



# **Updates from the EPA's Office of Pesticide Program Registration Division**

**NPIRS Conference  
April 13, 2023**

**Dan Rosenblatt; Acting Division Director**



# Agenda

- Current staffing picture
- OPP/RD FY23 priorities
- RD FY23 Accomplishments
- RD FY23 Process Improvements
- PRIA 5
- ESA Updates
- Stakeholder Interactions

**Vacancies (14 total):****2 Branch Chiefs****2 Product Managers/Team Leaders****15 ≤ GS-13 staff****Dan Rosenblatt, Acting Director**

Dan Rosenblatt, Deputy Director

Catherine Aubee, Associate Director

Bo Davis, Senior Regulatory Specialist

Paul Di Salvo, Senior Regulatory Specialist

**Invertebrate-Vertebrate Branch 1**

Jenn Saunders, Branch Chief

Jackie Herrick; PM 3

Autumn Metzger; acting PM 4

Senior Entomologist; Virna Stillwaugh

**≤ GS-13 Vacancies: 1****Invertebrate-Vertebrate Branch 2****Vacant, Branch Chief**

Tamica Cain; PM 10

Michael Walsh; PM 11

Debra Rate; Senior Regulatory Specialist

**≤ GS-13 Vacancies: 1****Invertebrate-Vertebrate Branch 3**

Dee Colby, Branch Chief

Venus Eagle; PM 1

**Melissa Bridges; acting PM 7**

Gene Benbow; Senior Regulatory Specialist

**≤ GS-13 Vacancies: 3****Fungicide Branch**

Cynthia Giles-Parker; Branch Chief

Nate Mellor; PM 21

Kristy Crews; PM 22

Kevin Ulrich; Senior Regulatory Specialist

**≤ GS-13 Vacancies: 2****Herbicide Branch**

Lindsay Roe; Branch Chief

Mindy Ondish; PM 23

Emily Schmid; PM 25

Sarah Meadows; Acting Senior Regulatory Specialist

**≤ GS-13 Vacancies: 2****Fungicide-Herbicide Branch****vacant; Branch Chief**

Shaja Joyner; PM 20

Heather McFarley; PM 24

Aswathy Balan; Senior Regulatory Specialist

**≤ GS-13 Vacancies: 1****Minor Use & Emergency Response Branch**

Eric Bohnenblust; Branch Chief

Nancy Fitz; Minor Use Team Leader

**vacant; Acting Emergency Response Team Leader****≤ GS-13 Vacancies: 1****Chemistry, Inerts, Tox. Assessment Branch**

Kerry Leifer; Branch Chief

Shyam Mathur; Chemistry Team Leader

Julie Breeden-Alemi; Acute Tox. Team Leader

Evisabel Craig; Inerts Team Leader

**≤ GS-13 Vacancies: 1****Information Services Branch****Rachel Holloman; Acting Branch Chief**

Raderrio Wilkins; Team Leader

**≤ GS-13 Vacancies: 3**



## OPP FY23 Priorities

- Registration and Registration Review
- Endangered Species Act Implementation
- Environmental Justice and Climate Change
- Advancing State of the Art Science
- Rulemaking, Guidance, Litigation, OIG/GAO, Petitions
- Employee Experience and Organizational Development
- Process and IT Improvement



## RD FY23 Priorities

- PRIA 5
- Review New AIs (RD has 18 for FY23)
- ESA implementation
- Support pest management for un-met crop and public health needs
- Modernizing workflows
- Refining Science Methods: (i.e. PFAS, NAMs)
- Partnership with FDA – jurisdiction issues
- Recruit for and Support Existing Division Staff Members



## RD FY23Q1/Q2 Accomplishment Highlights

- PRIA 5 work (technical assistance, passage, maintenance fee changes)
- ESA work (touchpoint meetings, trainings, regulatory work)
- Bobcat team establishment
- Webinar on NAMs for eye irritation
- Published FRN removing 12 PFAS inert ingredients from list of approved inerts
- Presented on eCSF builder to ~250 stakeholders

Type	Action	Q1	Q2	Q3	Total
PRIA	New Uses for Existing Chemicals	38	46	1	85
PRIA	PRIA New Products and Amendments	169	193	5	367
PRIA	Exclusive Use	0	0	0	0
PRIA	Inert Food Use Petitions	9	8	0	17
PRIA	Inert Non-Food Uses	1	4	0	5
Non-PRIA	Fast Track Label Amendments	96	60	4	160
Non-PRIA	Fast Track CSFs	91	86	3	180
Non-PRIA	Notifications	240	318	10	568
Non-PRIA	Minor Formulation Amendments	23	27	0	50
Efficacy	Invertebrate PRIA	9	10	0	19
Efficacy	Invertebrate Non-PRIA	0	1	0	1
Efficacy	Vertebrate	1	1	0	2
Chem-Tox	Chemistry	156	187	6	349
Chem-Tox	Acute Toxicity	138	143	9	290
Chem-Tox	Child Resistant Packaging (CRP)	4	4	0	8
Chem-Tox	Companion Animal	0	4	0	4



## RD FY23 Ongoing Process Improvements

- Extend the time period for receipt of the product specific data review (increased from 14 to 18 days prior to PRIA date from Q1 to Q2, working to make it higher)
- Refine the template for substantially similar reviews for acute tox
- Bobcat Team for CSF nonPRIAs
- Pilot with registrants to withdraw old nonPRIA actions
- Transition to Salesforce



## PRIA 5

- The Pesticide Registration Improvement Extension Act of 2022 (PRIA 5) was signed into law on December 29, 2022;
  - Authorizes collection of pesticide registration service fees and maintenance fees through fiscal year 2027;
  - Increases the average annual maintenance fee target from \$31M to \$42M, or an \$11M increase;
  - Raises pesticide registration service fees by 30% across the board for all categories, which projects to \$6M or more in additional PRIA fee collections annually;
- The omnibus spending bill funds the pesticide programs at a level more than \$11M above that for FY'22;
  - Resources specifically directed to ESA implementation;
- In all, between PRIA 5 and FY 2023 appropriations, roughly \$28M in additional resources are provided to EPA.





## **PRIA 5--Pesticide Registration Service Fees**

- Increases the number of covered fee categories from 212 to 226;
- Additional time provided:
  - for conventional new a.i. actions to account for ESA-related review (50% increase for outdoor);
  - For AD, BPPD, and RD actions to allow for FR Notice process and/or public participation process.
- PRIA 5 fee tables have been updated and posted to the web
- More to come...



## PRIA 5 Category Changes

- Category changes include but are not limited to:
  - Amended and new categories seed treatment uses for new active ingredients and new uses
  - APEC protocol for faster tolerance review
  - Protocol review for companion animal studies (5 mo. review)
  - Additional new product categories for efficacy for 7+ pests
  - Reduced risk comparative product pre-submission
  - EUP to MUP split out as a new code
  - Add new source of safener (inert) code
  - Petition to add 1 inert to commodity inert list code
  - Cancer reassessment code now an 'M' code for all divisions to use
  - New code for Certificate of Establishment (Origin)



## **PRIA 5 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 5--Set-asides

- Eliminates \$500K/yr set-aside to support efficacy guideline development and rulemaking for invertebrate pests of significant public health or economic importance with a mandatory schedule of deliverables;
- Revises previous set aside for review of inert ingredients and expedited processing of similar applications, to obtain sufficient resources to process non-PRIA submissions within their applicable deadlines;
- Vector Expedited Review Voucher (VERV) program- not more than \$500K/yr to create incentive for development and submission of pesticide tools to control pyrethroid or other insecticide-resistant mosquitoes which vector certain diseases by creating a voucher for expedited review (to the maximum extent practicable) by EPA of conventional new a.i.s;
  - Vouchers can be transferred between registrants;
  - EPA has 1 year from date of enactment to establish this program;
- Agency Training and Staff:
  - Not more than \$500K/yr to administer training and education for EPA employees relating to regulatory responsibilities and policies



## PRIA 5--Other Provisions

- Workforce assessment
  - Contractor to conduct assessment of current methodologies and data or metrics available to represent workforce implementation of PRIA 5, including an assessment of filled and vacant positions and FTE related to that implementation
- PRIA 5 amended FIFRA requiring Spanish language translation to end-use pesticide product labels;
  - Label changes to be through non-notification;
  - EPA shall cooperate and consult with State lead agencies for pesticide regulation to implement bilingual labeling
- Registration Review Round 1 extended to October 2026



## PRIA 5--IT Upgrades

- Not later than 1 year after date of enactment, 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.



## Endangered Species Act (ESA)

- Aims to conserve threatened and endangered plants and animals and the habitats in which they are found
- Requires federal agencies, in consultation with the U.S. Fish and Wildlife Service and/or the NOAA Fisheries Service, to ensure that actions they authorize, fund, or carry out are not likely to
  - jeopardize the continued existence of any listed species, or
  - result in the destruction or adverse modification of designated critical habitat of such species



## ESA Protection Policy for Pesticide New Active Ingredients

- On January 11th, 2022, EPA announced meaningful action to address its obligations under the Endangered Species Act (ESA)
- Prior to registration, EPA will evaluate potential effects on federally threatened or endangered (listed) species and their designated critical habitats when registering new conventional active ingredients (AIs)
- Previously, EPA was not consistently assessing potential effects of conventional pesticides on listed species during new AI registration
  - Resource-intensive litigation against EPA for registering new AIs
- The new policy will improve the legal defensibility of new AIs, which often have lower human health and ecological risks than older pesticides





# ESA Updates

- Internal ESA Trainings in February/March
  - 3 trainings: Overview of ESA Workplan, “What is ESA?”, and practical mitigation topics
  - Presentations from BEAD, EFED, PRD, OGC with follow-up office hour sessions
- New AIs
  - Implementing ESA protection policy for conventional new AIs
- PRD developed a Generic FIFRA Eco Mitigation workplan update in November 2022
  - Can be helpful for mitigation options for RD ESA decisions
  - Workplan update document with mitigation language: <https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf>
  - Recording of presentation: <https://www.epa.gov/endangered-species/epas-workplan-and-progress-toward-better-protections-endangered-species>



## Stakeholder/Partner Engagement

- Work directly with states – and state organizations (i.e. SFIREG, AAPCO)
- Presentations to outside stakeholders (EntSoc, Treated Wood Council, Wildlife Society Conference, North American Remotely Piloted Aerial Application Systems (RPAAS) Working Group, Tribal Pesticide Program Council)
- Attendance at Armed Forces Pest Management Board meeting
- Coordinated a seminar from Aquatic Pest Management Society on hydrilla biotypes and management implications
- Enforceable Label Training for OPP staff by AAPCO

ANY  
QUESTIONS  
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