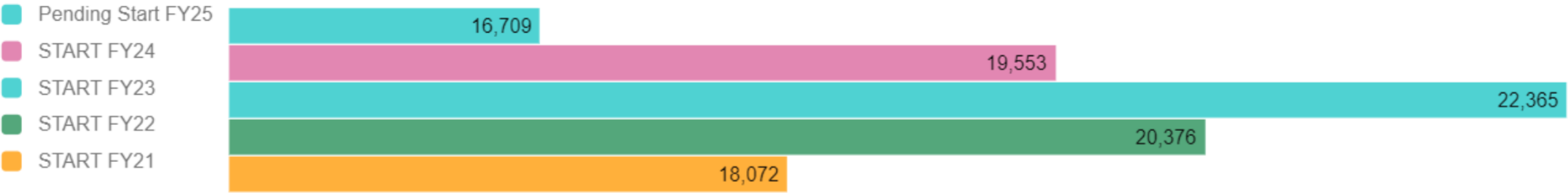
PRIA Work Completed vs Work Received by FQ



Total Backlog is Decreasing!

PRIA Backlog is Increasing

Total Pending Cases at the Beginning of FY25-FY21



Total Pending PRIA Cases at the Beginning of FY25-FY21



The Registration Division Leverages Salesforce Data to Reverse the Trend of a Growing Backlog of Cases

- 4FY Ago
- 3 FY Ago
- 2 FY Ago
- Last FY
- This FY



Total PRIA Cases Completed and Avg Days Late Last 5 Fiscal Years

Negative #s Are Early

