January 6, 2025

To: Joel Brubaker, President-Elect Trump Transition Team, U.S. Environmental Protection Agency

From: PRIA Coalition

Date: January 6, 2025

Re: Recommendations in Support of the U.S. Environmental Protection Agency

Office of Pesticide Programs

On behalf of the Pesticide Registration Improvement Act (PRIA) Coalition, which represents the industry that manufactures and distributes pest control solutions for growers, facilities managers, public health workers, animal health professionals, farmers, pet owners, pest control operators, lawn care professionals, and consumers, the undersigned organizations wish to convey recommendations to the presidential transition team – to ensure a fully resourced and predictably functioning Office of Pesticide Programs (OPP) in the U.S. Environmental Protection Agency (EPA). The PRIA Coalition is steadfast in its support for OPP and has undertaken robust advocacy campaigns supporting the timely reauthorization of PRIA with the goal of strengthening business-critical pesticide licensing activities performed by OPP, improving regulatory outcomes, and ensuring OPP has the capacity to fulfil its mission to register pesticides according to predictable timelines while protecting human health and the environment.

Background

Pesticides are a broad range of important products essential for crop protection, mosquito and pest control, disinfectants, water treatment chemicals, materials preservatives and more. Pesticides must be registered by OPP, which carefully reviews the risks and benefits of each product before it can be legally offered for sale in the United States. Pesticides are regulated within OPP under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

OPP's regulatory process is rigorous, taking up to 10 years before a new product is registered for sale and use. OPP's evaluation includes scientific reviews of product data, the potential impact on people, the environment, animals, and its effectiveness against pests and pathogens. The registration process begins with the submission of an application package by the pesticide registrant – a company that manufactures or formulates pesticides. OPP examines the ingredients of the pesticide; the ways and places the product will be used; the amount, frequency, and timing of its use; and storage and disposal practices. OPP also assesses the potential impacts to human health to ensure there is reasonable certainty of no harm to people and no unreasonable adverse effects to the environment, including non-target animals and endangered species.

In 2004, Congress enacted the Pesticide Registration Improvement Act (PRIA), modeled after user fee programs for prescription drugs and medical devices. The Act has been reauthorized on a bipartisan basis four times since then and prescribes a schedule of fees charged to registrants for pesticide registration actions under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). PRIA also established a companion program of product maintenance fees which supports re-review of each product registration on a 15-year cycle. The fees support personnel and technology at OPP specifically dedicated to registration activities.

In exchange, the law establishes timelines for those registration actions. Pesticide products that benefit from PRIA include not only crop protection products, but antimicrobials, biopesticides, disinfectants, and other products that protect human health, animal health, communities, and the environment. Under the law, OPP must meet statutory decision deadlines that enable new products to come to market and research and development investments to be made with confidence of market access. And the legislation requires EPA to report to Congress on its progress for completing its reviews and other defined actions on established timelines.

PRIA 5, enacted on December 29, 2022, increased fees paid by the pesticide industry for registration services by 30 percent from levels enacted in 2018. PRIA 5 also includes funding for worker protection education programs, pesticide risk reduction programs, and partnership grants. Years of declining OPP staffing, outdated information technology systems, and process deficiencies are delaying performance innovations and availability of critical pest control solutions for growers, facilities managers, public health workers, pest control operators, lawn care professionals, and consumers.

Office of Pesticide Programs (OPP)

OPP's core functions reside within seven divisions, they include:

- Antimicrobials Division (AD): responsible for all regulatory activities associated with antimicrobial pesticides.
- **Biopesticides and Pollution Prevention Division (BPPD):** responsible for all regulatory activities associated with biologically based pesticides, including product registration, amendments, experimental use permits, registration review. BPPD activities also include work to reduce pesticide risks.
- **Registration Division (RD):** responsible for regulatory activities associated with conventional chemical pesticides, including product registrations, amendments, tolerances, experimental use permits, and emergency exemptions, as well as evaluation and approval of inert ingredients.
- **Pesticide Reevaluation Division (PRD):** responsible for registration review and reregistration follow-up for conventional pesticides including, post-registration status activities, product reregistration and implementing certain tolerance reassessment decisions.
- **Biological and Economic Analysis Division (BEAD):** responsible for providing pesticide use-related information and economic analyses in support of pesticide regulatory activities.
- Environmental Fate and Effects Division (EFED): responsible for assessing the environmental properties and ecological effects of pesticides.
- Health Effects Division (HED): responsible for assessing pesticide exposure and risks to humans.

Budget & Appropriations

Because PRIA fees paid by pesticide registrants are intended to *supplement* rather than *supplant* annual appropriations for the licensing of pesticides, PRIA has included a "minimum appropriation," which is intended to sunset fee collections when annual appropriations fall below the minimum. This amount was commensurately increased by 30% to \$166 million in PRIA 5 to mirror the increase in fees paid by registrants. Total funding for the OPP under the Interior, Environment and Related Agencies funding bills (including PRIA activities) has fallen from a high of \$144 million in fiscal year 2004 (\$237 million current value¹). Fiscal year 2024 and proposed fiscal year 2025 funding levels were far below both budget requests and the minimum appropriations level in statute, which will further degrade OPP's ability to fulfill its statutory remit and adequately administer the pesticide program.

¹ CPI Home: U.S. Bureau of Labor Statistics

Federal funding for OPP is appropriated across *three* different funding accounts, with the bulk of OPP pesticide registration staff funded through the Environmental Programs and Management (EP&M) account. The PRIA Coalition supports the funding level of \$166 million required in PRIA 5, including \$147.1 million for the EP&M account, as well as maintaining funding in other two EPA accounts (State and Tribal Assistance Grants, or STAG, and Science and Technology, or S&T) that fund OPP.

Office of Pesticide Programs – Federal Appropriations

(In Millions of Dollars)

				FY 2025		
	FY 2022	FY 2023	FY 2024	President's Budget	Committee Recommendation	PRIA Coalition Request
Environmental Programs & Management	\$110.196	\$120.277	\$115.375	\$152.202	House: \$115.375 Senate: \$118.901	\$147.1
Science & Technology	\$5.886	\$6.153	\$5.900	\$11.181	House: \$0.000 Senate: \$6.376	\$5.9
State & Tribal Assistance Grants	\$13.294	\$14.027	\$13.000	\$14.027	House: \$13.000 Senate: \$13.000	\$13.0
Total	\$129.376	\$140.457	\$134.275	\$177.410		\$166.0

The imbalance between user fees and appropriations has left pesticide registrants with a disproportionate increase in fees and commensurate decrease in efficiency.

Recommendation:

A fully functional and efficient OPP is a business-critical licensing function for American manufacturers and their customers. The PRIA Coalition strongly encourages the Trump Administration to include additional funding necessary for EPA to review and approve pesticide registration actions on predictable timelines, so companies can bring innovative new products, and product uses to the marketplace.

Continue Ongoing OPP Work

OPP has initiated a number of important and helpful process improvements to clarify and streamline the registration, registration review, and related processes. Specifically, we ask that the Office continue its work in the following areas:

- Pesticide Registration Notice (PRN) 98-10 Revisions: Continue stakeholder engagement and development of updated draft to release a revision of 98-10 for public comment in FY 2025.
- Non-PRIA Backlog Reduction: Continue efforts to reduce the backlog through multiple approaches (e.g., focus and streamlined review of fast-tracks, non-PRIA amendment consolidation and prioritization, keep up with new notifications, non-PRIA stand down days, etc.)
- **Draft PRN 98-1 Product Chemistry Self-Certification:** Continue development of updated draft to release a revision of 98-1 for public comment that would expand ability for product-chemistry self-certification.
- Structured and Digital Labeling Efforts: Continue evaluation of a "proof of concept" data model that captures labeling data electronically and continued engagement with Pesticide Program Dialogue Committee (PPDC) Label Review Workgroup and state lead agencies.

- Increasing Predictability in Conventional Acute Toxicity and Product Chemistry Review
 Times: Take process improvement steps to provide more predictable timelines for pesticide
 product registration completion to registrants earlier in the process.
- **Draft Revised Confidential Statement of Formula (CSF) Formatting Scheme:** Consideration of a revised formatting scheme to allow for active ingredient sources with different purities to be on the same alternate CSF.
- Information Services Branch (ISB) Process Improvements: Update guidance for fee waivers, company transfers, company contacts, and payment processing/verification; work to digitize jackets, and continue maintenance fees process improvements.
- **Greater Use of Salesforce in Science Divisions:** Expand use of Salesforce in science divisions to provide more predictable timelines for completion.

Additional OPP Optimization

While the PRIA Coalition will continue to advocate for resources for OPP and to work with the Office on these ongoing initiatives, we also propose ideas to further optimize key policies and processes, without sacrificing OPP scientific rigor and independence. OPP must undertake substantial efforts to identify and implement impactful process and transparency improvements, given ongoing challenges around the number of submissions, reduced staffing, and outdated technology. Process and transparency improvements should focus on better understanding and utilizing registrant research and development processes and analyses to optimize risk assessment workflow, in addition to the identified process improvements outlined below:

Independent Third-Party Assessment of Agency Performance & Processes

Under PRIA 5, OPP must conduct an independent third party workforce and process assessment. The audit is critically important to improving OPP's service. The audit is intended to review and make recommendations about OPP's processes and performance. The agency has signed a contract with a vendor to conduct the audit, which, by statute, must be completed by December 29, 2024. The PRIA Coalition is concerned this deadline will not be met.

The third-party assessment must review OPP's:

- 21-day content screen;
- 45/90-day technical screen;
- Performance, processes, and progress towards reducing renegotiation rates and the average length of 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 specified deadlines;
- 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; and
- Performance, progress, and processes in completing registration review; and other appropriate issues, such as submissions by inert suppliers and fast-track amendments.

Recommendation:

The PRIA Coalition urges EPA leadership to facilitate a thorough, independent third-party assessment as required by law to identify critical process and infrastructure deficiencies and what regulatory improvements and process efficiencies can be implemented in advance of the scheduled fee increase and reauthorization of PRIA.

Missed PRIA Deadlines

According to OPP's own data, across the registering divisions, the Agency is missing its statutory timelines to complete regulatory decisions about 60 percent of the time and there is little predictability for timeframes. Missed and unpredictable decision review times – of both PRIA and non-coded PRIA actions (minor label changes, including notifications and amendments) – prevent market entry of new tools and novel chemistries to control pests, invasive species, diseases, and pest resistance.

Recommendation:

The agency must improve OPP transparency to provide estimated completion dates for each PRIA action. EPA OPP should leverage registrant capabilities to reduce their workload and meet PRIA statutory timelines. EPA leadership should also review the current structure of OPP divisions to better support robust risk assessment processes.

Information Technology Modernization

Salesforce has been working with OPP to modernize its information technology system. Salesforce migration was completed for all registering divisions late in 2023. Modernization of OPP's information technology system and implementation of a dashboard for registrants will provide real-time, accurate tracking system for all regulatory submissions. This initiative will provide registrants with confidential, real-time, accessible information on the status and progress of their regulatory submissions, thereby providing additional transparency and predictability in regulatory decisions.

Recommendation:

The PRIA Coalition recommends continuation of the Salesforce initiative to establish an information technology system that includes all registering and science divisions and provides real-time tracking systems for all regulatory submissions.

The benefits delivered by PRIA extend far beyond pesticide manufacturers. Whether the customer is a consumer, business, institution, utility, or government, each stakeholder relies on the availability of EPA-registered pesticides. Products protect homes, pets, livestock, yards, landscapes, sports fields, trees, structures, highway and utility rights of way, ground transportation routes and shipping lanes. Public health, institutional, and medical professionals can count on products to provide potable drinking water, clean swimming pools, and disinfected and rodent-free spaces and surfaces in hospitals, restaurants, airplanes, and school cafeterias. Predictable access to products also ensures that tools are available to protect pets from insect-borne diseases and parasites and keep food animals healthy and pest free. Innovative pest solutions also help protect military personnel from dangerous and nuisance pests when deployed overseas or stationed at home. Timely access to pesticides helps farmers and ranchers raise healthy crops to feed people and animals here in the U.S. and for export.

A well-resourced and transparent pesticide regulatory program is critical to a broad array of every U.S. business and citizen. Businesses need predictable review timelines to make critical short and long-term planning decisions that keep the supply of new and existing pesticide products available in the marketplace for consumers, professionals, and growers. Industry needs the predictability of PRIA's timelines to support new product research and development, delivering important pest solutions for known and emerging pests and pathogens.

We appreciate your attention to these topics and are available for further discussion.

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