PRIA Coalition Webinar

PRIA 5

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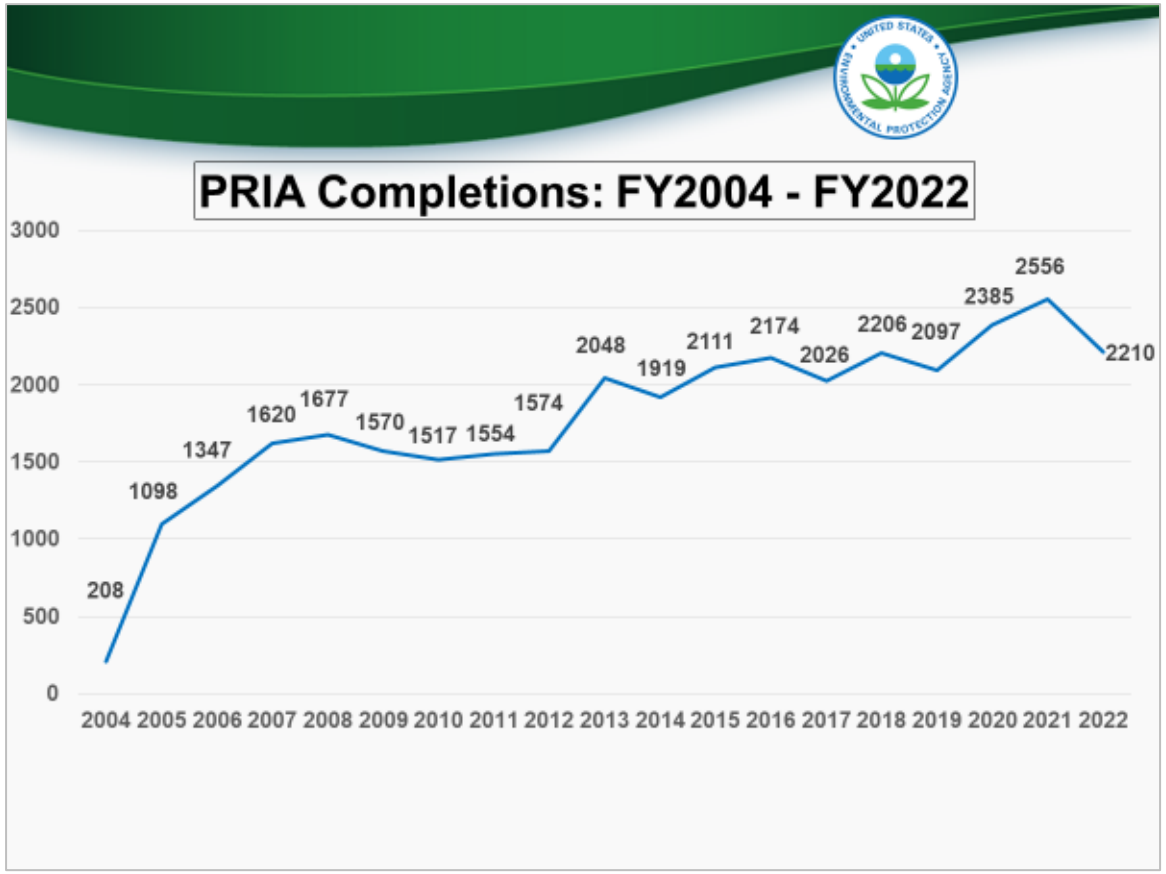
PRIA Coalition

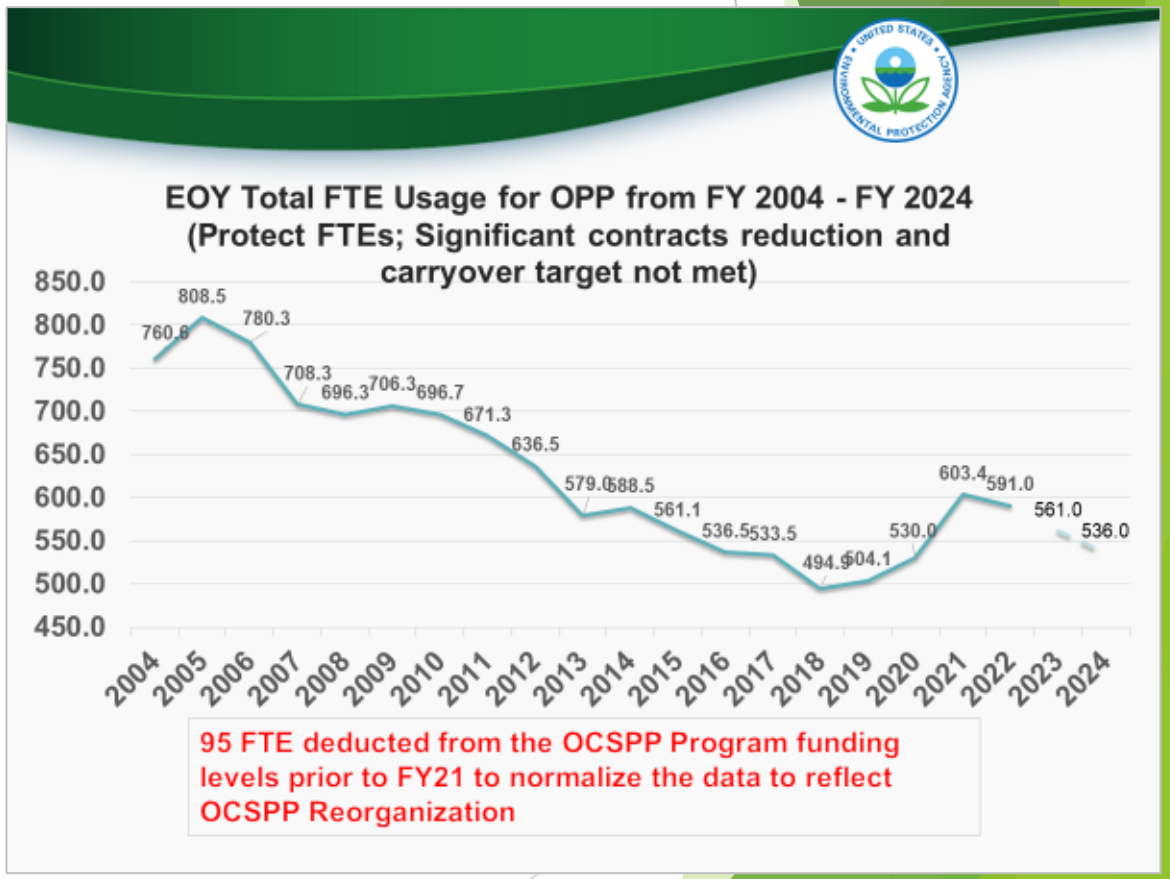
- Coalition Members:
  - American Chemistry Council's Center for Biocide Chemistries
  - Animal Health Institute
  - Biological Products Industry Alliance
  - CropLife America
  - Council of Producers & Distributors of Agrotechnology
  - Household & Commercial Products Association
  - ISSA, The Worldwide Cleaning Industry Association
  - RISE (Responsible Industry for a Sound Environment)

Pesticide Registration Improvement Act (PRIA)

- First authorized in 2004
  - PRIA was reauthorized by the Pesticide Registration Improvement Renewal Act of 2007, the Pesticide Registration Improvement Extension Act of 2012, and Pesticide Registration Improvement Act Extension of 2018
- Under PRIA: Companies must pay service fees according to the category of the registration action
- EPA must meet registration decision review time periods, which result in a more predictable evaluation process for companies
- Shorter decision review periods are provided for reduced-risk registration applications

EPA PRIA Metrics
(from 11/3/22 Quarterly PRIA Stakeholder Meeting)

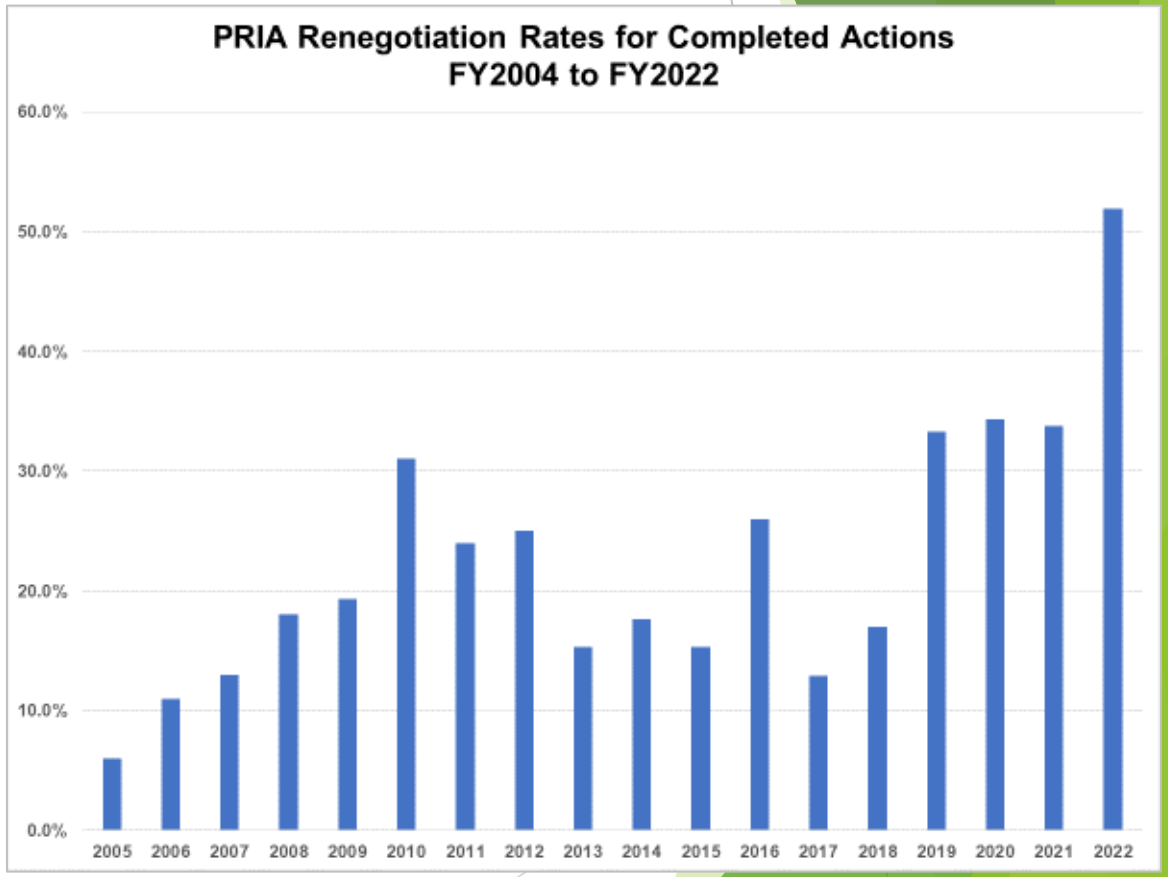




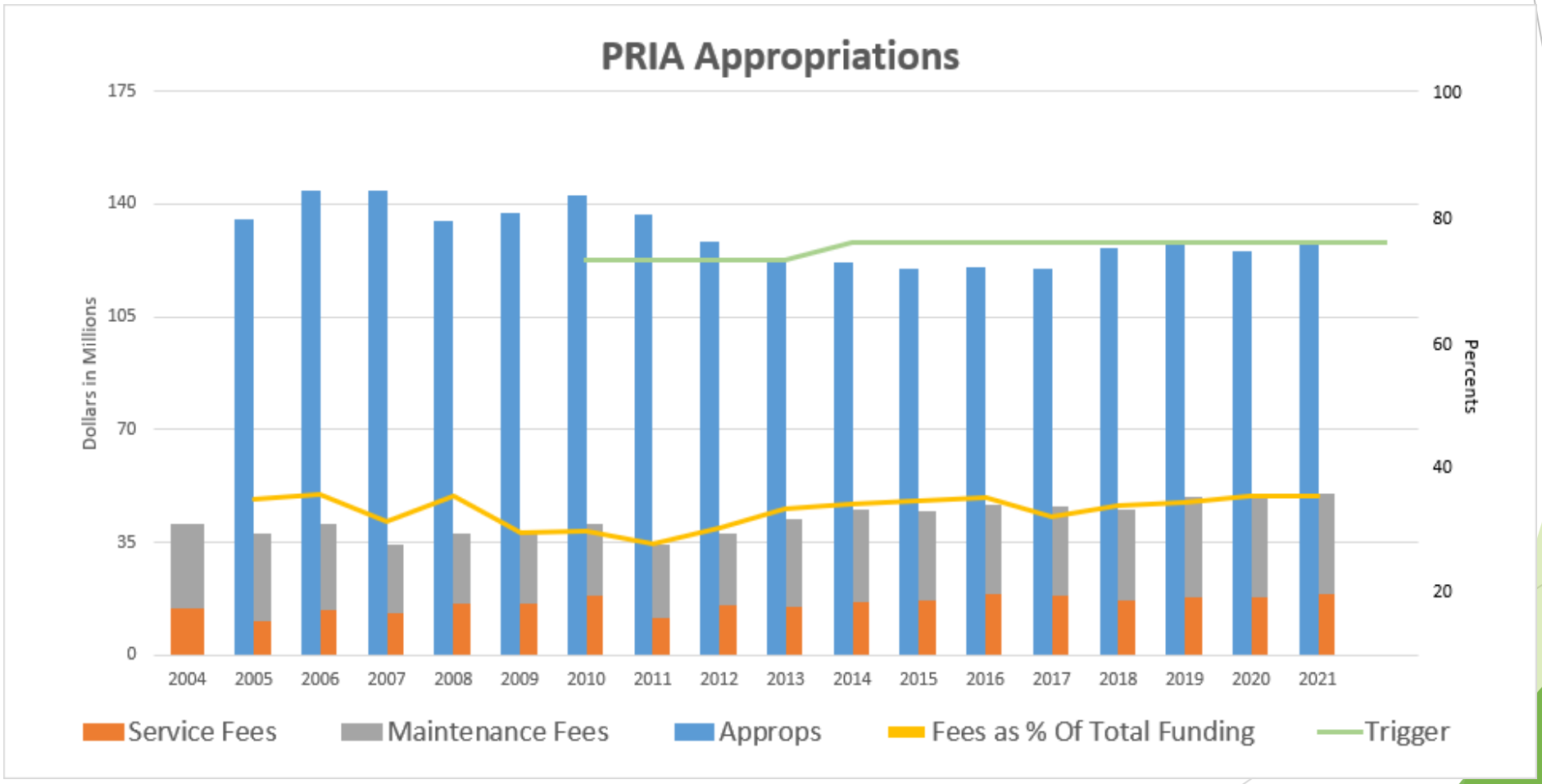
EPA PRIA Metrics
(from 11/3/22 Quarterly PRIA Stakeholder Meeting)

Historical % of Completed PRIA Decisions with Renegotiated Due Dates

FY	Antimicrobials	Biopesticides	Conventionals	Misc.	Inerts
2014	41/287 = 14.3%	30/129 = 23.2%	259/895 = 28.9%	1/575 = 0.2%	9/45 = 20%
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%

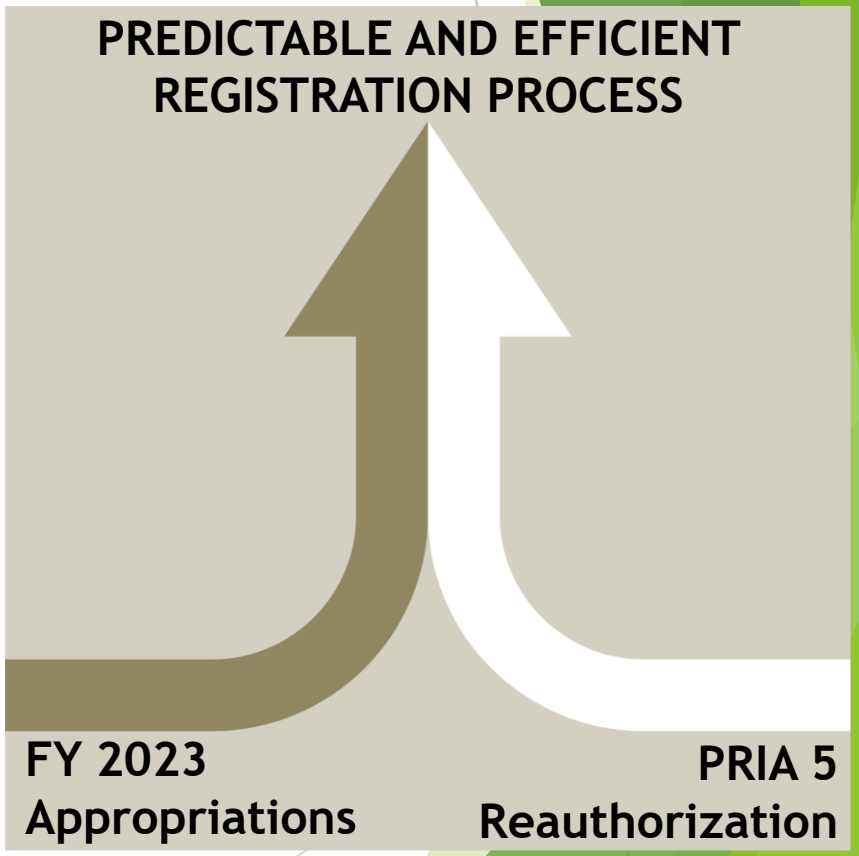


Pesticide Program Funding (2004-2021)



Our Approach: Appropriations and Reauthorization

- Work to increase annual appropriations for OPP
- Craft a PRIA 5 reauthorization bill that includes adequate resources for OPP, along with significant process improvements and efficiencies



PRIA Appropriations

- FY 2022 Funding: $129.367 million
- FY 2023 Funding: $140.457 million
  - Industry Request: $163 million
  - President's Budget: $138.341 million
  - House-Passed Funding: $158.675 million
  - Senate Draft Funding: $140.841 million
- PRIA Funding Trigger:
  - PRIA 4: $128.3 million
  - PRIA 5: $166 million
- FY 2024 appropriations process begins in February

PRIA 5 Addresses All PRIA Coalition Priorities

- Clean reauthorization free of extraneous policy issues
- Ensuring that EPA has the resources it needs to meet deadlines for both PRIA and non-PRIA actions, but also ensuring that there is more EPA predictability (accountability) around deadlines
- Create a mechanism to ensure that non-PRIA actions are processed in a timely manner and that current backlog is addressed
- Prioritize process improvements, efficiencies, and consistency among reviewers and registering divisions
- Ensuring that OPP user-fee based operations can continue during a government shutdown

PRIA 5 Funding:
A 30% Overall Increase in OPP Funding

- An additional $17 million in industry fees
  - Total of $67 million from industry
  - Up from the current $51 million
- A goal of an additional $37 million in additional federal appropriations
  - Total of $166 million from appropriations
  - Up from the current $128 million

PRIA 5 Funding: *Maintenance & Registration Fees*

Maintenance Fees = $42 million annually

- Up from the $31 million
- The caps will be as follows:
  - $172,200 for large businesses with 50 products or less;
  - $277,200 for large business with more than 50 products;
  - $105,000 for small businesses with 50 products or less;
  - $184,800 for small businesses with more than 50 products
- The per product fee is $4,875
- Average cap increase of $47,000
- Move all set asides to come from maintenance fees (Section 4 funds) to provide greater certainty and transparency of funding, rather than some from registration fees (Section 33 funds)
- Effective retroactively to October 1, 2022 (FY2023), supplemental invoices expected

Registration Fees = Estimated $26 million

- Up from the current $20 million
- In general, 30% increase for each fee category
- Registration fees will increase by 5%:
  - On October 1, 2024 (or after) IF EPA has begun to implement an information technology system and includes all registering divisions and provides a real-time, accurate tracking system for all regulatory submissions OPP
  - On October 1, 2026 (or after), IF EPA has begun to implement the appropriate process improvements identified in the third-party audit outlined below
- Continues the prohibition on tolerance fees
- Effective 60 days after enactment (February 27, 2023)

PRIA 5 Funding:
New Maintenance Fee Set Asides

- Create a set aside for processing registrant submissions not covered by a PRIA code and to clear the current backlog at 1/8 of the total maintenance fee fund (roughly $5.25 million per year)
- $500,000 set aside for EPA staff education and training to be conducted cooperatively through land grant institutions in partnership with HBCUs, 1890 institutions, or other minority-serving institutions
- $500,000 set aside for Vector Expedited Review Voucher (VERV) to incentivize development of new insect disease vector control methods, with any unused funds returning to general maintenance fee fund
- $500,000 set aside to begin development of public health performance standards for antimicrobial devices
- $500,000 set aside for education and training of clinicians
- $500,000 set aside to support the interagency agreement between EPA and CDC/NIOSH related to the SENSOR Pesticide Program, with a goal of increasing the number of participating states and/or improving the reporting of existing participants
- $350,000 set aside for grant writing technical assistance

PRIA 5 Funding:
Continued Maintenance Fee Set Asides

- Increase worker protection activities to an average of $1,500,000 per year (previously funded at 1/17 Pesticide Registration Fund, but not less than $1,000,000 per year)
- Pesticide Education Safety Program (continued at $500,000 per year)
- Partnership grants (continued at $500,000 per year)
- Good Laboratory Practices (GLP) inspections (continued at $500,000 per year)

PRIA 5 Funding:
Eliminated Maintenance Fee Set Asides

- Efficacy guidelines for public health pests (previously funded at $500,000 per year)
- Fast track and inert review set aside (previously funding at 1/8 to 1/9 of maintenance fees)

PRIA 5 Fee Charts:
*Highlights from **Registration Division** (Tables 1-6)*

- RD PRIA Technical Team (AHI, CLA, HCPA and RISE) compared average completion times to decision review times for all R and I codes
- Technical assistance from RD: time estimates for contractor review, FR notice, public comments process, and ESA
- For new outdoor AIs only, time increased 50% for ESA review
  - No time increase for ESA review where guidance is lacking, e.g., new indoor AIs, new uses, EUPs
- For several categories added 1 to 3 months for public participation process and or FR publication
- EPA must release DERs for all studies to applicant by end of decision review time

PRIA 5 Fee Charts:
*Highlights from **Registration Division** (Tables 1-6)*

Major changes to categories:

- Table 1: new R126: seed treatment active ingredient; accommodate changes from 2018 guidance
- Table 2: new R276, R277: new seed treatment uses; accommodate changes from 2018 guidance
- Table 3: new R281, R282: import tolerances using APEC protocol
- Table 4: new R361, R362: more combinations of multiple active ingredients and multiple target pests

PRIA 5 Fee Charts:
*Highlights from **Registration Division** (Tables 1-6)*

- Table 4: new R363: splits out repack of MUP as EUP from repack of EUP as MUP (R331)
- Table 5: amendments: no significant changes
- Table 6: new R278: Review protocol for companion animal safety study
- Table 6: new R279: Comparative product determination for reduced risk submission (voluntary)
- Table 6: delete R370: move cancer reassessment to Table 19

PRIA 5 Fee Charts:
ESA Footnote *(throughout charts)*

ESA footnote added to several PRIA codes:

- If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

PRIA 5 Fee Charts:
*Highlights from **Inerts/Miscellaneous***

- Table 18: new I017: add new source or safener
- Table 18: new I018: add one compound to commodity inert list
- Table 19: revised M001: regarding HSRB, adding “currently registered”
- Table 19: new M012: Certificate of Establishment
- Table 19: new M013: Cancer reassessment, combines R370 and A571
- Table 19: new M014: Pre-application nano-particle determination

PRIA 5 Fee Charts:
*Highlights from **Antimicrobial Division** (Tables 7-10)*

- Table 7 (New Active Ingredients):
  - Adjustment of fees for Non-Food Use and Indirect Food Use; Extension of most review timelines for public process
- Table 8 (New Uses):
  - Extension of most review timelines for public process
- Table 9 (New Products & Amendments):
  - Cancer Risk Reassessment moved to MISC codes
  - New End Use Products and Amendments adding new public health organisms—codes divided by 9/10 (vs former 25) organisms
  - Extended review time for A565, New MUP generic data package
- Table 10 (Experimental Use Permits and Other Actions):
  - Removes data review for devices making pesticidal claims from A522
  - New code for efficacy similarity determination

PRIA 5 Fee Charts:
*Highlights from **BPPD** (Tables 11-16)*

- All fees increased by 30%
- Table 11: Combine B610/B611, B600/B12, B613/B580/B590 because they require the same level of effort or were rarely being used and some timeframes were adjusted to accommodate public participation, science committees, ESA, and possibility of deficiency corrections (10-day and 75-day). Add explanatory text to B600 and B610 descriptions.
- Table 12: Combine B630/B642/B643, B640/B631, B644/B650 because they require the same level of effort or were rarely being used and some timeframes were adjusted to accommodate public participation, science committees, ESA, and possibility of deficiency corrections (10-day and 75-day). Add explanatory text to B630, B640, B644 and B645 descriptions.
- Table 13: Discontinue B652 and B671 (unused categories). Combine B674/B675 and update description. Combine B673/B676 and update description. Add two months to all categories except B674 recognize complexity. (Note: Added 2 months timing is consistent across all divisions.)

PRIA 5 Fee Charts:
*Highlights from **BPPD** (Tables 11-16)*

- Table 14: No change
- Table 15: Add explanatory text to B720/B721 descriptions.
- Table 16: Add explanatory text to B682 description. Add two new categories for pre-application conditional ruling on a non-food use determination and biochemical classification determination.
- Table 17: PIPS
- Table 19: M009 Includes EPA confirmation of eligibility for exemption for plant-incorporated protectants

PRIA 5 Fee Charts:
*Highlights from **BPPD** (Tables 17 - PIPs)*

- General
  - Renamed “Biopesticides Division — Emerging Technologies Pesticides”
  - Deleted duplicative categories and clarified others
  - SAP is now standalone option category (triggered as needed)
- Timeline Increase
  - EUPs: **+3 months**
  - New active ingredients: **+4 months**
  - Standalone tolerance exemption categories (more realistic and consistent)
  - ESA 50% timeline increase “footnote” may be applicable for these categories:
  - B780, B800, B820, B870, B880, B883, B884, B890, B922, B923, B924, B926 and B928
  - Applicant to negotiate at pre-submission stage

PRIA 5 Fee Charts:
*Highlights from **BPPD** (Tables 17 - PIPs)*

- New Categories (Driven by new emerging technologies)
  - Category for Biotechnology Notifications – EUP Determination
  - Categories for Genetically Engineered Animals Intended for Use as a Pesticide
  - Categories for Exogenous Applications of RNA to Elicit the RNA interference Pathway in Pests
  - Generic (non-PIP) amendment categories
    - EUP and registration amendments
    - Needed to cover amendments to new RNA and GE animal categories
    - Could also cover future emerging technology categories
      - If subsequently added in future reauthorizations of PRIA
  - M009 Non-FIFRA Regulated determinations
    - Adjust interpretation language to allow for PIP exemption determinations under the rule

PRIA 5 Process Improvements: *Renegotiation Rates*

- Specify allowable reasons for renegotiation of PRIA timelines:
  - If there is new or additional data or information from the applicant that is necessary for EPA to make a decision
  - If a public comment period generates significant comments that cannot be addressed within the original decision time
- New timeframes must be agreed to by the registrant and the Director of OPP
- EPA must provide the registrant a written letter that outlines the justification for why the additional time is needed and the number of days needed to allow EPA to make a regulatory decision
- During the 45-or 90-day technical screens, EPA shall verify and validate the accuracy of the PRIA fee category selected by the registrant
  - EPA must verify any PRIA fee category change in writing
  - If a new PRIA fee category is needed, the PRIA due date shall be calculated based on the original submission date
  - EPA shall develop a process to prevent double payment registration fees
  - EPA shall determine if a submission meets with qualifications for reduced risk
  - EPA shall to the extent practicable grant or deny data waiver requests
- EPA must continue to prioritize the action if EPA misses a PRIA deadline

PRIA 5 Process Improvements:
Registrant Submissions Not Covered by a PRIA Code

- Convert the maintenance fee set aside for inerts into a set aside to address registrant submissions not covered by a PRIA code (non-PRIA actions)
- EPA must seek stakeholder input and publish a plan to address the backlog and the expected annual workload for actions not covered by a PRIA code
- Additional reporting, audit and metric requirements related to these submissions

PRIA 5 Process Improvements:
Third-Party Audit

- EPA shall issue a competitive bid for an independent a third-party audit of the Agency's processes and performance and to make recommended process improvements. The audit must be completed within 2 years (December 29,2024) and must address, at a minimum, the following:
  - The 21-day content screen
  - The 45/90 day technical screen
  - Performance, processes, and progress towards reducing renegotiation rates and the average length or renegotiations
  - Performance, processes, and progress towards eliminating the backlog of registrant submissions not covered by a PRIA code
  - Performance, processes, and progress towards ensuring that all registrant submissions not covered by a PRIA code are completed by the deadlines specified in PRN 98-10: Notifications, Non-Notifications and Minor Formulation Amendments (October 22, 1998, and as amended) and as described in subsections (c)(3)(B) and 18(h) of section 3
  - Compliance with the statute's provisions related to renegotiations and registrant submissions not covered by a PRIA code
  - Information technology systems
  - Recommended improvements to employee training
  - Performance, progress, and processes in completing registration review
  - Other appropriate issues, such as submissions by inert suppliers and fast-track amendments

PRIA 5 Process Improvements: *IT Dashboards*

- Within one year (December 29, 2023) EPA shall create an **IT system** that:
  - Covers all registering divisions in OPP
  - Provides a real-time, accurate tracking system for all regulatory submissions to OPP
  - Provides a real-time, registrant-accessible dashboard that allows registrants to access the progress of their regulatory submissions online
  - Updates the Pesticide Submission Portal to ensure that label reviews are limited to current label changes, automate non-substantive changes, and allow for self-certification for certain actions

PRIA 5 Process Improvements: *Annual Reports*

- Eliminate unnecessary or unhelpful metrics in **Annual Report** from 67 to key metrics:
  - Information on each **PRIA action**, including the action code, the application date, the original decision due date, the dates of any renegotiations and the renegotiated due dates if applicable, the reasons for each renegotiation if applicable, the decision completion date if action has been completed, the status of action, and the reason for any denial or do not grant decision if applicable
  - Information on each **registrant submission not covered by a PRIA code**, including the application date, the type of regulatory action, the status of action, the reason for rejection if applicable, and the completion date if applicable
  - Information on the **screening processes**, including the number of applications successfully passing each type of screen, the number of applications that failed each type of screen, and the number of applications resulting in a rejection
  - Information on **Agency staffing**, including the number of new hires and personnel departures by each OPP division, the number of full time equivalent (FTE) by OPP division, the number of FTEs working on registration review activities, and the number of FTEs working registrant submissions not covered by a PRIA code
  - Maintain some metrics requested by the NGOs

PRIA 5 Process Improvements: *Endangered Species Act*

- EPA shall develop through notice and comment, guidance to registrants regarding analysis necessary to support the review of outdoor uses of pesticide products under the Endangered Species Act
  - Within 9 months of enactment (September 29, 2023) for new active ingredients or any registration review decision proposed for 1 or more outdoor uses
  - Within 1 year of enactment (December 29, 2023) for new out-door uses of a registered pesticide
  - Within 3 years of enactment (December 29, 2025) for antimicrobial pesticide products

PRIA 5 Additions: *Miscellaneous Additions*

- Add certificates of establishment (which serve as proof for pesticide exporters that the product is manufactured at an EPA-registered facility) to Gold Seal letters

- Specify that fee-based activities shall continue in the event of a government shutdown to the maximum extent practicable

PRIA 5 Additions: *Bilingual Label Requirements*

- A phase in of electronic Spanish labels via scannable technology or other electronic methods readily accessible on the product label
  - Only parts of the label contained in the **EPA Spanish Translation Guide for Pesticide Labeling**
- Phased in as follows:
  - Restricted use pesticides (RUPs) within **three years** (by December 29, 2025)
  - Non-RUP products that are designated as Toxicity Category 1 within **three years** (by December 29, 2025) for agricultural products and within **four years** (by December 29, 2026) for non-agricultural products
  - Non-RUP products that are designated as Toxicity Category 2 within **five years** (by December 29, 2027) for agricultural products and within **six years** (by December 29, 2028) for non-agricultural products
  - All other products within **eight years** (by December 29, 2030)
- Registrants of antimicrobial and non-agricultural use products may comply with the bilingual labeling requirement by providing la link to the safety data sheets (SDS) in Spanish (SDS option not available for non-agricultural RUPs)
- EPA shall seek stakeholder input on ways to make bilingual labels available to farm workers and implement a plan with in 3 years (by December 29, 2025)
- After the initial implementation dates, changes to label translations will be made the earlier of
  - The next time the end-product label is changed or amended as released for shipment
  - Within one year of publication of updates to EPA's Spanish Label Translation Guide for agricultural-use pesticide products
  - Within two years of publication of the updates to EPA's Spanish Label Translation Guide for non-agricultural use pesticide products
- The labeling will be done through non-notification
- EPA must consult with the states regarding implementation

PRIA 5 Additions: *Regulatory Information and Resources*

- Direct EPA to post on the Agency's website, aggregated on a single webpage, all EPA guidance pertaining to risk assessment, risk mitigation, benefits assessments, and cost-benefit balancing

- Direct EPA to post on the Agency's website, aggregated on a single webpage, links to resources, including organic farming (national list of allowed and prohibited substances); biopesticides and 25(b) minimum risk pesticides; integrated pest management (IPM) principles, and technical assistance for implementation of IPM

- These websites shall be posted by within 6 months of enactment (June 27, 2023)

PRIA 5 Summary

- A 30% increase in overall funding for OPP
- Coupled with policy and process changes that will:
  - Reduce the high rate of renegotiated PRIA actions
  - Increase the predictability of review timelines
  - Drive an enhanced culture of accountability within EPA's Office of Pesticide Programs (OPP)
  - Establish a process for addressing the non-PRIA backlog in a timely manner
  - Eliminate the ability for EPA to assign two PRIA codes (i.e., fees) to one regulatory submission (i.e., no double dipping)
  - Leverage self certification, where possible, for low-risk regulatory actions
  - Increase the accountability of the Agency to deliver the PRIA annual reports
  - Provide real time access by registrants to EPA tracking of completed and pending PRIA actions

PRIA Next Steps

- Coordinate with EPA on implementation issues, such as fee category interpretations
- Engage with EPA and the States regarding bilingual labeling implementation
- Coordinate with Congress on implementation oversight
- Advocate for $166 million in federal appropriations for OPP for FY 2024
- Organize a spring/summer workshop with EPA and the States to address implementation of new PRIA provisions such as bilingual labeling

Questions?

Thank you!