Business Processes Review and Optimization for EPA Office of Pesticides Programs

FINAL REPORT

September 30th, 2025

EPA BPA Contract #68HERC24A0003

TABLE OF CONTENTS

1. EXECUTIVE SUMMARY

1.1 Objectives and Approach

In early 2025, the Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP), in collaboration with Censeo Consulting Group, launched a Business Process Review (BPR) to evaluate and optimize key pesticide registration functions. This third-party assessment, conducted in alignment with mandates from the Pesticide Registration Improvement Act of 2022 (PRIA 5), aimed to identify operational improvements that could reduce backlogs, streamline reviews, and strengthen internal coordination.

The BPR centered on OPP's core registration processes, with **deep dives into three key areas: the initial content screen, preliminary technical screen, and registration review process**. **Additional analyses** covered the non-PRIA submission process, renegotiation protocols, workforce training, and IT system integration. This final report is informed by review of more than 100 documents and over 20 stakeholder interviews with nearly 80 EPA staff and registrants. Based on these inputs, Censeo conducted root cause analysis and synthesis of ongoing improvement initiatives using Censeo's holistic four-pillar (process, people, policy, and systems) evaluation framework to identify improvement opportunities.

Across all the topic areas, Censeo developed 79 recommendations for OPP to consider, 57 from the three deep-dive areas, and 22 from the progress assessments.

1.2 OPP Progress to Date

Before exploring the enduring challenges and potential solutions that Censeo uncovered, it is worth acknowledging the significant progress OPP has already made in modernizing its operations, improving registrant experience, and strengthening internal coordination. The office has actively worked to align its regulatory review processes with the goals of PRIA 5, while also investing in a digital transformation that extends beyond the statute's immediate requirements. Notably, OPP has replaced its outdated systems with a modern, Salesforce-based internal tracking system, including the registrant-facing MyPest portal, to improve registrant facing communication, create structured task flows, and improve visibility into application milestones. This system modernization—alongside EPA's broader digital transformation strategy—has laid the groundwork for future automation, performance monitoring, and inter-division coordination.

OPP has also made important strides to reduce the time and cost of reviewing and processing applications by expanding guidance for registrants. These resources now include best practices for non-PRIA cover letters, examples of common deficiencies identified during the initial content and preliminary technical screens, and action-specific checklists to support more complete submissions. This proactive guidance has helped reduce application errors, easing the burden on OPP reviewers and enabling more efficient processing.

Finally, OPP has implemented several measures to improve its own consistency and efficiency when processing PRIA and non-PRIA applications. PRIA-aligned protocols have been codified through updated templates and internal memos—especially around renegotiations and internal waivers—which should help establish clearer decision-making accountability. Significant effort has also been made to reduce the non-PRIA backlog of applications. OPP implemented streamlined reviews, scheduled time for teams to focus specifically on addressing non-PRIA applications, worked with registrants to withdraw outdated applications, and increased cross-training efforts to enable staff across divisions to work on non-

PRIA reviews. These endeavors have allowed OPP to considerably reduce the number of applications in the backlog and prevent the backlog from growing further.

These efforts signal that OPP is not only responsive to statutory reform under PRIA 5, but also proactively working to create a more transparent, efficient, and accountable pesticide registration system. As the organization continues to mature its digital platforms and refine its workflows, it is well positioned to take on more ambitious reforms.

1.3 Key Barriers to Efficiency

While OPP has made meaningful strides in improving core operations, our review—focused specifically on the deep dive processes of the initial content screen, preliminary technical screen, and registration review—surfaced persistent challenges that continue to impact efficiency and predictability. These barriers span multiple functions and levels, creating ripple effects across application review, decision-making, and coordination. Censeo's root cause analysis revealed three fundamental issues that pervade multiple processes under review:

1. **Underutilized tools and poor data quality**: While Salesforce offers key functionality to manage registration workflows, it is not yet fully aligned with the day-to-day needs of all users and still requires a fair amount of manual processing. As a result, some staff continue to work outside the system—communicating via email or tracking actions offline—which can reduce case visibility and limit the ability to automate tasks or flag emerging issues. Additionally, much of the initial application processing and screening occurs outside the system. Without full adoption of a unified system to manage OPP workflow, leadership cannot easily identify bottlenecks or reallocate resources to optimally manage its workload.
2. **Process fragmentation and unclear ownership**: Review steps are distributed across branches without clear responsibility for handoffs, leading to duplicative reviews, gaps in accountability, and inconsistent application of screening criteria.
3. **Limited guidance and knowledge gaps**: Many reviewers rely on outdated templates or informal peer support to learn key procedures. The absence of up-to-date standardized job aids or decision support tools results in high variability and delays, especially when turnover rates increase and newer staff join mid-review. This can lead to inconsistent decisions, higher error rates, an increased need for rework or clarification, and a general reduction in efficiency, all of which can reduce confidence in the process internally and externally.

These barriers are not isolated – they compound across stages and reinforce one another. For example, the absence of standardized tools exacerbates data entry inconsistencies, which in turn limits the value of performance dashboards or tracking systems.

1.4 Strategic Levers for Improvement

The 79 unique recommendations developed in this review and the additional actions in the related topic areas are designed to address these systemic challenges head-on, starting with how OPP coordinates across branches, manages data, and equips staff. Rather than broad or generic changes, **our recommendations identify practical, high-impact improvements that can be implemented incrementally**. These recommendations provide a **roadmap for reducing cycle times, improving consistency, and enhancing the registrant experience** – focusing on targeted, high-leverage fixes to the processes, tools, and norms that shape OPP's day-to-day operations. Our recommendations fall into three strategic opportunity areas:

1. **Automating Workflows and Modernizing Technology**: Reducing manual effort and enabling more seamless, system-supported reviews are critical to reducing processing timelines. A consistent theme in our recommendations is the need to fully develop and use existing tools (like Salesforce) more effectively and to ensure the integrity of data in those tools. Targeted improvements include:
    a. Automating key steps in the initial content and preliminary technical screens
    b. Creating a web-based portal for study submissions and a searchable database of past registration decisions
    c. Improving file storage and data quality within Salesforce to ensure easier access and enable data-driven decision making
    d. Enabling registrants to edit their own submission forms and expanding targeted Salesforce training to improve data entry accuracy and usability among OPP staff

2. **Driving Standardization Across Processes**: A key set of recommendations target inconsistencies that create unnecessary variation and rework. Greater standardization across process steps, submission formats, and terminology is key to improving both speed and quality – especially when paired with stronger data practices. Priority actions in this area include:
    a. Creating a uniform triage protocol and standardizing formats for science summaries
    b. Establishing a regular cycle to review and update policy documents and job aids to align with the latest regulatory guidance and interpretation
    c. Defining shared terminology and status labels to reduce internal ambiguity and improve registrant clarity
    d. Requiring consistent submission elements – such as structured cover letters and e-label formats – and improving how those inputs are logged and tracked in systems

3. **Fostering a Customer-Focused Culture**: Several recommendations focus on improving how OPP teams coordinate across branches and how they communicate with registrants. Central to this is ensuring that registration timelines and policy changes are visible and reliable – enabling shared ownership and more proactive engagement. Key improvements include:
    a. Sharing technical screen checklists with registrants and automating screen result notifications back to registrants
    b. Improving registrant-facing communication about PRIA codes, policy updates, application progress, and overall expectations
    c. Establishing clearer service standards and encouraging consistent use of pre-registration meetings
    d. Promoting a culture of transparency and accountability by ensuring systems are used consistently to track actions and outcomes

1.5 Anticipated Benefits and Organizational Impact

If implemented, the recommendations outlined in this report would **enable OPP to shift from reactive management to proactive, performance-driven operations**. These improvements go beyond efficiency gains – they unlock more powerful business intelligence, reduce regulatory friction, and build the infrastructure necessary to meet both current and future workload demands. **Key outcomes OPP can expect include**:

- **Faster cycle times** for early-stage screens and registration review, with process improvements through clearer roles, automation, and triage improvements

- **Higher data quality and performance visibility**, enabling leadership to make informed resource decisions, monitor throughout, and respond to potential threats early
- **Reduced staff rework and confusion**, as more consistent training, checklists, and process documentation improve clarity and coordination across roles
- **Improved registrant experience**, with faster feedback, more consistent communication, and greater confidence in OPP's timelines and process clarity

Benefits of improvements are likely to be gradual at the beginning and accelerate over time. Depending on the pace of OPP's implementation and other variables (e.g., resourcing levels/strategies, policy changes), **executing the recommendations in this report are conservatively estimated to yield 10-25% year-over-year increases in efficiency** over the next several years. Assuming application volumes remain constant, OPP could eliminate their application backlog in under five years while significantly increasing compliance with PRIA timelines for new applications.

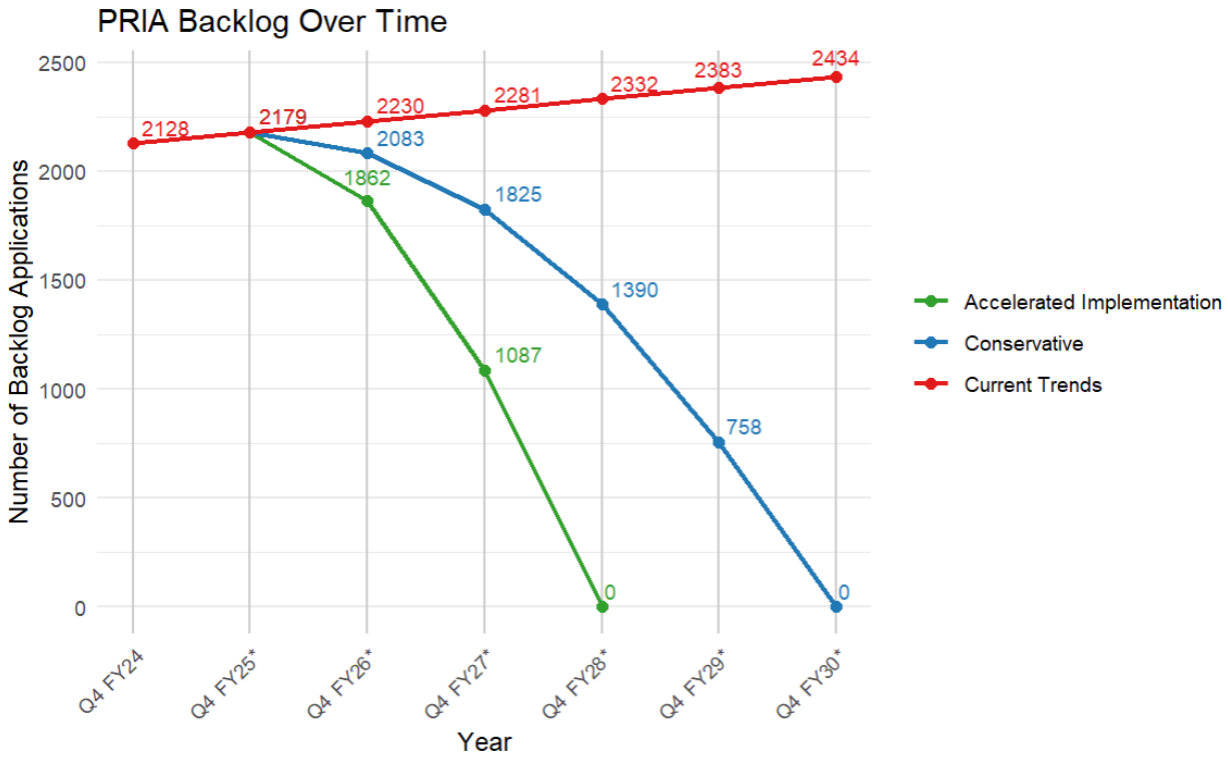

Figure 1: Annual improvements in efficiency could significantly reduce or eliminate the backlog in 3-5 years.

** Denotes projected values*

These benefits compound. Better tools improve data, better data enables accountability, and stronger accountability builds trust – both inside and outside OPP.

1.6 Next Steps for Implementation

All in all, this report provides a foundation for long-term improvement, but realizing these gains requires continued momentum, strategic prioritization, and clear ownership. Censeo recommends that OPP take the following next steps to transition from analysis to execution:

- **Prioritize a brief list of high-impact recommendations** to roll out over the next 3 to 6 months, based on feasibility, alignment with existing initiatives, and potential value.
- **Assign clear ownership** for each prioritized recommendation, with defined roles, timelines, and performance metrics to track implementation progress.
- **Stand up a cross-functional implementation working group**, including staff from each core function, employees from OPS, and an implementation partner team, to implement the recommendations, coordinate execution, identify interdependencies, and surface potential issues.
- **Develop regularly maintained dashboards to monitor application review cycle times and backlog reduction,** supported by improved Salesforce data practices.
- **Develop sprint plans for subsequent quarters** identifying specific recommendations to be implemented in future 3 to 6-month cycles, establishing time-boxed periods to work on defined tasks with clear objectives and deliverables.
- **Leverage findings to inform the upcoming workforce assessment,** ensuring that staffing structure and competencies are aligned to the process improvements underway.

To coordinate this work, **we recommend establishing a small cross-functional Program Management Office (PMO)**, **composed of OPP staff and implementation support staff, which could be supervised by a Deputy Director**. The PMO should manage interdependencies, track progress, and escalate implementation risks across workstreams.

This structure positions OPP to deliver visible, early impact while building momentum for sustained change. These steps will help OPP build sustained capacity and move from one-time assessment to continuous improvement, delivering on the commitments of PRIA 5 and beyond, strengthening OPP's ability to serve both its mission and its stakeholders, and setting the stage for data-driven policy discussions with industry for PRIA 6.

2. INTRODUCTION

2.1 Background and Overview

In December 2022, PRIA 5 was reauthorized with new mandates designed to enhance the efficiency, transparency, and accountability of EPA's pesticide registration process. Among these provisions were two significant requirements: (1) an independent workforce assessment to evaluate the adequacy of staffing resources implementing PRIA, and (2) a third-party process assessment to evaluate and improve OPP's operational performance under PRIA 5.

OPP has since undertaken several improvements aligned with PRIA 5 to enhance the efficiency and predictability of its pesticide registration process. To support more timely reviews, OPP has updated its technical and content screening checklists, clarified submission requirements, and expanded outreach to help applicants avoid common deficiencies. These efforts are designed to reduce early-stage delays and improve submission quality.

OPP has also revised internal procedures to limit the use of renegotiations, in line with new statutory constraints, and implemented a simplified process to track and manage deadline extensions. To address the backlog of non-PRIA applications, EPA has piloted streamlined review templates, encouraged registrants to consolidate or withdraw outdated submissions, and improved use of tools like Salesforce to manage workflows and communication.

In early 2025, EPA OPP, in collaboration with Censeo Consulting Group, initiated a comprehensive review and optimization effort. In accordance with the PRIA 5 requirement, this initiative encompasses a third-party evaluation of key business processes and a workforce analysis to help OPP address growing workload demands, improve review timelines, and strengthen internal operational alignment. This report focuses exclusively on the BPR, with the Workforce Assessment planned for the following year. The BPR covers a targeted evaluation of OPP's core registration and registration review functions including but not limited to the initial content screen, the preliminary technical screen, and efforts to reduce address the backlogs of PRIA and non-PRIA applications.

To support this work, Censeo executed a structured assessment approach involving qualitative and quantitative methods. The team first identified priority themes for inquiry, informed by the statutory requirements of PRIA 5, registrant experiences, and aligned to OPP's mission and operational context. The assessment framework guided the development of interview protocols, stakeholder engagement, and root cause analysis.

2.2 About EPA OPP

OPP plays a central role in evaluating, registering, and reviewing pesticide products to ensure they meet safety standards for human health and the environment. OPP operates at the intersection of science, regulation, and industry, where timely and predictable decision-making is critical to advancing EPA's broader goals. With a diverse portfolio that spans risk assessment, product labeling, data evaluation, and stakeholder communication, OPP's performance directly impacts both the pace of innovation and public trust in the regulatory system.

OPP is structured into seven specialized divisions, categorized into the regulatory divisions and the science divisions. These divisions collaborate to review pesticide applications, conduct scientific assessments, ensure compliance with labeling and data requirements, and engage with registrants and stakeholders. The office manages thousands of actions annually and is responsible for both pre-market

approvals and ongoing post-market oversight. Its work touches a wide range of users—from large agricultural producers to small businesses and public health agencies—and must balance scientific integrity, legal mandates, and operational efficiency.

2.3 PRIA 5

PRIA 5 was the latest reauthorization of PRIA legislation, enacted in December 2022. There were several objectives associated with PRIA 5, including ensuring that EPA had the necessary tools, resources, and funding to conduct its pesticide registration and review processes, making these processes more efficient, increasing communication and transparency, and prioritizing farmworker safety and the protection of endangered species. PRIA 5 also set aside funding for an outside contractor to conduct a workforce and business process assessment and provide recommendations on the implementation of PRIA 5. This report is part of that assessment.

These changes were important in securing funding for EPA and addressing some of the frustrations industry historically had with OPP's processes, particularly around the lack of transparency into the registration process. Historically, registrants had limited insight into OPP's registration process and were unable to see the status of their applications while OPP had considerable leeway to extend the PRIA due dates, leaving registrants unable to anticipate when the review would be completed. For companies preparing seasonal product launches or submitting new uses of safer chemistries, this uncertainty imposes real costs—ranging from delayed market entry to missed business opportunities. For EPA, it undermines the program's mission of supporting the availability of effective, lower-risk pesticide options. In short, when process timelines break down, both regulatory effectiveness and innovation suffer.

To address the gaps in communication, PRIA 5 mandated that OPP create a tracking system to provide registrants with access to real-time data on the status and progress of their applications (MyPest). PRIA 5 also instituted more reporting requirements for OPP, requiring additional annual reports and the release of data evaluation records to registrants. To reduce the number of renegotiations, PRIA 5 required that OPP supply registrants with a justification to extend the due date and limited the scope of potential justifications. The uncertain timelines were a function of inefficiencies in the process, and the process assessment was included in PRIA 5 to help OPP conduct its reviews more effectively.

This report looked at critical PRIA processes and evaluated the efforts OPP undertook to implement the updates laid out in PRIA 5 to identify additional opportunities for increased efficiency and provide recommendations on potential approaches. The Censeo team, as third-party assessors, reviewed ten topic areas as part of this process evaluation and developed this report to catalog their findings and recommendations.

2.4 How to Read This Report

This report is organized as follows:

- The Summary of Approach and Methodology section contains important background information on how this BPR was conducted and how to interpret its results.
- The PRIA Registration Areas: Deep Dives section covers the two PRIA deep dive areas (the Initial Content Screen and the Preliminary Technical Screen), including a process overview and root causes of challenges for each area as well as a combined list of detailed recommendations for both PRIA deep dive areas.
- The PRIA Registration Areas: Progress Assessments section covers the two PRIA progress assessments (Reducing Renegotiations Rates and the Small Business Fee Waiver), including an

area overview, key challenges, OPP progress made to date, and high-level recommendations for each area.

- The Non-PRIA Submission Areas: Progress Assessments section, which is formatted identically to the previous progress assessments section and covers the three non-PRIA progress assessments (Eliminating the Non-PRIA Backlog, Ensuring Non-PRIAs Are Completed by The Deadlines Described in PRN 98-10, and Compliance with the Provisions of PRIA 5 Relating to Non-PRIAs).
- The Registration Review Area: Deep Dive section that contains a process overview, root causes, and detailed recommendations for the Registration Review process deep dive.
- The Operational Enabler Areas: Progress Assessments section, which is formatted identically to the other two progress assessments sections and covers the two operational enabler areas: Information Technology Systems and Employee Training.
- The Conclusion section synthesizes key outcomes from this BPR.
- An Appendix with a glossary of acronyms, more details on the stakeholder interviews, and additional data visualizations not included in the main sections.

3. SUMMARY OF APPROACH AND METHODOLOGY

3.1 BPR Review Objectives and Approach

In early 2025, OPP launched this BPR to help assess and strengthen its core operational workflows – particularly those most critical to timely pesticide decision-making. PRIA 5 outlined ten key areas to be included in this business process review. These areas represent a mix of key processes/sub-processes, statutory responsibilities, and foundational enablers critical to overall performance. Across all areas, the BPR had three primary objectives:

- Map and analyze how key processes function across divisions
- Identify root causes of delays, redundancies, or inconsistencies
- Prioritize actionable improvements aligned with statutory goals and operational feasibility

To meet these objectives, the team applied a structured BPR methodology that combined qualitative and quantitative analysis. Conducted from late March to September 2025, the assessment focused on identifying systemic bottlenecks, inefficiencies and cross-cutting challenges that affect the pesticide registration lifecycle – especially when considering new PRIA 5 mandates.

The evaluation and assessment were guided by a four-pillar framework, as visualized and described below:

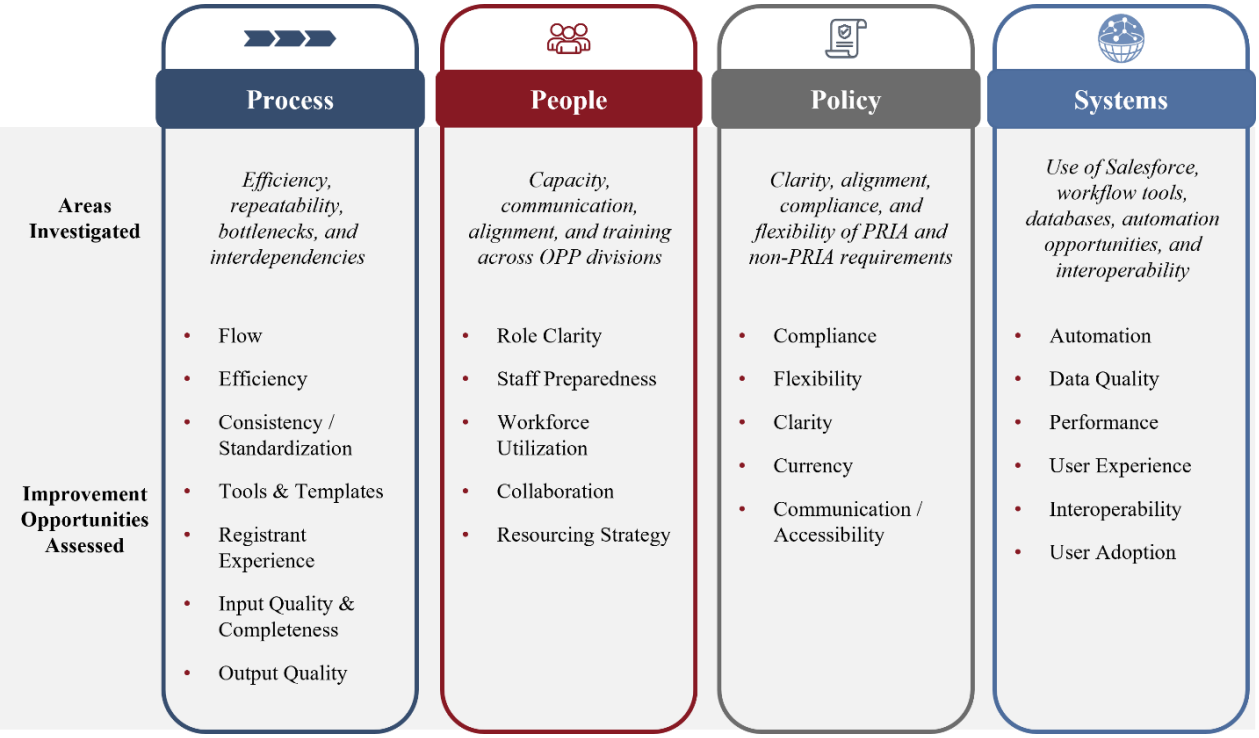

Figure 2: This framework guided a holistic assessment to uncover inefficiencies across key operational areas.

- **Process** – Assessed process flow, efficiency, and standardization, with emphasis on bottlenecks, registrant experience, and the quality of inputs and outputs
- **People** – Examined staff roles, workforce utilization, preparedness, and collaboration to determine organizational adaptability and long-term sustainability

- **Policy** – Examined the clarity, alignment, and accessibility of both PRIA and non-PRIA requirements, including the communication and organization of key policies
- **Systems** – Analyzed the use of tools such as Salesforce, MyPest, and internal databases to assess automation potential, data quality, user experience, and system performance

Although this BPR identified key challenges and recommendations across each of these pillars, it focused primarily on the process pillar, as PRIA 5 emphasized the importance of exploring frustrations that industry has historically had with OPP's processes. The upcoming training needs and workforce assessments will build on these process insights by capturing how workforce-related issues might be causing inconsistencies, bottlenecks, and inefficiencies within OPP processes.

3.2 Data Collection Approach

To support this review, the team collected and analyzed a range of data reflecting both internal and external perspectives on the process. These activities included the following:

- Document Review: Over 100 internal resources were reviewed, including process maps, SOPs, dashboards, templates, operational memos, and legislative materials. For progress assessments, OPP-provided documents (e.g., Renegotiation Memo, ISB workflow documentation, PRIA 5 guidance) were the primary data source.
- Stakeholder Interviews: Nearly 20 interviews were conducted with 40 OPP staff across Registration Division (RD), Pesticide Reevaluation Division (PRD), Antimicrobials Division (AD), Biopesticides and Pollution Prevention Division (BPPD), Biological and Economic Analysis Division (BEAD), Environmental Fate and Effects Division (EFED), Health Effects Division (HED), and 35 external stakeholders including registrants and trade association representatives. These interviews were conducted exclusively to explore deep-dive areas. Interviewees were selected by OPP and industry based on their direct involvement in process execution and ability to speak to cross-divisional or external challenges.
- Thematic Analysis: Interview data was thematically coded and organized by process and pillar to uncover recurring breakdowns, variation across divisions, and root causes of missed deadlines and inefficiencies.
- Cross-Process Synthesis: Because many issues—such as timeline ambiguity, inconsistent communication, and system fragmentation—appeared across multiple workflows, a synthesis exercise was conducted to identify common challenges and develop cross-cutting recommendations.

3.3 Area Grouping and Analytical Structure

To organize the evaluation, the team grouped the ten areas into four distinct groups based on statutory requirements, operational function, and their relationship to PRIA 5 mandates. These groupings are also reflected in the structure of the report:

- **PRIA Registration Areas** (referenced in FIFRA Section 33(f)(4)(B)):
  - Initial Content Screen
  - Preliminary Technical Screen
  - Reducing Renegotiation Rates
  - Small Business Fee Waiver
- **Non-PRIA Registration Areas** (not subject to PRIA fees but under OPP purview)
  - Eliminating The Backlog of Non-PRIAs

    - Ensuring Non-PRIAs Are Completed by The Deadlines Described in PRN 98-10
    - Compliance with the Provisions of PRIA 5 Relating to Non-PRIAs
- **Registration Review Area** (15-year pesticide re-evaluation process)
    - Registration Review
- **Operational Enabler Areas** (foundational support systems)
    - Information Technology Systems
    - Employee Training

Among these, three areas – **the initial content screen, the preliminary technical screen, and registration review** – were identified by OPP as processes that faced major delays and warranted **deep-dive reviews**. For each deep dive, the team conducted extensive analysis based on process documentation as well as internal and external stakeholder interviews. Each deep-dive section of this report includes a process overview, root causes of key challenges, and detailed recommendations identified for improvement.

All other areas, hereafter referred to as progress assessments, received a more limited review per the contracted scope of work for this effort. For each, the team reviewed relevant documentation and improvement initiatives completed / currently underway. The progress assessments of this report contain an overview of the area, key challenges, a list of the documents reviewed, a summary of OPP actions to date, and high-level recommendations for further improvements.

3.4 Recommendation Development for Deep Dive Areas

For the three deep dive areas, root cause analysis was conducted within the four-pillar framework – process, people, policy, and systems – to identify persistent structural challenges affecting OPP performance.

These root causes formed the basis for recommendations, which were prioritized along two dimensions:

- **Impact** – Potential to improve performance, PRIA 5 alignment, and system-wide efficiency and effectiveness
- **Ease of Implementation** – Organizational, policy, and technical complexity

Each recommendation falls into one of four categories as shown in Figure 3:

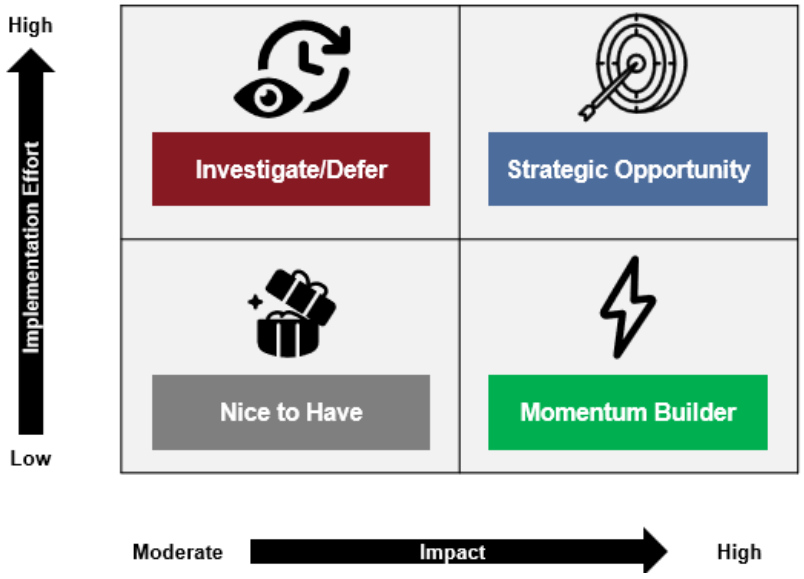

Figure 3: This framework helps categorize and prioritize recommendations based on their impact and feasibility.

This framework enables OPP to focus attention on the most actionable and impactful changes while still capturing incremental improvements that may be appropriate over time or with additional resources. The proposed order of implementation for each category of recommendations is as follows:

1. Momentum Builder
2. Strategic Opportunity
3. Nice to Have
4. Investigate/Defer

This prioritization should be viewed as a general guide for planning purposes. In general, OPP should prioritize the low effort, high impact recommendations first to generate momentum, while steadily pursuing some more resource-intensive initiatives that could bring about substantial benefits to OPP as resources allow. Once the high impact areas are addressed, OPP can assess which of the "nice to have" or "investigate/defer" areas are worth pursuing given other priorities.

3.5 Limitations

While the review was comprehensive in scope, certain limitations constrained aspects of the analysis:

- The team was unable to directly interview the ISB contractors responsible for conducting the initial content screen. Responses were provided via email by the Contracting Officer's Representative (COR), which limited our insight into day-to-day contractor workflows, pain points, knowledge/training gaps, and system use.
- Evaluations of progress assessments (e.g., renegotiations, small business waivers) were, in alignment with the contractual scope for this effort, limited to the documents provided by OPP, without supplemental interviews or firsthand observation of operational practices.
- The team did not have access to reliable Salesforce/CDX data, which constrained the ability to independently verify application-level timelines, workload distribution, or system performance metrics. OPP provided what data they could, but this was limited. The data is based on manual entry or status updates in the system by OPP staff, which we were informed are performed highly inconsistently, limiting the reliability of the datasets as the basis for conclusions about process issues or impacts. Other requested data did not exist, as OPP has not tracked certain metrics over time. Instead, the findings in this report are based on cross-functional interviews and available summary data.

Despite these constraints, the BPR team used triangulation across multiple data sources to produce representative, actionable findings grounded in real-world operational conditions.

4. PRIA REGISTRATION AREAS: DEEP DIVES

4.1 Introduction to PRIA Registration

PRIA Registration is the process by which OPP reviews and registers all new pesticides that qualify as PRIA applications, as outlined by PRIA 5. PRIA registration applications are more complex and substantive than non-PRIA applications, which go through a more streamlined review. As a result, PRIA registration applications also require registrants to pay an application fee that is intended to cover a portion of the costs of review. However, PRIA registration is often subject to significant delays that can impact the timeline for bringing new pesticides to market.

Delays beyond PRIA 5-specified review timelines are commonplace across PRIA applications. Censeo analyzed Fiscal Year 24 pending and completed PRIA application data provided by OPP. Figure 4 shows the distribution of application completion times as a percentage of OPP's stated decision review time. For example, an application that had a decision review time of 12 months and was completed in 12 months would have a *Percent of Decision Review Time* of 100%. If that application took 24 months to complete, its *Percent of Decision Review Time* would be 200%. Our analysis indicates that 85% of the 4,602 applications completed in FY24 were delayed and the average application took nearly twice as long (191%) as OPP's stated review time.

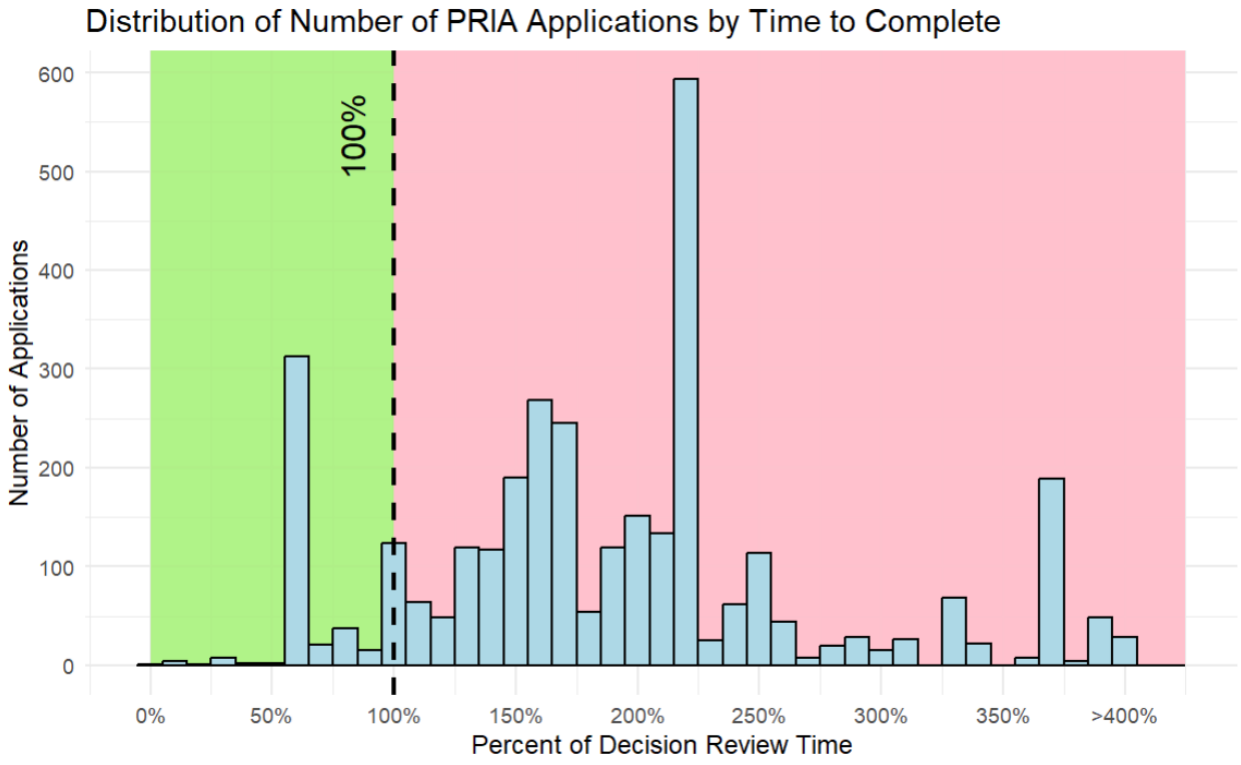

Figure 4: In FY24, only 15% of applications were reviewed within the stated review time.

Applications with longer review timelines face even greater delays. PRIA 5 attempted to define realistic review timelines for different types of actions based on their perceived complexity and required effort to review and process. However, the data indicates that not only are staff unable to complete actions within the current timelines in general with only 15% of applications completed within the stated review

time, but actions with longer prescribed timeframes are even more likely to be delayed and face substantially longer delays than more straightforward actions. This means that the most critical and complex applications for registrants (e.g., new products with new active ingredients) are often those with the most uncertain timelines.

Table 1 shows the extent of these delays and the extent to which they increase in frequency and duration based on the specified decision review time for the action. Of the 4,602 applications completed in FY24, applications with a stated review time of under 6 months have, on average, half the delay length of applications with a 6 to 12-month review time. Applications with a stated review time of over a year are 14% more likely to have a delay and that delay, on average, is more than triple the duration.

Specified Decision Review Time	Percentage of Applications with Delay	Average Delay Length	Median Delay Length
1 to 6 months	69%	84 days	58 days
6 to 12 months	80%	169 days	137 days
12 to 18 months	83%	257 days	174 days

Table 1: Delays in review tend to increase in frequency and length for more complex applications.

Figure 5 plots the standardized distributions of delays in review times relative to the PRIA 5-specified review timeline. This visualization reinforces the trend shown in Table 1: while all applications are likely to face delays, the more complex they are, the more frequent review cycles extend well beyond the PRIA 5 timeframe (evidenced by the long tail on the 12-to-18-month distribution).

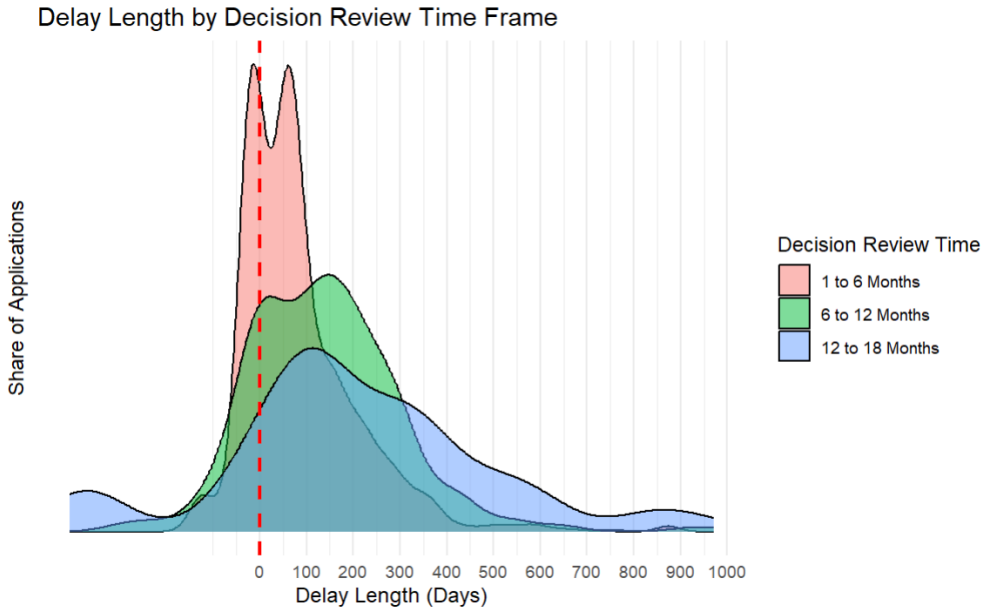

Figure 5: More complex applications with longer decision review times have longer delays on average[1].

[1] Figure 5 is a density chart: a visual representation of the distribution of the length of delays (in days), standardized across the 3 decision review timeframes. Unlike histograms, density charts provide a smoothed outline that estimates the probability distribution of data and highlights where observations are most concentrated. By examining the height and spread of each curve, one can quickly identify patterns, with higher curves corresponding to a larger number of applications.

The PRIA registration process requires significant improvement to reduce delays and backlogs. In light of these trends and the lengthy backlogs for PRIA registrations, it is clear the PRIA registration process is not working as intended. As one might expect, the process is very involved, consisting of multiple phases, each with its own validation steps and review cycles providing opportunities for delays if not performed promptly or efficiently. Although the process differs slightly based on what type of pesticide is being registered, a simplified version of the overall process flow is presented in Figure 6.

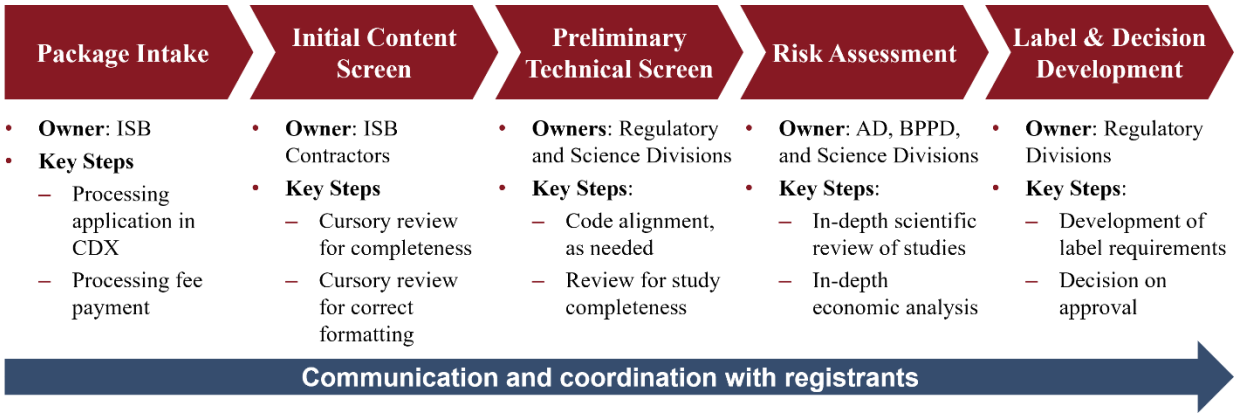

Figure 6: OPP's PRIA registration process includes multiple layers of review to ensure thorough evaluation and shared responsibility for each application.

Unfortunately, OPP could not provide data of sufficient quality that depicted the amount of time the application would spend in each phase of the review process to support more detailed analysis to determine the relative impact of each phase of the process on the overall registration timeline, as this data is not consistently collected. However, since both the initial content screen and the preliminary technical screen have specified timelines of their own which are frequently missed, these phases were prioritized in the business process review. The remainder of this chapter provides a more in-depth description of those process phases as well as root causes for delays and challenges within them and a combined list of recommendations across both process phases.

4.2 PRIA Registration Deep Dive Areas: Overviews and Challenges

Key deep dive areas. This section focuses on key pesticide registration processes that directly impact OPP's ability to meet statutory deadlines and deliver consistent, high-quality reviews under PRIA 5. The **initial content screen** and **preliminary technical screen** are two critical early-stage quality control steps designed to identify deficient applications before they move further in the review pipeline. These checks are critical for avoiding wasted effort spent on deficient applications that would otherwise be rejected and ensuring that applicants submit materials that meet OPP's requirements from the outset. Despite recent improvements, these processes remain constrained by outdated systems, unclear guidance, and resource bottlenecks. This deep dive analysis used root cause analysis and stakeholder input to uncover the main barriers and identify opportunities to streamline these processes, reduce delays, and improve overall program efficiency.

4.2.A Initial Content Screen: Overview and Root Challenges

Process Overview

The initial content screen is the process laid out by FIFRA Section 33(f)(4)(B)(i)(I) and is one of the processes for which the team conducted a deep dive analysis to better understand root causes of current

pain points and recommendations to address backlogs. PRIA mandates that this entire process, beginning with application intake and ending with the hand-off of the application to the preliminary technical screen phase, occur within 21 days. Figure 7 contains a visual process map of this initial content screen process.

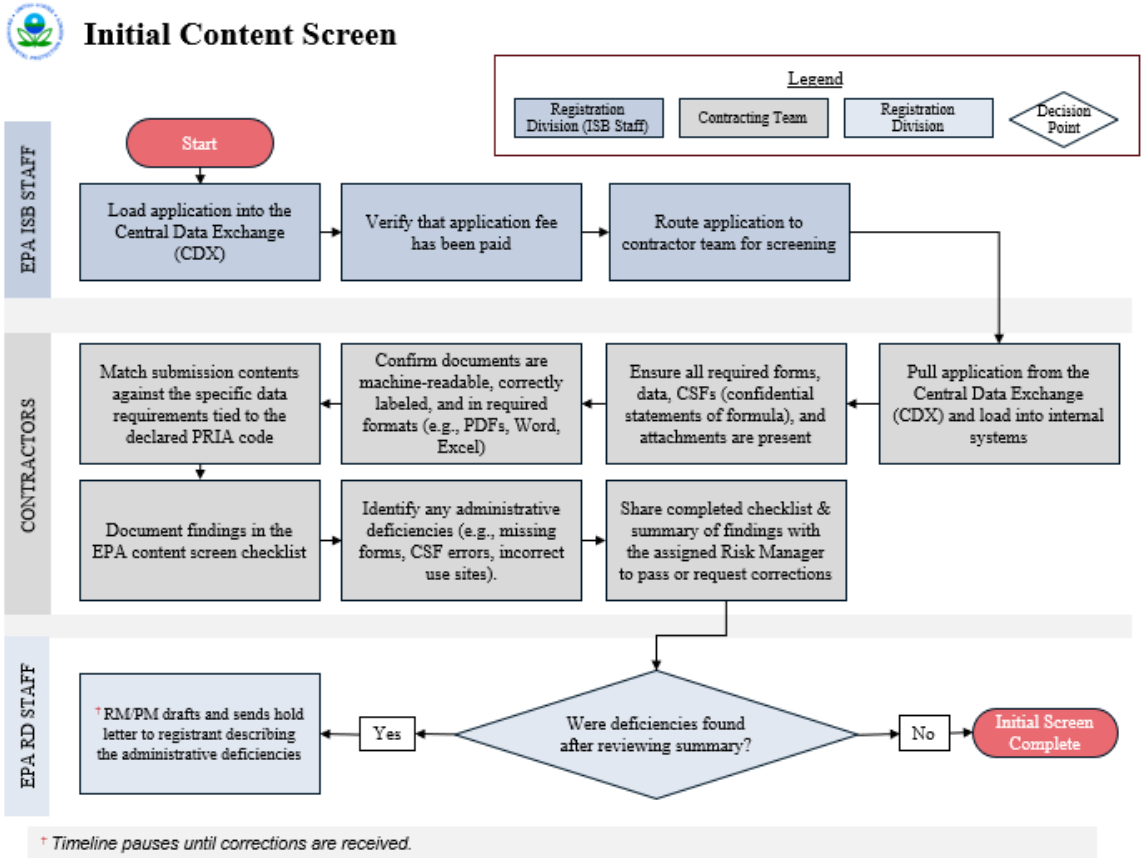

Figure 7: The initial content screen involves multiple hand-offs that require strong coordination for accurate and timely review.

Process initiation. The initial content screen is meant to be a 21-day process that is completed for all PRIA actions once an application and its corresponding registration service fee are received and processed. The 21-day timeline begins once the application is received through CDX by the Information Services Branch (ISB), who is then responsible for processing its intake and resolving any issues with the associated application fee. Once the application is loaded onto Salesforce and fee payments are resolved by ISB, the application is passed to the team of ISB contractors responsible for conducting the initial content screen itself. To complete this screen, the ISB contractors assess several aspects of the application as outlined by a review checklist, which includes the following:

- Does the application have the appropriate PRIA code?
- Are all required forms included?
- Are any inert ingredients included in the products approved for the uses?
- Are all materials present to address the appropriate data requirements?
- Does the application comply with formatting standards (e.g., submissions are in English or accompanied by an English translation)?

Importance of PRIA codes. It is important to note that the ISB contractors evaluate all the materials for a given application in accordance with the guidelines for the PRIA code under which the application was

submitted. Therefore, if the PRIA code is incorrect, that code should be changed and the application should be screened in accordance with the guidelines for the correct code.

Process close. Once the ISB contractors complete the initial content screen, they share the completed checklist along with a summary of findings with the assigned Product Manager (PM) within the regulatory divisions. The PM is assigned based on the ingredient type, within the corresponding regulatory division (AD, BPPD, or RD), and conducts a review of the ISB output. If the ISB contractors identify any deficiencies with the application, the PM then drafts and sends a hold letter to the registrant describing the deficiencies and asking that they be corrected. The registrant then must correct the deficiencies, or else OPP is expected to reject the application. If the ISB contractors do not identify any deficiencies with the application, the PM then advances the application to the next step in the process, which is the preliminary technical screen.

Automatic application advancement. It is important to note that once an application's 21-day timeframe lapses, the application is automatically moved forward within Salesforce to the preliminary technical screen phase and assigned to a Risk Manager (RM) within the regulatory divisions. However, the ISB contractors still have access to the application at this point and often conduct the initial content screen review even after the application has been moved forward in the system.

Key Challenges and Root Causes:

Frequent delays. OPP has been struggling to consistently complete the initial content screen reviews within the 21-day timeframe mandated by FIFRA. Delays within this process occur at a variety of different stages. Some delays occur before an application is even received by the ISB contractors, others occur during the initial content review itself, and others result from the back-and-forth between registrants and ISB to address deficiencies identified by the ISB contractors. These delays have resulted in very few initial content screen reviews being conducted on time, within the 21-day timeframe.

Root cause development. To better understand the delays noted above, the team discussed the initial content screen process with several key stakeholders, both within OPP and among the registrant community. In doing so, the following root causes of the delays were identified within the initial content screen process. These root causes were organized according to the four pillars of the analysis: Process, People, Policy, and Systems. Below is a list of all root causes, along with an explanation of how the root cause is actively leading to downstream delays. Each root cause is coded with the following acronyms, which are later used to connect the PRIA deep dive recommendations with the root causes they address:

- PR = Process-related root cause
- PE = People-related root cause
- PL = Policy-related root cause
- S = System-related root cause
- # = Number of root causes within the pillar

<u>Root Causes for Process Challenges</u>

- **PR1 – Constrained timelines due to front-end processing delays**. OPP staff noted that the ISB contractors often receive applications late in the 21-day screening window. This delay usually stems from ISB challenges with intaking the application from CDX and resolving fee issues with registrants. As a result, the ISB contractors have fewer days to complete the screen and report any deficiencies to the regulatory divisions, who must then relay them to the registrant for them to be addressed. This has been observed as a significant root cause for delays that trickle downstream.

- **PR2 – Insufficient registrant guidance**. Registrants often lack access to clear, detailed, and centralized guidance for navigating the pesticide registration process. Guidance documents are intended to be a practical application of policy, giving registrants real-world examples and insights into specific things to do or avoid for a successful application. While some resources exist, they are scattered, outdated, or written at too high a level to address the specific scenarios registrants frequently encounter. As a result, registrants—especially those with limited experience or capacity—struggle to interpret how broad policies apply to their specific applications. This can lead to confusion, inconsistent submissions, and a higher rate of deficiencies. Without more actionable and transparent guidance, registrants are left guessing what will meet OPP's expectations, increasing the likelihood of delays and rework. In the initial content screen process, better guidance would help registrants know which PRIA codes to use, which forms and studies they need to submit, and the correct format for each part of the application package.
- **PR3 – Outdated guidance for ISB contractors.** The ISB contractors performing the initial content screen rely on checklists and instructions created by OPP staff that are not always updated to reflect current policies. Without accurate guidance, the contractors may make mistakes that OPP staff must later correct, leading to additional delays.
- **PR4 – Lack of communication and coordination across stakeholders.** Although both regulatory staff and ISB contractors participate in the initial content screen process, they cannot communicate directly. All messages must pass through the Contracting Officer Representative (COR), which slows down communication and makes it hard for regulatory staff to ask timely questions or clarify issues. This communication bottleneck can lead to misunderstandings, duplicated work, and missed opportunities to catch errors early. More broadly, staff across regulatory divisions, ISB, and the ISB contractors described a general lack of transparency and coordination throughout the initial content screen process. Without a clear view of each team's roles and timelines, they struggle to respond to backlogs or prepare for surges in workload.

<u>Root Causes for People Challenges</u>

- **PE1 – Insufficient subject matter expertise among ISB contractors.** While much of the initial content screen does not require deep subject matter expertise, certain aspects – such as reviewing the PRIA code assigned to an application – demand core policy and scientific understanding. OPP staff noted that the ISB contractors are not always familiar with the nuances of each PRIA code. When an application has the wrong code, it gets reviewed against incorrect requirements, which vary by code. OPP staff later down the line must then identify the mismatch, re-code the application, and review it against the correct requirements before sending it to the science divisions for the preliminary technical screen, which delays the overall process. RD staff emphasized that this type of coding expertise is difficult to teach and cannot be easily captured in written guidance.

<u>Root Causes for Policy Challenges</u>

- **PL1 – Fragmented documentation of key policies.** Both registrants and OPP staff reported difficulty navigating the policies that govern the PRIA registration process. Important procedures are spread across many documents, and users must already be familiar with the policy landscape to know where to look. Moreover, these documents are not stored in a single, centralized location, making them hard to find and reference. This fragmentation increases the likelihood of inconsistent or erroneous interpretations of policy by both OPP staff and registrants and can necessitate more back-and-forth to clarify misunderstandings.

- **PL2 – Lack of policy that supports application rejection.** Although the initial content screen was designed to quickly correct or reject incomplete applications, almost no applications are actually rejected in this phase, even when they contain deficiencies. According to OPP staff, the rejection process is complex under current policy and is rarely supported by leadership. As a result, reviewers are left to work through corrections with registrants, a process that can take several weeks and contribute to downstream delays. This is exacerbated by the fact that applications must often be resubmitted when a significant deficiency is identified, as registrants are not able to directly edit their application in response to feedback from OPP staff.
- **PL3 – Potentially misaligned contract structure for ISB contractors.** While it was not possible to review the full contract for the ISB contractors conducting the initial content screens, OPP staff expressed concerns about capacity and alignment. Interviewees noted that the ISB contractors are understaffed relative to the volume of incoming applications and that the initial content screen process does not meet its intended objectives. These challenges may stem from misalignment between the contract's structure and the actual work required to support an effective screening process.

Root Causes for System Challenges

- **S1- Limited automation within initial content screens.** Many parts of the initial content screen (e.g., confirming documents are written in English) require little to no technical expertise and could be automated. Because these tasks are still performed manually, the ISB contractors spend more time on low-value steps, which slows down the screening process overall.
- **S2 – CDX system crashes.** Multiple interviewees reported frequent technical issues with the CDX portal, which is the system used to intake applications from registrants. The current system runs 24/7, without any scheduled downtime for maintenance or performance checks. As CDX does not receive consistent maintenance, minor issues can go unnoticed and over time result in unexpected major crashes that bring the whole system down. When CDX crashes, ISB must first resolve the issue before processing the fee payments and passing the application to the ISB contractors. These delays reduce the time contractors have to complete the initial content screen and often lead to missed 21-day deadlines.
- **S3 – Access restrictions for regulatory staff.** Once a PM within the regulatory divisions receives an application from the ISB contracts, they lack the access to perform certain actions that the ISB contractors have, such as directly editing a registrant's study documents. For example, if a signature is missing from a study page, ISB contractors can fix it directly, but PMs must ask the registrant to resubmit the entire study. This triggers a new MRID assignment, which is the unique 8-digit code assigned to each study submitted to OPP, and adds delays as the application is rerouted back to the original reviewer. Although these access restrictions aim to reduce editing errors, they also limit PMs' ability to resolve small issues quickly.
- **S4 – Limited visibility into fee status and screen completion.** Regulatory division RMs often begin conducting the preliminary technical screen for an application without knowing whether its initial content screen has been completed or if fee issues are resolved. Without this visibility, RMs may spend time on applications that are later pulled by ISB or significantly edited by the ISB contractors – time that could have been spent working through fully ready applications. This lack of transparency leads to frustration among regulatory staff and contributes to ongoing review backlogs.

4.2.B Preliminary Technical Screen: Overview and Root Challenges

Process Overview

The preliminary technical screen is the process laid out by FIFRA Section 33(f)(4)(B)(i)(II) and is one of the deep dives included in this business process analysis to better understand root causes of current pain points and recommendations to address backlogs. The preliminary technical screen is meant to be a 45- or 90-day process that is completed for all PRIA actions once an application's initial content screen is complete. The preliminary technical screen is to be completed within 45 days for submissions with decision review timeframes of less than or equal to six months and within 90 days for submissions with decision review timeframes greater than six months.

Figure 8 contains a high-level process map of this preliminary technical screen process.

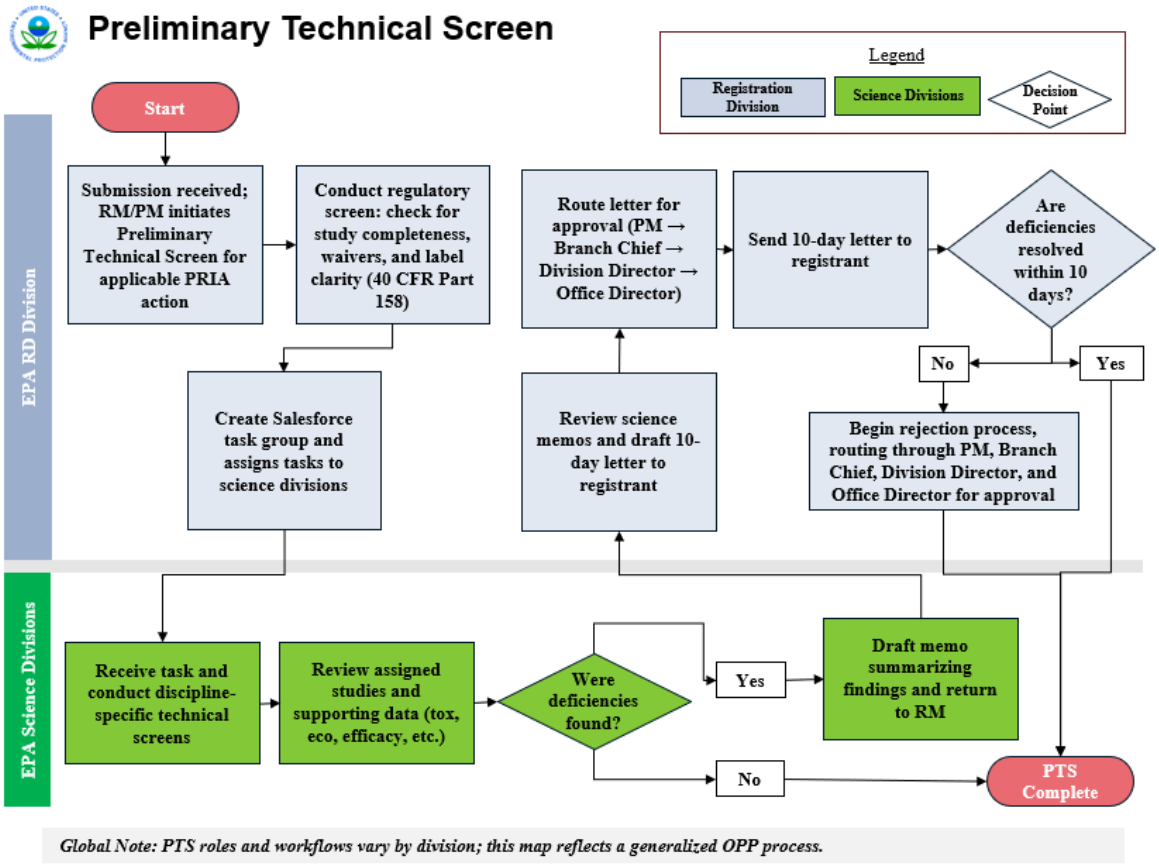

Figure 8: The preliminary technical screen introduces preliminary scientific review to support early quality control.

Process initiation. The timeline for the preliminary technical screen begins once the application is received by the RM within the regulatory divisions from the initial content screen team. At this point in time, the RM conducts a preliminary review of the application, including the following items:

- Does the application qualify for a reduced risk determination under subsection (c)(10) or (h) of section 3?
- If a data waiver request is submitted by the registrant for the application, should they be granted or denied?
- Is the application's assigned PRIA code and associated fee category accurate?

Science division reviews. Once this regulatory screen is complete, the RM sends the application out to the relevant science divisions for a more detailed review of the application's studies[2]. A team leader within each science division's risk assessment branch receives the application and assigns it to a risk assessor based on current workload and expertise. The risk assessors are then responsible for conducting a review of the application's studies to ensure that the right studies were provided and that there are no immediate gaps or deficiencies found in the data. A more in-depth review of studies is conducted during the risk assessment after the preliminary technical screen, but this review is intended to identify any glaring gaps or deficiencies. Once the risk assessor completes their review, they draft a memo summarizing the findings and send the memo back to the RM.

Addressing deficiencies. At this point, the RM compiles and reviews all memos from the various science divisions that reviewed the application. If any deficiencies were identified through the reviews and these deficiencies were identified within the 45- or 90-day window, the RM drafts a 10-day letter outlining all deficiencies. The regulatory divisions vary in the level of review required for the 10-day letter, with RD sending the letters up to the Division Director level while BPPD and RD have a more expedited process with authority at the PM level to sign before it gets sent to the registrant along with the memos from the science divisions detailing the gaps. A registrant then has 10 days to respond to this letter and address the deficiencies, corresponding with the regulatory division as needed to do so. Once all deficiencies are corrected, or if no deficiencies were identified, the preliminary technical screen is complete.

Application rejection. If a registrant cannot address the deficiencies within 10 days, and if the deficiencies were identified within the 45- or 90-day window, OPP can begin the process to reject the application under the terms identified in the 10-day letter. To do so, OPP must pass the rejection request by several individuals, including Branch Chief, Division Director, and Office Director. If approved by management, the registrant is notified of the rejection. Importantly, the preliminary technical screen phase is OPP's last opportunity to reject an application. Once an application moves to the in-depth science review, 75-day letters can be used to identify deficiencies but cannot result in rejection.

Short-term PRIA actions. Short-term PRIA applications, such as those that have a decision time of 30 days, do not receive a preliminary technical screen and instead advance directly to the risk assessment phase. OPP established this process to ensure that these applications are not held up in the preliminary technical screen phase, which in some cases could exceed the total time allowed for review. An example of these applications would be a request to certify that the product being exported is legally registered in the U.S. with EPA.

Key Challenges and Root Causes

Frequent delays. OPP has been struggling to consistently complete the preliminary technical screen reviews within the 45- or 90-day timeframes mandated by FIFRA. Delays often occur even before the preliminary technical screen review can begin; if the case has not yet reached the PM team and been assigned to an RM because of delays like those related to front-end payments, then the regulatory divisions may not know when to start the PTS. If the ISB contracting team faces other delays in the ICS process that move it beyond the 21-day timeframe, the PM team may have remaining ICS tasks to complete before they can move on to the PTS screen, eating into the 45- or 90-day PTS timeframe. Beyond that, delays can also occur within the preliminary technical screen review, as poor package submissions may have multiple rounds of deficiencies, necessitating back-and-forth between registrants

[2] It is important to note that for some divisions within OPP, including BPPD and AD, the science screen is conducted in-house as opposed to separate science divisions.

and regulatory divisions to resolve them. Poor packages are more likely to occur downstream in the PTS when the ICS is incomplete. These delays have resulted in very few preliminary technical screen reviews being conducted within the 45- or 90-day timeframe. Additionally, in some divisions, staff revealed in interviews the preliminary technical screen is not completed at all or reserved for only a fraction of incoming applications.

Root cause development. To better understand the delays noted above, the preliminary technical screen process was discussed with several key stakeholders, both within OPP and among the registrant community. In doing so, the following root causes of the delays were identified within the preliminary technical screen process. These root causes were organized according to the four pillars of the analysis: Process, People, Systems, and Policy. Below is a list of all root causes, along with an explanation of how the root cause is actively leading to downstream delays. Each root cause is coded with the following acronyms, which are later used to connect the PRIA deep dive recommendations with the root causes they address:

- PR = Process-related root cause
- PE = People-related root cause
- PL = Policy-related root cause
- S = System-related root cause
- # = Number of root causes within the pillar

Root Causes for Process Challenges

- **PR1 – Constrained timelines due to front-end delays.** Applications often arrive late to the preliminary technical screen due to delays in front-end processing and in the initial content screens. Although an application is automatically advanced to RMs at the 21-day mark, the screen has not always been completed, leaving reviewers unsure of what has already been assessed. As a result, RMs will often not begin working on a preliminary technical screen until close to – or even after – the deadline to complete the screen. With limited time, reviewers often cannot complete the PTS review before the deadline, allowing deficient applications to continue through the process and miss the last opportunity to be rejected.
- **PR2 – Lack of or inefficient prioritization**. Despite tight timelines and high volume of incoming applications, OPP lacks a consistent process to prioritize which applications should be reviewed first. For example, minor amendments to an existing registration should not require substantial time to review, but those submissions still face substantial delays while they sit in the backlog before any action is taken. Figure 9 shows the median delay length for the 4,602 PRIA applications completed in FY24 by application category. The median value for each category is displayed on its respective colored bar. The black error bars indicate the interquartile range, spanning from the 25th to the 75th percentile and containing the middle 50% of delay times for that category.

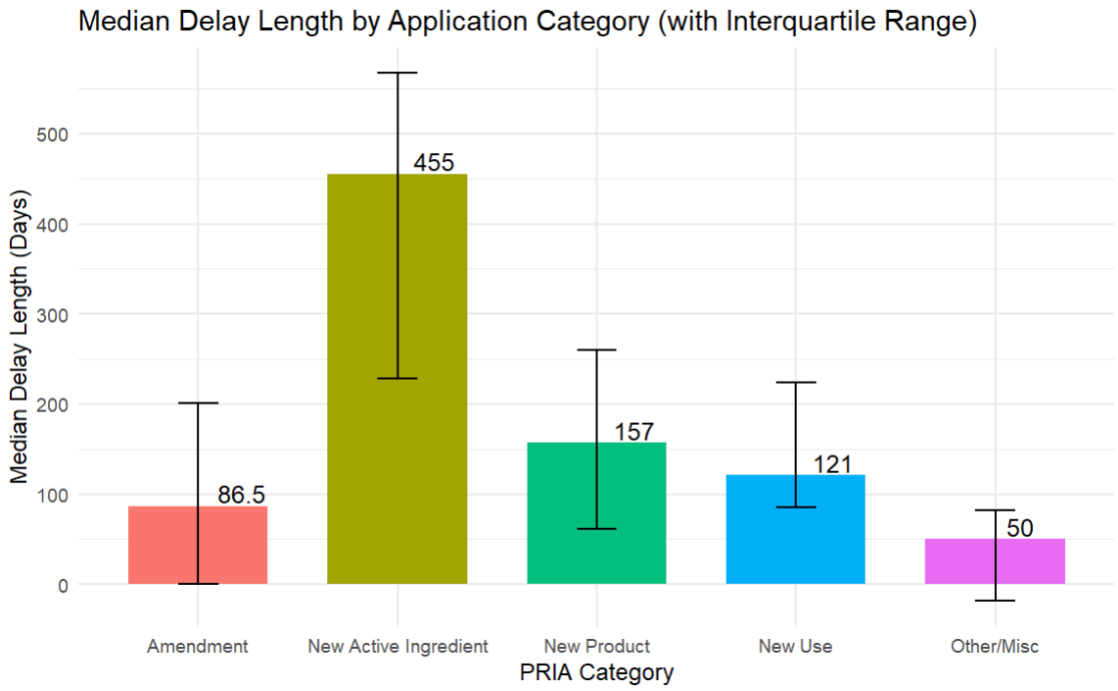

Figure 9: Registrations for new active ingredients face the most significant delays, but even minor amendments and new uses face delays of 100 days or more.

Some divisions triage applications based on PRIA code or complexity, but this is not done uniformly. As a result, high-complexity applications that might benefit most from a preliminary technical screen often miss the deadline for the rejection letter, and simple applications whose reviews should be very quick are still significantly delayed. This lack of prioritization prevents OPP from efficiently working through backlogs and, in some instances, from identifying deficiencies early in the process.

- **PR3 – Inconsistent decision-making in reviews.** Reviewers approach the preliminary technical screen with varying interpretations of scope and policy. Some conduct narrow, issue-specific reviews, while others perform thorough evaluations, even for applications concerning minor changes. These differences are not consistently tied to policy or application types but rather to the individual reviewer's interpretation and approach. This leads to inconsistent outcomes and conflicting guidance for registrants, who may be told one thing by one reviewer and something different later. For example, while working on a Confidential Statement of Formula (CSF) and giving the nominal concentration of an example of a new source, registrants may be initially told it falls within certified limits, only to be told later that it is inadequate, with no insight into the justification for the change in reasoning. In some cases, reviewers enforce changes not required by policy, adding unnecessary burden. When significant policy conflicts arise, registrants often need to escalate to leadership, which delays resolution. These inconsistencies are especially common among newer staff, suggesting potential challenges around onboarding training and staff turnover.
- **PR4 – Insufficient registrant guidance**. Registrants often lack access to clear, detailed, and centralized guidance for navigating the registration process. Guidance documents are intended to be a practical application of policy, giving registrants real-world examples and insights into specific things to do or avoid for a successful application. While some resources exist, they are scattered, outdated, or written at too high a level to address the specific scenarios registrants

frequently encounter. As a result, registrants – especially those with limited experience or capacity – struggle to interpret how broad policies apply to specific applications. This can lead to confusion, inconsistent submissions, and a higher rate of deficiencies. Without more actionable and transparent guidance, registrants are left guessing what will meet OPP's expectations, increasing the likelihood of delays and rework. Within the preliminary technical screen process, guidance would ideally provide a detailed look at what registrants need to include in their application package, including the specific thresholds and metrics reviewers are looking for. It would also outline common mistakes or deficiencies that registrants should avoid, along with examples of the correct way to do things.

- **PR5 – Excessive touchpoints and coordination bottlenecks**. The preliminary technical screen involves extensive back-and-forth within OPP and with registrants. When deficiencies are found, science teams must communicate them to RMs and then RMs summarize them in a 10-day letter to be shared with registrants. Interviewees noted that there is significant variation in how science staff summarize these findings and communicate them with RMs, making it challenging for RMs to then consolidate the information effectively and without losing any key points. Once they do, RMs then route these letters through multiple layers of internal review before being able to send them out to registrants. This slows communication and makes it difficult to identify and resolve issues within the 45- or 90- day window, causing delays and missed opportunities to address deficiencies early. Moreover, if reviewers ever decide to pursue rejection of an application, that requires even more levels of review and is often not supported by leadership other than in extreme cases.

Root Causes for People Challenges

- **PE1 – Inconsistent communication with registrants.** Registrants shared concerns about inconsistent and unclear communication from OPP staff. Response times vary widely across staff members, and there is no single channel for registrant communications. Responses given to registrants regarding their application timelines can also be vague and unclear, forcing registrants to send repeated messages, often across both email and MyPest, before receiving a clear answer. This results in registrants having to overwhelm OPP staff with messages across multiple channels (email and MyPest) before getting a clear response. This lack of consistency makes it difficult for registrants to track their application's status or take proactive steps to fix deficiencies and move their application forward.
- **PE2 – Insufficient customer service mindset**. There is not currently a strong cultural emphasis on the importance of meeting registrant needs within OPP. OPP reviewers prioritize environmental and health safety when conducting reviews, as they should, but there is less emphasis on supporting registrants through the process. Staff may not view registrants as key stakeholders whose needs also deserve attention. As a result, the registration process can feel burdensome, slow, and opaque to registrants, with delays that have real business consequences. This lack of a service mindset risks discouraging innovation within the pesticide industry and misses an opportunity to build more collaborative relationships with industry. A stronger focus on clear communication, responsiveness, and understanding registrant perspectives would help OPP better meet its full mission of efficiently bringing safe, effective, and innovative pesticides to market.
- **PE3 – Lack of industry expertise among OPP staff.** Many OPP reviewers come from scientific backgrounds and may lack familiarity with the pesticide industry's business practices, timelines, and operational realities. This can lead to confusion and miscommunication when OPP staff need to explain the rationale behind certain decisions. As a result, reviews may take longer and require

more back-and-forth with registrants. While some registrants have hosted training for OPP staff to help close these gaps, such efforts are irregular and not coordinated across the program.

- **PE4 – Potentially inefficient staff allocation.** Across many interviews, stakeholders expressed that OPP is understaffed. The team has received some initial data around workload to begin investigations into why OPP is understaffed, but the data is too limited in scope to truly determine the root cause. One hypothesis is that staff are not being allocated across divisions in proportions that match application distribution. The application load distribution for OPP reviewers in FY24 is displayed in Figure 10.

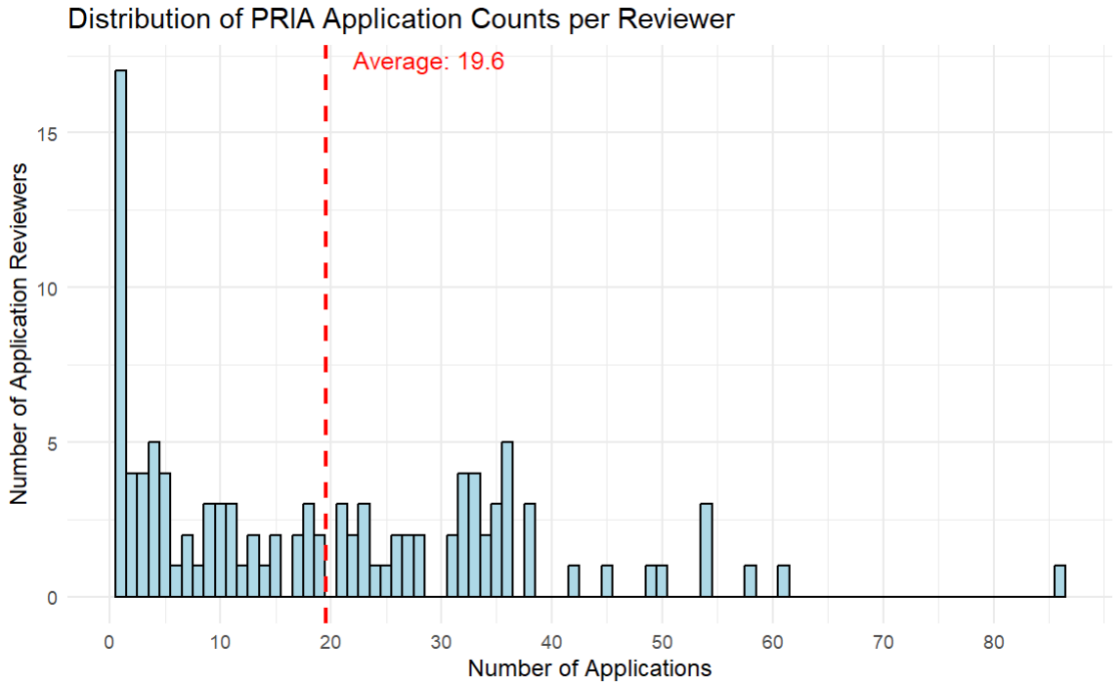

Figure 10: The number of applications assigned to reviewers varies significantly and can be as high as 50 or 60.

On average, a reviewer is responsible for 20 applications concurrently. Some staff are responsible for 50 or more applications concurrently, with one staff member responsible for 86 concurrent applications. Data on application management by division shows that RD staff are responsible for, on average, 53% more applications than AD staff and 25% more applications than BPPD staff. Average application numbers per reviewer in each division are presented in Table 2.

Team Division	Average # Applications Per Reviewer
AD	15
BPPD	18.4
RD	23

Table 2: On average, reviewers within RD are assigned the highest number of applications.

Based on the anecdotal evidence and the data shared above, the team believes that staff may be inefficiently allocated across divisions. The upcoming workforce assessment will investigate these inefficiencies and help the team identify their root causes. The workforce assessment will explore areas such as how staff is distributed within divisions, how applications are assigned to

staff, and how recent supplemental funding has impacted the workforce. In the meantime, this BPR has provided recommendations to alleviate burdens caused by potentially inefficient allocation of staff and overworked reviewers.

Root Causes for Policy Challenges

- **PL1 – Outdated policy and internal OPP guidance.** Another complicating factor in executing policy is that certain key manuals are outdated.. Even when updates to policy and internal OPP guidance documents are made, the changes may be documented in separate locations, making it difficult to see which aspects of the policy are still relevant. Changes in the pesticide industry are not always reflected in policy, creating more opportunities for OPP staff to develop their own individual standards and interpretations. Some internal checklists and tools for the preliminary technical screen are also over 10 years old, with many created in 2012. The processes in these tools may be obsolete or inefficient but remain the latest guidance on how to complete the screen.
- **PL2 – Fragmented documentation of key policies**. Both registrants and OPP staff reported difficulty navigating the policies that govern the PRIA registration process. Key procedures are distributed across multiple documents, requiring users to have prior knowledge of where to search. Additionally, the lack of a centralized repository makes these documents difficult to locate and reference. This fragmented structure increases the risk of inconsistent or incorrect interpretations of policy, often leading to additional back-and-forth to resolve confusion.
- **PL3 – No centralized record of past decisions.** OPP lacks a centralized system to document and share past review decisions, which makes it difficult to ensure consistency across reviewers and over time. Without access to prior determinations, reviewers may unknowingly contradict earlier guidance—sometimes identifying something as a deficiency that had been previously accepted without issue. This is especially frustrating for repeat registrants, who may have followed the same process for years only to be told it is now deficient, despite no change in formal policy. These contradictions lead to confusion, back-and-forth communication, and delays as registrants seek clarity and reviewers attempt to reconcile inconsistent precedents.

Root Causes for System Challenges

- **S1 – Limited automation within preliminary technical screens.** Despite the transition to Salesforce, OPP has not fully leveraged its automation capabilities to streamline the preliminary technical screen. The process still relies heavily on manual work, even for tasks that could be automated – such as verifying the presence of required studies based on the PRIA code. Current IT workflows either lack the functionality to support automation or would require significant updates to do so. Science teams, in particular, report creating manual workarounds just to complete basic screens. As a result, reviewers spend more time on routine tasks, which contributes to delays and missed PRIA deadlines.
- **S2 – Salesforce lacks certain document management functionality.** While Salesforce has improved team collaboration in some areas, it is missing important features needed to manage registrant documents, which are a central part of the preliminary technical screen. Registrants' study documents are not stored directly on the platform, so staff must manually download and review them outside the system. Moreover, Salesforce does not support bulk downloads or make it easy to share documents across teams, which creates coordination challenges. As a result, reviewers spend valuable time locating, downloading, and distributing files instead of focusing on the review itself.

- **S3 – Inaccurate timelines and statuses in Salesforce and MyPest.** Applications are automatically moved to the preliminary technical screen after they reach the 21-day deadline of the initial content screen, regardless of whether the initial content screen is complete. This creates confusion for OPP staff, who often cannot tell what work has already been done or where to begin their review. At the same time, both Salesforce and MyPest show that the application is under preliminary technical review, even if it has not been started, which misleads both internal staff and registrants about the application's true status. Due dates are often based on incorrect start dates and are not consistently updated when delays occur, further limiting transparency. As a result, staff lack visibility into timelines for when they should begin work, and registrants have no clear understanding of where their application stands or when to expect a decision, making it difficult to plan product launches.
- **S4 – Inconsistent adoption of Salesforce.** OPP has migrated to using Salesforce for reviews, but teams have been inconsistent in their adoption of the new tool. Some teams have incorporated it successfully into their processes and have created workflows that greatly help their reviews. Others called it a significant hindrance to being able to complete their work and explained that the tool makes their processes more complicated rather than simpler. This variation signals that not all teams are taking advantage of the automation and organization capabilities that the tool offers, limiting the efficiencies they are able to implement into their processes. Moreover, inconsistent Salesforce adoption further hinders communication, as some individuals will send messages through Salesforce and others through email or other channels, making collaboration difficult and more time-consuming.

4.3 PRIA Registration Deep Dive Areas: Recommendations

4.3.A Recommendations Overview

Recommendation classification. This section covers all the recommendations for improvement within the PRIA registration deep dive areas that could help lessen the number of delays plaguing the process. Each recommendation is associated with at least one of the two deep dive areas within the PRIA Registration process as well as the root cause(s) that it helps to address[3]. Moreover, all recommendations are categorized as either a momentum builder, strategic opportunity, nice to have, or investigate/defer. For a more detailed breakdown of what these categories mean, please see the Approach and Methodology section of the report.

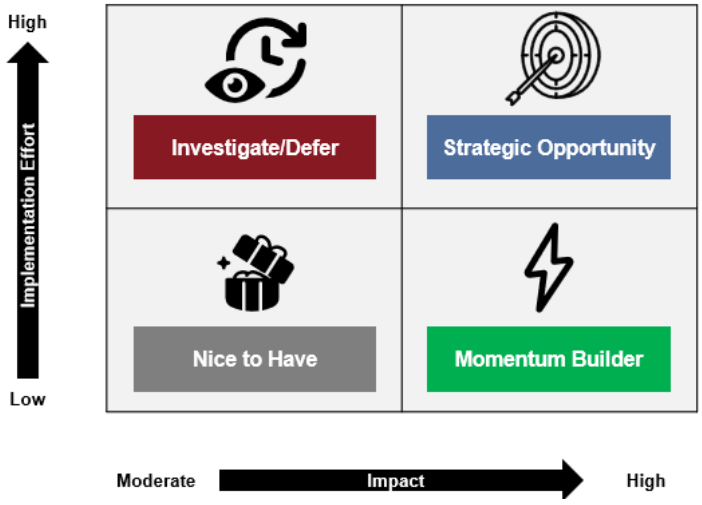

Figure 11: This framework helps categorize and prioritize recommendations based on their impact and feasibility.

Recommendation table and descriptions. Each category of recommendation has its own section that begins with a table summarizing the recommendations within the category, including a link to the detailed recommendation description and an indication of which of the four pillars (Process, People, Policy, or Systems) the recommendation is associated with. This summary table is followed by detailed descriptions of all the recommendations, why they would benefit OPP, and preliminary guidance on how OPP should approach their implementation. Each recommendation addresses at least one root cause from either the initial content screen (ICS) or the preliminary technical screen (PTS), using the acronyms attached to each root cause. For example, if a recommendation references ICS PR3 and PTS PL2, it addresses the third process-related root cause within the initial technical screen and the second policy-related root cause within the preliminary technical screen. Each of these root causes is also linked in the descriptions.

The team identified 44 total recommendations to address the challenges across both PRIA Registration deep dives area. Of those recommendations, 10 are momentum builders, 18 are strategic opportunities, 6 are nice-to-haves, and 10 should be investigated/deferred.

[3] Please note that to save space in the tables and parentheticals within this section, acronyms are used to refer to the two deep dive areas: ICS stands for initial content screen and PTS stands for preliminary technical screen.

4.3.B Momentum Builder Recommendations

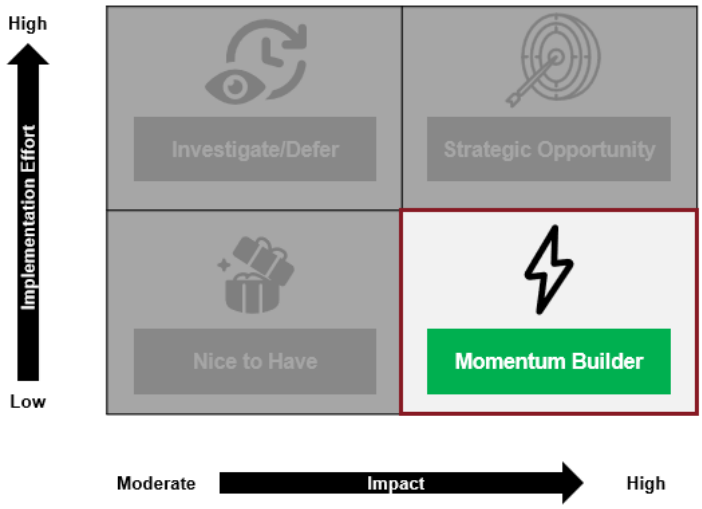

Figure 12: This framework helps categorize and prioritize recommendations based on their impact and feasibility.

#	Title	Process	People	Policy	Systems
1	Implement Automatic Alerts for Missed and Late ***Deadlines***	✓	✓		✓
2	Develop Clear Statuses for Applications within Salesforce and MyPest	✓			✓
3	Establish a Maintenance Calendar for CDX	✓			✓
4	Stop Initial Content Screen Work after 21-Day Deadline	✓			✓
5	Conduct a Thorough Review of the Contract Supporting the Initial Content Screen ***(ICS)***		✓	✓	
6	Strengthen Collaboration across All Initial Content Screen Stakeholders	✓	✓		✓
7	Improve Communication of Updates to PRIA Codes	✓	✓		
8	Limit Handoffs and Reviews for 10-Day Letters	✓	✓		
9	Establish Regular Team Meetings for Reviewers with Standard Agenda	✓	✓		
10	Standardize Format for Summarizing Science Findings	✓	✓		

1. Implement Automatic Alerts for Missed and Late Deadlines (ICS, PTS)

What: These automated alerts would come through Salesforce, with the option of an email alert that goes to the inbox of the team members responsible for the applications.

Why: Automatic alerts in Salesforce for missed or late deadlines would improve transparency and reduce the risk of stalled application reviews. These alerts would prompt reviewers to take action and prevent applications from slipping through the cracks. They would also make sure all internal review teams, including those that may be receiving an application later in the process, have more visibility into missed deadlines (ICS S4). Automating the alerts will reduce the burden on staff to communicate these updates while ensuring necessary updates are shared across stakeholders, improving coordination (ICS PR4). For the preliminary technical screen phase, this notification would also enable proactive communication with registrants, allowing RMs to notify registrants of delays and provide updated timelines, improving consistency and clarity in communications (PTS PE1).

How: When a screen's deadline is approaching, Salesforce can notify the assigned reviewer that they must provide their input within the assigned timeline and that, for the initial content screen phase, the application will automatically move to the next stage once the deadline arrives. To ensure that automatic alerts for missed or late deadlines are effective and accurate, OPP can establish expectations that reviewers check off tasks in Salesforce as they are complete and confirm that due dates are accurate (PTS S3). For the initial content screen, PMs can perform this check and for the preliminary technical screen, RMs can be responsible.

2. Develop Clear Statuses for Applications within Salesforce and MyPest (ICS, PTS)

What: These statuses would be incorporated into Salesforce, providing more detail in the Salesforce process flow to better capture who is responsible for the current step and the source of potential delays.

Proposed statuses include:

- "IN FRONT-END PROCESSING" - when with ISB for intake
- "OUTSTANDING FEE PAYMENT" - when fees are unresolved
- "IN INITIAL CONTENT SCREEN" – when with ISB contractors
- "WITH REGULATORY TEAM" – when with regulatory division staff
- "WITH REGISTRANT" – when awaiting deficiency corrections
- "PENDING" – when sitting in a queue

Why: Adding standardized, descriptive statuses to applications within Salesforce and MyPest would improve transparency into where each application is in the review process and help internal teams coordinate to identify the source of delays more quickly. Current statuses often do not reflect real-time progress, constraining the potential for collaboration across teams and limiting visibility for both OPP staff and registrants (ICS S4, PTS S3).

These statuses would support better workflow management and coordination across teams internally (ICS PR4). They would ensure that RMs within the regulatory divisions do not begin conducting a preliminary technical screen for an application whose initial content screen has not been complete or whose fee payments are still unresolved. They would also increase transparency for registrants into where their application is in the process, allowing them to better plan around accurate review timelines.

How: OPP staff can update the Salesforce workflows to include these additional statuses. Implementation may require minor Salesforce configuration updates and input from users to ensure alignment with actual process touchpoints.

3. Establish a Maintenance Calendar for CDX (ICS, PTS)

What: This would be a calendar outlining the exact maintenance work planned for CDX, the date and frequency of the update, the person responsible and the anticipated outcomes.

Why: A recurring, clearly communicated maintenance calendar for CDX system updates could reduce unplanned downtime, minimize delays in application intake, and improve coordination across teams (ICS S2). When CDX crashes, ISB cannot process applications, which shortens the window for ISB contractors to complete the initial content screen, contributing to missed 21-day deadlines (ICS PR1, PTS PR1).

A formal maintenance schedule would allow bug fixes to be applied during periods of low activity and would help avoid system disruptions during peak intake periods. Timelines for updates can be shared in advance with the ISB contractors and regulatory division PMs to improve planning and avoid workflow disruptions. Over time, predictable and proactive system maintenance would reduce the risk of front-end delays and improve overall process reliability.

How: OPP IT experts can create a tiered schedule based on potential impact and workload to determine what types of maintenance (e.g., routine checks, security updates, performance tuning, major upgrades, and backups) should be completed on what cadence. Once IT experts establish priority tasks and target frequency, OPP can determine the responsible owners and develop a plan for expected downtime, preparing communications to notify users when the system will be down.

4. Stop Initial Content Screen Work after 21-Day Deadline (ICS, PTS)

What: OPP should only perform initial content screen work within the 21-day timeframe so that once the deadline passes, the application automatically moves on to the preliminary technical screen without any question of if outstanding tasks were completed.

Why: Ending initial content screen work once the 21-day deadline passes would increase process consistency, reduce confusion over application ownership, and help address delays caused by front-end bottlenecks. This change would prevent the ISB contractors from continuing to make updates after the application reaches regulatory division RMs, ensuring that downstream work cannot be disrupted by delayed or overlapping edits (ICS S4, PTS S3). It would also allow contractors to shift their focus to new applications, helping them address high volumes of incoming applications.

How: OPP can consider implementing a block in Salesforce that prevents ISB contractors from editing applications once they pass to the preliminary technical screen team. OPP should also supplement this system adjustment with communication underscoring the value of having a clean handoff between the two process phases. Although OPP may consider shifting the responsibilities within the initial content screen as described in Recommendations 171717 and 181818, this recommendation can be implemented in the interim to improve efficiency across teams in the short-term.

A longer-term solution to this problem is to revisit the legislation and update the requirements and process for the initial content screen. One change could include lengthening the period of this initial screen to a number of days that OPP deems sufficient to consistently complete the screen. Another change would be to clarify and reinforce the scope and steps taken within this initial content screen, codifying

that the screen should be a high-level review that the materials submitted are present and correct for the PRIA code, and not an in-depth review of the materials themselves.

5. Conduct a Thorough Review of the Contract Supporting the Initial Content Screen (ICS)

What: OPP could conduct a thorough review of the current contract for ISB contractors working on the initial content screen to determine if objectives have shifted and if the contract structure as written fits with the goals for the process going forward.

Why: Reviewing the contract for the ISB contractors that support the initial content screen process would help determine how current roles, responsibilities, and resources align with the process goals. This review would identify any structural misalignments contributing to performance challenges (ICS PL3).

How: Although Recommendation 17 would potentially eliminate the need for the ISB contractors in the long term, this intermediary step could focus on whether the contract reflects the intended objectives of the initial content screen and whether staffing levels are adequate to meet current demand. If gaps emerge, adjustments can be made before reassigning responsibilities or reducing contractor involvement.

6. Strengthen Collaboration across All Initial Content Screen Stakeholders (ICS)

What: OPP should establish recurring meetings among all initial content screen staff to provide a regular forum for clarifying questions, sharing status updates, and aligning on guidance regarding applications.

Why: Improving coordination among all teams involved in the initial content screen process, including ISB staff, ISB contractors, and regulatory division PMs would reduce delays, eliminate duplicate effort, and improve consistency across reviews. Communication across these groups is currently fragmented, and teams often lack visibility into applications' status (ICS PR4, ICS S4). Increasing regular touchpoints would create a direct communication channel between regulatory division PMs and ISB contractors, improving handoffs and reducing confusion around how to conduct screens (ICS PE1).

Together, these actions would increase transparency, promote consistent decision-making, and enable more efficient collaboration through the initial content screen process.

How: These meetings should follow a standard agenda and take place on a pre-established cadence. Outside of meetings, Salesforce can serve as a centralized platform for tracking decisions, coordinating on applications, and maintaining a clear communication record. OPP could also establish a structured feedback loop between ISB contractors and regulatory division PMs to flag high-error PRIA codes or common registrant mistakes, allowing for targeted process improvements.

7. Improve Communication of Updates to PRIA Codes (ICS)

What: OPP should provide early alerts on PRIA code updates and include clear guidance on how the change impacts the ISB contractors' work.

Why: This communication could help ensure ISB contractors consistently review applications against the correct PRIA codes and reduce delays caused by miscoding (ICS PE1). Currently, ISB contractors receive limited notice about PRIA code changes and lack the context needed to apply them correctly. Without timely information, teams may use outdated codes or fee structures, resulting in rework by OPP staff later in the process and potential delays in reviewing applications (ICS PR3). Improved communication would reduce these errors and support more accurate, efficient reviews from the outset.

How: These updates could include notice of upcoming PRIA code changes at the start of each fiscal year. During the annual update, the PRIA Coordinator could develop a list of which PRIA codes will be affected and share it with ISB contractors. As codes are updated, the PRIA Coordinator should document the details of the change along with an example of how to apply it in practice.

8. Limit Handoffs and Reviews for 10-Day Letters (PTS)

What: OPP should consider reducing the number of internal reviews required for 10-day letters, capping the reviews at the PM level for most reviews and only requiring additional review for letters that meet specific criteria.

Why: Reducing the amount of review needed for 10-day letters would help OPP decrease delays and ensure deficiencies are communicated to registrants in time for resolution within the preliminary technical screen window. Currently, letters identifying deficiencies go through multiple rounds of review, often climbing the chain to increasingly senior staff. These handoffs add days or weeks of delay, leaving applications in limbo and limiting RD's ability to take timely action (PTS PR5). The extended review process also burdens already overstretched RD staff (PTS PE4). By minimizing unnecessary touchpoints, OPP could reduce coordination bottlenecks, speed up communication with registrants, and allow senior staff to focus on higher-priority work.

How: OPP should establish, document, and communicate exactly who needs to review most 10-day letters. Then, OPP should identify criteria for higher-complexity letters that warrant additional review (i.e., those with major policy implications or complex technical issues) and should document and communicate those criteria as well as the exact review needed for those letters. Once OPP establishes this leaner review process, they should periodically evaluate its impacts to assess for further adjustments.

9. Establish Regular Team Meetings for Reviewers with Standard Agenda (PTS)

What: OPP could set regular meetings for the regulatory and science team members working on the preliminary technical screens that allow the team to provide updates and coordinate reviews.

Why: More regular cross-division meetings will improve coordination and produce more consistent decision-making. Current meetings are infrequent and loosely structured, which limits their effectiveness. Standardizing these touchpoints will give teams a dedicated space to align on complex decisions, review application progress, and ensure consistent interpretation of policy and guidance (PTS PR3, PTS PR5).

How: OPP can hold these meetings at the start, midpoint, and near the deadline of a preliminary technical screen. These meetings should include all relevant staff – from both regulatory and science divisions – with the RMs facilitating the discussion. A standard agenda can include:

- Clarifying policy questions
- Reviewing outstanding registrant inquiries
- Validating the scope of the review
- Confirming that flagged deficiencies merit resolution.

This structure will help reduce unnecessary back-and-forth and help reviewers apply policy more consistently and effectively.

10. Standardize Format for Summarizing Science Findings (PTS)

What: This would be a template for science teams to use when communicating the results of their review to RMs, highlighting the key information needed to draft the 10-day letter.

Why: Creating a standard format for how science divisions summarize deficiencies during the preliminary technical screen process will help RMs draft 10-day letters more efficiently and reduce delays in communication with registrants. Currently, science teams submit memos in varying formats, which makes it harder for the RMs to consolidate findings and can lead to follow-up questions that delay the review process (PTS PR5). These inconsistencies increase the odds of missing the window to issue a 10-day letter and do not support timely communication with registrants (PTS PE1).

How: To streamline this step, OPP can:

- Develop a simple, consistent memo template for science divisions to use when submitting findings, potentially leveraging the existing template from BPPD
- Ensure the template captures all required information clearly and is easy to transfer into the 10-day letter template
- Consider implementing internal timelines for the regulatory and science team members to draft and send the 10-day letter, as interviewees noted instances where memos sit in a long queue before the corresponding 10-day letter is sent

These changes will improve internal coordination, reduce back-and-forth between teams, and support more timely communication with registrants.

4.3.C Strategic Opportunity Recommendations

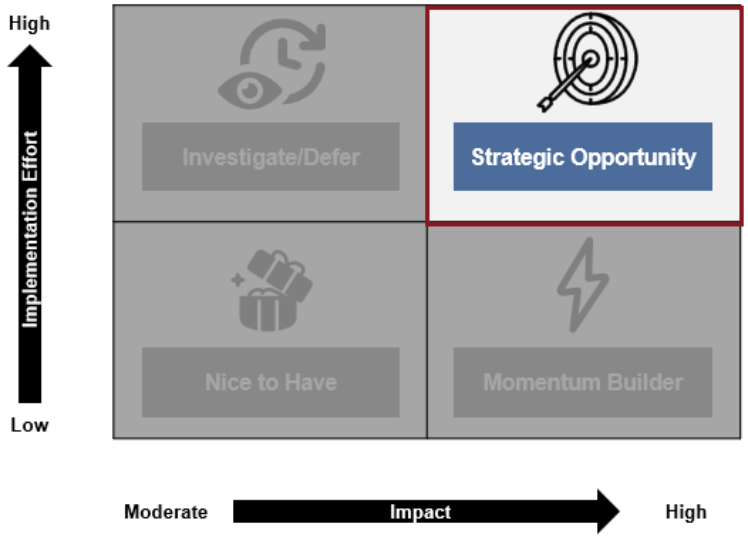

Figure 13: This framework helps categorize and prioritize recommendations based on their impact and feasibility.

#	Title	Process	People	Policy	Systems
11	Expand and Refine Registrant Guidance Materials	✓	✓		
12	Condense and Centralize Policy and Guidance Documents	✓		✓	
13	Establish Standards around Registrant Communication	✓	✓		
14	Allow Registrants to Self-Certify for Low-Risk Submissions ***(ICS, PTS)***	✓			✓
15	Develop Capability for Direct Data Entry and Targeted ***Edits by Registrants (ICS, PTS)***	✓		✓	✓
16	Encourage Consistent Use of Pre-Registration Meetings ***(ICS, PTS)***	✓	✓		
17	Automate the Majority of the Initial Content Screen Process	✓		✓	✓
18	Reassign Complex Parts of the Initial Content Screen to OPP Staff	✓	✓	✓	
19	Establish a Consistent Process for Triaging and Prioritizing Applications	✓			✓
20	Clarify Guidance on Expedited Screens	✓	✓		
21	Improve OPP Reviewer Training on PRIA Review Guidance and ***Policy***	✓	✓	✓	

#	Title	Process	People	Policy	Systems
22	Establish Regular Cadence to Update Policy Documents	✓		✓	
23	Implement Structured E-Labeling Format	✓			✓
24	Float Resources Across Divisions to Balance Workload	✓	✓		
25	Create Database of Past Review Decisions ***(PTS)***	✓	✓	✓	
26	Conduct Workforce Assessment ***(ICS, PTS)***		✓		
27	Develop a More Automated Method for Data Extraction	✓			✓
28	**Error! Reference source not found.**	✓	✓		

11. Expand and Refine Registrant Guidance Materials (ICS, PTS)

What: OPP should update existing registrant guidance materials and create new materials where needed to address common mistakes or new requirements.

Why: Improving the clarity and specificity of registrant-facing guidance would help reduce deficiencies in application submissions and minimize delays in the review process. More targeted resources would better support registrants – particularly those submitting complex or frequently misinterpreted application types – in preparing complete and accurate applications (ICS PR2, PTS PR4).

How: Review registrant guidance to identify where updates are needed and where guidance does not yet exist. In addition to closing gaps in existing content, OPP can enhance current materials by incorporating:

- Plain language wherever possible
- Glossaries to define key technical terms
- Clear formatting with headings, bullets, and concise summaries
- FAQ sections informed by common registrant questions
- Real-world examples of applying guidance
- Division- or branch-specific guidance developed by science teams for nuanced cases

OPP can prioritize updates based on how frequently registrants use guidance or how broadly it applies. Embedding these principles into future resources will improve consistency in submissions, reduce the need for follow-up communication, and enable applications to move more efficiently through registration.

12. Condense and Centralize Policy and Guidance Documents (ICS, PTS)

What: OPP should review all existing documents and resources to remove duplicative information, review conflicting guidance, and simplify materials before publishing all resources in a central and accessible location.

Why: Condensing and organizing both public-facing and internal guidance materials into streamlined, clearly labeled repositories would improve access to accurate information, reduce inconsistencies in interpretation, and support higher-quality applications.

This recommendation applies to both formal policy documents and informal process guidance or best practice materials, as none of these are currently stored in central locations (ICS PL1, PTS PL2). It also includes materials intended for public use (e.g., by registrants) as well as those for internal OPP staff (e.g., by reviewers). Streamlining access across both audiences would help reduce registrant confusion and improve consistency across reviews (ICS PR2, PTS PR3, PTS PR4, PTS PL1). Together, these efforts would reduce duplicative guidance, clarify outdated instructions, and ensure that all stakeholders can easily access the most current and relevant information to support timely, high-quality reviews.

How: Public-facing materials – including policy, templates, examples, points of contact, and best practices – should be reviewed, consolidated, and posted in a single, easy-to-navigate location, potentially within the EPA website. This repository should be searchable, filterable, and tagged with metadata (e.g., by application type, division, active ingredient, or use case) to allow users to find what they need quickly. A dedicated landing page should serve as a central hub, clearly accessible from other registration pages.

Internal guidance for OPP staff should be similarly consolidated and stored in a single, accessible location, ideally within Salesforce to align with staff workflows. This would ensure that reviewers have consistent reference materials and would reduce process variation and misinterpretation.

13. Establish Standards around Registrant Communication (ICS, PTS)

What: These standards should consist of clear, consistent guidelines for how and when staff interact with registrants to ensure professionalism, responsiveness, and mutual trust.

Why: Setting clear standards and accountability mechanisms for communication with registrants would improve the consistency and reliability of the interactions, creating a more transparent and user-friendly experience. This would help ensure all registrants receive timely, accurate, and equitable support, regardless of which OPP staff member they engage with (ICS PR2, PTS PE1).

How: Currently, communication with registrants varies widely across staff, leading some registrants to feel supported while others experience confusion around delays. Establishing formal communications could include:

- Defining expected response timelines for all registrant communications (e.g., 24 hours)
- Standardizing which communication channel to use (e.g., phone, email, or MyPest)
- Providing tips for interacting with registrants, such as using plain language, pointing registrants to relevant resources, and flagging often misinterpreted guidance for OPP reviewer awareness
- Implementing accountability mechanisms, such as a timer in Salesforce to track response time, with automatic flags when timelines are missed

These measures would increase trust, reduce frustration, and improve overall satisfaction with OPP's process for PRIA registration.

14. Allow Registrants to Self-Certify for Low-Risk Submissions (ICS, PTS)

What: For low-risk or routine submissions, registrants could attest that they meet certain requirements so that OPP does not need to complete a full upfront review of the application.

Why: Introducing opportunities for registrants to self-certify for low-risk application components would reduce front-end review workload and help prevent delays caused by manual checks during the initial content screen and the preliminary technical screen (ICS S1, PTS S1). This approach would streamline

processing for well-defined, low-impact changes while preserving program integrity through targeted audits and enforcement.

How: Registrants would affirm compliance with OPP-defined criteria for their application type and submit documentation attesting to the accuracy of their claims. OPP can validate a sample of these affirmations through routine audits and impose consequences for noncompliance. This would allow staff to focus on more complex, higher impact submissions

Examples of potential self-certification opportunities include:

- Confidential Statements of Formula (CSFs), when changes are minimal or administrative
- Minor label updates, such as formatting changes, typo corrections, and graphics
- Non-substantive formula adjustments authorized under PRN 98-10
- Good Laboratory Practices (GLP) for acute toxicity
- Applications for substantially similar (identical) products or repack registrations
- Additions of bacterial strains for public health disinfectants and sanitizers

Expanding self-certification for clearly defined use cases would reduce bottlenecks at the start of the review process, while audit mechanisms would help maintain accountability and public trust.

15. Develop Capability for Direct Data Entry and Targeted Edits by Registrants (ICS, PTS)

What: Registrants should have the ability to input their application information directly into OPP's system (i.e., Salesforce) and update specific areas of an application during a defined editing window.

Why: Allowing registrants to enter data directly and edit structured fields or pages within their applications in Salesforce would streamline the correction process, reduce the administrative burden, and accelerate application reviews. This approach minimizes errors at the point of entry, eliminates the need for staff to extract and reformat information from PDF documents, and reduces the reliance on full resubmissions for minor issues (e.g., missing signatures, incorrect formatting).

Since there are currently many administrative hurdles to rejecting deficient applications, reviewers often lean on negotiation with registrants to ensure compliant applications, which can require many edits to forms and be very time-consuming (ICS PL2, PTS PR5). Currently, small fixes often require a full application resubmission, which generates a new MRID, delays the review, and adds unnecessary workload for OPP staff and registrants alike (ICS S3). Improving the input and correction process for these deficiencies would mitigate some of the delays that result from the current negotiation approach. Enabling targeted edits would support greater process automation by reducing the manual handling of minor corrections (ICS S1, PTS S1).

How: Registrants should be allowed to input application directly to Salesforce and make direct edits to their application in response to feedback received by OPP. OPP can set this up so that registrants can only edit applications once they are released for editing by the OPP reviewer and not while OPP is actively reviewing the application. A flexible editing capacity would align with best practices used by other agencies like the Food and Drug Administration (FDA) and promote a more efficient, collaborative review process.

16. Encourage Consistent Use of Pre-Registration Meetings (ICS, PTS)

What: OPP could actively promote and facilitate early conversations with registrants to clarify requirements, identify red flags, and improve application quality.

Why: Encouraging more consistent use of pre-registration meetings could improve application quality and reduce preventable deficiencies. These meetings give registrants a direct channel to ask questions, clarify policy, and ensure they are submitting complete and accurate applications, which can be especially important for small businesses or less experienced applicants (ICS PR2, PTS PR4). These meetings can also help strengthen registrant engagement, increasing trust and satisfaction throughout the process (PTS PE2). When used, pre-registration meetings have helped registrants avoid common mistakes such as selecting the wrong PRIA code, formatting studies incorrectly, or omitting required forms. Expanding use of these meetings can help reduce early-process errors, support clearer communication, and reinforce a service-oriented approach to registrant engagement. Documenting the outcomes and guidance provided in the meeting will help ensure alignment between OPP staff and registrants, thereby reducing potential for misunderstanding or rework post-submission (PTS PR3).

How: To boost awareness and accessibility, OPP can include optional scheduling prompts within MyPest and highlight the availability of pre-registration meetings in existing communications. OPP could alternatively create a designated form to request a meeting and provide some context. Standardizing the format for pre-registration meetings, with an agenda checklist and common FAQs prepared, could also help make the meetings more efficient.

After each meeting, OPP can document the decisions from the meeting and upload a standard meeting outcomes/agreement file in CDX and MyPest. This will help ensure the application review is informed by and consistent with the guidance provided in the meeting.

17. Automate the Majority of the Initial Content Screen Process (ICS)

What: OPP should consider incorporating Salesforce validations (utilizing AI capabilities) to perform all routine and rules-based tasks within the initial content screen.

Why: Automating administrative steps in the initial content screen process would significantly reduce review time and minimize delays tied to manual processing (ICS S1). Automating key verifications would streamline reviews, mitigate effects of front-end delays and high volumes of applications, and reduce the burden on ISB contractors (ICS PR1, ICS PL3,).

Over time, automation could reduce or eliminate the need for contractor support altogether, allowing remaining non-automated tasks (e.g., code verification) to be handled by OPP staff with greater subject matter expertise during the preliminary technical screen.

How: Automation could be implemented through enhancements to the existing system (e.g., Salesforce AI capabilities) or integrated through third-party applications or APIs. Implementation would begin with a complete inventory of current steps within the initial content screen, followed by collaboration with IT staff and vendors to identify automation opportunities. Verifications that could be potentially automated include checking for required forms, confirming documents are in English and correctly formatted, and ensuring the number of studies listed matches the number provided. These automations could be implemented in the submission phase, using logic or system rules to check the application when the registrant submits it and prevent submission if criteria is not met. This could eventually remove the need for the bulk of the ICS checks, ensuring that only applications that satisfy ICS requirements can be submitted. A phased, agile approach to this automation that begins with low-effort tasks would allow OPP to build momentum while maintaining process integrity.

18. Reassign Complex Parts of the Initial Content Screen to OPP Staff (ICS)

What: OPP should consider reassigning the initial content screen workflow so that the most technical, nuanced, and high-complexity elements of the screen are conducted by OPP staff.

Why: Reassigning complex tasks within the initial content screen process, such as PRIA code verification, to OPP staff would improve accuracy and reduce delays caused by rework. These steps often require policy and scientific judgement that the ISB contractors lack the subject matter expertise to apply consistently (ICS PE1). Currently, OPP staff frequently conduct code alignment meetings when they receive an application for the preliminary technical screen to review and confirm the PRIA code, as the contractor team often misses potential mistakes in their review of the codes. Since this verification step is already being informally performed by OPP staff, formally assigning this responsibility to RMs to complete at the start of the preliminary technical screen would eliminate the need for additional contractor training and ensure more reliable code alignment from the outset (ICS PR3).

How: OPP should begin implementation by taking a complete inventory of current steps within the initial content screen to identify which items, such as PRIA code verification, would be best suited for OPP review. OPP should then confirm exactly who within the regulatory divisions should conduct these reviews and should communicate this adjustment to all affected parties. Although this change would involve a modest shift in roles, it would strengthen overall review quality and reduce the likelihood of errors moving downstream.

19. Establish a Consistent Process for Triaging and Prioritizing Applications (PTS)

What: OPP could create a structured process to evaluate incoming applications within the preliminary technical screen phase and assign them to the correct queue or reviewer based on their complexity, urgency, or completeness.

Why: Implementing a clear system to triage and prioritize applications within the preliminary technical screen process will help OPP efficiently address backlogs caused by upstream delays, ensure applications are reviewed according to their complexity, and reduce variation in review scope (PTS PR1, PTS PR3). This process would direct attention to applications most likely to have deficiencies, enabling earlier identification and resolution within the required PRIA timeframe and preventing severely deficient applications from advancing (PTS PR2). It would also ensure that simpler applications receive expedited screens, allowing OPP to more quickly work through backlogs. By helping staff to better manage their internal workflow, OPP can better comply with PRIA deadlines as well as meet the needs of industry to process applications quickly.

How: To support this, OPP can assign more complex applications to experienced staff that are less likely to make decisions inconsistent with past reviews or with formal policy. OPP can simultaneously create an expedited process (i.e., a less detailed screen) for simpler applications that require only a high-level screen and can be handled by more novice staff. This expedited screen could be similar to the existing streamlined procedures for Notifications and Fast Track Amendments but should ensure that the scope of the screen is truly limited to a high-level review. Additionally, OPP can triage applications with similarities to previous reviews to staff familiar with those cases to improve consistency and reduce redundant effort.

In addition to the above, OPP can automate routine checks such as verifying missing data waiver requests or correct units of measurement to allow staff to focus on review areas needing expertise, further reducing review times and workload.

20. Clarify Guidance on Expedited Screens (PTS)

What: If OPP implements more expedited preliminary technical screens, they should create clear and consistent guidance that reviewers can follow to process expedited applications more quickly without comprising quality or regulatory standards.

Why: Creating clear guidance for the new expedited screens proposed in Recommendation 19 would help OPP reduce unnecessary effort on simple applications and focus reviewer time where it is most needed. Currently, even minor changes can trigger full, detailed reviews based on individual reviewer discretion (PTS PR3). This has led to frustration in the registrant community that their needs for clear and efficient timelines are not appropriately considered (PTS PE2). The development of a clear expedited screen process will help reviewers manage tight timelines, reduce variation in review depth, and foster increased registrant satisfaction.

How: To implement an effective expedited screen process, OPP should:

- Establish clear criteria for expedited screen eligibility and communicate it to staff and registrants
- Outline the key components of an expedited review, including required and optional steps
- Train staff to conduct expedited screens without defaulting to full evaluations

21. Improve OPP Reviewer Training on PRIA Review Guidance and Policy (PTS)

What: This involves developing a structured, ongoing learning program that equips reviewers with the knowledge, tools, and judgment needed to apply PRIA registration policies consistently**.**

Why: Strengthening OPP reviewer training can help reduce inconsistent decision-making among preliminary technical screen reviewers and clarify how to interpret fragmented or hard-to-find guidance. Reviewers currently complete the preliminary technical screen with varying levels of depth and differing interpretations of guidance and policy, which contributes to inconsistent decisions communicated to registrants (PTS PR3, PTS PL3). While it is unclear whether training gaps are the primary cause of this, clearer and more regular training could help address this variation and improve understanding of how to apply policy consistently, particularly in cases where policy is high-level or spread across multiple documents (PTS PL2).

How: OPP can improve reviewer preparedness by building a more robust training curriculum that includes practical examples, clarity on when to apply streamlined versus detailed reviews, and expectations around consistency. A repository of both foundational and subject matter specific training materials would support onboarding for new staff and offer a reference point for experienced reviewers facing novel or unclear situations.

22. Establish Regular Cadence to Update Policy Documents (PTS)

What: OPP should establish a repeatable and structured process to review, revise, and approve policy documents on a scheduled basis to ensure guidance reflects the latest regulations.

Why: Creating a structured process to routinely review and update policy documents will ensure that staff and registrants rely on clear, current policy applicable to the preliminary technical screen. Many existing resources are outdated, with some more than a decade old, and OPP does not seem to currently follow a consistent schedule for revisiting them (PTS PL1). A proactive, recurring review process will reduce confusion, support consistent interpretation, and ensure policy keeps pace with evolving industry practices.

How: To avoid reactive policy updates, OPP can establish a set cadence to proactively evaluate and revise key policy materials. Each update should include a summary of the changes at the top of the document and an explanation of how to apply the revision moving forward. Once finalized, OPP should communicate changes to both staff and registrants, potentially through alerts in Salesforce and MyPest.

23. Implement Structured E-Labeling Format (PTS)

What: This involves moving from static, text-based product labels to a digital and standardized label format that makes label content easier to search, validate, update, and integrate into electronic systems.

Why: Implementing a structured, machine-readable format for pesticide labels would greatly simplify the review process, reduce deficiencies, and support future automation. With high application volumes and complex labeling formats, reviewers currently spend significant time manually locating key information on labels and identifying potential deficiencies (PTS S1). A standardized e-labeling format would ensure that information is presented consistently, helping staff quickly find the required elements and reducing variation across submissions.

In addition to improving consistency, structured e-labeling can enable automated checks to flag missing or miscategorized information. While it may limit registrants' ability to customize their label formatting and differentiate their products, this approach speeds up the overall review process, which would greatly benefit registrants.

How: Key steps in developing this format would include developing a data model with the standard fields and values, creating the submission system, establishing the validation rules, and performing an internal integration to link up to related tools. Once these are in place, OPP can develop training and guidance on how to use the e-labeling format and roll out the changes, using a change management approach to facilitate the transition. The format could be rolled out iteratively, beginning with a pilot group to test out functionality and make small improvements before progressing to a wide-scale implementation.

This recommendation would require updating FIFRA to mandate that registrants submit actions using the standard e-label format.

24. Float Resources Across Divisions to Balance Workload (PTS)

What: OPP should consider identifying "floater" staff within the preliminary technical screen phase who can be move from one division to another, based on incoming application volume.

Why: Divisions often face significantly different volumes of applications, contributing to the workload imbalances and straining capacity in high-volume areas (PTS PE4). These pressures are compounded by delays in front-end processing and by sheer volume of applications needing review (PTS PR1). To combat these effects, when a division faces a backlog or a spike in volume, OPP could temporarily assign work to floaters who could conduct streamlined reviews or at least complete specific components of the preliminary technical screen to support the original team. This target reallocation would enable OPP to better align staff expertise with application complexity and increase its ability to complete timely and thorough reviews.

How: To implement this, OPP could designate "floaters" to provide surge support across divisions. Floaters would be individuals with transferable skills and could be cross trained to gain familiarity in other areas as needed. These floaters would take on simpler preliminary technical screens, freeing up specialized staff to focus on more complex applications.

25. Create Database of Past Review Decisions (PTS)

What: This database would store documents with past review decisions, tagged with metadata to ensure that the database is easily navigable.

Why: As part of the preliminary technical screen, staff often spend valuable time reassessing issues that were previously addressed in similar reviews (PTS PL3). Reviewers sometimes issue guidance that contradicts previous decisions, leading to confusion and conflicting guidance for registrants that leaves them frustrated with the process (PTS PR3, PTS PE2). Developing a centralized, searchable database of past review decisions could improve consistency, reduce duplication of effort, and speed up review timelines.

How: This searchable database could be organized by active ingredient and could include the following details for each application:

- Active ingredient details
- Use case details
- Name of previous reviewers
- Details of guidance/decisions, including rationale

When prior decisions are superseded by updated policy, entries should be flagged with links to current guidance. To reduce implementation burden, OPP can explore building this database into Salesforce by aggregating existing data and workflows.

26. Conduct Workforce Assessment (ICS, PTS)

What: OPP should conduct a workforce assessment to identify potential inefficiencies within its current staffing allocation and determine where additional support is most effective.

Why: A workforce assessment would provide additional data on how workload compares to staffing, showing where demand exceeds staff capacity. Mapping skills to tasks would help determine if there are any mismatches between employee skills and assigned duties or how current employees could be better leveraged in other areas. The assessment would also assess role clarity, identifying any redundant roles or unclear responsibilities that create rework or bottlenecks (ICS PL3). This effort would allow the team to identify the root cause of any inefficiencies in the current staffing structure and help OPP develop a strategic plan to resolve any gaps (PTS PE4).

How: Once the scope and purpose of the workforce assessment are defined, the assessment team should gather quantitative data. Metrics like workload (caseload per person, caseload per division), time allocation (how long each type of application takes), staffing data (roles and responsibilities), and performance metrics (backlogs, delays, rework rates) can be collected and analyzed. Qualitative data should also be collected, with interviews and/or focus groups conducted with staff to gather additional insights. The assessment team will then be able to map processes and roles to visualize workflows, identify inefficiencies, locate the potential source, and analyze staffing gaps.

27. Develop a More Automated Method for Data Extraction (PTS)

What: OPP should explore automation tools that can assist reviewers within the preliminary technical screen to extract relevant data from registrant-submitted studies.

Why: Science divisions spend significant time combing through studies to pull out the necessary data they need to assess in the preliminary technical screen. Incorporating an automated tool to extract data

would reduce manual effort and free up staff to focus on higher-level analysis and decision-making. It would also standardize how data is captured to make it easier to compare across studies and would provide an opportunity to output the data directly into databases where it can be retrieved in later steps of the process (PTS S1). A tool that extracts and organizes key data from registrant studies and organizes it in an effective way for reviewers would help streamline reviews and reduce overall timelines.

How: Science division representatives should first identify what types of information could be universally pulled from all studies and how it should be formatted upon extraction. They should then partner with internal IT experts to identify or develop automation tools that meet reviewers' needs, perhaps leveraging Natural Language Processing tools or custom rule-based scripts. Tools should require minimal manual setup and be tailored to the level of precision and complexity typical in these assessments.

28. Foster a Stronger Customer Service Mindset (ICS, PTS)

What: OPP should promote a culture in which staff actively support, inform, and engage with applicants, maintaining regulatory rigor while focusing on being responsive, transparent, and helpful.

Why: Cultivating a customer service mindset among OPP staff would improve the registrant experience and reduce inconsistent and unclear communication (PTS PE1, PTS PE2). Doing so could result in faster, and higher quality submissions as registrants would have a better understanding of expectations and more opportunities to ask clarifying questions. Moreover, ensuring that OPP staff consistently consider the registrant perspective could help lessen decision-making inconsistencies that unnecessarily increase registrant burden and apply policy too strictly (PTS PR3). This mindset would build trust in OPP's objectivity and professionalism.

How: To help foster this cultural shift, OPP could provide regular training emphasizing the importance of registrant engagement, with leadership modeling these values and communicating this priority across the agency. An example of prioritizing the registrant experience is encouraging reviewers to follow regulatory guidance without being overly restrictive or prescriptive, which risks unnecessarily creating additional requirements for registrants. Also, incorporating customer service expectations such as understanding registrant needs, building strong relationships, and recognizing industry dynamics into staff performance evaluations would reinforce consistent, relationship-driven approaches throughout the program.

4.3.D Nice-to-Have Recommendations

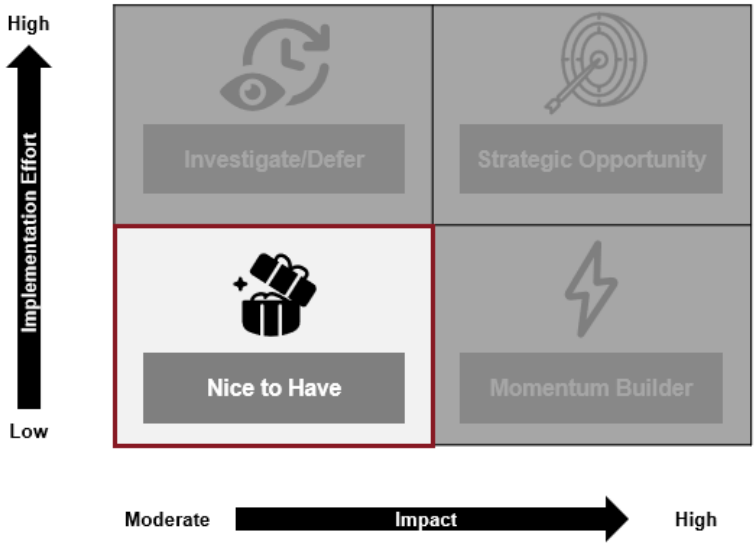

Figure 14: This framework helps categorize and prioritize recommendations based on their impact and feasibility.

#	Title	Process	People	Policy	Systems
29	Increase Access Rights for Regulatory Division Staff	✓			✓
30	Hold Applications with ISB Staff until Resolution of All Fee Issues	✓			✓
31	Standardize Required Cover Letter for Study Submission ***(PTS)***	✓			
32	Leverage AI to Draft 10-Day Letter	✓			✓
33	Work with Registrants to Develop Industry-Specific Trainings		✓		
34	Share Preliminary Technical Screen Checklists with Registrants	✓	✓		

29. Increase Access Rights for Regulatory Division Staff (ICS)

What: This would involve role-based access with granular permissions to designate which areas of the application different teams can edit within the initial content screen phase. More specifically, regulatory division staff should be granted permission to directly edit and resolve minor application deficiencies.

Why: Expanding access rights for regulatory division staff would reduce rework and allow experienced reviewers to resolve minor application issues directly. It would reduce the need for coordination between ISB and regulatory division staff, streamlining the process (ICS PR4). ISB contractors currently have greater system access than PMs, even after an application has been handed off to PMs, which limits the PMs' ability to fix issues efficiently (ICS S3). Granting additional access to regulatory division PMs to

edit studies directly would allow them to address minor issues in real time and help avoid unnecessary application recycling.

How: OPP should first map out current access rights and define roles and permissions. Then, they should modify the system permissions to grant regulatory division staff greater access and implement version control and audit logging to track changes. Once the system is updated, OPP can establish guidelines and trainings to inform regulatory division staff of changes before the updates are communicated out.

30. Hold Applications with ISB Staff until Resolution of All Fee Issues (ICS)

What: If an application has a fee issue, OPP should hold off on conducting further reviews and potentially pause the PRIA clock until the fee issue is resolved.

Why: Requiring ISB to resolve all outstanding fee issues before an application moves forward would prevent wasted review effort and improve clarity around application status. This change would ensure that only fully compliant applications proceed to the preliminary technical phase, reducing the likelihood of unnecessary reviews that must later be discarded.

Currently, some applications move forward to the preliminary technical screen phase before fee problems are resolved, leading to confusion among RD RMs and rework when those applications are later rejected or delayed (ICS PR4, ICS S4). Holding applications with ISB until payment is confirmed would create a clearer handoff and reinforce integrity by ensuring reviewers work only on compliant applications.

How: OPP can develop a Salesforce status that indicates fee issues to signal to staff that the application review is on hold. OPP can investigate the possibility of updating PRIA regulations to stop the PRIA clock when fee issues are identified and restart it once the issues are resolved.

31. Standardize Required Cover Letter for Study Submission (PTS)

What: OPP should require applicants to submit a cover letter that follows a specified template or format whenever they submit study materials.

Why: Requiring a standardized cover letter for all study submissions can reduce review time and help prevent common deficiencies in studies. With the volume of applications and the complexity of study documentation, reviewers benefit when applicants provide a concise summary that makes it easier to confirm required elements and locate key information quickly and consistently (PTS PR3).

While some registrants already include cover letters, making this a formal requirement and clearly communicating it in updated guidance would help set consistent expectations for registrants (PTS PR4). The cover letter template could also serve as a checklist for registrants, reinforcing what must be included to avoid errors or omissions.

How: OPP can begin by reviewing its current cover letter guidance and making updates as needed to ensure clarity and completeness. Over time, as cover letters become more uniform, OPP may explore incorporating metadata tags to highlight key study elements and further streamline the review progress.

32. Leverage AI to Draft 10-Day Letter (PTS)

What: OPP staff should input science division memos into and AI tool for it to extract key information and compile it into a 10-day letter, using the established letter template.

Why: To reduce the amount of time spent on drafting the 10-day letter, the regulatory divisions could utilize AI to review all the memos and create a first draft of the letter that regulatory staff would review

and edit as needed (PTS S1). This would enable the regulatory divisions to get the letters sent out to registrants faster, in turn making it quicker for the registrants to see and resolve those deficiencies.

How: OPP should first define key data points or deficiencies that should be extracted from science memos. AI models could then be trained on the deficiencies that OPP wants to track and could flag them accordingly, prioritizing the deficiencies based on inputs from the regulatory divisions. OPP should ensure that staff review the AI-generated letters and make adjustments as appropriate.

33. Work with Registrants to Develop Industry-Specific Trainings (PTS)

What: OPP should collaborate directly with industry to develop trainings that communication foundational knowledge on important industry topics.

Why: To help OPP staff better understand the context in which registrants operate, OPP can partner with registrants to develop industry-specific training. Many staff come from scientific backgrounds and may lack familiarity with industry practices, timelines, and operational constraints, contributing to miscommunication and strained relationships with registrants (PTS PE3). These trainings could improve understanding of the industry perspective, helping OPP to better anticipate challenges and strengthen collaboration. Incorporating these trainings as a supplement to existing reviewer onboarding sessions can help foster a more service-oriented mindset among reviewers by reinforcing the importance of understanding registrant needs (PTS PE2).

How: OPP can either have registrants deliver the trainings directly, as is done on occasion currently, or can create an internal team to coordinate with registrant representatives, co-develop the content, and then facilitate delivery to staff.

34. Share Preliminary Technical Screen Checklists with Registrants (PTS)

What: OPP should consider sharing the preliminary technical screen checklists directly with registrants so that registrants can use them as a tool when creating their applications.

Why: Although registrants know that these checklists exist, they do not currently have access to their contents. As a result, they are often left guessing as to what reviewers prioritize and what could be flagged as a deficiency in their application (PTS PR4, PTS PE1). Sharing these checklists could help registrants understand OPP's expectations and reduce deficiencies in their applications.

How: OPP staff can upload the checklists they use in the preliminary technical screen to an easily accessible location. To improve clarity, OPP can also provide guidance explaining what would cause an application to fail each checklist item, minimizing ambiguity and improving communication. These materials could be published on EPA's website or linked within MyPest.

4.3.E Recommendations to Investigate/Defer

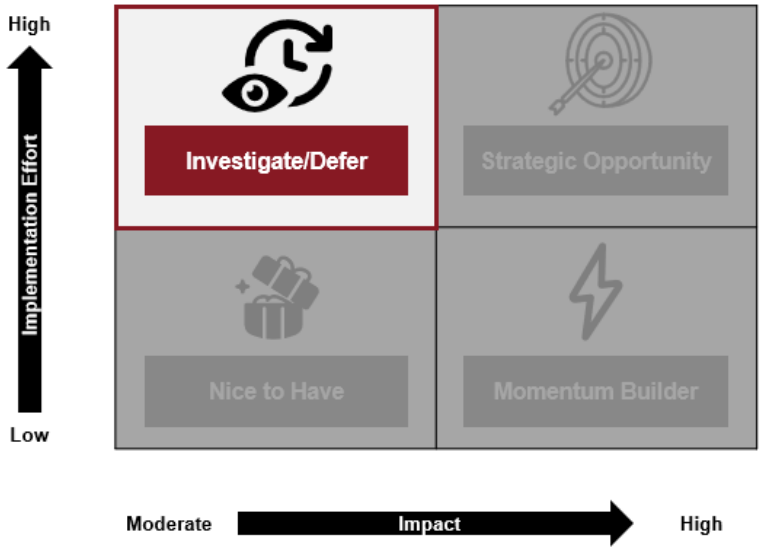

Figure 15: This framework helps categorize and prioritize recommendations based on their impact and feasibility.

#	Title	Process	People	Policy	Systems
35	Create Web-Based Portal for Registrants to Submit Studies	✓			✓
36	Consistently Follow FIFRA Policy Regarding Rejection of Applications ***(ICS, PTS)***	✓		✓	
37	Re-Evaluate PRIA Timelines with Industry Input ***(ICS, PTS)***	✓			
38	Host Regular Trainings or Office Hours for New/Frequent Registrants	✓	✓	✓	
39	Create a Shared Set of Terms for Processes, Milestones, and Policies EPA-wide ***(ICS, PTS)***	✓			
40	Send Automated Results of the Screen to Registrants	✓	✓		✓
41	Develop Resources to Support Verification of PRIA Codes	✓	✓		
42	Automate Steps of the Preliminary Technical Screen in Salesforce	✓			✓
43	Expand Salesforce Resources and Training	✓	✓		✓
44	Build Improved File Management Structure in Salesforce	✓			✓

35. Create Web-Based Portal for Registrants to Submit Studies (ICS, PTS)

What: OPP could design an online platform for registrants to securely upload study documents.

Why: Developing an online application submission portal that links directly to Salesforce could simplify the application process and improve the review process for OPP staff. Having a designated place to upload studies would ensure that all materials are stored in one central location, reducing confusion and improving document access (PTS S2).

This streamlined submission process can also reduce front-end delays that stem from CDX system crashes by enabling more direct access to study materials, helping reviewers begin their assessments sooner and meet critical deadlines (ICS PR1, PTS PR1). Direct integration with Salesforce would eliminate the need for manual downloading and uploading of files, saving time and increasing review efficiency.

How: Each applicant would have a secure log-in and be able to select a submission type (e.g., type of study) before filling out a structured web form with required fields like name of the study, active ingredient, and other key criteria to help manage the study documents within the system. The applicant should be able to upload documents, including a standardized cover letter, in the portal. OPP's IT team should make sure that this portal integrates with current systems and that the data is captured in the necessary format.

36. Consistently Follow FIFRA Policy Regarding Rejection of Applications (ICS, PTS)

What: OPP should implement FIFRA policy to reject deficient applications, applying clear and consistent standards to reject non-compliant applications in a uniform and timely manner.

Why: More consistently rejecting deficient applications could encourage registrants to submit higher-quality applications. Currently, rejections are rare within the preliminary technical screen phase and almost non-existent during the initial content screen phase, despite the provision allowing OPP to reject non-compliant applications within both of those stages (ICS PL2). This contributes to a high volume of deficient submissions that consume significant staff time and resources during review. The rejection process itself requires several levels of leadership review and is often unrealistic to complete within a given review timeline (ICS PR1, PTS PR1, PTS PR5). If an application is not rejected during the preliminary technical screen window, which is the last opportunity for rejection, and is later found to be deficient, reviewers are forced to use the 75-day letter to communicate and resolve deficiencies with applicants, which can delay reviews by several months.

Allowing deficient applications to proceed creates coordination bottlenecks, slows the review process, and risks application scope creep. Updating policy to clarify expectations and streamline the rejection process can empower staff to take timely action and maintain the integrity of the registration process.

How: OPP can review its rejection process and criteria for rejection to ensure compliance with FIFRA. OPP can then encourage reviewers to follow that process and reject applications that are deficient and unresolved within the designated timeframes.

37. Re-Evaluate PRIA Timelines with Industry Input (ICS, PTS)

What: OPP could update PRIA timelines to better reflect the amount of time OPP needs to complete their review for each PRIA code and for each phase of review.

Why: PRIA timelines are not currently met consistently, causing frustration and confusion from both registrants and OPP staff. Currently, the initial content screen is often not conducted within 21 days,

creating a trickle-down effect that, in turn, delays subsequent process step (ICS PR1, PTS PR1). Also, the current 45- and 90-day timeframes in the preliminary technical screen are often too short given the volume and complexity of applications, preventing OPP from completing reviews on time. Updating PRIA timelines for the initial content screen and preliminary technical screen could reduce delays and improve the registrant experience by aligning expectations with what is realistically achievable.

How: Both OPP staff and registrants have expressed interest in revisiting these timelines. OPP can work with industry to identify revised timeframes that reflect the actual duration needed to complete a thorough screen while still meeting the needs of registrants who prioritize predictability over speed. OPP can look at historical data to identify how reviews vary by PRIA code and by process phase. Then, OPP can propose data-backed timelines and coordinate with registrants to agree on updates that are realistic while still emphasizing the need for efficiency.

38. Host Regular Trainings or Office Hours for New/Frequent Registrants (ICS, PTS)

What: OPP could host designated sessions for certain registrants to interact with OPP staff and resolve any questions they may have regarding the registration process.

Why: Offering regular training sessions or office hours for new and frequent registrants would provide registrants with a structured opportunity to ask questions, better understand OPP expectations, and improve the quality of their applications. Interviewees noted that these sessions would be especially helpful for small registrants that may not be affiliated with trade associations, as they often lack access to support networks and guidance (ICS PR2, ICS PL1, PTS PR4, PTS PL2). These sessions would also provide touchpoints for repeat registrants that know the system well but may have more questions due to the volume of applications they submit.

How: OPP could post information about these sessions on the MyPest portal to ensure registrants are aware of the opportunity. Clear promotion and consistent scheduling would help maximize participation and improve overall application quality over time. OPP can share answers to FAQs on the EPA website after the trainings so that future registrants can easily see them as well. These sessions should utilize an open Q&A format and should be attended by at least 2 OPP staff from different divisions to answer questions. OPP could design a process for registrants to submit questions ahead of time so staff can prepare answers to those questions accordingly.

39. Create a Shared Set of Terms for Processes, Milestones, and Policies EPA-wide (ICS, PTS)

What: OPP should develop and implement a standardized language that everyone in the review process uses and understands consistently, with easily accessible resources to define key terms.

Why: Inconsistent use of terms for key tasks and processes creates communication challenges and inefficiencies in coordination (ICS PR4). For example, the term "technical screen," can refer to the initial content screen, the preliminary technical screen, or the in-depth risk assessment (PTS PR5). Standardizing terminology across EPA could improve coordination and reduce confusion among staff and registrants.

How: This effort to standardize language can include incorporating glossaries into guidance documents, establishing clear and consistent titles for tasks within MyPest and Salesforce, and providing accessible resources that list key terms and policies. These steps will ensure everyone uses the same language and understands expectations consistently.

40. Send Automated Results of the Screen to Registrants (ICS)

What: If OPP incorporates increased automation within the initial content screen as suggested in Recommendation 17, they could then send the automated results of the screen directly to registrants

Why: Providing registrants with automated results from the initial content screen could reduce delays, minimize back-and-forth communication, and help applicants quickly address deficiencies (ICS S1). This would also ease the communication burden on OPP staff and create a more predictable, transparent experience for registrants.

Currently, registrants must wait to receive feedback on the initial content screen from OPP staff, which can delay corrections and increase the likelihood of miscommunication. By automating the return of screen results, registrants could immediately see what they missed and either correct errors directly, if Recommendation 15 is implemented, or quickly prepare for resubmission, reducing the burden on OPP stakeholders to coordinate with registrants to resolve deficiencies (ICS PR4). This mirrors best practice from the FDA, whose fully automated screen provides applicants with results within 30 to 60 minutes of submission.

How: The automated screening tool could be a custom-built system, a Salesforce workflow, or utilize AI tools**.** An Application Programming Interface (API) could be used to connect the automated screening tool with CDX or MyPest, depending on where OPP determines it is most appropriate to display the screen outcomes. Once the results are in, the system can send an alert to the registrants to review the results and make any changes they need.

41. Develop Resources to Support Verification of PRIA Codes (ICS)

What: To aid ISB contractors in their review of applications, OPP could develop training resources on which applications fall under which PRIA categories and common errors to look for in reviews

Why: Developing more resources on PRIA codes could better support ISB contractors who may lack the subject matter expertise required to review these codes. Improved resources could allow the contractors to more consistently identify applications when were submitted under the wrong PRIA code (ICS PR3, ICS PE1). When a misalignment in PRIA code is caught later in the preliminary technical screen phase, OPP staff need to communicate the misalignment to registrants, registrants need to submit any new studies or data that may be required, and ISB may need to resolve any fee differences. Verifying PRIA codes early in the process would limit all these downstream delays associated with miscoded applications.

How: OPP can update existing PRIA code resources or create new ones as needed, consulting with the ISB contractors to identify where gaps exist. Potential resources could include key characteristics reviewers should look for within a given category, a list of common coding errors along with their correct counterparts, and a decision logic flow (e.g., "If X, then application is Y") to guide consistent evaluations.

42. Automate Steps of the Preliminary Technical Screen in Salesforce (PTS)

What: OPP should consider leveraging Salesforce capabilities to perform structured and repeatable checks and actions within the preliminary technical screen.

Why: Automating portions of the preliminary technical screen could reduce reviewer workload and accelerate the review process, better positioning OPP to meet PRIA deadlines despite early process delays (PTS PR1). With much of the process still completed manually, automation would help streamline routine tasks and allow reviewers to focus on more complex issues (PTS S1).

How: To implement this, OPP can start by mapping out all steps in the preliminary technical screen and assessing which ones are suitable for automation, identifying the level of effort required to introduce automation. Beginning with lower-effort opportunities will allow the team to see early gains while working toward broader automation over time. Potential automations include:

- Validation rules to flag if conditions are not met
- Page layouts that customize screens based on submission type or status
- Apex triggers for custom backend automation with complex logic
- Email alerts and notifications for registration and OPP staff

43. Expand Salesforce Resources and Training (PTS)

What: OPP should work to build up both the tools and the user knowledge needed to take advantage of Salesforce capabilities and increase system adoption across OPP.

Why: Inconsistent usage and a lack of shared workflows have limited Salesforce use across OPP, preventing staff from leveraging its automation capabilities and contributing to internal communication delays, particularly during the preliminary technical screen (PTS S1, PTS PR5). Adoption of Salesforce has varied widely between divisions, making it difficult for OPP to fully transfer over to the system (PTS S4). Expanding Salesforce onboarding support and establishing best practices for use could help increase Salesforce adoption, reduce duplicative manual work, and improve coordination across OPP.

How: To address this, OPP could improve uptake by offering expanded onboarding resources such as regular office hours, a peer buddy system for new or infrequent users, and division-specific trainings that demonstrate practical, day-to-day use cases. In parallel, OPP could identify workflows developed by high-utilization divisions, such as RD's project tracking tools, and promote them as cross-cutting best practices. Documenting and sharing these examples could give staff clear, replicable models for how Salesforce can support their work, driving broader engagement and increasing process standardization across the program.

44. Build Improved File Management Structure in Salesforce (PTS)

What: OPP should explore the possibility of creating more efficient ways to upload, store, access, and link to records within Salesforce so staff working on preliminary technical screens can easily manage files.

Why: Currently, staff must manually upload, download, and share documents across teams, which consumes time and creates bottlenecks in collaboration (PTS PR5, PTS S1, PTS S2). Improving file management within Salesforce would reduce delays caused by inefficient document handling and coordination challenges.

How: To streamline access and reduce the time that science division staff spend locating and handling files, OPP can build out a centralized, user-friendly file management structure within Salesforce with features such as:

- Easy-to-navigate file storage, including standardized document titles, searchable metadata tags, and consistent folder organization
- Bulk download capability to help staff efficiently access large sets of documents

- Standardized file formats, avoiding hard-to-use types like .tiff files
  File archiving options to preserve past documents while minimizing clutter and managing storing limits

These improvements will help staff focus more on reviews and less on locating, converting, or transferring files.

5. PRIA REGISTRATION AREAS: PROGRESS ASSESSMENT

Section contents. This section includes analysis of two interrelated policy and process areas—OPP's management of renegotiation requests and the small business fee waiver program. While narrower in scope, both play an influential role in OPP's overall workload and review timelines. Renegotiations can affect resource planning and timeliness, while the waiver process has implications for access and administrative efficiency, especially for small business registrants.

5.1 Reducing Renegotiations Rates

Overview

Goal of renegotiations. Renegotiation is OPP's formal process for extending the PRIA statutory decision review period when circumstances make it unlikely that the original deadline can be met. This authority, granted under FIFRA, allows OPP and the applicant to mutually agree to a new due date. Renegotiations are intended to be used sparingly—typically when delays are caused by unforeseen workload challenges, emerging science issues, or applicant delays—and must be documented and approved through a multi-step internal workflow.

Lack of clarity. The topic of renegotiations was explicitly addressed in PRIA 5 in response to longstanding concerns around the lack of transparency and accountability in how deadline extensions were handled. PRIA 5 sought to formalize this process, reinforcing that renegotiations must be justified, documented, and used sparingly to preserve integrity in the review schedule.

Process steps. While the overall renegotiation process is consistent across divisions, implementation details and timeliness vary. The high-level steps include:

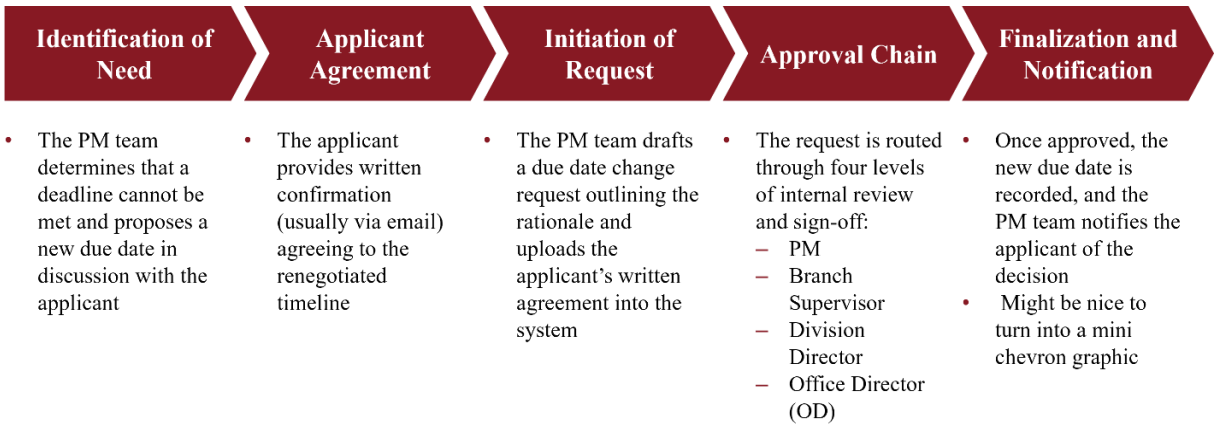

Figure 16: OPP's renegotiation process ensures timeline extensions are justified, documented, and internally approved.

Documents Reviewed

PRIA 5 Renegotiation Memo. To assess the current state of OPP's renegotiation process, we primarily reviewed the "PRIA 5 Renegotiation Memo" (May 5, 2023) provided by OPP. This internal guidance document outlines the procedural steps required for initiating, reviewing, and approving renegotiations across all divisions. It defines roles and responsibilities, required documentation, and expectations for how renegotiation should be positioned and tracked under PRIA 5. A key change in PRIA 5 was limiting the circumstances under which the decision time review period could be renegotiated. There are currently two situations that qualify:

1. If there is new or additional data or information from the applicant that is necessary for the reviewer to make a decision that cannot be made available within the original decision time review period.
2. A public comment period for the application creates significant comments that cannot be addressed within the original decision time review period.

While no external-facing guidance or system screenshots specific to renegotiations were provided, the memo references planned and current use of Salesforce fields to document renegotiation dates and status. It also reinforces the principle that renegotiations should be clearly justified with a documented rationale and highlights the importance of ensuring transparency to registrants. The memo was the most detailed source available and forms the basis for our understanding of the current policy and implementation challenges.

Future and current state process maps. We also reviewed the Future State Process Map and Current State Process Map (provided in related process documents), which contextualize how renegotiation fits into broader PRIA workflows. These maps helped identify where system automation might support or hinder renegotiation and where breakdowns may be occurring in communication, tracking, or escalation. Together, these documents inform a preliminary evaluation of both strengths and potential vulnerabilities in how renegotiations are currently handled.

OPP Actions to Date

New multi-level approval process. OPP has taken a number of steps to formalize and standardize its renegotiation process under PRIA 5. First, OPP implemented a multi-level approval process that begins with the PM/RM and proceeds up through Branch and Division Chiefs to the OPP Office Director. This structure creates multiple checks to ensure renegotiation is not used without sufficient cause.

New documentation and tracking mechanisms. Second, OPP has developed documentation and tracking mechanisms, including internal templates for recording renegotiation justifications and revised due dates. These documents are housed in internal systems and are occasionally surfaced for leadership oversight. Staff are expected to enter the new negotiated due date into Salesforce, although practices appear to vary across divisions.

New guidance. Third, OPP leadership has issued guidance—such as the May 2023 memo—emphasizing the importance of treating renegotiation as a last resort rather than a default response to delays. The memo encourages staff to work proactively with science divisions and registrants to avoid the need for deadline extensions unless absolutely necessary.

Recommendations for Further Improvements

Opportunities for continued enhancement. While OPP has taken steps to formalize the renegotiation process under PRIA 5, opportunities remain to improve transparency, consistency, and proactive decision-making. Based on our review of the current policy and internal documentation, the following recommendations would address the most pressing operational and communication gaps:

1. ***Require clear categorization of renegotiation reasons in internal memos or system fields***
   A short, standardized reason tag (e.g., internal workload, scientific uncertainty, registrant delay) would provide valuable data for management to track patterns and assess which divisions, product types, or process steps most frequently lead to missed deadlines. Over time, this data can support more precise resourcing or process reforms.

2. ***Formalize and standardize registrant notifications when renegotiations occur***
   A clear, consistent template that explains the rationale for delay and revised timeline would improve communication and trust with registrants—particularly those who may be confused or frustrated when decisions are pushed. This also reinforces OPP's professionalism and transparency in cases where delays are unavoidable.
3. ***Integrate automated deadline alerts and renegotiation triggers in Salesforce***
   By building alerts for actions approaching PRIA deadlines without a recorded decision or renegotiation, OPP can take a proactive stance rather than reacting after deadlines are missed. This also reduces last-minute escalations and ensures renegotiations are initiated earlier, with less administrative friction.
4. ***Develop a centralized renegotiation tracking dashboard across OPP divisions***
   This would provide leadership and PMs with real-time visibility into all actions with renegotiated deadlines, enabling better oversight and reducing the risk of overlooked or unmanaged extended applications. It also allows OPP to monitor where and why delays are occurring, surfacing systemic issues—such as science division backlogs or repeat coding errors—more quickly.
5. ***Publish aggregate renegotiation statistics annually as part of public-facing PRIA performance reporting***
   Sharing the volume and general causes of renegotiations in aggregate (not application-specific) can build trust with external stakeholders, including industry and advocacy groups, by showing that OPP is managing backlogs transparently and with accountability.

Impact of recommendations. Together, these improvements would help OPP **shift renegotiation from a reactive, manually-intensive process to one that is strategically monitored and used only when necessary**—with traceable reasons, timely approvals, and better communication. They also directly address key challenges raised in the internal memo, including inconsistent implementation, limited visibility, and the risk of over-reliance on renegotiation as a pressure valve for system delays. Implementing these changes would not only improve internal efficiency but also reinforce OPP's commitment to fair and transparent regulatory timelines.

5.2 Small Business Fee Waiver

Overview

Goal of fee waiver. As part of its implementation of PRIA, OPP offers a fee waiver program to support small businesses applying for pesticide product registrations. This waiver mechanism is designed to reduce the financial burden on smaller entities while ensuring they can access the regulatory system. Eligible applicants can qualify for either a 50% or 75% reduction in registration fees based on business size and annual revenue.

Criteria for qualification. To qualify, businesses must meet the following thresholds:

- 50% waiver: Fewer than 500 employees company-wide and total annual global gross pesticide sales under $60 million
- 75% waiver: Fewer than 500 employees and global pesticide sales under $10 million

Submission and review. Waiver requests must be submitted at the time of application, along with partial payment (25% or 50% of the full PRIA fee, depending on the waiver type). Applicants are also required to provide supporting documentation—including employee counts, total pesticide sales, and statements affirming eligibility. The waiver decision must be issued by OPP within **60 days** of submission. If granted and no additional fees are required, the PRIA timeline begins on the earlier of the date of approval or 60

days from the date supporting documentation was received.. If denied, the PRIA review period begins once the applicant pays the full remaining fee.

Process steps. The typical steps in the waiver process include:

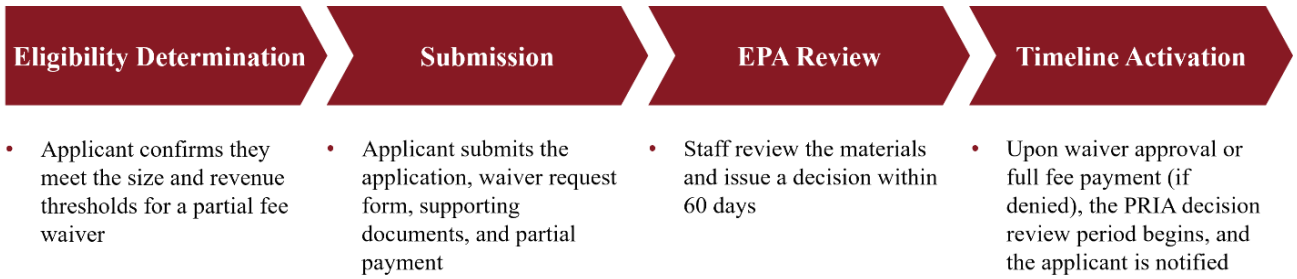

Figure 17: The small business fee waiver process outlines how eligible applicants can request partial fee reductions through structured review.

Process challenges. This process is critical for maintaining equitable access to OPP's pesticide registration system, particularly for new market entrants and resource-limited companies. However, gaps in transparency, tracking, and communication continue to create confusion and unnecessary delays for some small business applicants.

Documents Reviewed

ISB front-end workflow documentation. As the basis for our evaluation, we reviewed the "ISB Front-End Workflow" document provided directly by OPP. This document outlines the initial steps of application intake, including key interactions between internal systems and review teams.

Public-facing guidance. To understand the current state of the small business waiver process, we reviewed OPP's public-facing guidance materials, including the waiver submission form, detailed eligibility criteria, and timelines for approval. These documents were referenced during our independent literature review and analysis of OPP's PRIA program support materials. We also considered key themes and feedback raised during interviews with registrants, including a group of small businesses and consultants who represent them.

OPP Actions to Date

New clarifications to process. OPP has taken multiple steps to implement and clarify the small business waiver process under PRIA:

- Established public guidance outlining waiver eligibility, documentation requirements, and the 60-day decision window
- Developed a standardized waiver submission form and embedded partial payment functionality into OPP's application portals
- Integrated the waiver review into the front-end intake process to ensure PRIA timelines are only triggered after eligibility is verified
- Provided written communication to applicants regarding waiver outcomes, including next steps for payment or appeals

Recommendations for Further Improvements

Opportunities for continued enhancement. While OPP has taken steps to improve predictability and streamline the small business waiver process, key challenges remain—particularly for applicants without institutional support or access to industry associations. Stakeholders described the process as inconsistent, overly dependent on opinions and decisions of a single OPP staff member, and lacking clarity around expectations of small business applicants. To address these pain points, we recommend the following improvements:

1. ***Improve consistency and transparency in waiver determinations***
   Registrants noted that recent determinations seemed more stringent than past experiences, even when following the same guidance. OPP should adopt standardized review checklists and require brief rationale summaries for denials or documentation requests that are not explicitly required by policy. This would help ensure consistent application of criteria and reduce the perception of subjectivity, particularly when applicants are comparing decisions over time.
2. ***Update OPP's small business waiver webpage more frequently with current expectations and FAQs***
   Several small business registrants noted they do not belong to large associations or trade groups and rely exclusively on EPA's website for guidance. OPP should post updated examples, summaries of common documentation errors, and clarification on recurring issues. A quarterly review cycle for this content would help ensure applicants are not referencing outdated or incomplete information.
3. ***Mitigate single points of failure by increasing oversight and cross-training***
   Currently, waiver processing appears to rely heavily on one staff member. While stakeholders recognized that individual's professionalism, they also noted a lack of coverage when that person is unavailable. OPP should identify at least one additional reviewer trained in waiver protocols and consider a basic rotation or backup structure to ensure timely processing and prevent delays due to leave or unavailability. Increased review and oversight of fee waiver decisions could also help promote consistency.
4. ***Use MyPest to provide visibility into waiver request status and decisions***
   Applicants currently receive limited insight into whether their waiver has been reviewed, is pending, or requires additional documentation. OPP should expand its use of MyPest to show real-time status, key dates (submission, partial payment, pending decision), and any outstanding actions. This would reduce uncertainty and eliminate unnecessary email follow-up.
5. ***Collect and analyze waiver processing data to identify systemic improvements***
   OPP should tag each waiver request with basic metadata (e.g., outcome, cause of delay, documentation issue) to enable internal tracking. This would support improvements in processing efficiency, help identify where better public guidance is needed, and flag recurring problems that disproportionately affect small businesses.

Impact of recommendations. Together, these improvements would help create a more equitable, predictable, and accessible waiver process for small pesticide registrants – particularly those operating without association support or in-house regulatory expertise. By reducing unnecessary burdens and ensuring consistent communication, OPP can fulfill its intent to lower barriers to entry for small and emerging pesticide companies.

6. NON-PRIA REGISTRATION AREAS: PROGRESS ASSESSMENT

6.1 Non-PRIA Overview

Introducing non-PRIAs. Non-PRIA actions fall outside of the scope of PRIA and as a result do not have a statutory timeline or required fee mandated. These actions are generally less complex than PRIA actions, and include routine, administrative, or low-impact actions that can go through a streamlined review. Examples of non-PRIA actions are:

- **Minor formulation amendments** that do not impact safety or efficacy
- **Fast track amendments** or label amendments that require no data review
- **Agency-initiated amendments** like those needed to comply with a reregistration eligibility decision
- **Notifications** that do not require EPA approval beforehand but must be reported to the agency

Though there is no standard mandated timeframe for completing non-PRIAs, PRN 98-10 lays out target deadlines for completing different actions that range from several weeks to several months, varying based on workload and complexity. Generally, the target deadlines are 30 days for notifications, 45 days for minor formulation amendments, and 90 days for fast-track amendments. An exception is antimicrobial product notifications, which require EPA to issue a denial/disapproval letter no later than 30 days after receipt.

Non-PRIA Process Flow. Registrants submit an action as a non-PRIA if they believe it falls within the defined criteria and prepare the package according to the requirements for that action. The typical process steps are outlined below:

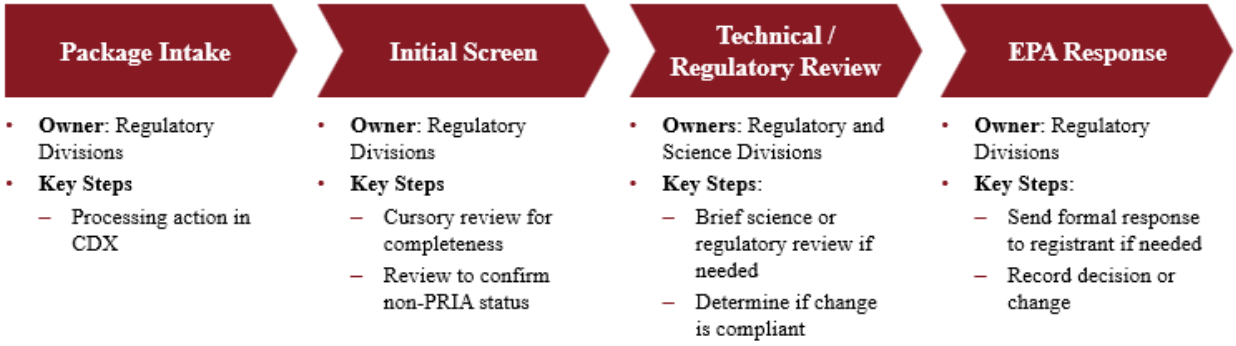

Figure 18: The non-PRIA process is flexible but follows a structured format for review.

Process challenges. While the non-PRIA actions tend to be simpler and at lower complexity, they still require administrative oversight and review. The lack of statutory timelines means backlogs arise when resources are constrained, as OPP focuses on reviewing PRIA-covered actions that do have associated deadlines and fees. Gaps in tracking and transparency result in limited visibility into the status of non-PRIA actions, and inconsistent interpretation of PRN 98-10 create confusion and inefficiencies in reviewing and finalizing label changes.

Non-PRIA Analysis Scope

Parameters of Review. Our investigation covers two primary topics related to non-PRIA actions: eliminating the backlog of non-PRIAs and ensuring non-PRIAs are completed according to the target deadlines set out by OPP for each action. The documents reviewed, actions taken by OPP, and the recommendations developed all fall within the scope of efforts to reduce the backlog and enhance OPP's ability to meet target deadlines. These topics were not part of our deep dive assessment, and as such our inputs for analysis were limited to the documents, data, and anecdotal information provided from interviews with OPP staff and members of industry.

Documents Reviewed

Censeo reviewed **18 internal and external facing documents** that were relevant to reducing the non-PRIA backlog. These documents were provided by OPP and were analyzed and used to inform the recommendations in this report. This section provides a high-level summary of the documents reviewed, categorized by document theme and whether the document was intended to be used by OPP (internal), or by the registrants (external). Further detail on each of the documents reviewed can be found in the appendix.

Internal

Internal documents were produced by OPP leadership and management to guide and inform the application review process. The internal documents reviewed by Censeo are grouped into three categories:

- **Strategic Decisions**: Formal communications from management that establish high-level goals and outline new procedures, guidance, and recommendations for staff to implement.
- **Instructions and Guidance**: Step-by-step directions for executing and documenting specific work processes.
- **Templates and Checklists**: Standardized forms that guide reviewers through specific procedural steps.

External

External documents were designed to be distributed or made available to registrants to help streamline the application process. The external documents reviewed by Censeo are grouped into three categories:

- **Formal Instruction**: Policies and excerpts from official agency manuals that explain procedural requirements.
- **Quick Tips**: Documents that provide registrants with best practices, specific examples, and lists of common errors to help them create higher-quality submissions.
- **Instruction and Guidance**: Step-by-step directions for executing and documenting specific work processes.

6.2 OPP Actions to Date

OPP has already taken significant action to improve operational efficiency, strengthen communication, and reduce the size of its non-PRIA backlog. Figure 19 displays the total backlog of all non-PRIA actions since the end of FY23.

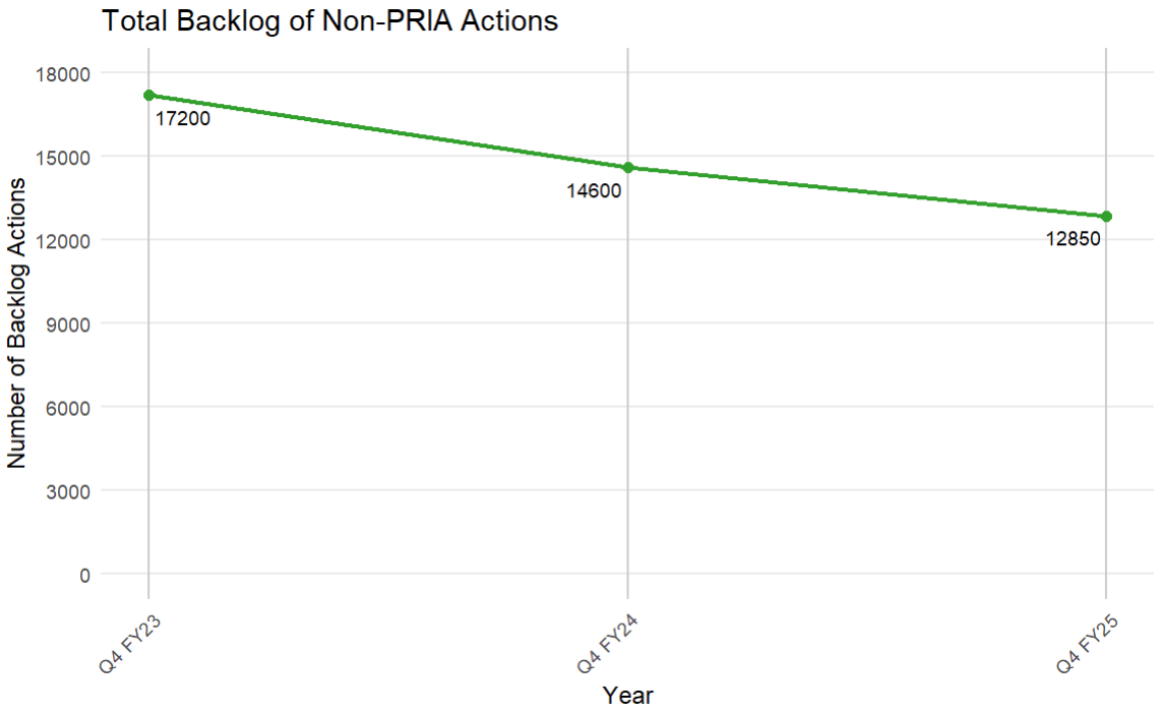

Figure 19: OPP's actions to date have reduced the overall non-PRIA backlog by 25% in 2 years.

OPP's backlog-reduction efforts to date have primarily focused on reducing backlogs of fast-track amendments, minor formulation amendments, and notifications, which are most impactful to industry. Since FY22, OPP has reduced its backlog of fast-track amendments, minor formulation amendments, and notifications by over 58%. This section highlights notable actions OPP has already implemented in reducing the non-PRIA backlog. By building upon these existing actions, OPP can see continued success in reducing their backlog and prevent one from building back up in the future.

Internal Process and Workflow Optimization

OPP has taken multiple internal actions to improve process review efficiency and application throughput. Various "best practices" and checklist documents were created to standardize the review process and provide guidance for application reviewers within different divisions. OPP also implemented a "fast track" process for label reviews to expedite applications that only have minor revisions, limiting the scope of review to process them quicker. For these fast-track applications, reviewers are instructed to only look at highlighted or relevant sections of notification review, vastly cutting down on unnecessary work.

OPP has also implemented several collaborative and department-wide improvements. Teams created bi-weekly or monthly blocks of time specifically to work on application review. These working sessions were strategically scheduled for effective collaboration between science and regulatory times. Additionally, OPP has improved training and recruitment efforts to leverage staff from other disciplines and have developed a process to share ongoing work across the division.

To specifically focus on the backlog, OPP designated several tiger teams within divisions whose focus was working through the backlog of non-PRIA actions. These targeted efforts were part of a push to see a large reduction in the existing backlog to make it easier for OPP staff to meet future non-PRIA applications target deadlines.

Improved Registrant Guidance

OPP improved communication with registrants by providing them with additional resources, tools, and guides. OPP created numerous "best practices" media, such as a "cover letter best practices" Word document and a webinar on the complete submission process from start to finish. Webinar materials remain publicly available for future parties to use. OPP also created resources to prevent registrants from making common mistakes that could result in a deficient application through a "common reasons a notification might be rejected" document.

Downsizing the Queue

OPP has effectively engaged with registrants to help prioritize pending submissions. Under OPP's guidance, registrants were able to identify top priority actions and withdraw outdated or superseded submissions, substantially reducing the backlog. AD also closed out all notifications submitted before 10/01/2022, removing around 2,000 actions from the queue. OPP made sure to communicate these efforts with registrants, so they were aware of the change to their applications.

Leveraging Automation

OPP has begun to leverage technology and automation in parts of the application process. OPP has implemented a template in Salesforce that is being used to generate favorable letters. Due to the success of this process, OPP is beginning to build additional templates for other standardized communication, such as unfavorable letters.

6.3 Eliminating the Backlog of Non-PRIAs

Overview

Non-PRIA backlog. OPP has seen an influx of pesticide applications year after year, with an all-time high reached in 2021. Many of these applications are non-PRIA submissions, which are not subject to decision time review periods, and can range from minor changes to more complex requests. As more applications come into OPP, staff must decide where to allocate their time and historically prioritized PRIA over non-PRIA applications due to regulatory requirements. This has resulted in the growth of the non-PRIA backlog, which by the end of FY24 had grown to over 3,200 for the subset of non-PRIA actions that includes fast-track amendments, minor formulation amendments, and notifications.

Backlog mitigation. With fluctuating resource levels, a growing workload, and increased complexity of incoming applications, OPP has had to be creative to keep the non-PRIA backlog in check. Industry's focus is on fast-track amendments, minor formulation amendments, and notifications, so OPP's strategy has focused on addressing that subset of the non-PRIA backlog. OPP developed and began implementing a holistic strategy to reduce the number of applications currently in the backlog and prevent any future backlogs from occurring.

In FY24, OPP successfully reduced its non-PRIA backlog of fast-track amendments, minor formulation amendments, and notifications by over 1,100. If OPP can maintain this completion rate and volumes remain steady, they could eliminate the backlog by the end of fiscal year 2027. Executing the recommendations in this report is conservatively estimated to expedite the completion of this backlog by multiple quarters.

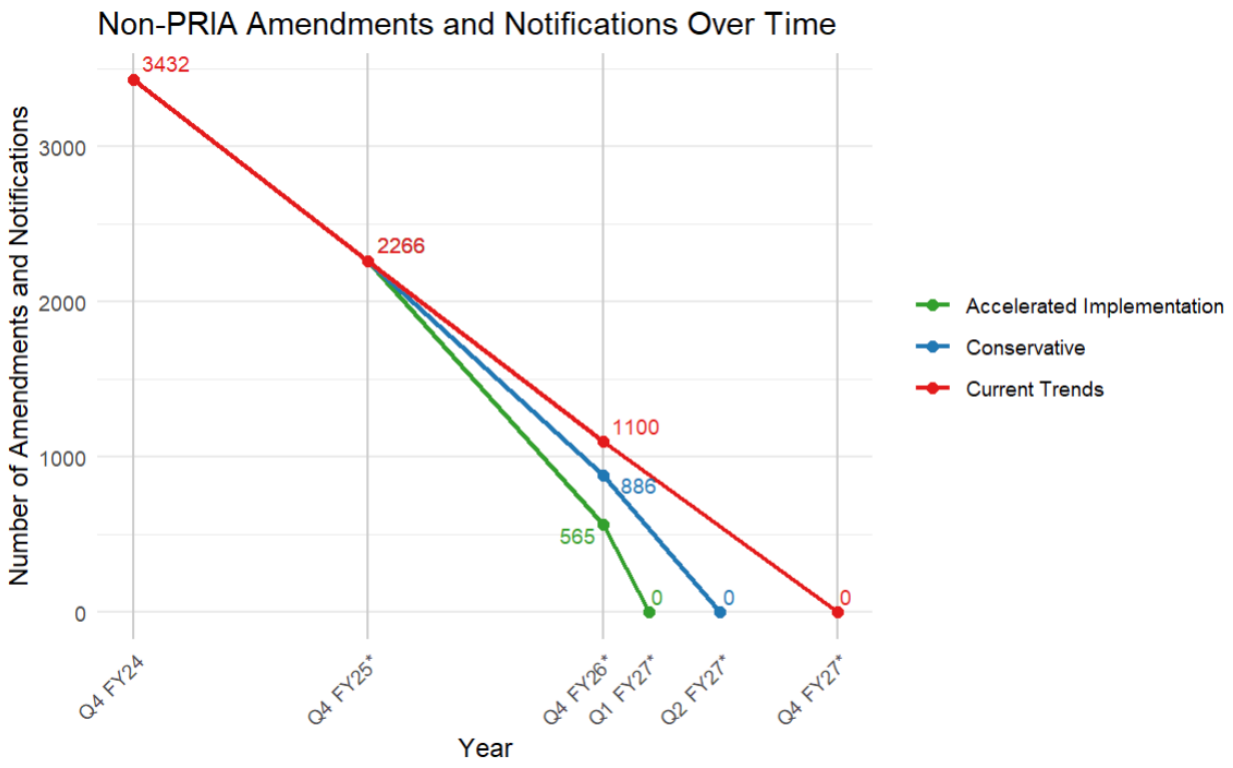

Figure 20: Improvements in efficiency can build upon OPP's existing success and hasten the completion of the amendment and notification backlog.

** Denotes projected values*

While completion of this subset of the backlog is projected to be completed relatively soon, there are still many other backlogged actions like incident reports, response to terms/conditions of registration, and voluntary cancellation requests that make up the majority of the total non-PRIA backlog. Though the backlog of these actions is less of a priority to industry, OPP continues to commit resources to these actions to reduce the total backlog of non-PRIA actions.

6.4 Ensuring Non-PRIAs Meet Target Deadlines

Overview

A subset of non-PRIA actions are described in PRN 98-10 and include the following:

- **Notifications**: Changes limited in scope and clearly marked
- **Non-notifications**: Changes a registrant can make without notifying EPA
- **Minor formulation amendment**: Additional allowed changes to the produce formulation

PRN 98-10 timeframes. These are minor changes to the label and formulations, and PRN 98-10 establishes that OPP will make every effort to prepare an appropriate response to the registrant, either accepting or rejecting the changes. This timeframe is 30 days for notifications and 45 days for minor formulation changes.

Fast track amendments. Fast track amendments are another type of non-PRIA action, not subject to PRIA fees. They include labeling changes or basic/alternate product formulation changes that do not require registrants to submit supporting data. OPP established a target timeframe of 90 days to review all fast-track amendments.

Missed deadlines. While OPP is not statutorily required to meet these timeframes as it is with PRIA actions, the timeframes help to provide registrants and OPP staff with an expectation of how long each action will take to complete and assist with workload planning. However, OPP has failed to meet these timeframes for many notifications, fast track amendments, and minor formulation amendments, which continue to make up the non-PRIA backlog.

Censeo analyzed 1,469 non-PRIA actions completed in FY24 and Table 3 shows the extent of these delays and the frequency in which they occur by non-PRIA action. All three non-PRIA actions have delays over 86% of the time, with delays on average ranging from ten months to over a year. Fast-track applications are delayed the longest, with a mean and median delay of approximately a year. Given that these actions are supposed to take 30 to 90 days, there is a lot of room for OPP to improve their application turnaround time.

Non-PRIA Action	Percentage of Applications with Delay	Average Delay Length	Median Delay Length
Fast Track Amendment	86%	486 days	344 days
Minor Formulation Change	88%	326 days	205 days
Notification	86%	295 days	184 days

Table 3: All non-PRIA actions face frequent and severe delays.

Figure 21 plots the full distribution of these delays. This visualization echoes the information shown in Table 3: the majority of applications are delayed as presented by the curves being to the right of the 0-delay length value. Additionally, fast track amendments have the longest delays, as a greater portion of the curve is in the right-side tail.

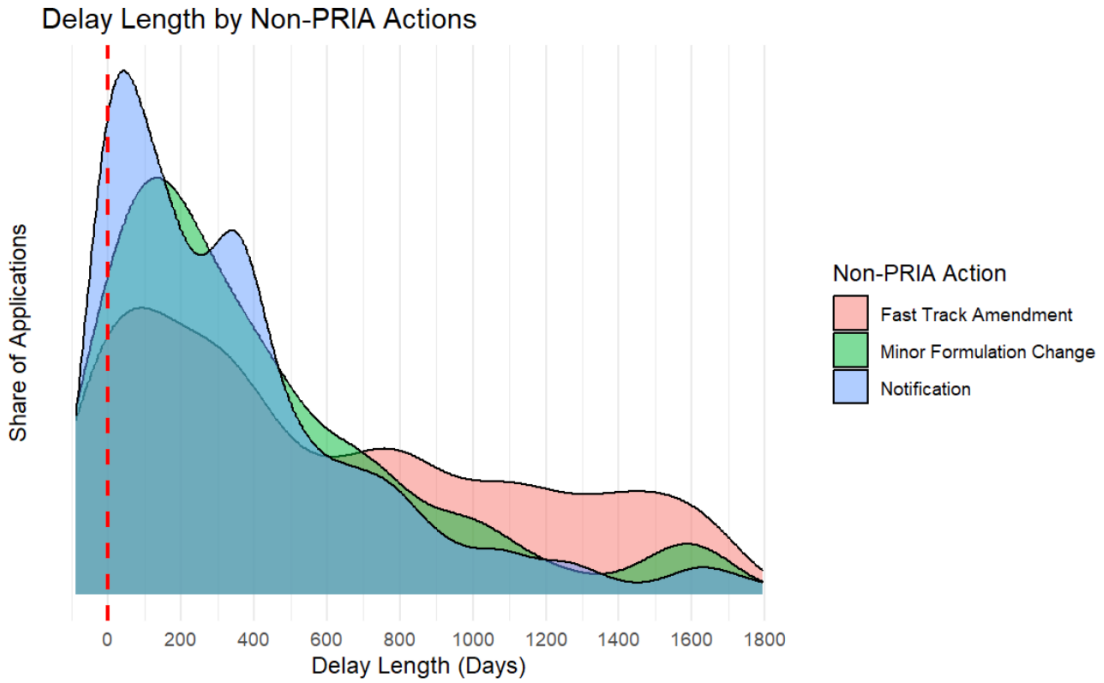

Figure 21: While all actions experience delays, Fast Track Amendments have the longest.

Meet expected timeframes. A common theme mentioned in registrant interviews was a desire for consistent deadlines. For example, notifications are often assumed "accepted" after their timeline for review has passed. Issues arise when OPP has delayed in reviewing the action, and once the action is finally reviewed, it is ultimately rejected. At this point, the product may already be in the market, resulting in lost time and resources for the registrant. When OPP sets expectations for how long a particular non-PRIA review will take, they should make every effort to meet the target deadline and communicate with the registrants if they are unable to meet it, laying out why it has not been met and an updated expected timeframe. Timeliness is a high priority for OPP and our recommendations here focus on ways OPP can provide additional predictability to registrants.

6.5 Non-PRIA Recommendations

Recommendations for Further Improvements

While OPP has taken many steps to reduce the non-PRIA backlog and more consistently meet its target deadlines, some challenges remain. These include inconsistency in executing policy and related processes, limited visibility into application status, and outdated guidance, which compound the issues resulting from limited staff capacity.

PRIA recommendations still apply. The PRIA and non-PRIA reviews have similar process flows and procedures, though the PRIA review is more in-depth. To that end, many of the recommendations listed in the above PRIA Registration section also apply to the non-PRIA review process and could help OPP see process improvements and greater efficiency across all types of pesticide reviews. This is especially true for recommendations around consolidating and refining internal and external policy, creating more guidance documents and templates, triaging applications, leveraging AI, and improving internal collaboration.

Non-PRIA recommendation descriptions. The following recommendations are specifically aimed at reducing the current non-PRIA backlog and improving OPP's ability to meet target deadlines. Each recommendation has a label to indicate whether it is focused on mitigating the backlog, meeting deadlines, or both, along with a detailed description of the recommendation. The recommended improvements include:

1. ***Use AI to verify non-PRIA submission changes are permissible (Backlog)***
   Many of the common deficiencies for non-PRIA actions are changes made that do not fall under non-PRIA criteria. This includes adding or changing label language outside of what is outlined in the cover letter and adding or changing language that should instead be modified by an amendment. To prevent registrants from making these changes, OPP can utilize AI to automatically identify changes that are not allowed, such as adding in public health pests, and flagging them for registrants and/or OPP reviewers. To leverage AI consistently and effectively, OPP would first need to implement the structured e-labeling format mentioned in the PRIA recommendations, which requires updating FIFRA. This change would simplify reviews, flagging potential impermissible modifications and directing the reviewer's attention to areas of the label that have been changed.
2. ***Improve consistency in executing policy for non-PRIA actions (Backlog)***
   Registrants noted that there is variation among OPP staff in how they interpret non-PRIA guidance, especially when reviews change hands. To improve consistency, OPP should create a standard checklist for each division and all non-PRIA actions, leveraging materials that have already been created in some divisions. OPP staff should also be provided with clear

documentation defining what qualifies and disqualifies a submission as non-PRIA, with specific examples. In ambiguous cases, OPP can develop a process to elevate the application to management for documented resolution that will improve transparency, predictability, and alignment across OPP staff and registrants.

3. ***Use MyPest to provide visibility into non-PRIA application status (Backlog, Deadlines)***
   OPP should expand its use of MyPest to show the real-time status of the application, including if the application is confirmed to be non-PRIA, if the application is in the science or regulatory review, or if a change has been found noncompliant, and if the application was accepted. The PM or other OPP staff member completing the action can update the status, providing the divisions and registrant with an up-to-date reflection of their non-PRIA submissions. MyPest could also be used to alert the registrant if any action is required of them and serve as the form of communication between OPP staff and the registrant. This makes it easier for registrants to plan their product distribution and sales as they can see when expected decisions will be made.
4. ***Limit the scope of fast-track amendment reviews (Deadlines)***
   Registrants reported that some changes eligible for fast-track reviews were instead given full reviews, creating unnecessary work. OPP should clarify expectations by standardizing fast-track criteria and revise checklists for staff to specify required forms and information should be evaluated in the review, reigning in the scope of the reviews to reduce the overall timeline for each. Registrants can highlight all changes in the cover letter and in the application itself, and staff should limit reviews to those areas unless a Team Leader or PM approves reclassification of the application from fast-track to another action type. This will simplify the fast-track review process and improve consistency among OPP staff to make sure that fast-track reviews live up to their name, without staff expanding the scope of the review unnecessarily.
5. ***Conduct a deep dive process review of fast-track amendments (Backlog, Deadlines)***
   Beyond the variation in scope of the fast-track amendments mentioned above, OPP does not have an established system in place to prioritize fast-track amendments and ensure they are completed in a timely manner. Fast-track amendments may sit in-house, frustrating registrants who would like to see a quick resolution. To investigate the root cause of these delays and develop strategies to improve process efficiency, OPP can conduct a deep dive process review of fast-track amendments. Similar to the deep dive process reviews conducted in this report for the ICS and PTS, a team can review key process documentation for the fast-track review process and speak to key stakeholders to identify pain points and opportunities for improvement. This review would enable OPP to design and implement recommendations to move fast-track amendments through the queue more effectively.
6. ***Create, review, and update registrant guidance (Backlog)***
   To improve the quality of incoming applications, OPP can develop more guidance materials to help registrants across divisions. These additional materials include specific guidance for common non-PRIA actions, best practices on how to format the application package to make the review process more efficient for OPP staff, and FAQ documents for non-PRIAs. Once these materials are created and uploaded to OPP's website, OPP should establish a set cadence to review and update them as needed to resolve any gaps, points of confusion, or incorporate updates to policy. As changes are made, they should be highlighted for registrants, outlining what specifically is new and expected. This will ensure registrants understand the expectations for their applications and are operating under the latest guidance, making deficient applications less likely.
7. ***Update PRN 98-10 (Deadlines)***
   OPP should consolidate and update PRN 98-10 to include all amendments that have been made in one cohesive version that users can reference as the source of truth and broaden the definition of

non-PRIA actions that qualify for an expedited review. This includes reclassifying additional actions to be non-notifications that are currently notifications and reclassifying other amendments and/or other actions to be notifications. There is also the potential to allow registrants to self-certify minor changes, such as correcting typos in the label, directly, without requiring notification. Expanding the criteria for these actions will reduce the burden of work that OPP staff must complete, as they have a more streamlined review process. The definition of what constitutes a notification should also be clearly spelled out, ensuring that actions that classify as notification are treated as such. PRN 98-10 should also clearly lay out the procedure for processing notifications, providing registrants with an expectation of the timeline and the key steps in the review process. OPP staff should be mindful of this distinction and not subject notifications to a deeper review or approval process that is more consistent with amendments. Updating PRN 98-10 will help registrants better understand current expectations and reduce delays caused by confusion or misinterpretation of the policy. Though widely used by both registrants and OPP staff, PRN 98-10 has not undergone a full update since 1998, and past amendments are scattered across multiple sources. Creating a clean, updated version of PRN 98-10 that integrates all past amendments will provide a clear reference point, improve application quality, and support more consistent decision-making. Once all updates are implemented, the new version should be uploaded to a publicly accessible location for users to reference.

Impact of recommendations. These proposed improvements will improve OPP's capacity to process non-PRIA applications in a timely manner. With standardized approaches, streamlined reviews, and improved guidance materials for both internal and external parties the non-PRIA process will become more predictable for registrants while reducing the level of effort placed upon OPP staff to complete their reviews.

7. REGISTRATION REVIEW AREA: DEEP DIVE

7.1 Registration Review Deep Dive Area: Overview and Challenges

Process Overview

Registration Review Objectives. OPP is required to review each active ingredient in registered pesticides at least every 15 years to ensure continued compliance with health and environmental safety standards. While each review is tailored to the specific active ingredient, all follow a standardized process managed by the Pesticide Re-evaluation Division (PRD) for ingredients falling under RD's purview, a dedicated branch for re-evaluation within AD, and a variety of staff within BPPD. This process is illustrated in Figure 22:

Figure 22: The registration review process follows a science-based framework with multiple points for public input to ensure pesticide safety remains up to date.

Process initiation. To formally initiate a review, regulatory staff follow a structured sequence of regulatory actions in alignment with regulations outlined in FIFRA Section 3(g). Regulatory staff initiate a registration review by opening a public docket for a pesticide registration review case and publishing a Preliminary Work Plan (PWP) for public comment. The PWP, which is drafted by a Chemical Review Manager (CRM) in the regulatory divisions, outlines the current uses of the active ingredient based in part on its label, the anticipated risk assessment and data needs, and an estimated timeline for review. For PRD, risk assessments are conducted by separate divisions. EFED and HED perform scoping work, and BEAD conducts an analysis that informs the PWP. The science divisions (BEAD, EFED, and HED) also look at all the data to see if they are still accurate and current and identify any data gaps. After a public comment period of at least 60 days, regulatory staff review the feedback from the science teams and produce a Final Work Plan.

Data call-in and risk assessment phases. Next, regulatory staff may issue a data call-in (DCI) to the relevant registrants if the science divisions (BEAD, EFED, HED) believe additional studies or information are needed to complete the risk assessment. HED also looks at the PWP and FWP to determine if any additional data is needed to support the Endocrine Disruptor Screening Program (EDSP). Any data received is then sent to and reviewed by the science divisions to assess the human health and ecological aspects of the active ingredient and its uses. HED and EFED complete their own draft risk assessments which the CRM then compiles to create the formal draft risk assessment. This draft risk assessment is then released for public comment, and all divisions evaluate feedback and finalize the assessments accordingly. BEAD completes a benefit/impact assessment, typically once the draft risk assessments are completed and risk mitigation options have been developed. OPP consults with other services (U.S. Fish and Wildlife Service and the National Marine Fisheries Service) for any action that "may affect" listed species in the Endangered Species Act (ESA) consultation, where OPP provides the

services with its own analysis of the effects of a pesticide on listed species and their designated critical habitat.

Proposed Interim Decisions/Proposed Final Decisions. Once risk assessments are complete, the regulatory division develops a Proposed Interim Decision (PID). This document outlines:

- Findings from the risk and benefits assessments
- Any proposed human health or ecological risk mitigation measures (typically changes to label requirements)
- Results of the formal ESA consultation, if needed and available, and any mitigation measures necessary to finalize ESA consultation
- If additional data is needed to evaluate possible endocrine effects associated with a chemical as part of the Endocrine Disruptor Screening Program (EDSP)
- If a cumulative assessment is needed, which looks beyond the risks posed by a single chemical and evaluates whether exposure to multiple chemicals that share a common mechanism of toxicity could pose health risks when considered together
- Whether EPA believes additional data are needed, and if so, a description of the data (a DCI may be issued to the registrant if required)
- Deadlines for completing any required actions

Negotiations with the registrant to address the identified risks occur at the PID phase, prior to issuing an Interim Decision (ID), and registrants are aware of made aware of the required label changes prior to the issuing of a decision. Once both the registrant and OPP agree on the risks and mitigation requirements, the review will move forward.

Many chemical cases require a second risk assessment, an amended PID, or other work completed before proceeding with an ID or a Final Decision (FD). The number of steps involved vary on a case by case basis, but the processes within each phase are consistent.

Interim and Final Decisions. This PID then undergoes another 60-day public comment period. After addressing public comments on the PID, regulatory staff may issue:

- An Interim Decision if risk assessments are complete but ESA and EDSP consultations are ongoing
- A Final Decision once all risk, benefit, EDSP, and ESA assessments are finished

ESA compliance. ESA compliance involves coordination with the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service to determine the effect the pesticide may have on endangered species or critical habitat. OPP has developed strategies to help make progress on the ESA and is working on establishing the system and the tools necessary to implement. These measures will take place in the PID and ID stages to address ESA through the application of the strategies or FIFRA IEM where applicable.

EDSP compliance. The EDSP is an internal OPP process that has been linked to the registration review process for the past few years. HED evaluates the chemicals in the PWP and FWP stage to determine if additional data are needed to conduct endocrine screening. If yes, this data is included in the DCI to streamline the data calls for the registrants. The final decision takes the results of the EDSP into account, ensuring the decision is consistent with the Federal Food, Drug, and Cosmetic Act.

Label changes. Once either an interim or final decision is issued, regulatory staff notifies the registrant of any required label updates based on the registration review. Registrants have 60 days to submit amended labels, which regulatory staff then reviews to ensure consistency with the decision.

Key Challenges and Root Causes

Frequent delays. OPP faces persistent delays in completing registration reviews within the 15-year statutory timeframe, with bottlenecks emerging at multiple stages of the process. Many delays occur during the DCI phase when OPP is waiting for registrants to submit data and others occur during the risk assessment phase while science teams review all the data, as teams must balance competing priorities. Other delays can result from the internal OMB review, which may last months beyond the expected timeframe. Delays also arise from the coordination with other federal agencies to assess ESA compliance, as other agencies must work through their own backlogs and under-resourcing. These delays have prevented OPP from meeting registration review deadlines for some cases, and this backlog continues to increase.

Root cause development. To better understand the delays noted above, the team discussed the registration review process with several key stakeholders, both within OPP and among the registrant community. In doing so, the following root causes of the delays were identified within the registration review process. These root causes were organized according to the four pillars of the analysis: Process, People, Systems, and Policy. Below is a list of all root causes, along with an explanation of how the root cause is actively leading to downstream delays. Each root cause is coded with the following acronyms, which are later used to connect the recommendations for registration review with the relevant root causes they address:

- PR = Process-related root cause
- PE = People-related root cause
- PL = Policy-related root cause
- S = System-related root cause
- # = Number of root causes within the pillar

Root Causes for Process Challenges

- **PR1 – Unstructured labeling.** There is no one standard format for labels, leading to inconsistencies that make information extraction difficult and time-consuming. This slows down the overall registration review process and the final label approval as OPP staff must hunt for relevant information. It also prevents label information from being easily entered into structured fields in the systems as a format like a PDF would enable. Without a designated area for all the required information, OPP staff must rely more on judgement calls to determine whether the label complies with standards.
- **PR2 – Untimely data submissions from registrants.** The DCI phase of registration review can take 7-8 years, largely due to the time and resources registrants need to gather new data and submit study results to OPP. With hard to enforce deadlines and limited incentives for registrants to submit data promptly, registrants often take longer than expected in completing their data submissions, sometimes sending them along to OPP after risk assessments have concluded. This forces OPP teams to revisit earlier study review steps before being able to initiate PIDs, resulting in multi-year delays.
- **PR3 – Evolving science.** Given the protracted length of the registration review timeline, new scientific studies often emerge after a registration review is well underway, requiring additional

DCIs and risk assessments. Staying current with evolving science is challenging and can prolong risk evaluation.

- **PR4 – Untriaged waiver requests.** Registrants can submit waiver requests in response to DCIs, but these often sit in long queues before review. If ultimately denied, the delay prevents registrants from starting the required data collection earlier, which in turn pushes the data collection timeline back even further.
- **PR5 – High review volume.** With over 760 open registration review cases – reviewers are stretched thin, especially as staffing levels have not kept pace with demand. Risk assessments are time-intensive and require coordination across OPP and with the public. New product registrations, which are often prioritized due to shorter statutory timelines, further constrain reviewer capacity. As a result, many registration reviews exceed the 15-year timeframe.
- **PR6 – Low transparency for registrants.** OPP staff do not have established requirements around communicating with registrants during the registration review process, nor do they have SOPs in place to make sure that any communication that does occur follows a standard format. As a result, registrants often lack visibility into the status and timelines of registration review cases, making it difficult to plan or engage. Although reviews are conducted at the active ingredient level, outcomes can affect many products – not just those of registrants directly involved. As a result, some miss public comment opportunities or are surprised by label changes that affect them. This contributes to frustration in the registrant community and missed chances for meaningful input.

<u>Root Causes for People Challenges</u>

- **PE1 – Weak PRD–science division collaboration.** PRD oversees registration reviews for RD and manages collaboration and coordination across all involved divisions. However, PRD has difficulty working with science divisions to move reviews along and make sure all teams are collaborating effectively. Although coordination meetings between PRD and science divisions do exist, they are infrequent and often unproductive due to competing priorities and inconsistent preparation. PRD has challenges tracking and communicating delays, and there is no central location to document these delays outside of email, as the functionality to do so is not yet built out in Salesforce. These disconnects limit the opportunities for knowledge-sharing and slow down the risk assessment phase.
- **PE2 – Siloed science divisions.** Science divisions must collaborate closely on risk assessments, but limited cross-division communication leads to duplication, misalignment, and rework. Divisions often do not work on the same cases in parallel, as an active ingredient may require a longer review from one division than another. These misaligned timelines make collaboration difficult. For example, EFED's drinking water assessment can affect HED's toxicology and BEAD's economic assessments, but if EFED completes its work long after the others, HED and BEAD may need to revisit and revise their assessments. Duplication can also occur when divisions rely on different assumptions - for example, independently extracting use information from a label and reaching different conclusions. These inconsistencies must then be reconciled before decisions can be finalized. Overall, limited coordination makes it difficult to balance the competing priorities that the science divisions face and make sure the chemical review can progress on time, undermining efficiencies, complicating collaboration, and potentially resulting in conflicting risk assessments.
- **PE3 – PRD–RD disconnect.** When a registration review results in new label requirements, those changes must be reflected in future registration decisions. However, PRD does not consistently communicate these updates to RD, who reviews new product applications. There is potential for a

similar disconnect within AD, where there are designated branches for re-evaluation and registration on the regulatory side. As a result, registrants must resubmit applications with revised labels instead of having changes automatically carried forward – leading to delays in the registration process and extra burden on registrants.

Root Causes for Policy Challenges

- **PL1 – ESA and EDSP complexity**. To issue a final decision on a registration review case, OPP must first complete consultations required under ESA and EDSP. ESA reviews require coordination with agencies like the FWS and can take years due to data volume and partner agency backlogs. These requirements have been incorporated into the registration review process in the last few years, and OPP staff are still adapting workflows to incorporate them. As a result, many reviews remain stuck at the interim decision stage.

Root Causes for System Challenges

- **S1 – Systems not tailored for registration review.** Current IT systems were primarily designed to support new registrations and are less well-suited to support the nuances of the registration review process. As a result, key functions – like generating case numbers and tracking label changes – must be done manually. Teams often switch between multiple systems to manage cases, which increases effort and the chance of lost information. Although existing tools could support review functions, they are not configured accordingly, limiting automation and slowing progress.
- **S2 – Minimal automation.** Registration review still depends on manual tasks, including data extraction and case monitoring. Limited system capabilities and inconsistent Salesforce use prevent teams from benefiting from potential automation capabilities, leading to inefficiencies and delays in the process.

7.2 Registration Review Deep Dive Area: Recommendations

7.2A Recommendations Overview

Recommendation classification. This section covers all the recommendations for improvement within registration review that could help reduce delays and increase efficiency of the process. Each recommendation is associated with at least one of the root causes(s) that it helps to address. Moreover, we have categorized all recommendations as a momentum builder, strategic opportunity, nice to have, or investigate/defer. For a more detailed breakdown of these classifications, please see the Approach and Methodology section of this report.

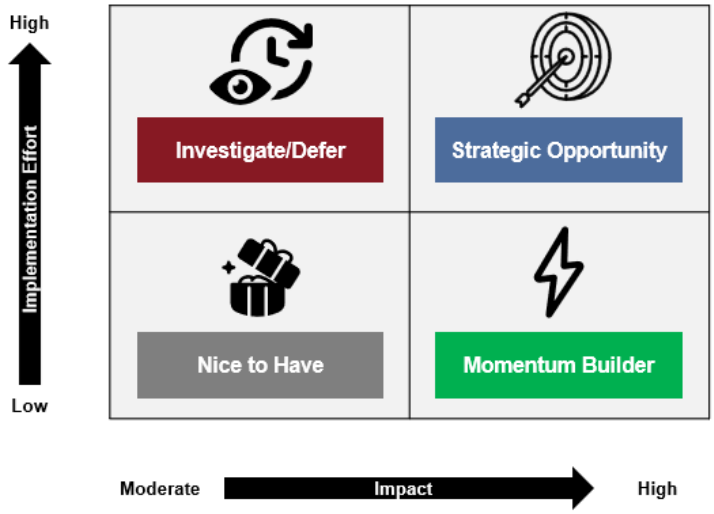

Figure 23: This framework helps categorize and prioritize recommendations based on their impact and feasibility.

Recommendation table and descriptions. Each category of recommendation has its own section that begins with a table summarizing the recommendations within the category, including a link to the detailed recommendation description and an indication of which of the four pillars (Process, People, Policy, or Systems) the recommendation is associated with. This summary table is followed by descriptions of the recommendations, why they would benefit OPP, and preliminary guidance on how OPP should approach their implementation. Each recommendation addresses at least one root cause from registration review, using the acronyms attached to each root cause. For example, if a recommendation references PR3 and S2, it addresses the third process-related root cause and the second system-related root cause within registration review. Each of these root causes is also linked in the descriptions.

Breakdown of recommendations. The team identified 13 total recommendations to address the challenges within the registration review area. Of those recommendations, 3 are momentum builders, 4 are strategic opportunities, 3 are nice-to-haves, and 3 should be investigated/deferred.

Applicable recommendations from PRIA registration areas. Please note that certain recommendations from the PRIA Deep Dives section are applicable for the registration review process as well but have not been fully detailed in this section to avoid redundancies. These recommendations, along with an explanation of why they would improve the registration review process, are listed below.

Some of the recommendations in this section may not apply to all regulatory divisions, as they have different organizational structures in place to process registration review. PRD is distinct from its

registration counterpart RD, whereas the other regulatory divisions of AD and BPPD conduct their registration reviews within their respective divisions.

Momentum Builders

- PRIA Rec. 1 -
- Implement Automatic Alerts for Missed and Late ***Deadlines (ICS, PTS)***
    - **Why:** Automatic alerts would hold reviewers accountable and prevent items from falling through the cracks (PR5). Aligning alerts with each registration review would ensure timely notifications, allowing staff to adjust timelines promptly and making it easier for PRD to notify science divisions of delays (PE1), Alerts would also serve as a reminder to PRD to keep registrants informed as timelines shift (PR6).
- PRIA Rec. 2 - Develop Clear Statuses for Applications within Salesforce and MyPest ***(ICS, PTS)***
    - **Why:** Clear case statuses would improve transparency for both internal and external stakeholders. In Salesforce, accurate statuses would help PRD track assessment progress and coordinate across science divisions (PE1, PE2). Once MyPest is rolled out for registration review, accurate statuses would give registrants better visibility into timelines improving satisfaction (PR6).

Strategic Opportunities

- PRIA Rec. 13 - Establish Standards around Registrant Communication ***(ICS, PTS)***
    - **Why:** Establishing registrant communication standards would improve registrant visibility into active cases and promote a more consistent registrant experience (PR6). This is especially relevant for registration review, as registrants may be interfacing with multiple PRD staff across simultaneous reviews.
- PRIA Rec. 24 - Implement Structured E-Labeling Format ***(PTS)***
    - **Why:** Reviewing labels and implementing label changes are major components of registration review. A structured, machine-readable format for pesticide labels would reduce review time and support future automation (PR1, PR5, S2) Structured labels that can be automatically processed would also help ensure that all registration review staff specifically are using the same set of parameters when reviewing use information from labels and therefore coming to more consistent decisions (PE2).
- PRIA Rec. 28 - Develop a More Automated Method for Data Extraction ***(PTS)***
    - **Why:** Risk assessments take years to complete due in part to the volume and complexity of scientific studies reviewers must manually analyze (PR3, PR5). A tool that extracts and organizes key data from registrant studies and organizes it in an effective way for reviewers would help streamline reviews and reduce overall risk assessment timelines.

Recommendations to Investigate / Defer

- PRIA Rec. 37 - **Error! Reference source not found.**
    - **Why:** A stronger customer service mindset would help OPP work more effectively with registrants, identifying opportunities to help reduce the backlog. Engaged registrants may also be more timely in providing data submissions during the DCI phase (PR2).
- PRIA Rec. 44 – Build Improved File Management Structure in Salesforce ***(PTS)***
    - **Why:** Better file management in Salesforce would help reviewers more efficiently handle the many study documents involved in registration review. Ensuring PRD representatives are engaged internally in OPP and in resolving outstanding Salesforce items will allow better tracking and filing of information related to cases once the updates are

incorporated. Involving registration review staff when implementing this recommendation will ensure the structure meets process needs and is not just catered for the registration process (S1).

Impact of recommendations. All the above recommendations could help strengthen and reduce inefficiencies within the registration review process in addition to the initial content screen and preliminary technical screen phases of the PRIA registration process.

7.2B Momentum Builder Recommendations

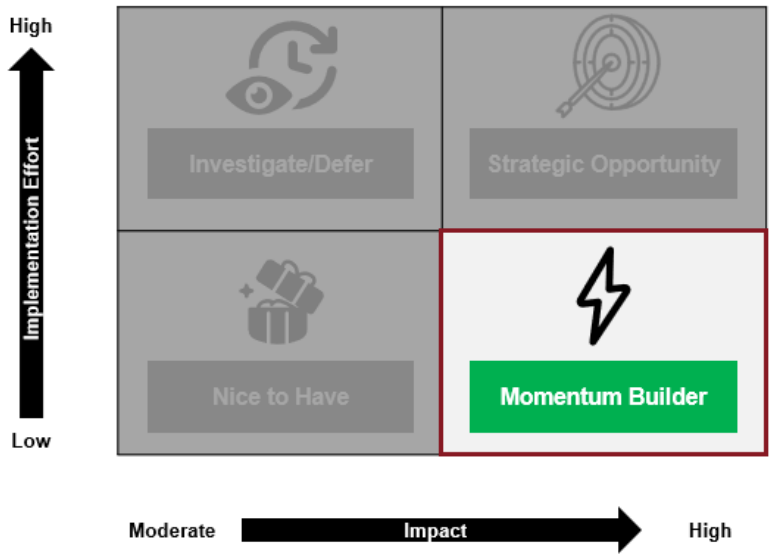

Figure 24: This framework helps categorize and prioritize recommendations based on their impact and feasibility.

#	Title	Process	People	Policy	Systems
1	Triage Waiver Submissions for Quick Review	✓			✓
2	Set Clear Deadlines for Data Submissions ***Implement Automatic Alerts for Missed and Late Deadlines***	✓		✓	
3	Create Channel for Cross-Division Communications		✓		✓

1. Triage Waiver Submissions for Quick Review

What: OPP should prioritize reviewing waiver submissions to ensure they are assessed and either approved or denied promptly upon receipt.

Why: Currently, waivers can sit in queues for weeks or months before review. When a waiver is ultimately denied, registrants lose valuable time that could have been used for data generation, delaying the overall process (PR4). This also contributes to longer DCI timelines (PR2) and exacerbates the overall case backlog (PR5). Faster waiver decisions would give registrants more time to collect data if their requests are denied, minimizing delays further down the line.

How: OPP staff should monitor new waiver submissions and assign them immediately to a CRM for review. OPP could also implement automatic alerts in Salesforce to notify staff working on registration reviews when new waivers are submitted, lessening the burden on staff to monitor incoming waivers (S2). To make the waiver review process quicker, OPP can develop checklists and criteria decision matrices (when to waive vs deny) for the reviewer to reference and easily determine if the request should be

granted. OPP can also templatize decision language to send when a waiver is either approved or denied, simplifying the process of notifying registrants of the decision.

2. Set Clear Deadlines for Data Submissions

What: OPP should establish a new internal policy that sets a firm deadline for data submissions within the DCI phase and make clear that data submitted after the risk assessment phase will not be accepted. OPP should explore what enforcement mechanisms can help meet deadlines.

Why: Establishing clear deadlines would reduce delays caused by late data and minimize the need for rework (PR2). Doing so would also help mitigate risks introduced by evolving science, which can complicate reviews when assessments must be revised based on new data submitted late (PR3). Starting the risk assessment earlier and reducing mid-review changes would help cut back on the overall review level of effort and timeline, while reducing the growing backlog (PR5).

How: Registration review teams should work with representatives from the registrant community to determine feasible submission timelines, potential constraints, and align on expected data standards and formats. The timelines for data submission may vary by data complexity, study duration, the number of registrants affected by the study, or other factors. Once agreed upon, these deadlines should be incorporated into relevant policy documentation to ensure that they are enforceable and widely communicated with internal staff and registrants using Salesforce and MyPest.

OPP can allow some degree of flexibility for the deadlines, adjusting them based on various pre-determined factors including the capacity of the registrant to meet those requirements and the complexity of the study required. Registrants could coordinate with OPP staff to determine what specific deadlines apply to their circumstances.

3. Create Channel for Cross-Division Communications

What: OPP should establish a shared communication channel that allows the regulatory and science divisions to message each other directly and record case-specific conversations.

Why: Communication challenges across divisions are a major source of inefficiency within PRD's registration review process. Science teams often operate on different timelines and lack visibility into each other's work, leading to duplication and inconsistencies (PE2). Collaboration between PRD and science divisions is also inconsistent and ineffective, especially during risk assessments (PE1). Meetings to share updates occur infrequently, and communication often occurs via email, which can result in certain individuals missing information. Improving communication within a centralized platform would reduce the chance of missing or duplicating work, allow more efficient coordination, and help teams keep pace while working through ongoing reviews.

How: OPP should recommend that important cross-division communications be logged in one central location. Teams can leverage Salesforce or another tool for this channel, as long as the chosen channel is easily accessible for all users and already being used for case reviews. Once a channel is established, reviewers could use case-linked comments to share updates, questions, decisions, and inputs. This channel could also be used by PRD for communicating and documenting any delays in cases.

7.2C Strategic Opportunity Recommendations

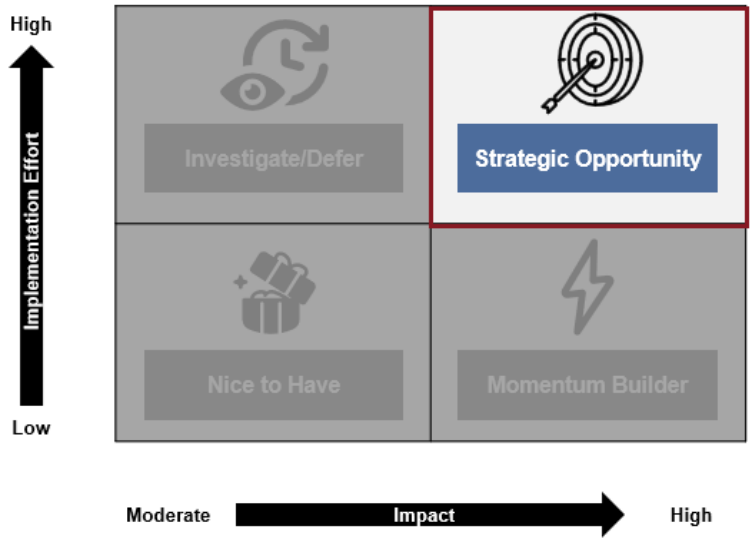

Figure 25: This framework helps categorize and prioritize recommendations based on their impact and feasibility.

#	Title	Process	People	Policy	Systems
4	Incorporate Risk-Based Approach for Reviews ***Implement Automatic Alerts for Missed and Late Deadlines***	✓		✓	
5	Align on Key Assumptions Made during Registration Review	✓	✓		
6	Expand Salesforce Workflows to Address Registration Review Needs	✓			✓
7	Establish More Effective Cross-Divisional Meetings	✓	✓		

4. Incorporate Risk-Based Approach for Reviews

What: OPP should adopt a more risk-based approach to registration review by prioritizing full reviews for higher-risk active ingredients and scaling back the frequency or depth of reviews for lower-risk ones.

Why: Currently, OPP aims to complete a full registration review for every active ingredient every 15 years, regardless of risk level. This contributes to large review backlogs and strains staff capacity (PR5). Focusing resources on reviews of higher-risk ingredients could help OPP reduce the overall level of effort to complete registration reviews while ensuring the most critical cases are prioritized and completed efficiently.

How: To implement this approach, OPP should begin by establishing a definition of high-risk versus low-risk ingredients, drawing on historical risk assessment data, toxicology profiles, exposure potential, and public health relevance. The regulatory divisions could establish this classification during the product

registration process and the teams working on re-evaluation could revisit it when registration review is set to begin. If new information or regulations arise that would impact the risk of a defined ingredient, the registration review teams should determine if the review cadence or depth should be adjusted. Once OPP defines risk levels, they should explore policy options for adjusting review schedules according to the ingredient's risk level, documenting any new approach established.

5. Align on Key Assumptions Made during Registration Review

What: Throughout the review process, reviewers should meet and confirm key scientific and policy assumptions used during the registration review, logging them for a particular active ingredient within Salesforce.

Why: Currently, science teams may operate based on different assumptions without visibility into what assumptions other teams on the review are using (PE2). This lack of alignment leads to inconsistent reviews and inefficiencies in resolving discrepancies. There may be conflicting conclusions necessitating rework, which opens the door to errors and biases. A shared repository of key assumptions made during registration review would improve consistency, reduce duplicative work, and ensure reviewers are operating from a common understanding – especially as new data and science evolve (PR3).

How: At the beginning of the risk assessment period, the review team should meet to align on the assumptions they are making as they begin their individual assessments. OPP could use Salesforce or another shared platform to record the assumptions they utilize when reviewing and assessing the studies, tagging the assumptions by active ingredients, use patterns, and study types. Once these are established, the CRM for the review should monitor the assumptions and continue to check in with the science division members to track if the assumptions remain the same or change at any point in the review. If changes arise, the CRM should document the change to the assumption and alert the other team members to that change so they can modify their own assessments as needed.

6. Expand Salesforce Workflows to Address Registration Review Needs

What: OPP should continue expanding Salesforce functionality to better support the registration review process, focusing on automating high-impact tasks and tailoring workflows to scientific review needs.

Why: Salesforce, while broadly used within OPP, is not currently optimized for registration review (S1). Teams rely on manual workarounds to track label changes, generate case numbers, and monitor progress, leading to inefficiencies and increased administrative burden (S2). Better leveraging Salesforce's automation capabilities can reduce this burden and free up time for scientific analysis.

How: OPP should identify high-impact pain points within the registration review process and work with in-house Salesforce experts to explore automation options. A cross-functional working group of science reviewers and IT staff should co-develop these workflows to ensure they meet on-the-ground needs and are user-friendly. A key step will be to gather requirements with Salesforce experts to determine how to incorporate the recommended improvements, outlining where the system can better support the registration review process and what additional features and functionalities are needed to better align with the process needs. Potential areas for increased functionality include adding in task routing, creating automated alerts for upcoming deadlines or pending reviews, implementing status tracking, uploading and storing documents for access, and logging who makes which changes.

7. Establish More Effective Cross-Divisional Meetings

What: PRD should convene more effective, regular meetings with science divisions to discuss ongoing registration review cases. These meetings should have a clear cadence and an agenda to support collaboration on risk assessments.

Why: Current meetings between PRD and science divisions are inconsistent and often unproductive due to a lack of preparation (PE1). However, when structured effectively, these meetings are a valuable tool for identifying risks early, resolving data issues, and working through backlogs. (PR5). Improving these cross-divisional meetings would strengthen coordination and help manage high review volumes.

How: PRD should work with science team leads to establish a standard meeting schedule, ideally occurring at key milestones within the registration review process. Each meeting should include a defined agenda, designated cases for discussion, and pre-work requirements for all participants. Potential agenda items include:

- Current status on each risk assessment
- Updates on assessments from each division (key findings, concerns, outstanding questions)
- Cross-cutting issues (e.g., conflicting assumptions or risk estimates, shared data needs or overlapping studies, impact of findings on other divisions or the overall conclusions)
- Timeline alignment, including estimated deadline for review and any delays

Teams should use the meetings to surface questions regarding active cases, validate timelines for risk assessments, and proactively resolve issues.

7.2D Nice-to-Have Recommendations

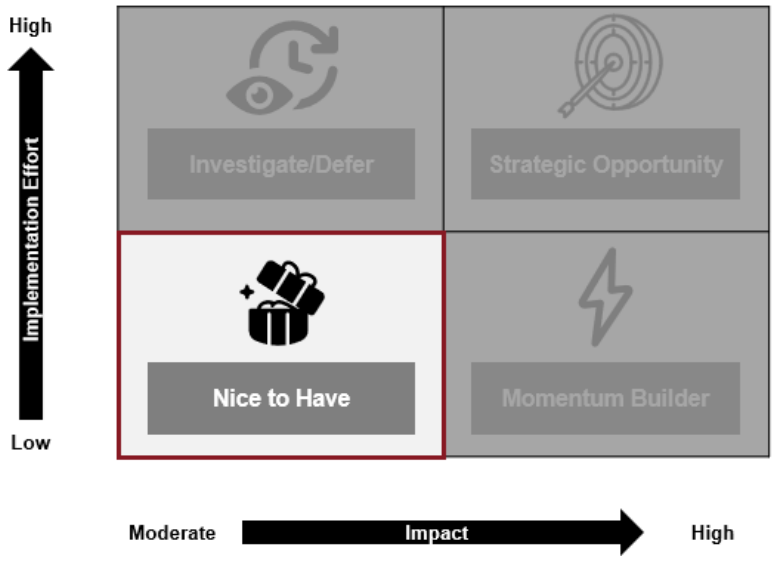

Figure 26: This framework helps categorize and prioritize recommendations based on their impact and feasibility.

#	Title	Process	People	Policy	Systems
8	Create a Mechanism for Registration Review Teams to Update Registration Teams on New Label Guidance	✓	✓		
9	Establish a Public Database of Active Registration Review Cases	✓			✓
10	Create Policies and Procedures for Collaboration with External Agencies	✓	✓	✓	

8. Create a Mechanism for Registration Review Teams to Update Registration Teams on New Label Guidance

What: OPP should establish a mechanism for teams working on registration review to communicate new label requirements from registration review cases to those working on the registration applications so that regulatory divisions can apply those requirements directly to new product registration cases that contain the relevant active ingredient.

Why: Currently, dedicated registration review staff do not consistently share updated label requirements with their registration counterparts, even when those requirements apply to new products (PE3). This forces registrants to resubmit updated labels during the new product registration process, which creates unnecessary back-and-forth and delays. A more direct handoff between the registration review and traditional registration teams would streamline the process and reduce burden on registrants. For example, if PRD notified RD of new requirements, RD should be able to implement the updated guidance directly in relevant new product registration cases so that registrants do not have to worry about resubmitting applications to address the change.

How: The respective re-evaluation teams and registration teams should collaborate to determine the best way to implement this communication. Teams could consider using Salesforce or another lightweight

system to flag relevant label updates, minimizing additional burden on reviewers. When new label requirements arise, the registration review teams can alert those working on registration actions, who can then look to see which active applications are impacted by the change and make the updates directly.

9. Establish a Public Database of Active Registration Review Cases

What: OPP could create a public-facing database of active registration review cases to enable registrants to track cases that may affect their products.

Why: Although registration review is conducted at an active ingredient level, its outcomes often affect a wide range of products. Registrants not directly involved in a case may still be impacted by its results but may miss opportunities to participate in public comment periods (PR6). A centralized database would increase transparency for registrants, improve engagement, and allow registrants to proactively identify and engage in cases relevant to their products.

How: OPP should publish the database in a searchable, centralized location. If the goal is broad access, EPA's registration review webpage may be appropriate. If intended for registrants only, MyPest could be used. The database should include each case's active ingredient(s), potentially affected uses or product types, and current review status.

10. Create Policies and Procedures for Collaboration with External Agencies

What: OPP should develop formal standards for collaboration with external agencies involved in ESA compliance, including timelines, communication channels, meeting protocols, and key points of contact.

Why: The ESA compliance step often delays registration review final decisions, as collaboration with external agencies such as FWS can be time-consuming and unstructured (PL1). Establishing shared expectations and protocols could reduce delays and help OPP achieve ESA compliance more efficiently.

How: OPP teams should identify common challenges in the current collaboration process and work with partner agencies to co-develop practical solutions. These standards should be clearly documented and shared with all staff involved in ESA compliance and may take the form of a Memorandum of Agreement/Memorandum of Understanding (MOA/MOU). OPP could also consider going to external agencies for the ESA review only once the risk assessment is largely completed. This would enable OPP to go to the agencies with a clearer set of proposed actions, improving collaboration and making it easier to incorporate the external reviews into OPP's workflow.

7.2E Recommendations to Investigate/Defer

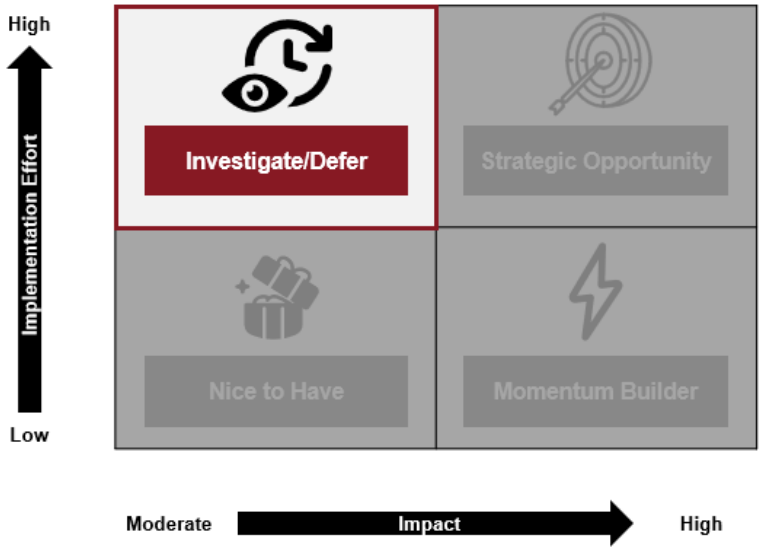

Figure 27: This framework helps categorize and prioritize recommendations based on their impact and feasibility.

#	Title	Process	People	Policy	Systems
11	Communicate the Importance of Meeting Data Submission Deadlines ***Implement Automatic Alerts for Missed and Late Deadlines***	✓	✓		
12	Continue Efforts to Migrate all Data into Salesforce	✓			✓
13	Designate Individuals to Monitor and Share Key Scientific Developments	✓	✓		

11. Communicate the Importance of Meeting Data Submission Deadlines

What: OPP should make the expectations, rationale, and consequences of meeting or failing to meet data submission deadlines clear to registrants.

Why: The DCI phase is a major source of delay, often taking seven to eight years to complete (PR2). Registrants have limited incentive to submit data early, as registration review outcomes may restrict product use. Offering tangible benefits for earlier submissions or outlining the potential consequences for late submissions could encourage registrants to provide data faster, thereby reducing delays.

How: OPP should gather input from staff on the benefits of having registrants meet data submission deadlines, hosting an internal working session to do so. Highlighting the benefits of submitting new data in a timely manner could encourage registrants to respond to DCI's sooner. For example, registrants may benefit from knowing about new risks in their products as soon as possible to avoid potential legal risks down the line. Also, while common perceptions among registrants are that registration review will only lead to more restrictions on their products, the opposite may be true in an environment where many EPA regulations are becoming less restrictive. In addition to highlighting potential benefits of more efficient registration reviews, OPP should also be explicit about what regulatory actions are likely to occur in the

event that data is not provided by the deadline. Once a list of benefits and consequences is developed, OPP can consult with select representatives from the registrant community to gauge which ideas would meaningfully impact submission behavior. Once aligned, OPP can then disseminate this communication more broadly with registrants.

12. Continue Efforts to Migrate all Data into Salesforce

What: OPP should continue its work to migrate all key registration review data into Salesforce to reduce inefficiencies caused by data fragmentation.

Why: Although migration efforts are underway, reviewers still rely on multiple systems to access and reconcile information, which slows down their work (S1). Consolidating this data into a single system would improve efficiency and support timely completion of reviews.

How: Science divisions should identify frequently used datasets that are not yet in Salesforce. OPP IT teams can then prioritize migrating this data into Salesforce while ensuring accuracy, preventing data loss, and clearly communicating any system changes to staff.

13. Designate Individuals to Monitor and Share Key Scientific Developments

What: OPP should designate a cross-functional team to monitor emerging scientific developments and share key insights with relevant staff.

Why: Given how rapidly science evolves, keeping up to date on the latest advances and newest studies is a significant time commitment (PR3). A dedicated group could centralize this effort, ensure consistent dissemination of findings, and reduce the burden on individual reviewers to stay up to date on scientific developments that are relevant to their work.

How: This group should include at least one representative from the regulatory teams working on registration review and risk assessors from different science divisions and branches. Members could monitor developments in their respective areas and share relevant insights across teams. Regulatory division staff working on registration reviews could help coordinate regular meetings and standardize the format for sharing updates.

8. OPERATIONAL ENABLER AREAS: PROGRESS ASSESSMENT

8.1 Information Technology Systems

Overview

This section summarizes the various IT-related insights, challenges, and recommendations that were captured throughout the report. Previous sections provide more detail on how IT systems interact with different topic areas, with this section providing a general overview of the Censeo team's assessment of OPP's IT systems. Three IT systems were reviewed as part of this report.

Central Data Exchange (CDX). The CDX portal is the system developed and maintained by EPA to intake data for a number of programs, used in OPP to intake applications from registrants. The 21-day timeline for the initial content screen begins once the Information Services Branch receives the application through CDX. After the application fee is paid, the application is routed to the contractor team for screening. However, the system does not have a consistent maintenance schedule and is prone to technical issues and unexpected crashes, which can delay the intake process.

Salesforce. OPP recently replaced previously outdated systems with a modern, Salesforce-based system. This system is used internally to manage registration workflows, and many OPP staff have successfully integrated it into their review processes and reaped the benefits. However, other teams have found it to be a hindrance, leading to inconsistent adoption across the office. While Salesforce has improved operational efficiency in important ways through its application tracking, communication, and document templating features, it currently lacks many key functionalities such as automatic status updates and storing documents within the platform.

MyPest. MyPest is a registrant-facing portal of the new Salesforce system intended to provide real-time data on the status and progress of applications. Updates OPP staff make to the internal Salesforce tool are reflected in the external facing MyPest portal to relay important application updates to the registrant. However, the information presented in MyPest can be misleading, with application statuses not always reflecting the actual stage of review due to inaccuracies in Salesforce. Inaccurate data that OPP staff see in the internal facing portal of Salesforce is mirrored back to registrants, though the registrants have an even more limited view of the application progress compared to internal staff.

Current Challenges & Inefficiencies

Poor Data Quality and Inaccurate Timelines. A large cause of inefficiency is the poor quality and unreliability of data within the systems. Data is also often unstructured (e.g., PDFs), making it difficult to process, analyze, report on, or leverage for automation. One example of unreliable data is with system statuses that do not reflect the reality of an application's progress. Staff reported that they have limited insight into the true status of an application, as Salesforce may show the application in the preliminary technical screen phase when key steps in the initial content screen have not yet been completed, but staff have no way to know what truly has been completed or not. This creates misleading timelines in both Salesforce and MyPest, causing confusion for both reviewers further down the process and registrants awaiting upstream.

Inconsistent User Adoption. There is significant variation in how OPP staff use Salesforce. Some teams have successfully integrated the tool and its workflows, while others find it burdensome or lacking functionality, so they continue to track actions offline or communicate via email. Furthermore, different divisions have been onboarded at different times, leading to varying levels of system knowledge and adoption across OPP. This inconsistent adoption prevents the OPP from fully realizing the benefits of a unified system. It fragments communication, makes collaboration difficult and time-consuming, and limits leadership's ability to identify bottlenecks or manage workloads effectively.

Limited Automation. Despite the capabilities of a modern platform like Salesforce, many key processes remain manual. The initial content and preliminary technical screens still rely on manual checks for tasks that could be automated, such as verifying the presence of required studies or confirming document formatting. Science teams report creating their own manual workarounds to complete basic screens. This reliance on manual effort slows down reviews, contributes to missed deadlines, and consumes valuable staff time that could be focused on higher-level analysis.

Technical Issues and Limitations. The systems themselves have functional gaps and stability problems that create bottlenecks. The CDX portal used for application intake suffers from frequent crashes, which delays the start of the entire review process. Furthermore, Salesforce, while an improvement, was not designed with all of OPP's specific needs in mind. While it possesses the capabilities, Salesforce is not used as the document repository for OPP, with Documentum instead taking on that role. This adds another system into the mix and creates more work for staff who must hop between each system to complete various tasks. Documentum also lacks the ability to perform bulk downloads, forcing staff to manually download files and share them outside of the system. The Salesforce system is also not well-tailored to the nuances of the registration review process, forcing teams to manage key functions like case numbering manually.

Actions to Date

OPP's Digital Transformation initiative has worked to modernize systems, improve data and document management, and provide users with tools that better fit their needs. Specific improvements include:

- Moving from mostly paper to entirely electronic workflows
- Launching Salesforce CRM for registration and registration review workflows
- Leveraging automated workflows with the Salesforce CRM including those for data call-ins, some regulatory letters, and deficiency documents
- Deploying early phases of MyPest as an interactive customer application
- Ensuring information in hardcopy and old digital records remain available and accessible
- Using coded programs to batch similar public comments
- Automation of biological evaluation analyses

Recommendations

Automate workflows. OPP can better leverage the automation capabilities of existing systems to reduce time-consuming manual work. By automating rules-based tasks in the initial content and preliminary technical screens, such as using Salesforce validations or AI to perform routine checks for document formatting and form completion, OPP can significantly reduce manual processing time. This would mitigate the effects of high application volumes and free up staff to focus on more complex issues.

AI can also be leveraged to streamline document-heavy tasks, such as automatically extracting key data from scientific studies and generating first drafts of 10-day deficiency letters, which would speed up communication with registrants. Further efficiency can be gained by implementing automatic alerts in Salesforce for upcoming or missed deadlines and by sending automated results of the initial content screen directly to registrants, allowing them to address deficiencies faster and reducing the communication burden on OPP staff.

Improve data quality. OPP can improve the accuracy and clarity of information within Salesforce and MyPest to provide a more reliable picture of the work being done. Developing a standardized and more detailed set of application statuses for the full registration and registration review processes would provide greater transparency for both internal teams and registrants. This increased visibility would help staff coordinate more effectively and give registrants a clearer understanding of their application's progress. Additionally for leadership, a centralized dashboard to track renegotiated deadlines across all divisions would offer real-time visibility into delays and their root causes, enabling more data-driven oversight.

Increase system functionality and adoption. OPP can streamline its review workflow by addressing core functional gaps in its systems and improving how staff interact with them. To resolve challenges with document handling, a more user-friendly file management structure should be built within Salesforce, complete with features like searchable metadata tags and bulk download capabilities. OPP can also improve registrant experience and reduce administrative burdens by creating a dedicated web-based portal for study submissions and by developing the capability for registrants to directly edit specific fields in their applications to correct minor deficiencies.

To address inconsistent system use among staff, Salesforce onboarding and training should be expanded with division-specific use cases. Promoting best practices from high-utilization teams through knowledge sharing events can drive broader engagement and increase process standardization across OPP divisions.

8.2 Employee Training

Overview

For the employee training topic area, the Censeo team was not provided with any specific training materials to evaluate. Another contractor team is actively conducting a training needs assessment, but the results were not available at the time of this report.

Insights for this section are gleaned from inputs provided by interviews with staff and registrants, which primarily focused on the process, and ad hoc training materials like manuals that may have been provided as documentation for other topic areas.

Current Challenges & Inefficiencies

Shifting environment. OPP has dealt with constant changes, from evolving policies and updating systems to staff turnover and vacancies. These fluctuations introduce challenges for OPP staff and disrupt their ability to get work done efficiently. Frequent changes interrupt workflows, require repeated retraining, and create uncertainty about current procedures and standards. These shifts can happen so quickly that by the time updated training materials are developed, procedures may have already changed again, leading to confusion, inconsistent application of the processes, and time lost in clarifying the correct steps and best practices.

Challenges in maintaining materials. These constant changes also make maintaining training materials difficult. OPP has a decentralized training model, with materials developed and housed by smaller groups within the office to address specific issues, gaps, and processes that are relevant to that office's domain. In instances where issues cross divisions or teams, there are not effective mechanisms in place to enable knowledge sharing so that materials developed by one team could be utilized by another team facing a similar issue. Instead, teams often develop their own approaches to the same problem, causing further complications and inconsistencies if these approaches do not match.

Staff also deal with a lack of time and resources to dedicate to maintaining training materials. Those responsible for updating the materials are also responsible for a full-time workload and have to choose where to spend their time most effectively. As a result, training teams are comprised of ad hoc members who do not have the capacity to develop comprehensive training materials or conduct training sessions, especially given the number of updates that would be needed to reflect the latest guidance.

Registrant experience. OPP's challenges with training are apparent even to registrants, who noted in interviews that some OPP staff appear to have inadequate training resulting in inconsistent decisions that do not reflect provided guidance and vary individual to individual. Registrants would also prefer more consistency in communication—they specifically requested that OPP conduct training to standardize expectations for engaging with registrants. This includes providing opportunities for OPP staff to learn more about the registrant experience and the pesticide industry.

Actions to Date

PRIA 5 Training Set-Aside project. OPP has undertaken an effort to inventory all the existing materials related to OPP trainings, which includes standard operating procedures and guidance documents along with other materials. This effort, called the PRIA 5 Training Set-Aside project, has already revealed that OPP has nearly 1,000 items dispersed across numerous locations.

Improving consistency. Outside of the inventory effort, OPP has begun to address some of the challenges outlined above, and improvements implemented to date include:

- Consolidating the divisional team's internal resources, developing centralized locations to house training materials relevant for their processes
- Establishing a formal mentor/buddy system for new employees
- Increasing interdivisional cross-training and participation in committees
- Surveying employees to better understand training needs
- Scheduling recurring office hours to increase knowledge transfer

Recommendations

Develop a plan from inventory effort. Once the results of the PRIA 5 Training Set-Aside project are in, OPP can evaluate the current state of training materials and identify key gaps and opportunities. Potential areas of focus include standardizing training materials across divisions to improve consistency and develop a single source of truth for staff, making materials more accessible to staff across divisions, and improving engagement with staff with increased training sessions tailored to staff's most pressing needs or information gaps.

The workforce assessment will build off insights obtained from the training project. Beyond looking at knowledge gaps and the skills staff need to know to perform their jobs effectively, this assessment will determine how many people are needed in which roles in each division to operate optimally. Coordinating this effort with improving training will ensure the right people are in the right roles and are provided with the knowledge they need to succeed.

Establish communications training. To create a more positive and consistent experience for registrants engaging with OPP staff, OPP can create a training program detailing how, when, and what to share with the registrants. Using a standard form of communication, such as the MyPest portal or email, is one step, and ensuring that OPP staff are held to an expected response timeframe is another aspect. OPP can determine the level of detail that is required in their responses, but establishing these standards will help create more predictability for registrants, which is their main request.

9. IMPLEMENTATION OF RECOMMENDATIONS

Successful implementation of the recommendations in this report will require disciplined program management, phased execution, and sustained leadership engagement. To ensure measurable improvements in OPP's registration processes—particularly in the Initial Content Screen (ICS) and Preliminary Technical Screen (PTS), where much of the backlog and processing challenges originate—**we recommend that OPP establish a centralized Implementation Program Management Office (PMO)**.

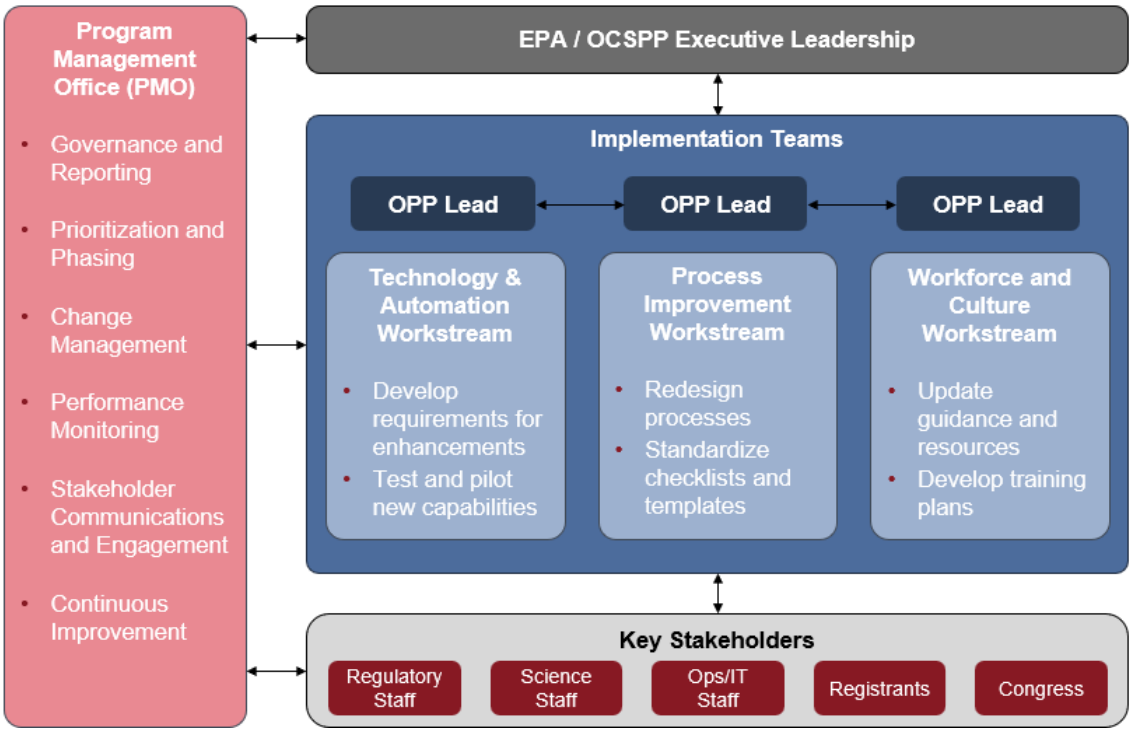

Figure 28: Example Implementation PMO Concept of Operations (CONOPS).

This PMO would be responsible for coordinating and driving execution of recommendations, monitoring progress against defined metrics, and serving as a central point of accountability across divisions. The PMO's core functions should include:

- **Prioritization and Phasing:** Sequencing initiatives to deliver early wins while laying the groundwork for long-term improvements.
- **Governance and Reporting:** Establishing clear decision-rights, escalation paths, and performance reporting to OPP leadership and external stakeholders.
- **Change Management:** Coordinating communications, training, and stakeholder engagement to reduce resistance and ensure adoption.
- **Performance Monitoring:** Using KPIs and process metrics to track decreases in cycle times, backlog reductions, and quality improvements, enabling data-driven course correction.

This PMO would be organized around three key workstreams, centered around the three strategic levers for improvement identified in this report. Each of these workstreams would include a portfolio of

initiatives, ranging from momentum builders to deliver practical and high-impact changes and immediate value, along with longer-term strategic initiatives. This approach would enable OPP to build early momentum while laying the foundation for continuous improvements in cycle times, consistency, and the overall registrant experience.

Workstream 1: Automating Workflows and Modernizing Technology

The first workstream focuses on reducing manual effort and enabling more seamless, system-supported reviews to shorten processing timelines. A recurring theme in our recommendations is the importance of fully leveraging existing tools, such as Salesforce, while strengthening data quality to support decision-making. Sample tasks within this workstream could include:

- ***Momentum Builder***
  - **Automatic Alerts for Missed and Late Deadlines**: Enhance automated alerts in Salesforce to enable greater transparency and reduce risk of stalled application reviews.
- ***Strategic Priority***
  - **IT Modernization:** Integrating updated inert ingredient databases and developing dashboards to track case progress and workload distribution.
- ***Continuous Improvement and "Nice to Haves"***
  - **AI-Enabled Screening Pilots**: Test advanced analytics or AI tools to support automated screening and prioritization of select submission categories.

Workstream 2: Driving Standardization Across Processes

The second workstream would lead efforts to decrease unnecessary variation and rework by strengthening consistency across reviews. Standardizing process steps, submission formats, and terminology is critical to improving both efficiency and quality, particularly when supported by better data practices as outlined in the first workstream. Sample tasks within this workstream could include:

- ***Momentum Builder***
  - **Standardized Applicant Communications**: Develop common terminology and consistent status labels for describing processes and phases within OPP systems.
- ***Strategic Priority***
  - **Process Redesign:** Reducing redundant steps and rework in ICS/PTS, informed by process mapping and cycle time analysis.
- ***Continuous Improvement and "Nice to Haves"***
  - **Applicant Self-Certification Tools:** Deploy pre-submission self-check features for registrants to identify deficiencies before submission.

Workstream 3: Fostering a Customer-Focused Culture

The third workstream centers on strengthening how OPP engages with registrants and coordinates internally to provide a more predictable and transparent experience. By making timelines, policies, and the criteria for a successful submission more visible and reliable, OPP can build trust and reduce unnecessary back-and-forth. This workstream emphasizes improving communication, setting clear service standards, and reinforcing accountability across teams. Sample tasks within this workstream could include:

- ***Momentum Builder***
    - **Standardized Applicant Communications**: Adopt uniform templates for deficiency notices and status updates to improve clarity and reduce applicant follow-up.
- ***Strategic Priority***
    - **Backlog Elimination:** Expanding the proven non-PRIA backlog reduction strategies to PRIA actions, with targeted closeouts and prioritization of high-impact submissions.
- ***Continuous Improvement and "Nice to Haves"***
    - **Registrant Feedback Loops**: Establish ongoing engagement mechanisms to refine guidance and identify emerging process pain points.

This phased approach organized by strategic opportunity theme will enable OPP to tackle the most pressing process bottlenecks immediately, while also investing in foundational improvements that will sustain performance gains over time across all recommendation areas. By centralizing accountability in a PMO, focusing on momentum builders and strategic priorities, and applying rigorous monitoring, OPP can measurably improve timeliness, transparency, and efficiency in pesticide registration.

10. CONCLUSION

Since PRIA 5, OPP has demonstrated a clear commitment to modernizing the pesticide registration process—working to improve timeliness, reduce backlogs, and pilot new tools to support efficiency. Through this project and several other outreach efforts, OPP has demonstrated a clear commitment to better understanding the root causes of challenges throughout its current registration processes, the business impacts on the registrant community, and ways to reduce delays to strengthen our national economy. They have undertaken a sweeping digital modernization effort that, while still in progress, has already meaningfully increased the productivity of the OPP workforce. Likewise, they are gradually updating and improving templates and guidance for staff to further reduce administrative burden. Equally important, the administration has provided additional resources throughout the office to increase overall capacity, help accelerate application processing, and reduce backlogs.

While this momentum is encouraging, the transformation required to sustain this progress will demand leadership commitment, coordinated action, and continued investment across several years. This report demonstrates the magnitude of the current challenges and opportunities within three core registration processes—the Initial Content Screen (ICS), Preliminary Technical Screen (PTS), and Registration Review—as well as in supporting areas such as non-PRIA actions, renegotiations, IT systems, and workforce training.

The assessment identifies three strategic opportunity areas that will guide implementation going forward:

1. **Automating Workflows and Modernizing Technology** – Leveraging tools like Salesforce to replace manual steps, improve data quality, and enable real-time performance tracking.
2. **Standardizing Processes and Strengthening Governance** – Reducing variation across divisions through updated guidance, templates, and policies, and clarifying decision-making authority to ensure consistency and accountability.
3. **Enhancing Workforce Capability and Customer Experience** – Aligning staffing with workload, improving training, and fostering a more consistent, transparent experience for registrants.

The 79 process-specific recommendations in this report—and additional actions in related topic areas—offer a concrete, actionable roadmap for delivering these strategic opportunities. Implementing them in phases will enable OPP to realize early wins, address structural challenges, and build a foundation for continuous improvement.

In doing so, OPP will be positioned to institutionalize best practices, reduce reliance on ad-hoc fixes, and ensure that improvements are sustained across leadership transitions and workload fluctuations. This will not only improve day-to-day operations but also provide a more predictable, transparent, and efficient experience for registrants, stakeholders, and the public. The recommendations can also serve as an input to the upcoming development of PRIA 6, by ensuring that any policy changes reinforce process, technology, and training improvements made as a result of this report and that timeframes and fees are appropriately calibrated.

The Need for Sustained Support

While we have recommended several “momentum builders” throughout this report, the most impactful changes are likely to take several years to fully implement. To achieve the full benefits of these changes, OPP will need to maintain dedicated resources, leadership commitment, disciplined governance, and dedicated implementation support. Continued investment will ensure the progress made since PRIA 5 is

sustained, that short-term backlog reduction efforts are paired with continuous, long-term, process improvements, and that OPP remains equipped to meet statutory deadlines while delivering a more efficient and predictable registration experience for all stakeholders.

Just as importantly, this investment will safeguard OPP's ability to respond to future shifts in workload, statutory requirements, and emerging scientific and regulatory needs. By committing to these improvements over the long term, EPA will not only address today's most visible process challenges, but also strengthen OPP's operational resilience, enable faster integration of new science and policy, and enhance public trust in pesticide regulatory decisions.

Maintaining this focus will allow OPP to evolve from incremental improvements to a fully modernized registration system—one that consistently meets the expectations of Congress, registrants, and the public while supporting EPA's broader mission to protect human health and the environment.

11. APPENDIX

10.1 List of Acronyms

Acronym/Term	Definition
AD	Antimicrobials Division
BEAD	Biological and Economic Analysis Division
BPPD	Biopesticides and Pollution Prevention Division
BPR	Business Process Review
COR	Contracting Officer Representative
CRM	Chemical Review Manager
CSF	Confidential Statement of Formula
DCI	Data Call-In
EDSP	Endocrine Disrupter Screening Program
EFED	Environmental Fate and Effects Division
EPA	Environmental Protection Agency
ESA	Endangered Species Act
FWS	Fish and Wildlife Service
HED	Human Effects Division
ICS	Initial Content Screen
ISB	Information Services Branch
OPP	Office of Pesticide Programs
PID	Proposed Interim Decision
PM	Product Manager
PMO	Project Management Office
PRD	Pesticide Reevaluation Division
PRIA	Pesticide Registration Improvement Act
PTS	Preliminary Technical Screen
PWP	Preliminary Work Plan
RD	Registration Division
RM	Risk Manager

Table 4:4 List of acronyms used throughout report.

10.2 Organizations and Stakeholders Interviewed

#	EPA OPP Offices
1	Biopesticides and Pollution Prevention Division
2	Antimicrobials Division
3	Environmental Fate and Effects Division
4	Biological and Economic Analysis Division
5	Human Effects Division
6	Registration Division
7	Pesticide Reevaluation Division

Table 55: Censeo interviewed representatives from seven different OPP offices.

#	Organization
1	Innvictis
2	Syngenta
3	Crop Life America
4	The Household and Commercial Products Association
5	Arxada
6	The American Chemistry Council
7	SC Johnson
8	DC Legislative and Regulatory Services Inc
9	ISSA, The Worldwide Cleaning Industry Association
10	Biological Products Industry Alliance
11	AgroSpheres
12	The J.R. Simplot Company
13	Delta Analytical Corporation
14	Bayer
15	The Biotechnology Innovation Organization
16	Responsible Industry for a Sound Environment
17	The Animal Health Institute
18	Spectrum Brands
19	Elanco
20	Council of Producers and Distributors of Agrotechnology
21	W.F. Young
22	Ramboll
23	Lallemand Plant Care
24	Hazel Technologies, Inc
25	Haviland Consumer Products, Inc
26	BASF Corporation

Table 6: Censeo interviewed representatives from 26 registrant organizations.

10.3 Sample Interview Questions

The questions first focused on getting an understanding of the process at hand and of the interviewee's role in that process. The interview remained focused on the main challenges or inefficiencies the interviewees witnessed in the process, digging in deeper to get to the root causes. The questions were organized into themes based on the four pillars in the analysis framework – process, people, policy, and systems – and the team made sure to touch on each theme throughout the course of the interview. Each interview also gave the interviewees the opportunity to share their own recommendations for how the process could be improved, which we incorporated into our analysis.

Sample Interview Questions for OPP Staff

- Can you describe this process in your own words?
- Where in the process do bottlenecks typically arise?
- Who owns or champions this process? Are roles clearly defined?
- How do you engage with the registrants throughout this process?
- How would you rate the quality of the inputs coming from registrants for this part of the process?
- What policy change – if any – would unlock the most improvement for this process?
- Are there any needs that staff feel are not met by current systems/tools? Are there any pain points (e.g., slow tools, confusing interfaces, missing technology)?
- As OPP leadership continues to search for ways to improve this process, what are your recommendations?

Sample Interview Questions for Registrant Stakeholders

- Can you provide us with an overview of the steps you follow when submitting a pesticide registration application?
- What steps of the process are the most difficult or time-consuming?
- What parts of the process do you think operate smoothly and where do you think there is room for improvement?
- How do you engage with OPP throughout the process?
- How would you rate the quality of resources provided by OPP? What additional resources would help you better navigate this process?
- Have there been any changes you believe have improved the flow of the process? What other changes would you like to see?
- Do you feel that the current systems/tools meet your needs?
- As OPP leadership continues to search for ways to improve this process, what are your recommendations?

10.4 Details on Non-PRIA Documents

Internal

Internal documents were produced by OPP leadership and management to guide and inform the application review process. The internal documents reviewed by Censeo are grouped into three categories:

- **Strategic Decisions**: Formal communications from management that establish high-level goals and outline new procedures, guidance, and recommendations for staff to implement.
- **Instructions and Guidance**: Step-by-step directions for executing and documenting specific work processes.
- **Templates and Checklists**: Standardized forms that guide reviewers through specific procedural steps.

Strategic Decisions

Censeo reviewed 5 strategic decision documents that outline changes to the review process to improve efficiency and reduce the non-PRIA application backlog.

1. **Non-PRIA Strategy Memo – January 2024**: Provides guidance on doing partial fast track label amendment reviews and on how to share notification and fast-track amendment work across branches, shares info about new initiatives added to the strategy, and lists recommendations provided during a listening session.
2. **Notification and Fast Track Amendment Actions Memo – September 2023**: Introduces RD's new strategy for addressing the backlogged notification and fast-track amendment actions and goals of the strategy and provides a list of recommendations for achieving the goals.
3. **Reducing the Number of Label Comment Cycles – No Date (ND):** Provides a list of recommendations targeted at reducing the number of label comment cycles in response to concerns expressed during listening sessions.
4. **Sharing Notifications and Fast Track Amendments Across Branches – ND:** Outlines the process for how non-PRIA work can be distributed across the division to ensure that individual staff have enough non-PRIA work to reach their goals and that the whole division reaches its overall goal of decreasing the non-PRIA backlog.
5. **Shorten a Label Amendment Review Final – July 2024:** Provides guidance on label and CSF amendments that do not warrant review of data by science teams. Instruction and Guidance

Templates and Checklists

Censeo reviewed 3 template and/or checklist documents that provide application requirements and criteria for reviewers.

1. **Biochemical non-PRIA or PRIA Amendment Abbreviated Review Template – ND:** Template used when conducting review of an amendment.
2. **CSF Checklist – ND:** Checklist for how to conduct general application review and Confidential Statements of Formula.
3. **Label Checklist – ND**: Checklist for how to conduct BPPD label review.

Instruction and Guidance

Censeo reviewed 3 instruction and/or guidance documents meant to inform reviewers how to engage with certain aspects of the review process.

1. **Non-PRIA Letter User Guide - Knowledge Salesforce – March 2025:** Provides instructions on how to use the non-PRIA letter generation functionality for decision letters.
2. **SS and CC Documentation SOP – March 2024:** Provides instruction on the documentation and retrieval of reviews for storage stability and corrosion characteristics studies.
3. **HCPA December 2024 – December 2024:** Regulatory committee meeting deck that provides a list of common deficiencies and how HCPA members can help, additional process improvements, status of PRIAs, FY24 registration review highlights, and 25 planned actions for the registration review, among other information.

External

External documents were designed to be distributed or made available to registrants to help streamline the application process. The external documents reviewed by Censeo are grouped into three categories:

- **Formal Instruction**: Policies and excerpts from official agency manuals that explain procedural requirements.
- **Quick Tips**: Documents that provide registrants with best practices, specific examples, and lists of common errors to help them create higher-quality submissions.
- **Instruction and Guidance**: Step-by-step directions for executing and documenting specific work processes.

Formal Instruction

Censeo reviewed 3 formal instruction documents describing official procedures for various registration actions.

1. **Chapter 4: Types of Label Reviews – December 2011:** Provides a comprehensive set of information needed to conduct label reviews.
2. **Pesticide Registration Manual Chapter 6 – ND:** Details the process and requirements for submitting an application to amend a registered pesticide product.
3. **Pesticide Registration Manual Chapter 7:** Outlines the procedures for making minor modifications to a registered pesticide's labeling or formulation.
4. **Pesticide Registration Notice 98-10 – ND:** Details the types of modifications that registrants can make to a registered pesticide product without needing to submit an application for EPA approval in advance, utilizing the notifications, non-notifications, or minor formulation amendment processes.

Quick Tips

Censeo reviewed 3 quick tips documents describing best practices for submitting applications.

1. **Antimicrobials Divisions: Best Practices – ND:** Provides best practices and detailed guidance for submitting pesticide applications.

2. **Common reasons a notification may be rejected – October 2024:** Lists the most common errors the Registration Division encounters when reviewing notifications.
3. **Cover Letter Best Practices – ND:** Provides suggestions and a template letter for how to write effective cover letters for pesticide label amendments.