



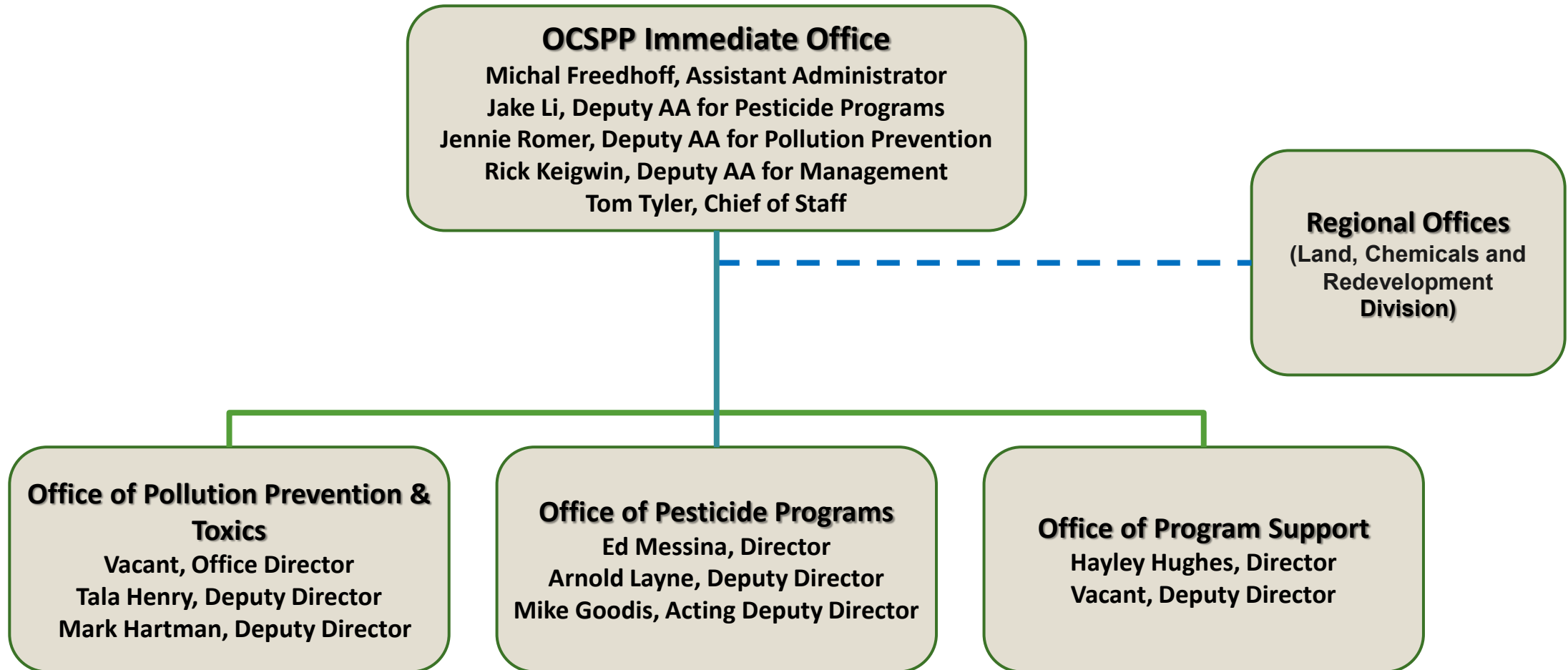
Pesticide Program Dialogue Committee

October 27-28, 2021

**Office of Pesticide Programs
U.S. Environmental Protection Agency**



OCSPS Overview: Organization Structure





Office of Pesticide Programs

Edward Messina, Director
Arnold Layne, Deputy Director, Management
Michael Goodis, (Acting) Deputy Director, Programs

Endocrine Disruptor
Screening Program

Antimicrobials Division

Anita Pease, Director
Steven Weiss, Deputy Dir.
Lisa Christ, Associate Director

Biopesticides and Pollution Prevention Division

Charles "Billy" Smith, (Acting) Director
Anne Overstreet, Deputy Dir.

Registration Division

Marietta Echeverria, (Acting) Director
Daniel Rosenblatt, Deputy Dir.
Catherine Aubee, Assoc. Dir.

Pesticide Re-evaluation Division

Elissa Reaves, Director
Tim Kiely, (Acting) Deputy Dir.

Health Effects Division

Dana Vogel, Director
Donald Wilbur, Deputy Dir.
Greg Akerman, Associate Dir.

Environmental Fate and Effects Division

Jan Matuszko, (Acting) Director
Rose Kyprianou, (Acting) Deputy Dir.
Brian Anderson, Assoc. Dir.

Biological and Economic Analysis Division

Kimberly Nesci, Director
Neil Anderson, Deputy Dir.

OPP Org.
Structure



Agency and Program-wide Priorities

Draft FY 2022-2026 EPA Strategic Plan Framework

Mission: To Protect Human Health and the Environment

Principles: Follow the Science, Follow the Law, Be Transparent, Advance Justice and Equity



Strategy 1:

Ensure Scientific Integrity and Science-Based Decision Making



Strategy 2:

Consider the Health of Children at All Life Stages and Other Vulnerable Populations



Strategy 3:

Advance EPA's Organizational Excellence and Workforce Equity



Strategy 4:

Strengthen Tribal, State, and Local Partnerships and Enhance Engagement



Goal 1:

Tackle the Climate Crisis



Goal 2:

Take Decisive Action to Advance Environmental Justice and Civil Rights



Goal 3:

Enforce Environmental Laws and Ensure Compliance



Goal 4:

Ensure Clean and Healthy Air for All Communities



Goal 5:

Ensure Clean and Safe Water for All Communities



Goal 6:

Safeguard and Revitalize Communities



Goal 7:

Ensure Safety of Chemicals for People and the Environment



Strategic Goal: Ensure Chemical and Pesticide Safety

Protect the health of families, communities, and ecosystems from the risk posed by chemicals and pesticides:

- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Food Quality Protection Act (FQPA) and the Pesticide Registration Improvement Extension Act of 2018 (PRIA)
 - Protecting people and the environment from the risk that pesticide use can pose
 - Reviews and registers new pesticides and new uses
 - Evaluates pesticides that are already in the market
 - Evaluating pesticides to protect human and ecological health
 - Endangered Species Act (ESA): Considers the effects determinations or protections of federally threatened and endangered species



OPP Priorities

- Considering the effects determinations or protections of federally threatened and endangered species
- Ensuring OPP's regulatory actions include special considerations for environmental justice concerns
- Ensuring OPP's regulatory actions include special considerations for Climate Change concerns
- Advancing critical science and policy issues
- Working towards PRIA 5
- Progressing the registration review program
- Working collaboratively with state partners and other stakeholders to implement program
- Continuing Employee Engagement, Process Improvements and IT Improvements

EPA Moving Forward on ESA

- We have made a lot of progress on the scientific analysis used to conduct a biological evaluation; however, science is only one part of the equation
- EPA wants to pivot with an eye towards ways we can begin to identify and implement protections for listed species earlier so that we can be more aligned with the ESA
 - We will continue to work and consult with the Services, as appropriate and meet our litigation related commitments (which are only increasing)
 - We created cross-divisional initiatives to meet ESA obligations
- EPA intends to focus its efforts on working with our stakeholders to identify mitigations for protecting species in the short term and not wait for completion of the entire consultation process
- EPA looks forward to working with stakeholders to realize our shared goal of protecting vulnerable species in a manner that is both effective and practical and ensures the availability and benefits of pesticides



ESA Biological Evaluations and Consultation Initiation

- EPA completed multiple draft or final Biological Evaluations, leading to listed species determinations for some of the most widely used insecticides and herbicides in the United States. These actions include:
 - Releasing final Biological Evaluations on **methomyl and carbaryl**, which were the first BEs to use the revised method.
 - Releasing draft Biological Evaluations for **atrazine, simazine, propazine, and glyphosate**.
 - Releasing draft Biological Evaluations on **imidacloprid, thiamethoxam, and clothianidin**.



Environmental Justice

- OPP is committed to making environmental justice a critical component of our work and is currently carrying out several initiatives,
- Example:
 - researching how to compare shallow private drinking water well locations in high agricultural areas and urban settings
 - to better understand pesticide exposure through drinking water for these populations
 - developing groundwater modeling scenarios for areas across the country where private drinking water wells overlap with vulnerable aquifers

EPA Climate Change

In October 2021, Administrator Regan released the Agency's Climate Adaptation Action Plan that describes the following steps we will take to address the impacts of climate change:

- Integrate climate adaptation and consideration of climate impacts into EPA programs, policies, rulemaking processes, and enforcement activities.
- Consult and partner with tribes; state, local, and territorial governments and other federal agencies; community groups; scientists and adaptation experts; businesses; and other stakeholders to increase the resilience of the nation, with a particular focus on advancing environmental justice.
- Implement measures to protect the agency's workforce, facilities, critical infrastructure, supply chains, and procurement processes from the risks posed by climate change.
- <https://www.epa.gov/system/files/documents/2021-09/epa-climate-adaptation-plan-pdf-version.pdf>



Enhancing Scientific Integrity

- March 2021, Assistant Administrator, Michal Freedhoff, issued an office-wide internal memo that affirmed her commitment to scientific integrity as an essential and critical element to our work.
- October 2021, Assistant Administrator, Michal Freedhoff, issued an office-wide internal memo, indicating next steps in her commitment to strong science in the review of chemicals and pesticides. These steps include:
 - establishing two internal science policy advisory councils
 - creating a new senior-level career position to serve as a science policy advisor in OCSPP
 - making further improvements to policies and procedures

EPA FY21 Programmatic Support

- Over 11,000 submissions via Portal
- Over 5,000 registration actions completed
- OPP Ombudsman responded to approx. 5000 messages from the public
- The Center for IPM responded to over 2,200 public inquires for information on IPM, pesticides, pests, and its webinar series (10-fold increase)
- Responded to over 100 congressional inquires



FY21 Registration Highlights

- Overall, 2,400 PRIA actions completed
 - 97.5% on-time completion rate
- Registered 14 new active ingredients



FY21 Registration Highlights

- **60** Section 18 emergency exemption decisions, providing growers with tools to control economically threatening pests, including:
 - Includes Asian citrus psyllid, foot and mouth disease, weedy rice, glyphosate-resistant palmer amaranth, coffee leaf rust, brown marmorated stink bug, and hemlock woolly adelgid

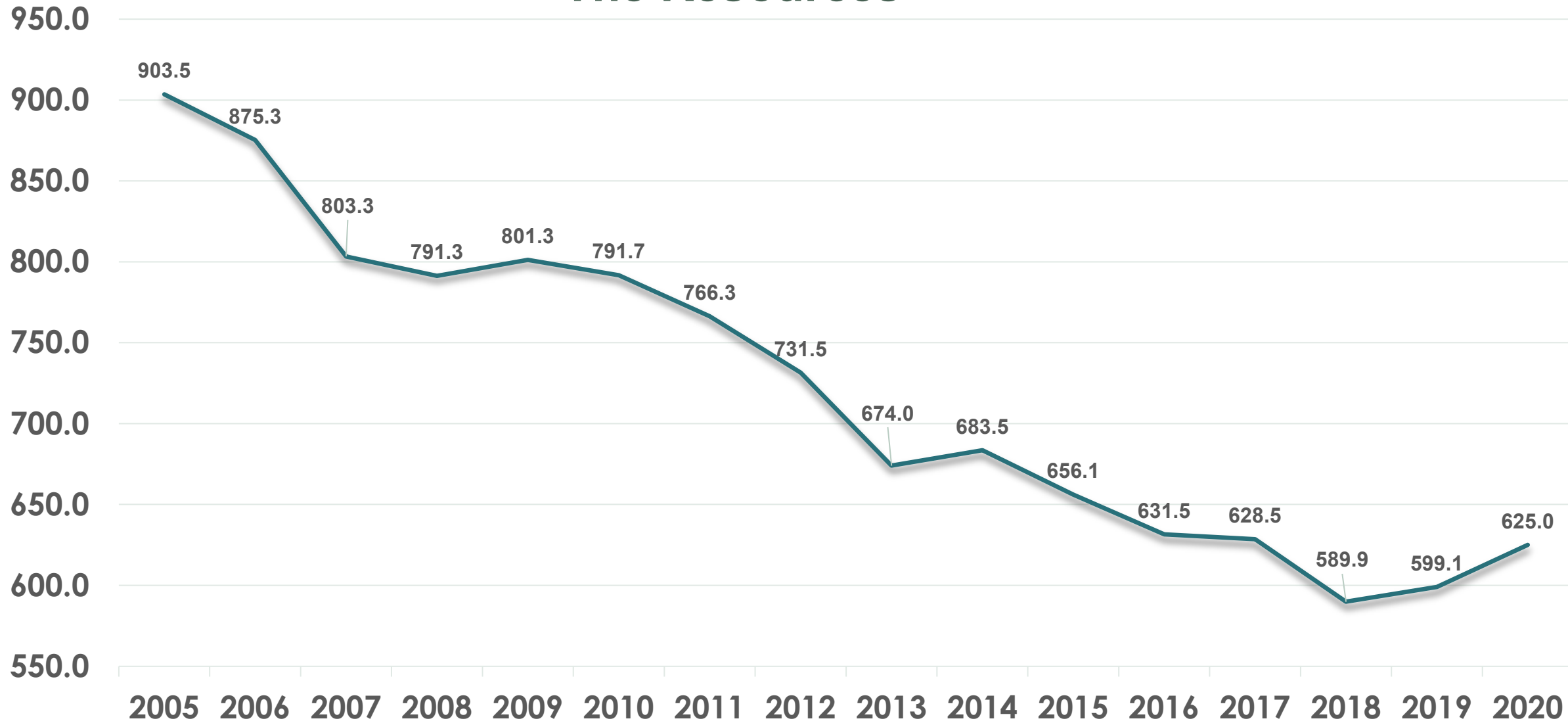
EPA FY21 Registration Highlights

- EPA registered several new pesticides including conventional, biochemical, microbial pesticides, and antimicrobial, including:
 - Fluindapyr
 - Picarbutrazox
 - 1-ACC
 - *Purpureocillium lilacinum* strain PL11
 - Sodium benzoate
- Check OPP's [Pesticide News Stories](#) for announcements about these and other new active ingredients.

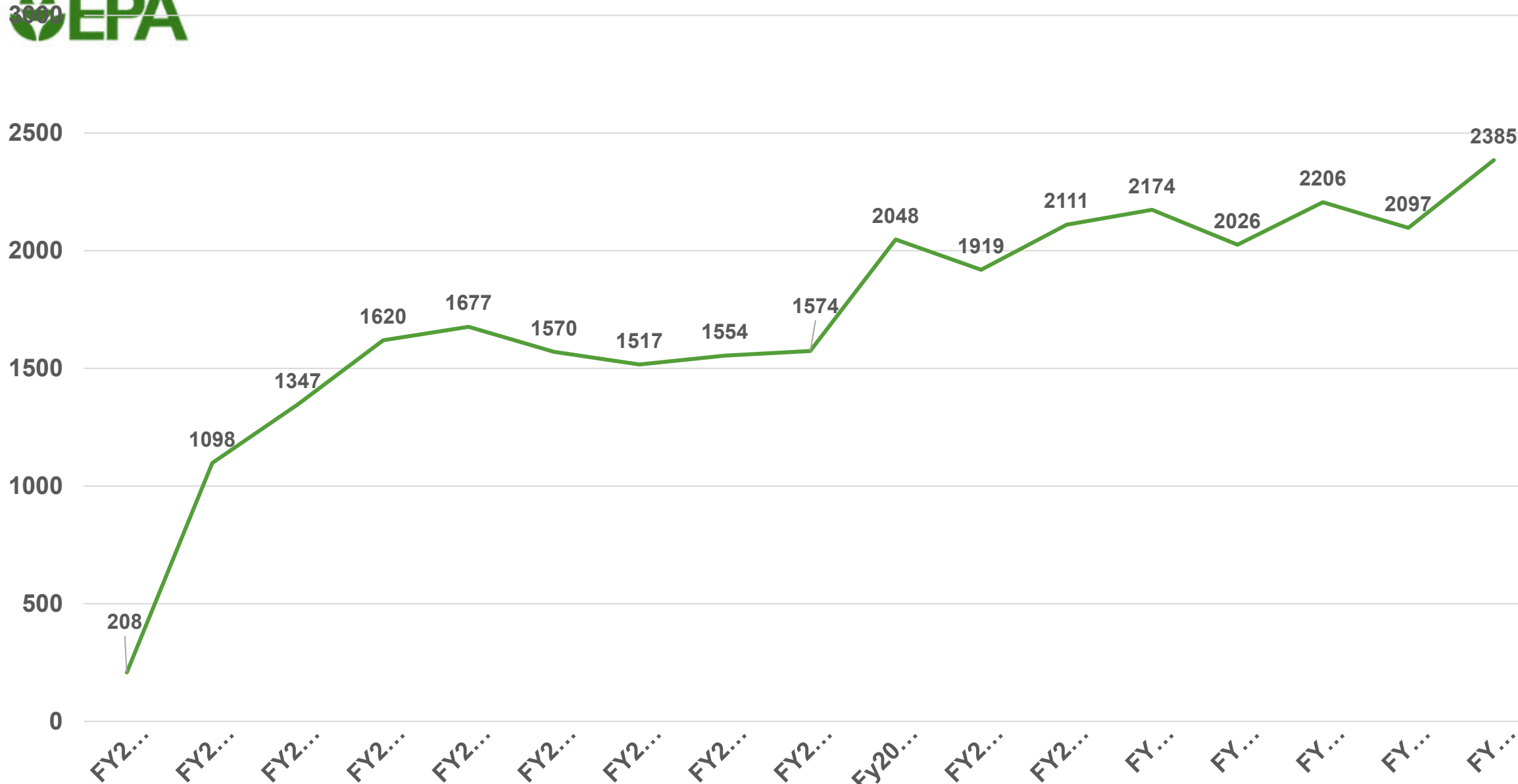
EOY Total FTE Usage for OPP from FY 2005 - FY 2020



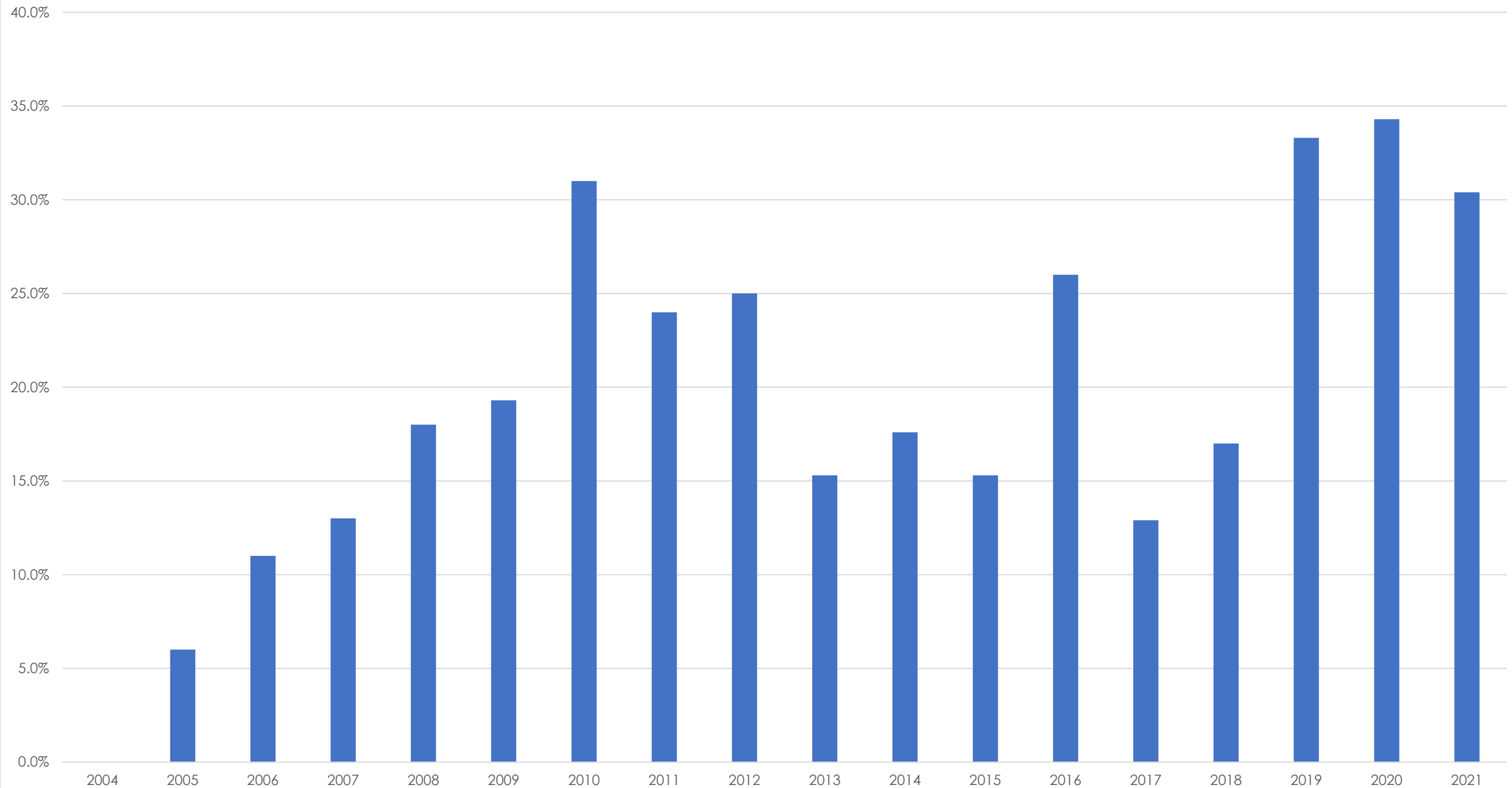
The Resources



PRIA Completions, FY2004 - FY2020



PRIA Renegotiation Rates, FY2004 to FY2021 (YTD)

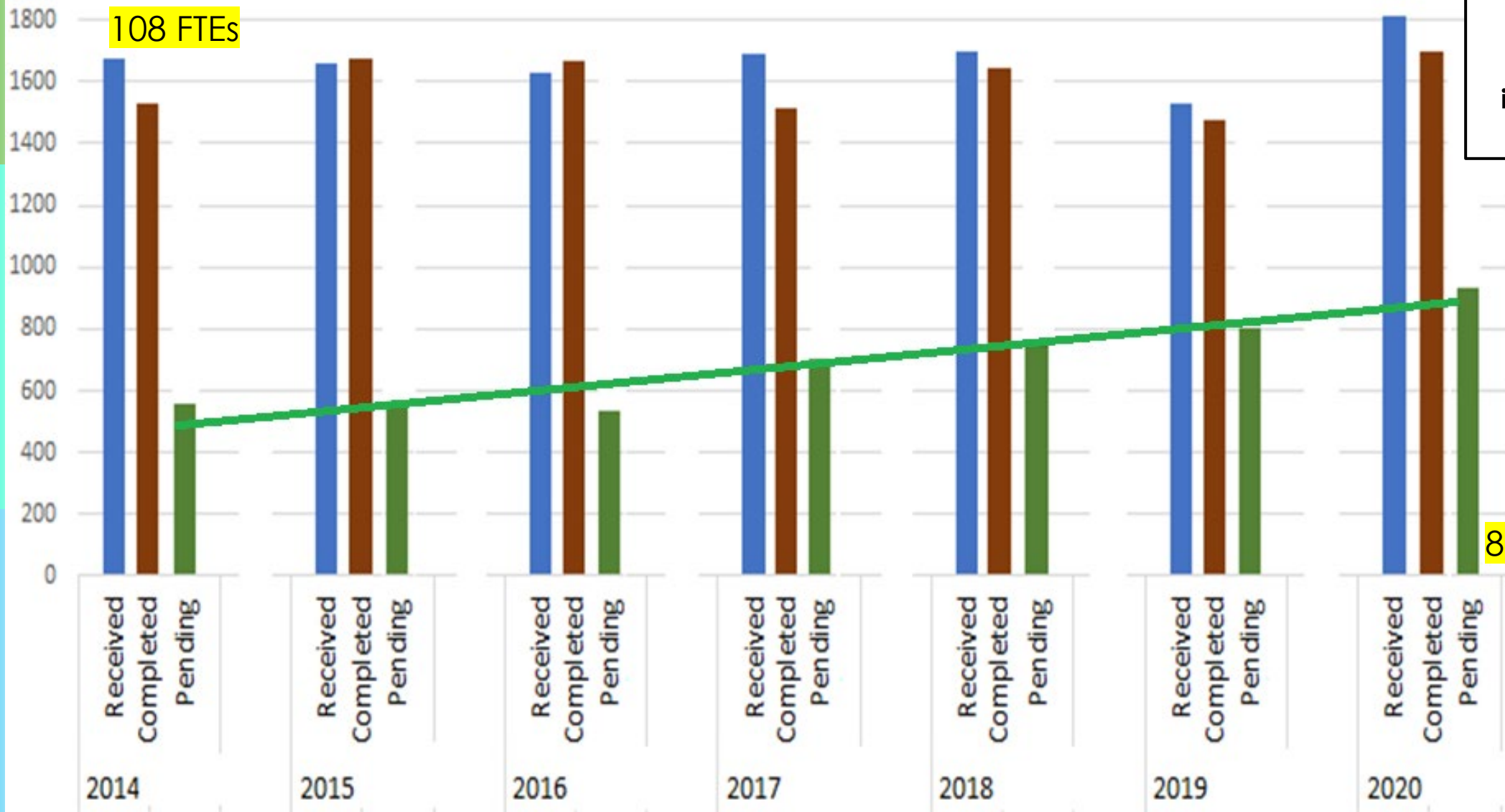


RD's PRIAs Received, Completed, Pending FY14-FY20



108 FTEs

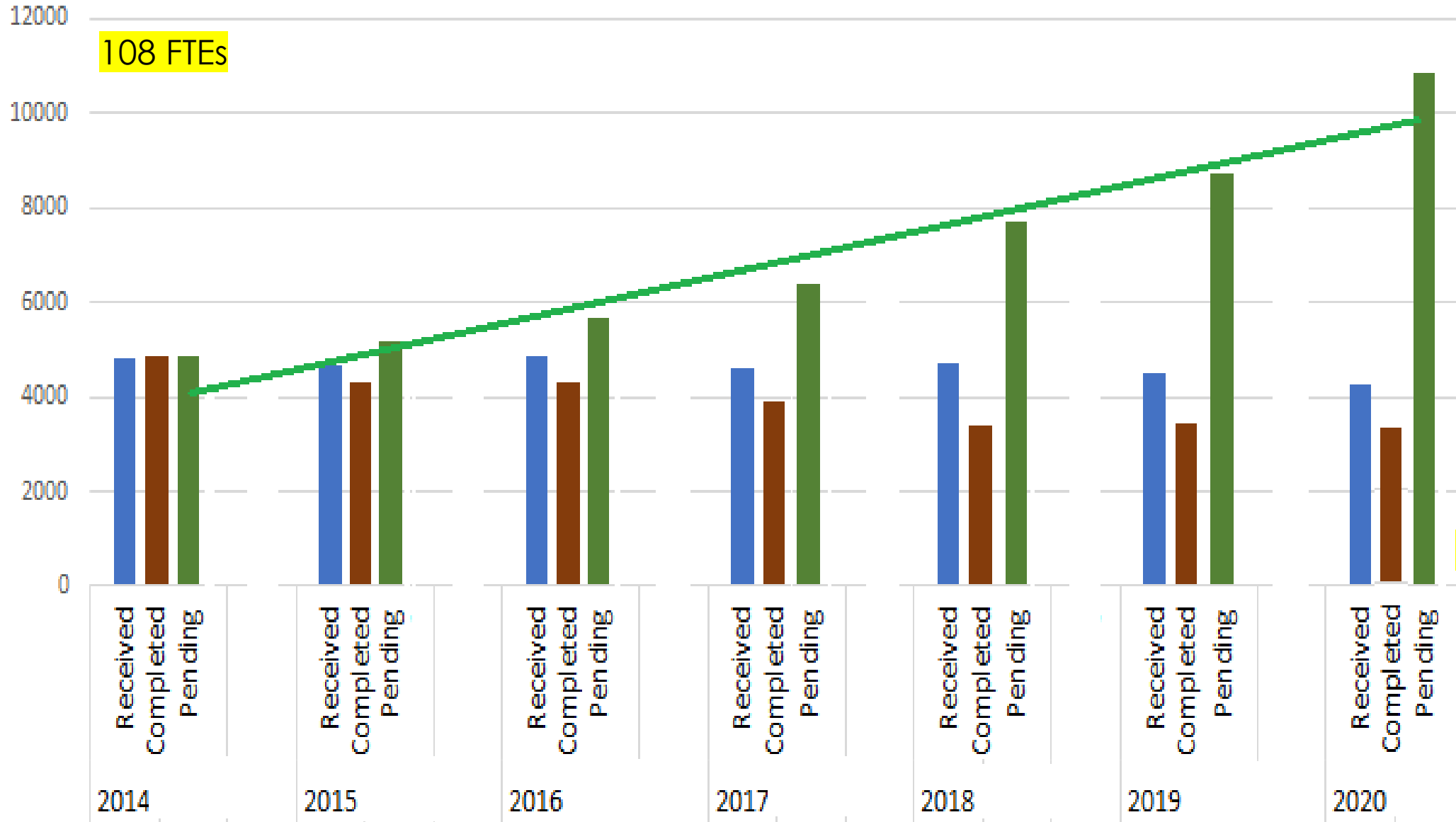
50% increase in
(to **900**
applications)
in pending PRIAs
since FY2014



87 FTEs

RD's Non-PRIAs Received, Completed and Pending

FY14-FY20



100% increase (to **11,000** applications) in pending non-PRIAs since FY2014

108 FTEs

87 FTEs

EPA COVID-19

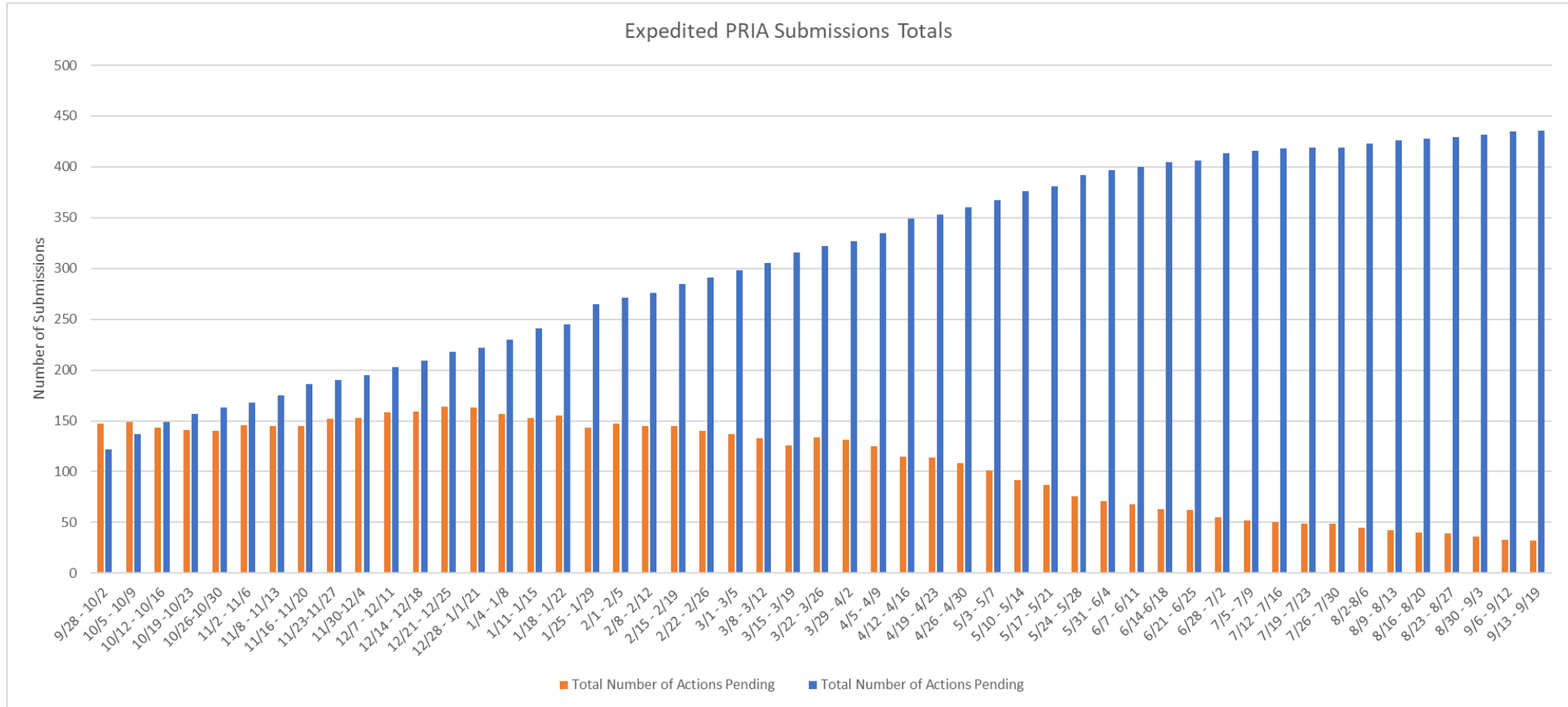
- Completed over 300 expedited actions, in response to COVID-19
 - added 73 products to List N (570 total)
- Completed laboratory efficacy testing of many List N products and other chemistries against human coronavirus strain 229E and SARS-CoV-2
- Registered Copper Surfaces for residual long-term effectiveness against Coronavirus on a wide range of surfaces, including doorknobs and handrails
- Issued emergency exemptions to 6 states for Grignard Pure indoor air treatment and 3 states for BIAXAM use on airlines
 - revoked emergency exemptions issued to TX and AR for SurfaceWise 2 due to company misconduct and scientific concerns regarding product performance.
 - considered new information to revoke Sec.18, including SSURO
- Approved the first disinfectant for alpha and beta variants
- Hosted a webinar on best practices for disinfecting schools & day cares



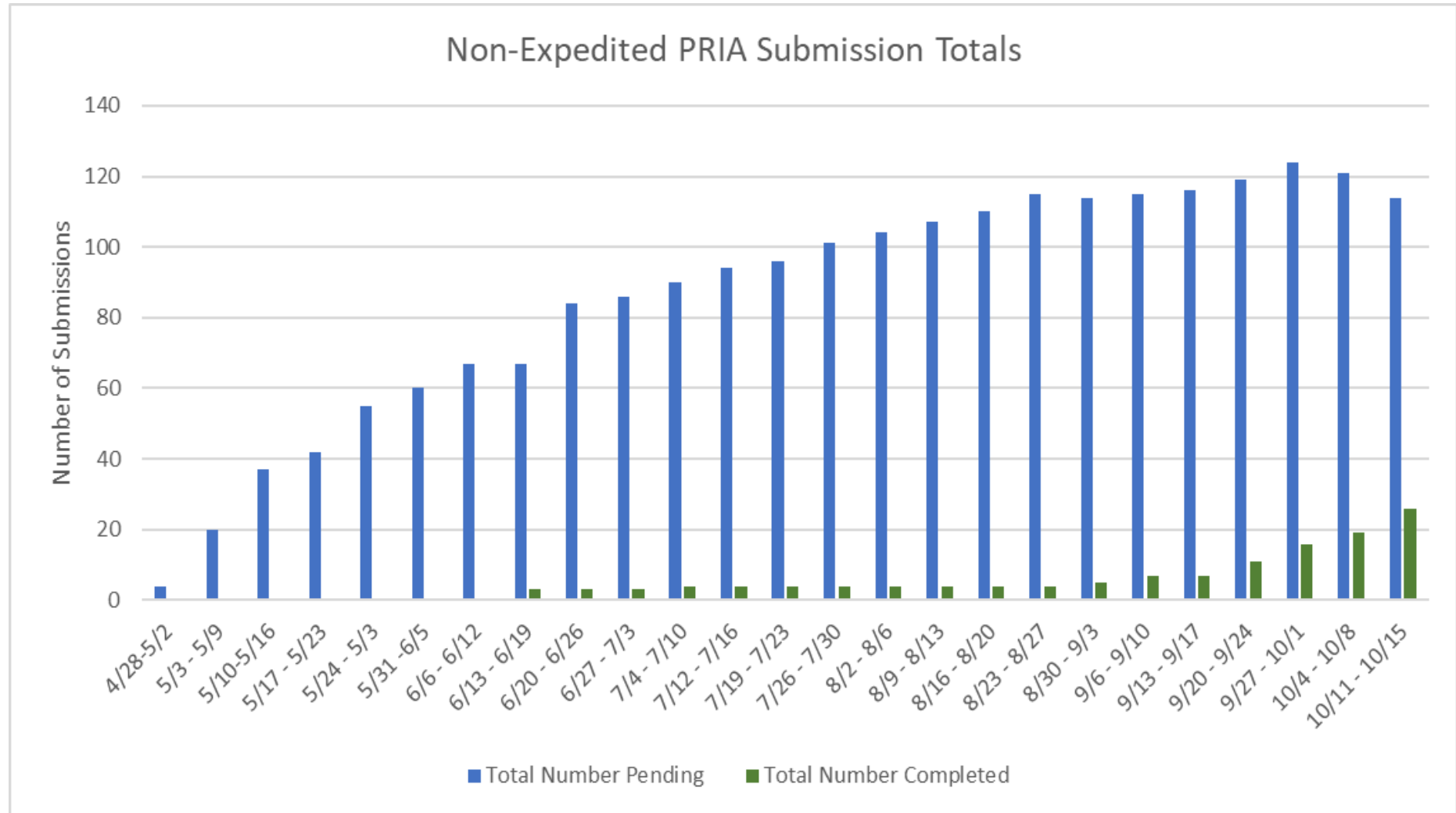
Disinfectant Policy Update

- In April 2021, the CDC announced that the risk of being infected with COVID-19 by touching contaminated surfaces is considered low.
- Given this information, EPA is no longer prioritizing public health emergency requests for new products that address surface transmission of SARS-CoV-2.
- EPA is shifting resources to expedite applications for products with novel COVID-19 claims, such as killing of airborne SARS-CoV-2.

PRIA Expedited COVID Submissions



PRIA Non-expedited COVID Submissions



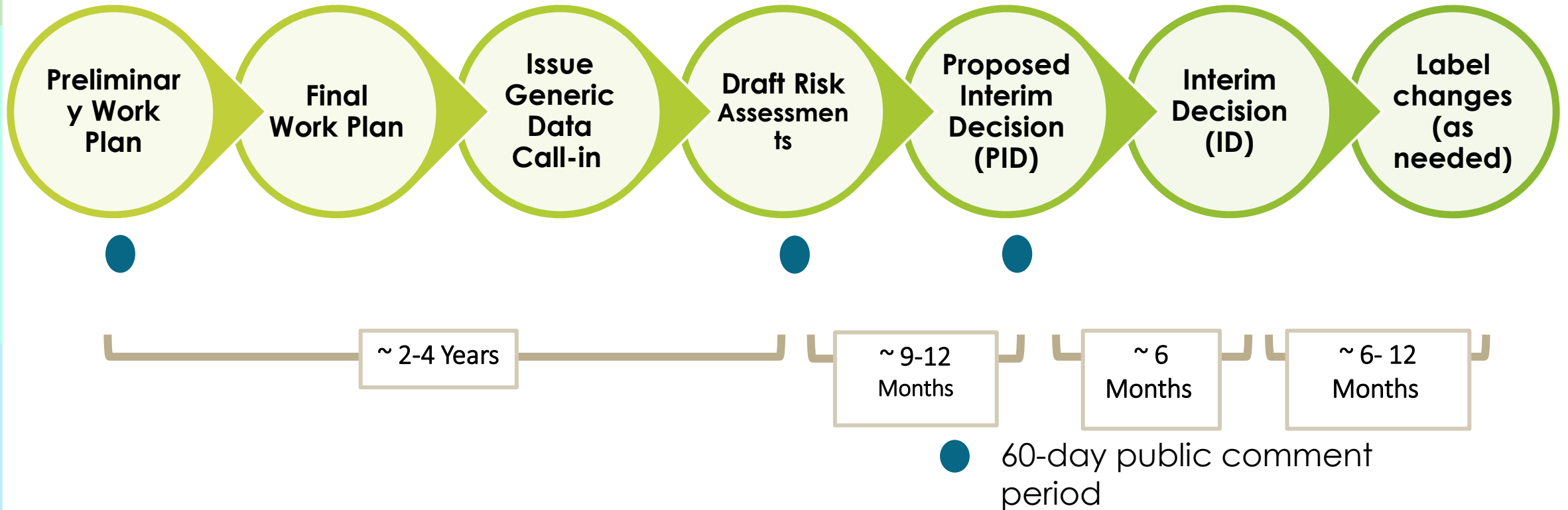


EPA Program Accomplishments

- 682 draft risk assessments completed (~94% complete!)
- 610 proposed interim decisions complete (~84% complete!)
- 555 final or interim decisions complete (~76% complete!)



Registration Review Process





Types of Data Required for Registration and Registration Review

- Product chemistry to assess labelling.
- Product performance data to support labelled pest claims.
- Data from studies to determine hazards to companion animals.
- Toxicity studies that determine hazard to humans.
- Residue chemistry data to determine the nature & magnitude of residues.
- Applicator and post-application exposure studies to determine exposure for workers and homeowners (residential).
- Environmental fate data.
- Data from studies to determine hazard to the environment.



EPA Registration Review Risk Reduction

- Under Round 1 (2007) 26 conventional chemicals have been canceled.
- More than 70% of conventional chemical decisions require human health and/or ecological risk mitigation.
 - Nearly 30% of decisions require human health risk mitigation
 - Nearly 60% of decisions require ecological risk mitigation

EPA Registration Review Risk Reduction

- **Reduced Bystander Exposure**

- Restricted application methods, application sites, aeration specifications and/or required a buffer or mandatory spray drift language for **ethofumesate, formetanate, gamma cyhalothrin, myclobutanil, paraquat, propargite and PPO** to protect bystanders near application areas.

- **Improved Worker Protection**

- Required mitigation such as adding or modifying personal protective equipment, reduced application rates, and/or eliminating uses for **dimethenamid, coumaphos, cyhalothrins (lambda and gamma), formetanate, flumioxazin, NAA, PPO, and terbacil.**
- Reducing application rates, adding application restrictions, negotiating use deletions or increasing restricted entry intervals (REIs) for **ethofumesate, formetanate, lambda cyhalothrin, myclobutanil and paraquat** to address post-application risks to workers.

EPA Registration Review Risk Reduction

- **Reducing Ecological Risk of Pesticides** – where applicable, Interim Decisions included measures to:
 - Reduce spray drift by either requiring minimum droplet size or adding advisory language
 - Reduce the risk of plants developing resistance to herbicides
 - Reduce potential risk to non-target organisms by establishing a maximum annual application rate
 - Reduce risk to non-target organisms by negotiating use deletions
- **Reducing Dietary Risks**
 - To reduce potential dietary exposure to formetanate, particularly for areas which rely on drinking water by means of private wells, EPA limited application only to areas with a soil pH above 6.5 where formetanate can readily degrade.



Registration Review Updates

Pentachlorophenol

- In March 2021, EPA issued the Proposed Interim Decision to cancel the registration of pentachlorophenol, the heavy-duty wood preservative used primarily on utility poles, due to significant human health risks to workers.
- After considering comments concerning the PID, EPA intends to finalize the decision to cancel.

Irgarol

- In April 2021, EPA issued the interim decision for irgarol on the cancelation of its use as an active ingredient in antifoulant paint due to risk concerns to both freshwater and marine plants, including causing the bleaching of coral.
- The interim decision will also protect public health by requiring irgarol powders—which are used to preserve sealants, vinyl roofing, cements, and other building materials—to be sold in packaging that reduces users' exposure.

EPA Registration Review Updates

Chlorpyrifos

- In August 2021, EPA issued the final rule revoking all “tolerances” for chlorpyrifos, which establish an amount of a pesticide that is allowed on food.
- EPA intends to issue a Notice of Intent to Cancel under FIFRA to cancel registered food uses of chlorpyrifos associated with the revoked tolerances.
- The tolerances for chlorpyrifos will be revoked on February 28, 2022, six months after the final rule published on August 30, 2021, in the Federal Register.
- The rule was issued in response to the Ninth Circuit’s order directing EPA to issue a final rule in response to the 2007 petition filed by Pesticide Action Network North America and the Natural Resources Defense Council.
- After considering public comments, the Agency will proceed with registration review for the remaining non-food uses of chlorpyrifos by issuing the interim decision by the end of 2022, which may consider additional measures to reduce human health and ecological risks.

EPA Registration Review Updates

Glyphosate

- In early February 2020, EPA issued the Glyphosate Interim Decision, which included mitigation and label changes to target pesticide sprays on intended pests, protect pollinators, and reduce the problem of weeds becoming resistant to glyphosate.
- In November 2021, EPA expects to release the final BE for glyphosate and initiate consultation with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service.

Paraquat

- In August 2021, released the interim decision for paraquat, finalizing new, stronger safety measures to reduce exposure.
- The ID includes the following enforceable mitigation measures:
 - Limiting aerial applications and requiring residential buffers
 - Prohibiting pressurized handgun and backpack sprayer applications
 - Requiring enclosed cabs or respirators for groundboom applications
 - Increasing the Restricted Entry Interval (REI) for several crops



Registration Review Updates

Carbaryl

- On June 8, 2021, EPA released a revised draft human health risk assessment and a draft ecological risk assessment for carbaryl, a N-methyl carbamate insecticide used to control pests in terrestrial agricultural use sites.
- Specific findings in the revised draft human health risk assessment include residential, occupational handler, and aggregate risks of concern. EPA found no dietary risks of concern.

Sulfuryl Fluoride

- In May 2021, EPA published the Sulfuryl Fluoride Draft Interim Re-entry Mitigation Measures Memorandum in response to an Office of Inspector General audit and extensive analytical testing in OPP's Ft. Meade chemistry laboratory.
- This early mitigation was proposed to address potential re-entry risks from the use of SF in residential fumigation in advance of the regular Registration Review schedule.
- The comment period for this early mitigation and the risk assessments closed on September 23, 2021.



Registration Review Updates

Neonicotinoids

- In February 2020, EPA published the Proposed Interim Decisions for the neonicotinoids; **acetamiprid, clothianidin, dinotefuran, imidacloprid, and thiamethoxam** with proposed new measures to reduce potential ecological risks, particularly to pollinators.
- After reviewing public input, the agency anticipates issuing Interim Decisions in 2022.
- In August 2021, EPA released its draft biological evaluations (BEs) for clothianidin, imidacloprid and thiamethoxam.
- The draft BEs found that each chemical is likely to adversely affect at least one individual of certain listed species under the Endangered Species Act or their designated critical habitats.



Registration Review Updates

Rodenticides

- The draft risk assessments for the rodenticides were completed in 2020.
- The comment period closed and comments are being considered in drafting the Proposed Interim Decisions, which EPA plans to issue in 2022.
- The Interim Decisions for the rodenticides are also scheduled for 2022.

Pyrethroids

- Throughout 2020 and 2021, EPA published numerous proposed interim decisions as well as some interim decisions for the pyrethroids.
- EPA plans to publish the remaining pyrethroid interim decisions in 2022.



New Guidance, Methodologies and Models

- Issued Guidance to Waive Toxicity Tests, allowing researchers to forego testing chemicals on animal skin in certain circumstances to determine whether pesticides lead to adverse effects:
 - expected to save up to 750 test animals annually from unnecessary testing
- Issued Test Guidelines for Fire Ants and Invertebrate Pests of Pets
- Issued 3 new methodologies to improve surface water drinking water assessments
- Issued Analysis of Subsurface Metabolism in Groundwater Modeling for public comment
- Issued interim guidance and associated test methods for registering products that claim to have "residual" or "long-lasting" efficacy claims against SARS-CoV-2
- Terminated temporary guidance for protective equipment (e.g., respirators, amendments to PRN 98-10) due to return to adequate supplies following shortages in FY 2020 due to COVID-19
- Initiated ASTM review process for draft method for quantitative testing of antimicrobial products following extensive stakeholder collaborations



PFAS and Pesticide Containers

- In September 2020, EPA became aware of PFAS contamination of a mosquito control product used in Massachusetts.
- In December 2020, EPA studied the fluorinated high-density polyethylene containers used to store and transport the product and determined the fluorination process used may be the source of the contamination.
- In March 2021, EPA became aware of a second mosquito product, used in Maryland, that may be contaminated with PFAS and released testing data showing PFAS contamination in the containers was extremely small.
- In September 2021, EPA released an internally validated method for the detection of 28 PFAS compounds in oily matrices, such as pesticide products formulated in oil, petroleum distillates, or mineral oils.
- The new method is intended to help pesticide manufacturers, state regulators, and other stakeholders test oily matrix products for PFAS.



Registration Review Updates

Collecting Pet Incident Data

- In August 2021, EPA announced its plan to collect pet incident data on **MGK-264, piperonyl butoxide, pyrethrins, and amitraz**, used in agricultural and non-agricultural settings, including residential pet products.
- These data would allow the agency to conduct a comparative assessment of pet incidents across registered pet products to better determine whether changes to pet product registrations and labels are necessary.
- EPA also sought public comment on petition for Seresto Pet Collars.

EPA FY21 Registration Highlights

Dicamba

- On September 9, 2021, EPA sent letters to registrants of products containing dicamba for post-emergent uses, reiterating their legally required duty under FIFRA section 6(a)(2):
 - *if at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects of the pesticide, the registrant shall submit such information to EPA.*
- Currently, EPA is working with growers, state agencies and other experts to evaluate the effectiveness of the current requirements.
 - EPA held a dicamba listening session on Aug. 30, 2021, with the Weed Science Society of America, various academics, state agriculture extension agents, and the U.S. Department of Agriculture.
 - On Sep. 2, 2021, the Agency held another listening session with the Association of American Pesticide Control Officials.



Agricultural Worker Protection Standard Application Exclusion Zone Rule Update

- Until further notice from EPA, the 2015 WPS remains in effect with no changes to the AEZ provisions
 - Final Rule published October 30, 2020
 - December 2020 - Lawsuits filed challenging AEZ Final Rule; proceedings stayed by the court
 - Preliminary injunction has stayed the effective date
 - EPA enjoined from implementing the provisions
 - Preliminary injunction in effect until December 20, 2021
 - Ongoing litigation could extend injunction

EPA Certification of Pesticide Applicators Rule

- On October 19, 2021, EPA provided information on the March 2022 regulatory deadline in Certification for Pesticide Applicator Rule
- EPA regional teams are coordinating with headquarters staff on finalizing agency review of submitted certification plans. To date, EPA:
 - completed review of 29 of 63 state, territory, and tribal certification plans
 - plans to complete the remaining reviews within a couple months
 - plans to complete reviews of the federal agency certification plans
- EPA acknowledges the many challenges facing certifying authorities to meet the 2017 rule timeframes to revise certification plans
- Prior to October 1, 2021, EPA was unable to take action on revising the certification rule because of a prohibition of such actions imposed by the Pesticide Registration Improvement Act of 2018 (PRIA 4)
- EPA is in the process of developing a rule that would extend the date by which plans must be approved and ensure existing plans can remain in place during this time-limited extension

EPA FY21 Process Improvements

- Launched new process improvement efforts and visual management to better track issues with new pesticide active ingredients to address common issues with application packages
- Converted paper process for Gold Seal Letters to an electronic system for Industry exports of pesticides
 - hosted a public webinar to explain changes to the process for issuance of Gold Seal Letters
- Developed device determination tracking system
- Reduced backlog of ecological incidents in the Incident Data System by more than 60%
- Developed additional, new SOPs to gain efficiencies for individual pesticide workflows
- Continued to deploy IT Modernization and Digital Transformation Work



Thank You!



Questions & Answers