

# OPP Updates for PPDC

**Ed Messina, Director  
Office of Pesticide Programs**

**May 31, 2023**



# Office of Pesticide Programs

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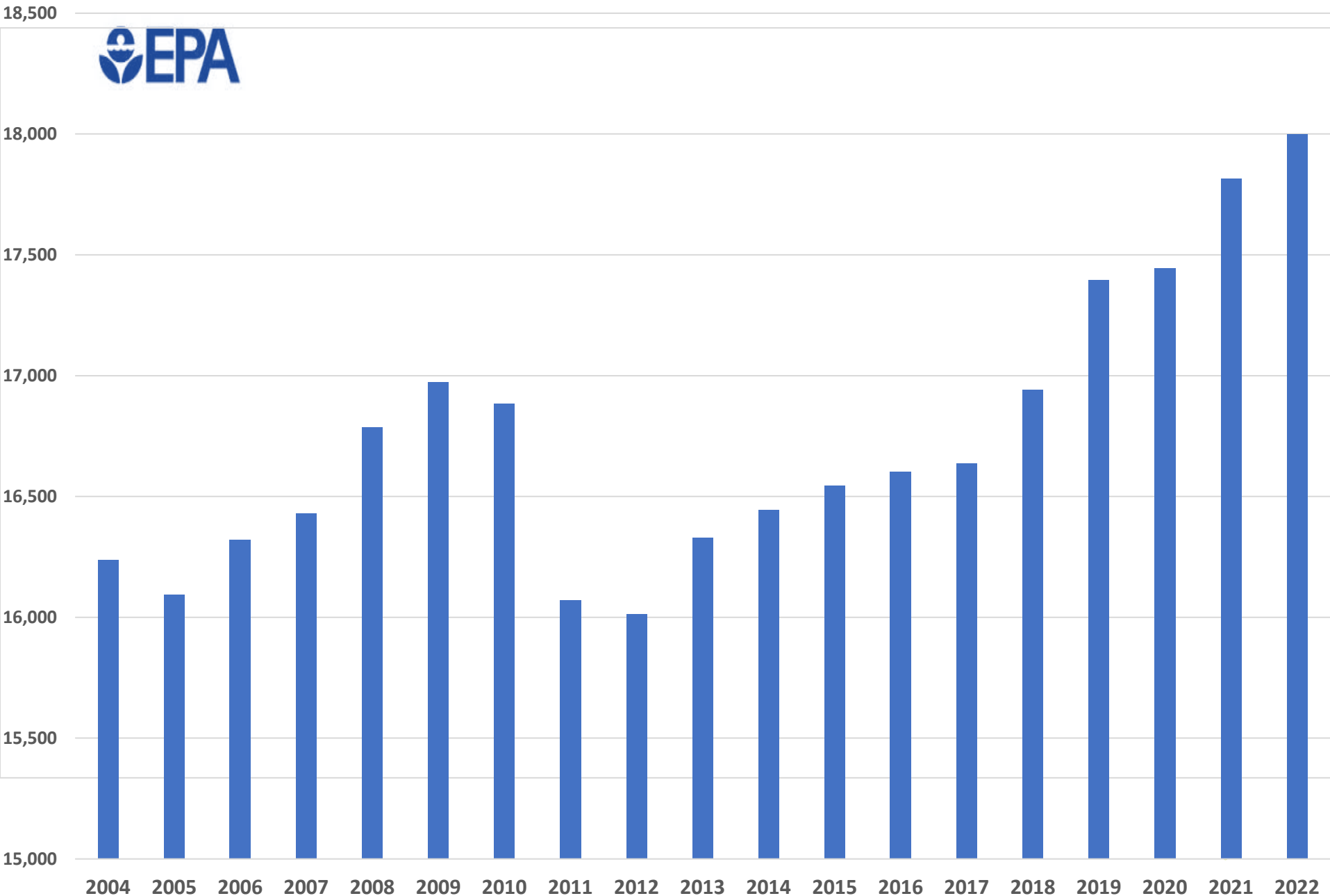
# OPP-wide Priorities

- PRIA 5 Implementation
- Registration and Registration Review
- ESA Implementation
- Implementation of Agency Priorities
  - Environmental Justice
  - Climate Change
- Advancing State of the Art Science
- Rule-Making, Guidance, Litigation, OIG, and Petition Responses
- Employee Experience/Organizational Development /Process and IT Improvements (GP2W) (People, Processes, and Technology)

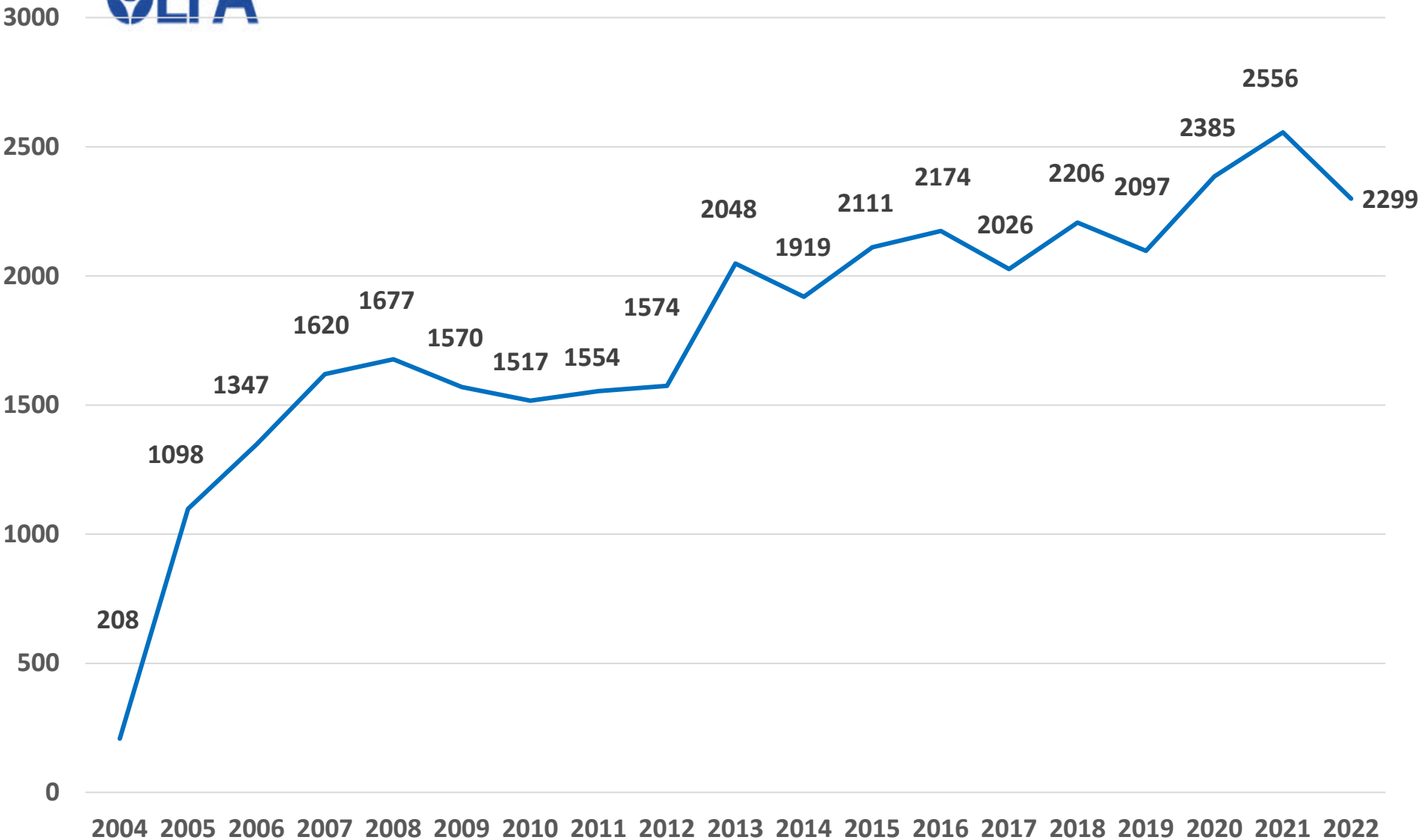
# OPP FY22 Highlights

- Over **11,500 submissions** via Portal
- Over **7,700 PRIA and non-PRIA actions** completed
- Registered **13 new active** ingredients
- **38 Section 18** emergency exemption decisions (Covid-19, herbicide resistant amaranth species in peanuts and sugar beets, coffee leaf rust)
- OPP Ombudsman responded to approx. **2,700** (Jan-Sept) **messages from the public**
- Center for Integrated Pest Management hosted **10 IPM webinars** (over **9,900 attendees**) and responded to over **2,800 public inquires**
- Responded to a high volume of public health related inquiries: efficacy testing methods and claims for products intended to be effective against **public health pathogens (179), Monkeypox and COVID-19 (150), pesticidal devices (360)**
- Reviewed labels and website materials for more than **40 products submitted** by EPA regional offices and state partners to ensure compliance **with device regulations**
- Collected \$31.6M and \$23.95M in maintenance and PRIA fees

# Section 3 Product Registrations, 2004-2022



# PRIA Completions: FY2004 - FY2022



# Pesticide Registration Improvement Act (PRIA)

- The Pesticide Registration Improvement Act and its four reauthorizations provide a fee-for-service structure for EPA review of pesticide applications and set statutory decision time frames for review of those applications.
- PRIA provides two funding sources to EPA's pesticide program:
  - One-time registration service fees (i.e., PRIA fees) for the evaluation of new applications submitted to the EPA; and
  - Annual FIFRA maintenance fees assessed to products currently in the marketplace, a significant portion of which are used to support the re-evaluation of pesticides in order to meet statutory deadlines, including the new deadline of **October 1, 2026**, for completing the first round of registration review.
- Both PRIA registration service fees and maintenance fees are meant to supplement appropriations in funding these activities, and do not represent the total costs for EPA to conduct these activities.

# Section 711 of the Consolidated Appropriations Act, PL-117-328 (Dec. 29, 2022)

## INTERIM REGISTRATION REVIEW DECISION REQUIREMENTS

*(A) that is associated with an initial registration review described in subsection (a);*

*(B) that is noticed in the Federal Register during the period beginning on the date of enactment of this Act and ending on **October 1, 2026**; and*

*(C) for which the Administrator has not, as of the date on which the decision is noticed in the Federal Register, made effects determinations or completed any necessary consultation under section 7(a)(2) of the Endangered Species Act of 1973 (16 U.S.C. 1536(a)(2)).*

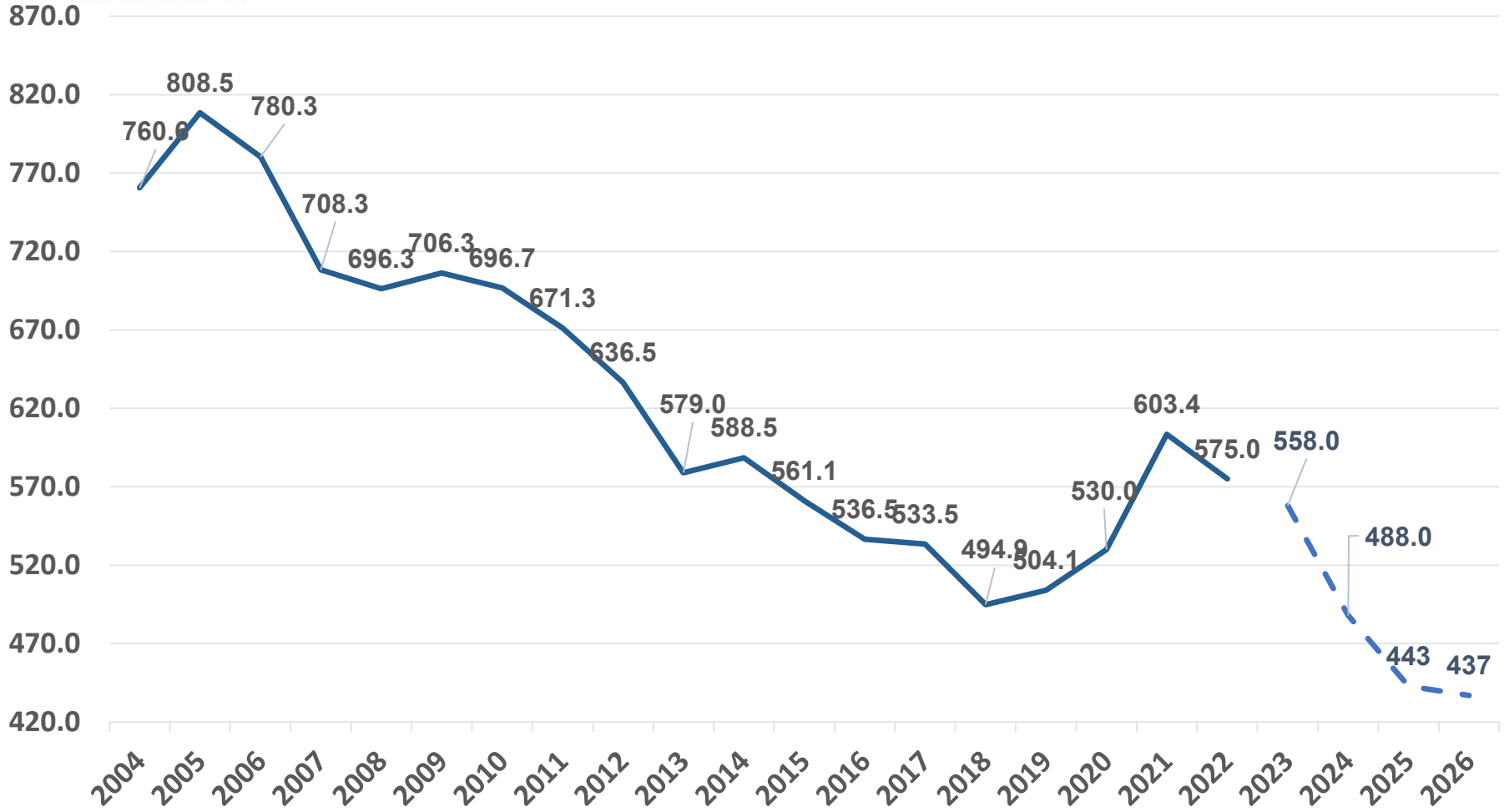
*(2) REQUIREMENTS.—Any covered interim registration review decision shall include, where applicable, **measures to reduce the effects** of the applicable pesticide on—*

*(A) species listed under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.); or*

*((3) CONSULTATION.—In developing measures described in paragraph (2), the Administrator shall take into account the **input received** from the Secretary of Agriculture and other members of the interagency working group established under section 3(c)(11) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a(c)(11)).*

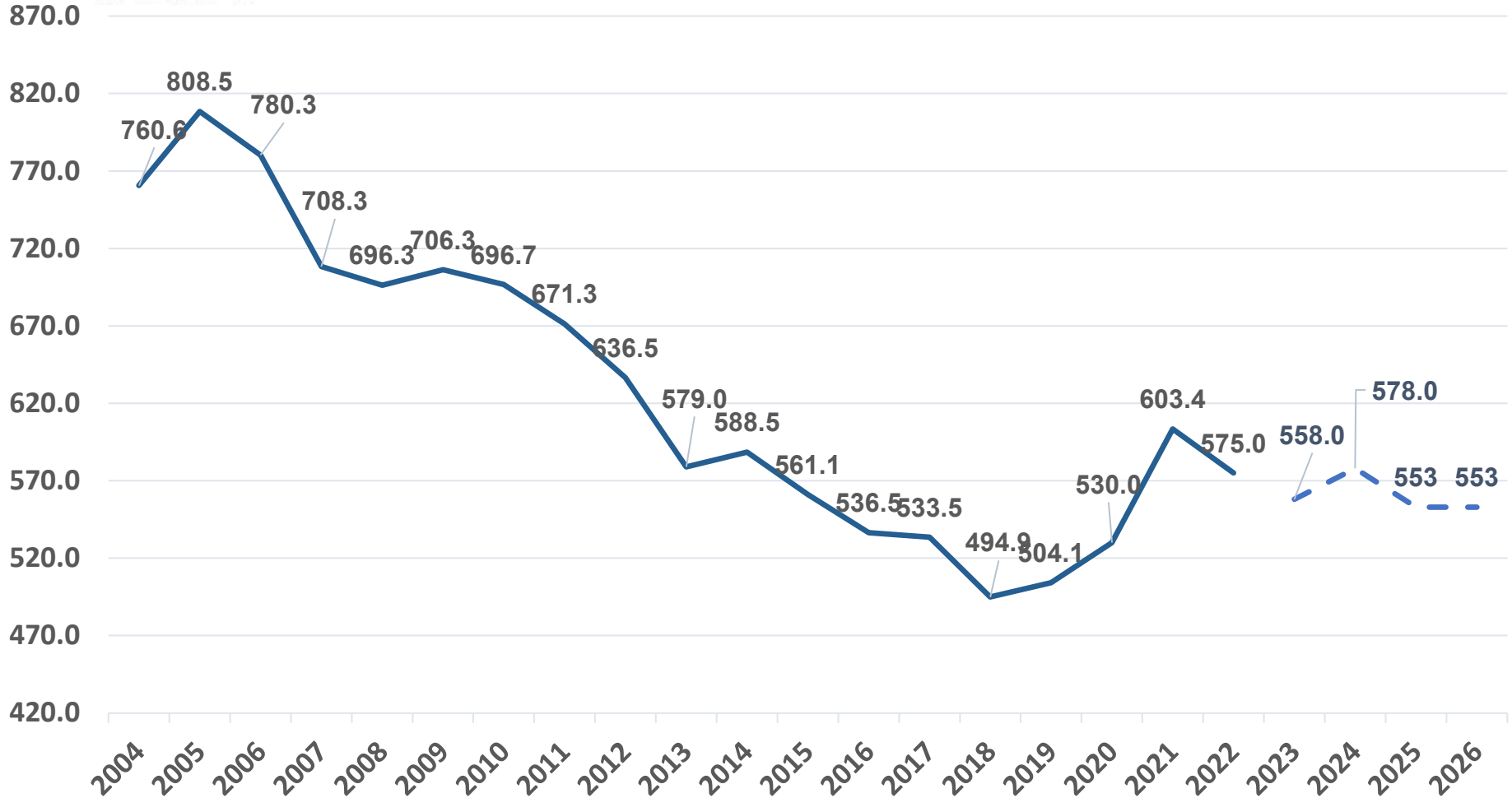


# EOY Total FTE Usage for OPP from FY 2004 - FY 2026 (PRIA 4 Scenario)



95 FTE deducted from the OCSP Program funding levels to normalize the data to reflect OCSP Reorganization and those FTE being moved to OPS. Cut to FTE to keep contracts

# EOY Total FTE Usage for OPP from FY 2004 - FY 2026 (PRIA 5 Scenario)



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

# PRIA 5 and Appropriations

- **PRIA - Increase in fees and funding for OPP (+\$11m for maintenance; + projected \$6m for registration)**
- **FY23 appropriations - \$11m increase, targeted at ESA**
- Omnibus - October 1, 2026, deadline extension (IDs with measures to reduce exposure/risk)
- Maintenance fee set-asides for:
  - Non-fee regulatory actions- to reduce backlog and meet statutory timeframes
  - Pesticide Safety grants including Farmworker Training and Education, Health Care Provider Training, Partnership Grants, and Pesticide Safety Education Program (EJ Session)
  - Performance Standards Development for Antimicrobial Devices
  - Vector Expedited Review Voucher program
  - Pesticide Surveillance Program – funding for interagency agreement with CDC/NIOSH to support the SENSOR program (EJ Session)
  - Training

# PRIA 5 and Appropriations- cont'd

- Bi-lingual Labeling for Pesticides (EJ session)
- ESA Guidance to Registrants (ESA Session)
- PRIA process improvements, including renegotiation provisions for submissions
- IT Upgrades
- Centralized Webpage for guidance and pesticide related resources
- Posting of Data Evaluation Records for PRIA actions
- Audit of OPP Processes and Workforce
- Government Shutdown Provisions
- Reports to Congress
- <https://www.congress.gov/bill/117th-congress/house-bill/2617/text> (CTRL F “pesticide”)

# PRIA 5 Implementation- Completed

- In January, EPA sent out a second invoice for maintenance fees, reflecting the PRIA 5 collection level of \$42M annually
- In February, EPA posted the updated fee tables to the PRIA website along with updates to related webpages
- EPA has sought stakeholder input on ways to make bi-lingual labeling accessible to farmworkers (due date of **June 2023**)
- EPA has reached out to state lead agencies regarding implementation of bi-lingual labeling provision of PRIA 5
- EPA has put out for public comment Endangered Species Act (ESA) guidance to registrants for outdoor uses of new active ingredients, registration review cases (due date of **September 2023**)

# Vector Expedited Review Vouchers

- PRIA Language:

“In addition to amounts otherwise available, for each of fiscal years 2023 through 2027, the Administrator shall use not more than \$500,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund to establish and carry out the Vector Expedited Review Voucher program in accordance with subparagraph (B).”

- OPP Team Members:

IO (Susan Jennings), RD (Virna Stillwaugh, Elizabeth Andrews), OGC (Aaron Newell), BPPD (Alan Reynolds), BEAD (Monisha Kaul), HED (Christina Schwartz), EFED (TBD)

# Vector Expedited Review Vouchers

- EPA will issue a voucher to a registrant if they submit, and receive approval, for a new vector control product
- When redeemed, voucher entitles the holder to expedited review for different pesticide
- Program will be established by 12/22/2023
  - To incentivize development of new insecticides for disease vectors (initially, mosquitos)
- OPP is progressing towards implementation
  - Working to create administrative oversight, clarify criteria for qualification and design a process to expedite the actions
- Meetings:
  - Met twice with FDA to discuss their lessons learned
  - Met once with IVCC (Innovative Vector Control Consortium) to discuss implementation ideas
- Goal: allow vouchered products to be expedited with minimal impact on scheduling for standard PRIA outputs

# PRIA 5 Implementation- FY 2023 Due Dates

- **June:**
  - Seek stakeholder input on ways to make bi-lingual labeling accessible to farmworkers. Upcoming Webinar
  - 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 Endangered Species Act (ESA) guidance to registrants for outdoor uses of new active ingredients, registration review cases
- **December:**
  - Establish Vector Expedited Review Voucher 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



# Progress in Meeting Pesticide Registration Review Deadline

- In the past 15 years, 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 decisions 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

# Progress in Meeting Pesticide Registration Review Deadline

- ✓ 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 (23% of total number of cases).



# Progress in Meeting Pesticide Registration Review Deadline

- Use the QR code below for more information on EPA's progress in meeting the pesticide registration review deadline.



# Atrazine

- In June 2022, released proposed revisions to September 2020 interim decision (ID) for public comment.
- Developed new proposed risk mitigation to decrease runoff as part of a partial voluntary remand of the atrazine ID following litigation.
- Comment period closed October 2022. EPA received about 68K comments on the proposed revisions and is now reviewing the comments and developing responses to them.
- Upcoming FIFRA SAP Public Virtual Meeting (August 22-24, 2023)
  - Focus will be on the Agency's 2023 reevaluation of 11 atrazine cosm studies identified at the 2012 SAP meeting as warranting further review.
  - The Agency would like the FIFRA SAP's feedback on its evaluation of the 11 cosm studies, their potential inclusion or exclusion in the analysis, and if appropriate, whether they show an effect or no effect on the aquatic plant community.

# Chlorpyrifos

- February 2022 cancellation of all food-uses
- Pending litigation in the Court of Appeals for the Eighth Circuit concerning the Agency's final rule revoking all tolerances for chlorpyrifos.
- Oral argument was held on December 15, 2022, and the court has not yet issued its decision.
- On January 13, 2023, two administrative hearing requests on the NOIC were submitted. A hearing date has not been scheduled.
- On April 4, 2023, EPA published the final cancellation of food uses for several registrants, as well as several registrations. The return programs for Corteva and Adama have been approved.

# Rodenticides

- The draft risk assessments for the rodenticides were completed in 2020.
- On November 29, 2022, EPA released the proposed interim decisions (PIDs) for 11 rodenticides in registration review
  - includes additional mitigation measures to protect human health and mitigate ecological risk to non-target organisms, including potential effects on federally listed endangered and threatened (listed) species
- The PIDs cover 3 first-generation anticoagulant rodenticides four second-generation anticoagulant rodenticides, and four non-anticoagulant rodenticides
- The PIDs build on a previous risk mitigation decision for 10 rodenticides in 2008 by proposing additional mitigation measures.
- The Interim Decisions for the rodenticides are scheduled for 2023.

# First Pesticide Tolerance for Hemp

- On April 10th, EPA established the first pesticide tolerance for hemp for a conventional pesticide. This tolerance is for the herbicide ethalfluralin.
- EPA issued a final tolerance rule that established the maximum amount of ethalfluralin residues allowed to remain in or on hemp seed. EPA accepted labels for this pesticide that now contain directions for use on hemp.
- Interregional Research Project No. 4 (IR-4) and the registrant worked on this application.
- As this is the first instance of establishing a food tolerance for hemp, EPA considered the agronomics of hemp production and developed science policies to guide assessment of potential human health exposure and risk from application of ethalfluralin on hemp.
- This approval is intended for producers of hemp which contains low THC content. Use is not labeled for production involving marijuana.
- There are 98 biopesticides registered in addition to ethalfluralin. Link to the hemp website: <https://www.epa.gov/pesticide-registration/pesticide-products-registered-use-hemp>

# Dicamba

- February 2023, EPA approved labeling amendments that further restrict the use of over-the-top dicamba in Iowa, Illinois, Indiana, and South Dakota.
- The amendments, which were requested by product registrants, following discussions with those states, are intended to reduce risks from the use of over-the-top dicamba.
- The revised labeling prohibits the use of over-the-top dicamba application on dicamba-tolerant crops after June 12 in these states, except SD which is June 20.
- This restricts over-the-top dicamba application to earlier in the growing season, when temperatures are likely to be lower, and is intended to reduce the potential for dicamba to volatilize and drift off-site.
- Among other requirements, the product registrants must add the amended labeling to their training and educational materials and disseminate this information to pesticide authorities and agricultural extension services to assist users in their local area.



# Dicamba

- These amendments follow amendments EPA approved for Minnesota and Iowa in March 2022.
  - The amendment for Minnesota remains the same.
  - For Iowa, the new amendment supersedes the previous amendment. Therefore, over-the-top dicamba can no longer be applied after June 12 in Iowa.
- As EPA continues to review dicamba-related incidents and considers the regulatory tools available to further address these incidents, the Agency is ready to support state-implemented restrictions that reduce risks from the use of over-the-top dicamba.
- If a state wishes to further restrict the over-the-top uses of dicamba, it may use FIFRA section 24(a) to do so, or registrants and states can work together to submit a label amendment containing state-specific restrictions for EPA approval.
- To view the amended labeling, visit docket EPA-HQ-OPP-2020-0492 at [www.regulations.gov](http://www.regulations.gov).

# Dicamba

- As part of Registration Review, on August 18, 2022, EPA issued a second addendum to the 2016 human health risk assessment and a draft ecological risk assessment for public comment.
  - In the human health assessment, there were occupational handler risks of concern identified which could be offset using respirators and engineering controls.
  - The ecological risk assessment identified risks of concern to a wide variety of organisms with terrestrial plants having the highest risk exceedances.
- The public comment period on these assessments closed on October 17, 2022. 746 comments were submitted and are currently being reviewed by the Agency.
  - The most common topics discussed in the submitted comments were concern over off-target movement from dicamba applications impacting non-target plants/crops and wildlife habitat, dicamba usage data, and benefits of over-the-top uses of dicamba for agriculture.
- After reviewing the comments, EPA's next step in the registration review process will be to publish a proposed interim decision (PID), currently planned for 2024.
  - In addition to mitigating risks, EPA will be considering early ESA mitigation as pesticides go through the reevaluation. This ESA mitigation is intended to occur before a BiOp is issued for a pesticide.
- EPA's Draft Risk Assessment Addendum and submitted comments can be found in docket EPA-HQ-OPP-2016-0223 at [www.regulations.gov](http://www.regulations.gov).

# Application Exclusion Zone Requirements

- On March 13, 2023, EPA published a proposed rule that would improve and modernize the pesticide Application Exclusion Zone (AEZ) requirements under the 2015 Agricultural Worker Protection Standard (WPS).
- The Agency proposed to reinstate several provisions from the 2015 WPS to strengthen protections for farmworkers and bystanders including:
  - Where the AEZ requirements are applicable, including:
    - beyond an establishment's boundaries; and
    - when individuals are within easements (such as easement for utility workers to access telephone lines).
  - Reestablishing AEZ distances for ground-based spray applications (e.g., boom sprayers) of:
    - 25 feet for sprays using medium or larger droplet sizes when sprayed from a height greater than 12 inches from the soil surface or planting medium; and
    - 100 feet for sprays using fine droplet sizes.

# Application Exclusion Zone Requirements

EPA also proposes to retain **(Continued)**:

- a clarification that suspended pesticide applications can resume after people leave the AEZ; and,
  - an “immediate family exemption” that allows only farm owners and the farm owners’ immediate family to remain inside enclosed structures or homes while pesticide applications are made.
- Public comment closed on May 12, 2023, and EPA is currently reviewing the comments.
- [www.regulations.gov](https://www.regulations.gov), Docket [EPA-HQ-OPP-2022-0133](https://www.regulations.gov/docket/EPA-HQ-OPP-2022-0133)

# Certification of Pesticide Applicators Rule

- In 2017, EPA issued a final rule revising the Certification of Pesticide Applicators (CPA) regulations in 40 CFR 171 to:
  - Improve the competency of certified applicators of restricted use pesticides (RUPs),
  - Increase protection for noncertified applicators using RUPs under the direct supervision of a certified applicator, and
  - Establish a minimum age requirement for certified and noncertified applicators using RUPs.
- EPA finalized two rules extending the date by which modified plans must be approved:
  - Original regulatory deadline: March 4, 2022
  - Final deadline: **November 4, 2023**
- The deadline was extended, in part because of the impact of the COVID-19 public health emergency on certification programs, as well as the complexity of EPA's review of plans.
- Regions facilitate review and approval of the state, territory, and tribal certification plans; OCSPP reviews and provides concurrence.
- Existing RUP applicator certification programs may stay in effect until **November 4, 2023**.
- Program changes may go into effect at different times, according to plans' implementation schedules.

# Certification Plan Reviews & Approvals

- All **68 Plans** have been thoroughly reviewed by EPA.
- All Plans have been returned to SLAs and Tribes for revisions.
- **29 Approved Certification Plans (SLA + Federal) as of May 26, 2023.**

## 6 Tribal Plans

- **No Plans approved yet**
- All Plans back with respective tribes

## 56 SLA Plans

- **24 Plans Approved**
- 15 / 33 not-yet approved Plans back with SLAs
- 17 / 33 are back with EPA after revisions

## 6 Federal Agency Plans

- **5 Plans Approved**
- 1 EPA-administered Plan for Indian Country under internal review

# Ethylene Oxide (EtO)

- On April 11, EPA proposed new health protections to reduce exposure to Ethylene Oxide (EtO), including more stringent air emissions standards and additional protections for workers who are exposed to the gas used to sterilize medical devices and dried herbs and spices.
- EPA is proposing a comprehensive set of new mitigation measures that will decrease risk for workers who use EtO to sterilize products and for other people in communities near sterilization facilities.
- EPA is proposing to increase control measures on the use of EtO in the Proposed Interim Decision, such as
  - Prohibiting certain uses of EtO where alternatives exist including use in museums, archival settings, beekeeping equipment in NC, cosmetics, and musical instruments;
  - Reducing the amount of EtO that may be applied for medical device sterilization while meeting applicable standards for sterility assurance

# Ethylene Oxide (EtO)

- EPA is proposing **(continued)**
  - Requiring engineering controls that reduce worker exposures to EtO, such as automation or emissions capture technology; and
  - Mandating Personal Protective Equipment (PPE) in sterilization facilities when EtO is detected using state-of-the-art monitoring technology.
- EPA's Proposed Interim Decision and EPA's Draft Risk Assessment Addendum, can be found [on EPA's website](#) and in docket EPA-HQ-OPP-2013-0244 at [www.regulations.gov](http://www.regulations.gov).
- The docket will be open for public comment for 60 days after publication in the Federal Register. The public comment period closes on **June 27, 2023**.



# Organophosphates

- On March 15<sup>th</sup>, EPA released the updated occupational and non-occupational spray drift exposure risk assessments for diazinon, ethoprop, tribufos and phosmet.
- EPA assessed the potential risks to people who mix, load, and apply the four pesticides, farmworkers who work with crops that have been treated with these pesticides, and bystanders who are potentially exposed to spray drift, including families living in agricultural communities.
- Although registration review for these pesticides was not scheduled to be completed until 2025-2026, after recognizing that several of uses of these four pesticides present significant human health risks, EPA is taking accelerated and early action to address these risks.

# Organophosphates

- The updated exposure risk assessments are now available in the registration review dockets, [EPA-HQ-OPP-2008-0351](#) (diazinon), [EPA-HQ-OPP-2008-0560](#) (ethoprop), [EPA-HQ-OPP-2008-0883](#) (tribufos) and [EPA-HQ-OPP-2009-0316](#) (phosmet) at [www.regulations.gov](http://www.regulations.gov).
- EPA expects to issue the proposed interim decisions in fiscal year 2025 (tribufos) and fiscal year 2026 (ethoprop, diazinon and phosmet).
- **April mitigation announcement:**
- <https://www.epa.gov/pesticides/epa-reaches-agreement-early-mitigation-measures-initiative-organophosphate-pesticide>
- **May mitigation announcement:**
- <https://www.epa.gov/pesticides/epa-reaches-agreements-early-mitigation-measures-three-more-organophosphate-pesticides>

# Plant-Incorporated Biotechnologies to Protect Against Pests

- On May 25, EPA released a final rule exempting a class of plant-incorporated protectants (PIPs) created using genetic engineering from registration requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and from the food or feed residue tolerance requirements under the Federal Food, Drug, and Cosmetic Act (FFDCA).
- This rule ensures that public health and the environment are protected while reducing costs for the regulated community, consistent with [Executive Order 14081](#) on advancing biotechnology.
- <https://www.epa.gov/pesticides/epa-finalizes-rule-accelerate-use-plant-incorporated-biotechnologies-protect-against>

# PFAS in Pesticide Products

- OPP Update – May 30<sup>th</sup>
- EPA did not find any PFAS in the tested pesticide products, differing from the results of a published study in the Journal of Hazardous Materials.
- EPA also released its newly developed and validated analytical methodology used in the testing process alongside the summary of its findings.
- EPA is confident in the results of this newly released method, which is specifically targeted to detect the presence of PFAS in pesticide products formulated with surfactants.

# EJ Session One-Pagers

- Afternoon session to discuss environmental justice (EJ) activities
- Providing updates on EJ-related activities through written updates on certain activities
  - National Environmental Justice Advisory Committee Charge Document on Farmworkers and Pesticides
  - Children’s Health/Children’s Health Protection Advisory Committee (CHPAC) Consultations on consideration of legally working children in pesticide exposure assessment and take-home pesticide exposure
  - Early Organophosphate Pesticides Mitigation
  - Ethylene Oxide Risks and Mitigation

# Sign-up for OPP Pesticide Updates

## Get pesticide news story updates by email:

- Go to [epa.gov/pesticides](https://www.epa.gov/pesticides)
- Go to the “Recent Highlights and Pesticide News” box in the right corner
- Click on “View more pesticide news” at the top
- Go to the “Other Resources” box at the right
- Under, “Get pesticide updates by email,” enter your email address and click “Sign up”

Pesticide News Story Updates

