Balancing Wildlife Protection and Responsible Pesticide Use: How EPA's Pesticide Program Will Meet its Endangered Species Act Obligations

2022

www.epa.gov/endangered-species

Table of Contents

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EXECUTIVE SUMMARY

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Background

EPA has both an opportunity and a responsibility to address the decades-old challenge of how its Pesticide Program meets its obligations under the Endangered Species Act (ESA). In past decades, the Agency has met those obligations for less than 5% of the thousands of pesticide actions it completes annually under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The reasons for this failure are multifold, including the unusual complexity of ESA pesticide reviews. The entire process, including consulting with federal wildlife agencies to adopt protections, can take at least 4 years for a single pesticide and up to 15 years in rare cases. FIFRA requires that EPA reevaluate every pesticide every 15 years, including the hundreds that affect species listed under the ESA. ESA obligations also exist for many registrations of new pesticides, new uses of existing pesticides, and amendments to pesticide labels. In total, thousands of FIFRA actions will require an ESA review over the next decade alone.

EPA's Pesticide Program has been unable to keep pace with its ESA workload, resulting not only in inadequate protections for listed species but also litigation against the Agency that has increased in frequency in recent years. EPA has faced over 20 lawsuits, covering over 1,000 pesticide products, challenging its failure to meet ESA obligations. As a result, EPA's current ESA priorities are driven almost entirely by litigation settlements and other court-enforceable deadlines. Over the next six years, existing court-enforceable deadlines will require EPA to complete ESA reviews for 18 pesticides—the most the Agency estimates it can handle during this period based on its current capacity and processes. And ongoing litigation and settlement discussions for other lawsuits cover dozens of additional pesticides and will likely fill the Agency's ESA workload beyond 2030. Even though these litigation deadlines have determined most of the ESA workload for the next decade, that workload is estimated to cover less than 5% of EPA's future pesticide actions that trigger ESA obligations. Because the Pesticide Program currently lacks the capacity and efficient processes to fully meet its ESA obligations on those remaining pesticide actions, it remains vulnerable to additional lawsuits.

This situation creates significant uncertainty for farmers, other pesticide users, and pesticide registrants. For example, if a court vacates a pesticide action, users may lose access to the pesticide for the several years likely needed for EPA to meet its ESA obligations for that action. Without certain pesticide products, farmers could have trouble growing crops that feed Americans and public health agencies could lack the tools needed to combat insect-borne diseases.

EPA's Pesticide Program is at a critical juncture and needs a new vision. This is why the Agency has embarked on an unprecedented effort to improve the current ESA-FIFRA process in collaboration with the U.S. Fish and Wildlife Service (FWS), National Marine Fisheries Service (NMFS), U.S. Department of Agriculture (USDA), Council on Environmental Quality (CEQ), and stakeholders especially environmental and agricultural ones. In the last year alone, EPA has taken several important steps. This includes deciding to meet ESA obligations when registering new conventional pesticides, incorporating mitigation for ESA species much earlier in the FIFRA process for certain pesticide decisions, and revitalizing the ESA-FIFRA Interagency Working Group. This workplan is another important step, reflecting the Agency's most comprehensive thinking to date on how to improve its ESA-FIFRA work to meet its mission of protecting human health and the environment while supporting responsible use of pesticides for agriculture, public health, and other important purposes.

A Vision of Success and Challenges to the Vision

To guide its ESA-FIFRA work, EPA has developed a vision of a successful process. Success means that EPA is protecting ESA species and their habitats from pesticide effects to an extent that fulfills its obligations under all federal laws. EPA would be achieving this goal while minimizing impacts to pesticide users, supporting the development of safer technologies to control important public health and agronomic pests, and completing timely pesticide registration decisions. EPA would also become a trusted expert in protecting listed species through its pesticide decisions, using real-world, up-to-date information.

To achieve this vision, EPA has identified at least six key challenges that must be overcome.

- First is the large and growing number of FIFRA actions that trigger ESA review, at a time when the Pesticide Program's staffing is roughly at the FY 2013 level.
- Second is that the current ESA-FIFRA process generally does not result in protections for listed species that is both practical for pesticide users to implement and timely to protect species.
- Third is that FIFRA registrations are often geographically broad, cover many pesticide uses, and affect many types of listed species. All of this creates unique scientific and other challenges for EPA's ability to meet its ESA obligations.
- Fourth is the need to better harmonize the FIFRA process with the ESA process. For example, the current FIFRA process assesses each pesticide on a chemical-by-chemical basis, but this approach is unsustainable across hundreds of pesticides, many of which affect hundreds of listed species. This is one reason that the entire ESA-FIFRA process currently spans at least 4 years for one pesticide.
- Fifth is a series of challenges related to data and scientific methods. For example, better and more refined data on where species occur and how best to protect them from pesticide exposure would result in more effective and cost-efficient protections. But gathering and analyzing these data would likely extend the ESA-FIFRA process even longer and require additional agency capacity. Thus, EPA needs to balance the benefits of more or better data, with the goal of expediting the ESA-FIFRA process.
- Finally, an effective ESA-FIFRA process requires strong working relationships among EPA, FWS, NMFS, and USDA. All four agencies are working toward this goal but still have room for improvement.

Strategies and Actions to Achieve Vision

To address these challenges and advance EPA's vision, the workplan establishes four overlapping strategies and multiple actions to implement each strategy. The first strategy is for EPA to meet its ESA obligations for all FIFRA actions. Because EPA cannot meet all these obligations immediately while also complying with statutory deadlines for FIFRA actions, the Agency will generally prioritize those actions as follows:

- The top tier includes actions with existing and future court-enforceable deadlines and the registrations of new conventional pesticide active ingredients.
- The second tier includes the large number of remaining conventional pesticides, without court-enforceable deadlines, that EPA reevaluates every 15 years (*i.e.*, FIFRA registration review).
- The third tier includes all other FIFRA actions for conventional pesticides (*e.g.,* new uses of existing pesticides) and FIFRA actions for non-conventional pesticides (*e.g.*, biopesticides).

The workplan provides EPA's rationale for these priority categories and the estimated number of actions in each category that may require an ESA review.

The second strategy is for EPA to improve its approaches to identifying and requiring ESA protections to address pesticide effects. These improvements will include the following:

- Identify and incorporate protections for ESA species earlier in the FIFRA process, with a focus on species that EPA considers vulnerable to pesticides.
- Proactively adopt protections for ESA species facing the greatest risk to their survival from pesticides, such that if EPA did not adopt those protections, the Agency may be in violation of the ESA's substantive obligations.
- Identify flexible options for pesticide users to decide how best to protect ESA species affected by pesticides, including through a federal pilot project being launched in 2022 to identify and implement practical conservation practices across approximately two-dozen listed species.
- Where multiple pesticides are used for the same crops and affect the same species, begin coordinating species protection measures across those pesticides to ensure the measures are consistent. In 2022, for example, EPA will begin coordinating opportunities between newly registered pesticides and existing pesticides undergoing their periodic 15-year reevaluation.
- Where pesticide effects on ESA species cannot be practically avoided or minimized, create opportunities to offset the residual effects through habitat restoration and other conservation actions. Doing so can provide greater flexibility for pesticide users and directly further species recovery, especially in response to climate change.
- Adopt other policy and program improvements to support the above actions.

The third strategy is to improve the efficiency and timeliness of the ESA-FIFRA process, in collaboration with FWS, NMFS, and USDA. This strategy includes developing different approaches for EPA to meet its ESA obligations, which may include assessing all pesticides intended for a particular use at the same time, and consulting with FWS or NMFS regional staff to efficiently incorporate more localized data on species, protection measures, and pest control practices.

The final strategy is to improve EPA's stakeholder engagement. This will include seeking help on more or better data for ESA assessments and expanding dialogues with growers and non-agricultural pesticide users.

Closing and Future Steps

The workplan is a living document that will evolve based on lessons learned through implementation. Within the next two years, EPA will reevaluate its progress under the workplan and decide whether and how to update it. EPA cannot achieve most of the actions in the workplan on its own. The Agency welcomes stakeholder feedback on the workplan, especially on opportunities to help implement species protection measures and provide better data to expedite ESA-FIFRA analyses.

INTRODUCTION

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EPA's mission is to protect human health and the environment. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Endangered Species Act (ESA) are important laws that allow EPA to meet its mission of protecting the environment. Through these and other laws, EPA decides how best to regulate pesticide uses to ensure they achieve society's pest control goals without unduly harming human health or the environment, including ESA-listed endangered and threatened species. This is a formidable task, considering the tens of thousands of pesticide products and amendments that will require ESA review in the coming decade, combined with the over 1,600 listed species in the United States. Moreover, information on the vulnerability, biology, and location of many of these species is limited, especially information on how pesticides may impact their survival. These and other challenges are partly why EPA's Pesticide Program has struggled for decades with meeting its ESA obligations. Even though EPA has approved over 1,000 pesticide ingredients and thousands of pesticide uses over the past decades, it has met its ESA obligations for less than 5 percent of those actions.

This low rate has resulted in over 20 lawsuits against the Agency challenging its failure to meet its ESA obligations. The lawsuits have compelled EPA to meet these obligations by assessing the effects of pesticide actions on listed species and, in most cases, consulting with one or both of the federal wildlife agencies on those effects. Indeed, nearly every consultation on pesticides is in response to lawsuits, which now largely set EPA's pesticide consultation workload and schedule. To date, most of these consultations have covered commonly used pesticides that affect many listed species. The consultations are typically very complex, lengthy, and resource-intensive for all involved, with many spanning no fewer than 4 years and some extending to 15 years. EPA's pesticide program has already agreed, through court-enforceable settlements, to completing 18 ESA assessments within the next six years, which is the most assessments it can accommodate based on its current process and staffing, while also meeting its other near-term ESA obligations. EPA is also in settlement discussions that could result in similar agreements for dozens of additional pesticides. Yet all of these assessments reflect less than 5% of the total ESA assessments that EPA would need to complete as part of past, current, and future FIFRA actions. If EPA does not complete this work, it will continue to face legal challenges to its pesticide actions. This creates uncertainty for farmers and other pesticide users, who could lose access to pesticides if a court vacates a FIFRA action.

EPA must focus on how to achieve the goals of ESA and FIFRA differently than in the past—to break the decades-old cycle where ESA goals were not met, and the resulting litigation became the main driver and priority setter of how EPA fulfills its ESA obligations. The old approach has been expensive for EPA, expensive for the parties to the lawsuits, and frustrating for all stakeholders—all while listed species remain inadequately protected. These reasons are why EPA's Pesticide Program is at a critical juncture, and why the Agency has issued this workplan.

In 2021, prompted by the escalating challenges of fulfilling its ESA obligations for pesticide decisions, EPA began developing a comprehensive, long-term approach to meeting those obligations. This effort was not the Agency's first attempt to address this complex issue. Over the decades, EPA has pursued various approaches to this issue and has stated several times that it would develop a plan to meet its ESA obligations. Although EPA has made some progress on improving its ESA-FIFRA program, much more work remains.

Informed by EPA's past efforts and by its recent discussions with stakeholders and lawmakers, EPA in 2021 began holding a series of internal and external meetings on how the Agency could fully address its ESA obligations. These include quarterly ESA-FIFRA meetings with stakeholders and a widely attended January 2022 public listening session on improving the ESA-FIFRA process.[1] The outcome of all those dialogues is this workplan, which reflects EPA's experiences, assesses its future ESA workload, and describes administrative and other improvements that EPA will pursue or consider pursuing. The workplan thus reflects the Agency's most comprehensive thinking to date on how to create a sustainable ESA-FIFRA program.

The Magnitude of EPA's Pesticide Program

Safe pesticide use offers important contributions to society, particularly in the production of U.S. food and fiber and the protection of public health from insect and rodent pests. Generally, there are more than 17,000 registered pesticide products containing more than 1,200 active ingredients, with uses including insect repellents, household cleaners, lawn and garden chemicals, hospital disinfectants, biotech products, and a wide range of agricultural chemicals.

In arriving at policy decisions that are informed by sound science, EPA seeks to balance the interests of many stakeholders. These include more than 88 million households; more than two million farms; 23,000 commercial pest control firms; a dozen major pesticide producers; another 100 small producers; 1,700 pesticide formulators; 25,000 distributors; several industry, grower, farmworker, and environmental associations and non-government organizations; and state, local, and tribal entities.

Although this workplan focuses on ESA and FIFRA obligations, EPA also has obligations under the Federal Food Drug and Cosmetic Act (FFDCA). Further, several amendments to FIFRA, through successive versions of the Pesticide Registration Improvement Act (PRIA), set timeframes for EPA to complete pesticide actions. EPA must meet these obligations alongside those of the ESA.

The workplan is structured as follows. The next section, *A Vision of Success*, describes EPA's long-term vision for its ESA-FIFRA work. This vision statement acts as the Agency's north star to navigate the complexities of this issue, and informs the strategies and actions described later in this document. The following section, *Background and Challenges to Vision*, provides a detailed discussion on the background of key ESA-FIFRA issues and the major challenges to achieving this vision. EPA provides this extended explanation so the public can understand why meeting ESA obligations in full is difficult and how stakeholders can help EPA solve those challenges more effectively. The following section, *Strategies and Actions to Advance Vision*, is the core of the workplan, describing the strategies and actions that EPA has developed to advance its vision. This section also describes how EPA will prioritize certain types of FIFRA actions over others for ESA determinations, given that the Agency cannot immediately meet its ESA obligations for all backlogged and future FIFRA actions that trigger ESA obligations. The workplan concludes by discussing opportunities for the public to engage with EPA on implementing the approaches described in the document.

1 Visit EPA's Interagency Working Group: Public Meeting on Endangered Species Pesticide Issues webpage.

Primer on ESA Concepts and Process

Under FIFRA, EPA decides whether to register pesticide products containing **new active ingredients** and **new uses** of currently registered pesticides, and reevaluates all existing registered pesticides every 15 years as part of **registration review**. Those are the major actions that may trigger an ESA assessment for potential effects on ESA listed species and their designated critical habitats.

An ESA assessment begins with EPA determining whether a FIFRA action may have any effect on a species or critical habitat. If EPA finds "**no effect**," no further ESA analysis is needed. If EPA finds "**may affect**," the agency further assesses whether the pesticide's use is either "not likely to adversely affect" (**NLAA**) or "likely to adversely affect" (**LAA**) the species or designated critical habitat. In general, likely harm to even one individual of a species triggers an LAA. EPA describes its findings in a **biological evaluation** that it provides to the U.S. Fish and Wildlife Service (FWS), the National Marine Fisheries Service (NMFS), or both agencies (the Services). For brevity, this workplan refers to all these findings as "**ESA determinations**."

FWS (Department of the Interior) and NMFS (Department of Commerce) are charged with administering the ESA. FWS is responsible for most listed species, while NMFS is responsible for listed marine species and anadromous fish. Most nationwide pesticide consultations involve both Services.

For an NLAA finding, EPA seeks the concurrence of the Services in that finding. If the Services concur, no further ESA process is needed. For an LAA finding, EPA formally consults with the Services. During formal consultation, the Services determine whether the EPA action is likely to **jeopardize** any listed species or **destroy or adversely modify** any critical habitat—both of which the ESA prohibits. Unlike the LAA/NLAA findings, the jeopardy/adverse modification findings assess effects on the entire species, including its ability to recover under the ESA. If the Services *propose* jeopardy/adverse modification, they work with EPA and the registrant to negotiate mitigation measures to avoid these findings. If the measures are adequate, the Services conclude no jeopardy/adverse modification. If the measures are inadequate, the Services conclude jeopardy/adverse modification and recommend mitigation that, if adopted, will avoid these prohibitions. Those measures are called reasonable and prudent alternatives (**RPAs**) and are in addition to label restrictions adopted under FIFRA or in a biological evaluation. Even for animal species not at risk of jeopardy/adverse modification, the ESA requires the Services to develop mitigation—called reasonable and prudent measures (**RPMs**)—to minimize the effects of any **incidental take** on the species. Incidental take includes unintended injury to or death of an individual of any listed animal species. In practice, the potential for take of an individual animal triggers an LAA finding.

At the end of formal consultation, each of the Services issues a **biological opinion** that describes its findings and mitigation recommendations. The biological opinion also includes an **incidental take statement** that exempts the pesticide action from the ESA's take prohibition, if the terms and conditions of the statement are followed. If EPA implements the biological opinion through changes to a pesticide registration or label, any person who follows those requirements faces no ESA liability when applying the pesticide.

To implement the mitigations resulting from formal consultation, EPA may require changes to a pesticide's registration, label, or use instructions. When those changes are needed only in specific regions rather than nationwide, EPA may implement the changes through geographically specific Endangered Species Protection Bulletins. *Bulletins Live! Two* is EPA's current online endangered species bulletins system.

Primer on FIFRA Registration Review Process

*After publication EPA generally holds a 60-day public comment period.

Under registration review, EPA reviews each registered pesticide at least every 15 years to ensure that each pesticide can carry out its intended function(s) without creating unreasonable adverse effects to human health and the environment. Each pesticide review is unique but all undergo the same basic registration review process.

EPA initiates a registration review by establishing a public docket for a pesticide registration review case and opens the docket for public comment. The docket contains a **Preliminary Work Plan (PWP)** summarizing information EPA has on the pesticide and the anticipated path forward. The PWP includes facts about the pesticide and its current use and usage, anticipated risk assessment and data needs, and an overall estimate of the time needed for the reviews. Once comments are received during the 60-day comment period for the PWP, the information received will be used to update the **Final Work Plan (FWP)**, which is also included in the docket. If data are needed to update the risk assessments, EPA will issue a **Data-Call In (DCI)** notice to the registrant under FIFRA section 3(c)(2)(B).

Once all the required data are received, the Agency will review and incorporate all information into **Draft Risk Assessments (DRA),** which always strive to include the best available science. The DRAs are placed in the public docket for a 60-day comment period.

If ecological or human health risks are identified in the DRA, then the **Proposed Interim Decision (PID)** will present the Agency's proposed findings on the FIFRA standard, including the results of formal ESA consultation, if needed, and the bases for these proposed findings; proposed modifications to the use of the pesticide to address risks of concern; state whether additional data are needed; specify any proposed labeling changes; and identify deadlines for completing any required actions. The PID is published in the public docket for a 60-day comment period.

After considering comments on the PID, EPA will issue an **Interim Decision (ID),** including an explanation of any changes from the PID and response to significant comments received on the PID. The Agency then publishes a Federal Register notice announcing the availability of the ID. The ID may require new or impose interim risk mitigation measures; identify data or information needed to complete the review (DCI); and require within 60-days of the ID publication the submission of updated pesticide labels.

EPA will issue a **Final Decision (FD)** after it completes a listed species assessment and any necessary ESA section 7 consultation with the Services. The decision will also account for the Endocrine Disruptor Screening Program.

At the outset of the workplan, readers should note two limitations in the document's ability to provide a complete, detailed path for EPA to fully meet its ESA obligations. First, the workplan does not provide a schedule for completing ESA determinations for all the pesticides in registration review. One reason is that EPA has already agreed to completing 18 ESA determinations over the next six years as part of litigation-driven agreements, which is the most the Agency can accommodate based on current processes and staffing (see Appendix A for current schedule and *Background and Challenges to Vision* section for more information). A schedule for ESA determinations for registration review beyond that timeframe is unlikely to reflect the most efficient approach for completing those assessments, given the major process improvements EPA expects to implement during this time. EPA hopes that these improvements will allow the Agency to complete more ESA determinations in the future. Further, EPA is currently addressing approximately 18 additional ESA lawsuits on FIFRA actions covering over 1,700 pesticide products, with some of those lawsuits likely to result in EPA agreeing to complete additional ESA determinations, under court-enforceable deadlines, that extend beyond the next six years.

A second reason for the lack of a schedule is that at the current pace at which EPA and the Services are completing pesticide consultations, this process would span decades for all pesticides that have their first cycle of FIFRA registration review ending in October 2022. To address this challenge, the Agency needs to prioritize certain FIFRA actions over others as part of fulfilling its ESA obligations and to work with the Services to develop and adopt program improvements that drastically reduce the complexity and duration of pesticide consultations. Because EPA does not yet know how much those improvements will expedite the ESA-FIFRA process, it sees limited value at this time to developing an ESA schedule that is likely to change considerably in several years. EPA plans to begin adopting the near-term improvements in this workplan and assess how much those actions improve the ESA-FIFRA process. That experience will give EPA a far better foundation for developing an overall schedule within the next three years for conducting ESA determinations for registration review decisions.

A second limitation of this workplan is that although some strategies and actions are well developed, others are only in their initial stages of discussion. Thus, this document may read more like a "plan to develop a plan" for certain actions. This is the inevitable outcome of a document that covers near-, medium-, and long-term actions, with the latter two influenced by factors largely outside of EPA's control such as its funding levels in annual appropriations and litigation. Even though those actions are described with less specificity, they remain crucial for readers to understand EPA's path to achieving its vision. Based on EPA's implementation of the workplan, other administrative improvement actions will become evident over the coming years. Thus, readers should consider this workplan as a living document that will evolve based on lessons learned through implementation. Within the next two years, EPA will reevaluate its progress under the workplan and decide whether and how to update it. EPA's hope is that within two years, the process improvements described in this workplan will allow the Agency to begin increasing the number of ESA assessments it can complete annually.

A VISION OF SUCCESS

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Before beginning this significant and challenging process, EPA developed a vision of success. EPA has adopted the following vision to guide this workplan and the Agency's ESA-FIFRA work generally.

> ***EPA's Office of Pesticide Programs is protecting federally listed threatened and endangered species and their designated critical habitats from pesticide effects to an extent that fulfills our obligations under all federal pesticide use and species protection laws. Our program is achieving this goal while minimizing impacts to pesticide users, supporting the development of safer technologies to control important public health and agronomic pests, and completing timely pesticide registration decisions. Our program is also working with stakeholders and our federal partners so that we are trusted experts in protecting endangered species through pesticide registration and registration review decisions. In making these decisions, we are performing credible analyses that answer the scientific questions needed to protect species using real-world, up-to-date information.***

EPA developed this vision mindful of the goals of stakeholders and other federal agencies. EPA thus hopes that all its partners and stakeholders see aspects of the vision that resonates with their goals. After all, meaningful, enduring improvements to the ESA-FIFRA process cannot occur without broad consensus about what the process is striving to achieve.

EPA wrote this workplan on its own because the ESA imposes duties on all federal agencies, including EPA, to meet its legal obligations. The workplan describes how EPA will achieve this with the help of other federal agencies and stakeholders.

Several specific parts of the vision deserve further explanation. First, as evident from the first line of the vision, EPA will meet its ESA obligations. This objective, however, cannot exist in a vacuum. EPA also strives to minimize the regulatory impacts of protections because doing so promotes its other legal and public policy goals of providing pesticides for agriculture, public health protections, and natural resource management. Further, EPA has FIFRA deadlines for pesticide actions that it strives to meet independent of ESA obligations. Those deadlines provide certainty to growers and other pesticide users about the availability of pesticides.

Second, EPA cannot address the ESA-FIFRA challenge on its own. Even though EPA developed this workplan independently to help meet its ESA duties, it seeks the help of stakeholders, the Services, USDA, and lawmakers to implement the workplan. Further, the workplan explains the many ways that EPA needs to change how it approaches its ESA obligations for FIFRA decisions. EPA, however, will also need to work with other organizations to change how they approach these issues. For example, in the short term, as EPA strives to build a workable process, EPA will encourage stakeholders to allow EPA to focus more of its time and resources to implement conservation measures needed to meet its ESA obligations, and less on certain data, methodology, or modeling issues that have limited bearing on the outcome of ESA consultations. EPA will also work with stakeholders to support greater flexibility for EPA to test new policies tailored to the complexities of pesticide consultations. EPA will continue to work with stakeholders to give EPA the ability to meet its ESA obligations at a pace that is realistic given the existing workload and EPA's commitment to follow this workplan. In short, EPA needs all organizations and stakeholders to work toward a common goal, such as the one in EPA's vision of success.

Finally, EPA seeks to work closely with its partners and earn their trust in viewing the Agency as an expert in ensuring that FIFRA decisions are adequately protecting listed species. EPA realizes that it has much work to do before it reaches this goal. The Agency is working hard to develop the expertise and capacity to protect listed species by implementing flexible mitigations that reflect real-world pesticide usage, exposure, and effects.

One Workplan, Multiple Audiences

Given the long and complicated history of pesticide consultations, EPA expects a range of interest in this workplan. EPA has written the workplan for many audiences, recognizing that no single document can convey the ideal amount and level of information to any single audience. Below is information to help the primary audiences understand how they can use this workplan.

- For all audiences, the workplan describes EPA's plans to significantly improve its process to meet its ESA obligations as part of FIFRA decisions.
- For the Services and USDA, the workplan describes opportunities for interagency coordination on ESA-FIFRA improvements, including actions that require the input and leadership of all four agencies.
- For Congress, the workplan describes EPA's progress under the 2018 Farm Bill, Section 10115 (FIFRA Interagency Working Group) and informs general oversight of the Agency's ESA and FIFRA work.
- For pesticide registrants and users, the workplan describes EPA actions to improve predictability about the ESA-FIFRA process and opportunities to work with EPA on those improvements.
- For environmental organizations, the workplan describes EPA actions to adopt protections for listed species, better meet its ESA obligations, and provide opportunities to work with EPA on those improvements.

BACKGROUND AND CHALLENGES TO VISION

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To meaningfully improve the ESA-FIFRA process, EPA first needs to articulate for the public its understanding of the current process and the main challenges to developing a more effective one. Given the unusual complexity of this issue, it is understandable that some aspects of the process and challenges are not well understood outside of EPA, making it difficult to appreciate the barriers the Agency faces to meeting its ESA obligations. The goal of this section is to fill that knowledge gap and help the public and other agencies to engage with EPA more constructively on ESA-FIFRA issues. As a result, this section is lengthy and detailed. Readers who are more interested in understanding EPA's plans to improve the ESA-FIFRA process may want to skim or skip this section. At the same time, this section does not describe every challenge, only those that EPA views as the most significant in the coming years to EPA meeting its ESA obligations.

Overview of Different Types of Pesticides

Throughout this workplan, EPA will reference the three types of pesticides it regulates.

Conventional pesticides are all active ingredients other than biological pesticides and antimicrobial pesticides. Conventional active ingredients are generally produced synthetically (*i.e.*, synthetic chemicals that prevent, mitigate, destroy, or repel a pest or that act as a plant growth regulator, desiccant, defoliant, or nitrogen stabilizer).

Antimicrobial pesticides are intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.

Biopesticides are certain types of pesticides derived from such natural materials as animals, plants, bacteria, and certain minerals. For example, canola oil and baking soda have pesticidal applications and are considered biopesticides. Biopesticides fall into three major classifications: Biochemical, Microbial, and Plant-Incorporated Protectants (PIPs).

Large and growing workload

Most EPA actions under FIFRA require an ESA determination and possibly formal consultation. These decisions fall into three broad categories: (1) registration of new pesticides, (2) registration review of existing pesticides, and (3) other FIFRA decisions on existing pesticides, including registration of new uses of existing pesticides and FIFRA section 18 emergency use exemptions. To date, EPA has completed ESA determinations and, if necessary, consultations for less than 5% of these actions, leading to a large backlog of actions that continues to grow (Appendix A).

In addition to this backlog, the Agency will also have many future actions that trigger ESA obligations. In particular, the registration of new active ingredients, the ongoing 15-year cycle of registration review for each registered active ingredient, and the approval of new uses and pesticide label amendments of registered pesticides will amount to tens of thousands of FIFRA actions over the next decade alone that require an ESA review.

To better describe the level of effort required of EPA to meet its ESA obligations for each category of FIFRA action, **Table 1** shows the estimated required full-time equivalents (FTEs) for actions in each category. These estimates are based on EPA's current processes, which need optimization to meet the large and growing ESA workload. The process improvements described in this workplan are expected to reduce the FTEs for most or all actions, but the extent of the reductions is unknown at this early stage.

Apart from the growing workload and backlog challenges, the Pesticide Program's staffing levels have declined from a high of 808 (2005) to 603 (2021). Changes in PRIA IV enabled EPA to more fully use FIFRA maintenance fees to support the Pesticide Program's activities since 2018, which helped support more FTEs during this time (**see Figure 1**). Current decreases in the FIFRA maintenance fee account may result in EPA being unable to maintain the same FTE level using funds from this account.

Meeting ESA obligations for registration and registration review decisions alone will require a multifaceted approach, including capacity, resources, improved processes, updated technology, workload analysis, and increased stakeholder collaboration. For example, assessing effects on listed species and their critical habitats involves spatially explicit effects determinations that identify where a pesticide can be used and where species are likely to be found, and an evaluation of species' habitats and biological characteristics. Likewise, to implement early ESA mitigation as part of a FIFRA action, EPA must identify effective and feasible mitigation options, which may depend on acquiring information about species characteristics and habitats, evaluating that information, evaluating how pesticides may enter those habitats, and mitigating those effects. The increased complexity and specificity of ESA determinations, and the increased variety of mitigation options, require additional communication with the regulated community and other stakeholders. Further, even if EPA were to incorporate early species mitigation as part of a FIFRA action, it is likely that consultation with the Services would still be needed in many cases.

Table 1. Level of effort required of EPA to complete both FIFRA and ESA obligations for each category of FIFRA action, based on current EPA processes.

EPA's Required Effort Per FIFRA Action, Including Meeting ESA Obligations	
FIFRA Action	**FTEs for Action**
New Active Ingredients Registration	
Conventional Pesticides	5.5
Antimicrobials	5.5
Biopesticides	1.0
Registration Review	
Conventional Pesticides	8.5
Antimicrobials	8.5
Biopesticides	1.0
New Uses for Existing Pesticides	
Conventional Pesticides	2.5
Antimicrobials	3.0
Biopesticides	0.5
Other Expansions of Existing Use Patterns	
Conventional Pesticides	1.5
Biopesticides	0.5
Geographically Limited Registrations	
Section 18 emergency exemptions (conventional pesticides)	0.5
Experimental Use Permits	1.0
Commitments Prioritized Due to Litigation	
Conventional pesticides	34 (OPP alone)
ESA Pilots and Method/Process Development	
Conventional Pesticides	6.0
Antimicrobials	18
This table estimates the required effort (FTE) for EPA to complete ESA assessments for all FIFRA actions requiring those assessments. The estimated effort is based on EPA's current ESA-FIFRA process and methods, and accounts for preparing risk assessments, identifying appropriate mitigations, implementing risk management decisions, and consulting with the Services when appropriate. Based on the actions in this workplan, EPA expects efficiency gains to its process over time but is currently unable to quantify those gains.	

These risk assessment, risk management, and consultation processes substantially increase the time and effort for making pesticide registration decisions. The following are the main types of FIFRA actions for which EPA expects to increase its ESA workload in the coming years, based on the Agency's goal of meeting its ESA obligations.

Historically for some actions in registration review, the Pesticide Program has completed ESA determinations as part of litigation settlements. OPP must continue to meet its court-enforceable deadlines across various settlement agreements under registration review (Appendix A). Conducting these biological evaluations currently requires 3 to 4 FTEs for each evaluation, compared with about half that level of effort for non-ESA registration review ecological risk assessments. The Agency has agreed to court-enforceable deadlines to complete draft or final biological evaluations for 18 registration review pesticides over the next six years. In addition, EPA has agreed to or is in discussions that could result in completing biological evaluations on dozens of additional pesticide registration or registration review actions under court-enforceable deadlines that would extend beyond six years.

In January 2022, EPA announced that it will incorporate ESA determinations and protections into its registration process for new conventional active ingredients. The ESA component is expected to more than double EPA's workload for these actions, including to conduct the ecological assessment and mitigate for effects to species. EPA conducts approximately 10 new conventional active ingredient risk assessments per year and may have 15 or more applications for conventional registrations that are in different stages within the regulatory process. New active ingredients, however, represent a very small fraction of the total number of registration actions. Each year, EPA receives hundreds of applications for new uses for existing conventional pesticides, other amendments, and emergency exemptions.

Similarly, under registration review, EPA comprehensively reevaluates hundreds of conventional pesticide active ingredients on a 15-year cycle. Incorporating ESA assessment and risk management into registration review, as described above for new active ingredients, similarly requires more effort and resources. When EPA reevaluates a pesticide through registration review, it considers all registered uses of the pesticide. Thus, the reevaluation and accompanying ESA determinations are often complicated by the regulatory history of the pesticide and the availability of additional information on the pesticide.

EPA is currently unable to incorporate ESA assessment and risk management across all the types of pesticide registration and registration review decisions, while also complying with statutory deadlines for FIFRA actions. Although some FIFRA actions will not require formal consultation or extensive ESA analyses, most others likely will. This challenge is heightened by EPA's recent commitment to incorporate ESA determinations into its new conventional active ingredient decisions and by its need to address other regulatory and statutory deadlines.

PESTICIDE PROGRAM FTEs AND COMPLETED PRIA ACTIONS: FY2004-FY2021

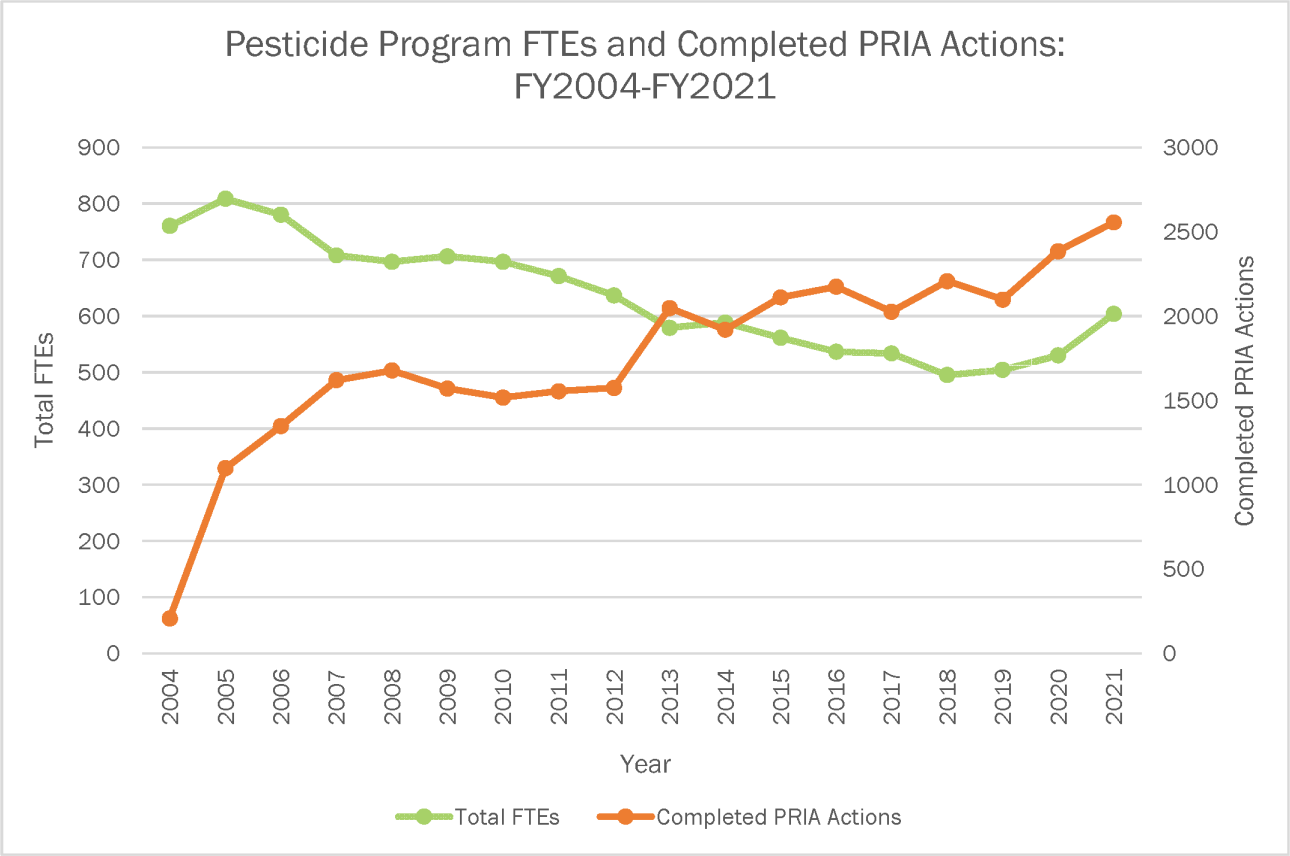

Figure 1. The graph above shows the Pesticide Program's total FTEs and the number of completed PRIA actions from 2004 to 2021. Increasing FTEs since 2018 reflect changes in PRIA IV that has enabled EPA to more fully use FIFRA fees to support OPP activities.

These estimates are based on EPA's current approaches to meeting its ESA obligations, including the 2020 Revised Method for ESA determinations for registration review.[1] Although EPA developed the approaches to increase efficiencies, some aspects of the approaches remain resource intensive and must be made more efficient. Further, ESA assessments require a high level of specialized education, training, expertise, and judgment that comes from years of experience. Thus, EPA cannot simply assign unexperienced staff to cover the resource gap. EPA would need to hire scientists with specialized education and train and mentor them for several years before they could independently conduct ecological risk and ESA pesticide assessments.

EPA's capacity to fully meet its ESA obligations at this time is limited and continues to place listed species at risk and the Agency at considerable risk of ESA lawsuits. Further, because the Agency's ESA workload is already at capacity for conducting ESA determinations for conventional pesticides in registration review for at least the next six years, any future court decision or legal settlement to complete an ESA determination during that time will stretch the Agency's already very thin program capacity and may undermine EPA's ability to meet its other ESA commitments. EPA is striving to increase the number of ESA determinations it can complete annually, partly through process improvements described in this workplan and the FY2023 President's proposed budget that includes an additional $4.9 million and 10 FTE to integrate ESA requirements in conducting risk assessments and making risk management decisions.[2] How these improvements would translate to increased number of ESA determinations is unclear at this early stage.

A final challenge related to workload is that EPA's ability to fully meet its ESA obligations also depends on the ability of the Services to provide timely review of EPA's "not likely to adversely affect" findings and, where necessary, complete formal consultation and issue final biological opinions. Because FWS is the lead agency for most listed species, EPA will work with the agency's national consultation program to ensure our joint priorities are aligned, which is especially important to a workable pesticide consultation process.

Lack of process for identifying and requiring practical and timely mitigation

The most important conservation outcome of pesticide consultations is to mitigate adverse pesticide effects to ESA species and critical habitat. The current consultation process, however, does not always produce mitigation that is both practical for pesticide users to implement and timely to protect species. There are several aspects of this challenge, some related to developing mitigation and others related to implementing mitigation.

1 EPA. Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides (March 2020).
2 EPA. FY 2023 Budget In Brief (March 2022).

First is the geographic scope of ESA mitigation. In a variety of situations, mitigation should be location-specific and tailored to the needs of a specific population, ecosystem, and pest control practice. For example, if a narrow-range endemic beetle may be exposed to pesticides from only two sources, ideal mitigation for the species should address those sources without regulating other pesticide users. This outcome, however, requires local knowledge about the sources and the species. National-level pesticide consultations lack a consistent process of coordinating with local species experts and pesticide users to identify mitigation options tailored to local conditions. This type of coordination would require considerable time and resources. Under EPA's system of developing mitigation, some landowners and pesticide users have regarded those requirements as overly broad or inapplicable to their situation. This is partly because they may not recognize that national-level consultations must rely on more precautionary mitigation measures when geographically refined data are unavailable or prohibitively difficult to obtain. Conversely, other mitigation requirements may sometimes not be refined enough to address all effects to a species. For example, a uniform 100' spray buffer might not address exposure in situations where individuals of a species periodically wander beyond the buffer zone. EPA has no way of knowing the precise location of suitable habitat for all species, so mitigation measures may not always cover all suitable habitat or areas where individuals of a species occur, especially for migratory species. To address this uncertainty, EPA will need to work with the Services and others on monitoring of mitigation measures and updating future mitigation techniques to reflect the results (*i.e.*, adaptive management).

A second aspect of the challenge is timing. Historically, ESA-specific mitigation for pesticide consultations has often been developed as part of formal consultation (often with each of the Services separately, under different timelines), after EPA spends considerable time and resources developing a biological evaluation. Because that mitigation occurs years later in the ESA process and typically after FIFRA registration review label mitigations, the opportunity to streamline assessments and consultations based on early mitigation is lost. EPA does not currently have a specific process for identifying early ESA mitigation across all its FIFRA decisions, especially an established process that allows registrants to propose early mitigation.

Third, the current process for developing biological evaluations focuses on effects to individual organisms, whereas EPA's ultimate obligation is to avoid jeopardy and adverse modification based on species-level effects on survival and recovery and to minimize the effects of incidental take. Following longstanding ESA regulations, EPA has historically focused on individual-level effects in determining whether a pesticide "may affect" and is "likely to adversely affect" individuals of a listed species or critical habitat. This determination, however, generally does not consider mitigation to protect survival and recovery for the entire species, which occurs only during formal consultation to evaluate jeopardy and adverse modification. But when mitigation is identified during formal consultation (*e.g.*, NMFS salmonid biological opinions), considerable work has already gone into developing a biological evaluation, creating a lost opportunity to identify and adopt the mitigation earlier. Recently, however, EPA has begun to address this issue by also assessing the likelihood that the effects may rise to the level of jeopardy for the species or adverse modification for their critical habitat, and implementing mitigation designed to prevent such effects (*e.g.*, January 2022 registration of the herbicide Enlist). The Agency expects to expand this approach to other pesticides, as discussed in the next section.

Fourth, during registration review, the process of implementing mitigations in a final biological opinion is time consuming and cumbersome. One reason is that EPA's current process of reviewing and approving amended labels in the registration review program requires manual updates, which is resource intensive and time consuming for long or complex labels. Although shifting to electronic labeling would address most of the problem, the Agency has not yet adopted this approach.

Fifth, in situations where EPA cannot identify mitigation that adequately avoids and minimizes effects to listed species, the Agency currently lacks a specific approach to incorporate compensatory mitigation, also known as offsets, into nationwide pesticide consultations. FWS defines offsets as measures to "compensate for remaining unavoidable impacts after all appropriate and practicable avoidance and minimization measures have been applied, by replacing or providing substitute resources or environments…through the restoration, establishment, enhancement, or preservation of resources…."[1] Habitat restoration and preservation are among the most common types of offsets. Because EPA lacks a process for incorporating offsets into FIFRA actions, the Agency is unable to take advantage of all mitigation options to address pesticide effects on species. The Agency also has less flexibility to offer registrants and growers to mitigate effects, because avoidance and minimization in the form of label restrictions are the only available tools. The flexibility of including offsets as an option is crucial because EPA must also consider impacts to growers when the Agency decides whether and how to regulate pesticides. Even if EPA were to adopt significant label restrictions, unavoidable effects to certain species are likely to remain for many widely used pesticides. For example, it is difficult to conceive that aerial spraying of adult mosquitocides could be performed in a manner that avoids exposure to all populations of listed species in all counties where they occur, partly because the presence and location of many populations of these species are poorly known, especially for highly mobile species (*e.g.*, butterflies) or species without well-defined habitats (*e.g.*, habitat generalists). Although monitoring or other approaches for evaluating the effectiveness of mitigation would resolve some of these uncertainties, unavoidable effects will still occur in many situations. Another example is the sizable number of pesticides that lack reasonable options to fully avoid effects to pollinators in indeterminately blooming crops. Some of those pollinators, however, do have existing conservation programs (*e.g.*, wildflower plantings) that could be augmented through offsets for the species, thus potentially reducing the likelihood of jeopardy/adverse modification.

The absence of offsets as an available mitigation option also limits EPA's ability to direct mitigation in ways that contribute the most to species recovery, especially because many recovery actions qualify only as offsets. That is, those actions cannot be implemented through site-specific avoidance and minimization of pesticide exposure. For example, species that require conservation measures to adapt to climate change may benefit disproportionately from offsets that focus on improving future habitat needed for recovery, even if the species does not yet occupy the habitat. The same may be true for species threatened primarily by invasive species or disease, which could be alleviated through conservation measures that directly address those threats.

4 FWS. Endangered Species Act Compensatory Mitigation Policy (Dec. 2016).

The sixth barrier to effective mitigation is that the current ESA-FIFRA process does not always result in comparable mitigation for pesticides with similar risks to the same ESA species. For example, if a species is affected by five pesticides, one of which comes up for registration review five years earlier than the other four, the ESA mitigation required for that pesticide would take effect before EPA has determined mitigation for the other pesticides. Thus, the first pesticide has more ESA restrictions than the others, until they complete registration review. Even if EPA were able to assess multiple pesticides within a similar timeframe, the most expeditious process to achieve mitigation is generally through negotiations with pesticide registrants, which vary across pesticides. In addition, EPA currently lacks an agreed-upon set of mitigation measures for listed species, which makes standardization of ESA mitigation across pesticides difficult.

FIFRA actions create unique challenges for ESA consultations

Pesticide consultations are truly unusual in terms of their complexity and geographic scope. In particular, pesticides are applied by millions of people in response to specific pest problems that may differ widely across time and place. National-level pesticide consultations—a process that includes developing biological evaluations and opinions—must address all species effects that are reasonably certain to occur, as there are no subsequent regional- or site-specific consultations through which EPA can work with the Services' regional or field offices to address site-specific effects.

Another reason these consultations are challenging is that a pesticide may or may not be used to the full extent allowed by its label (it is extremely unlikely that a pesticide would be applied at the maximum rate to all treatable acres simultaneously). Pesticide labels are intentionally flexible to allow users to apply pesticides at different times and rates best suited to a user's particular pest issue, as it is impossible for EPA to prescribe specific use conditions for every possible application scenario. In addition, growers typically only use pesticides when needed because of the costs of using pesticides (with some exceptions such as pesticide seed treatments) consistent with integrated pest management principles. Thus, EPA's registration action authorizes a variety of application scenarios involving an unknown but often large number of pesticide users. This variation and uncertainty make pesticide consultation fundamentally different from consultations on most other federal projects, which have a well-defined geographic scope (*e.g.*, a bridge either is or is not built in a specific location). Another difference is that the indirect effects of pesticides on listed species (*e.g.*, effects on prey or habitat) are often far more difficult to evaluate than for ESA consultations on infrastructure or construction projects. Because of these differences, the adverse effects of pesticide actions and the estimation of incidental take is considerably more difficult than for the average federal action undergoing consultation.

At various times since the 1980s, EPA and the Services have tried to develop workable ESA consultation approaches for FIFRA decisions, with mixed success. Examples include the 2004 Overview Document, 2013 National Academies of Sciences report on this topic, and the 2015 interagency Interim Approaches for Nationwide Pesticide Consultations to implement some of the report recommendations.

EPA then developed its Revised Method for conducting its biological evaluations for registration review chemicals in 2020, but a complementary document for conducting formal consultation and developing Services biological opinions does not currently exist. In March 2022, EPA finished consulting with FWS on its first national-level pesticide biological opinion, based on a biological evaluation that used the 2015 Interim Approaches and supplemented with elements of the 2020 Revised Method. Although NMFS has completed consultation on over 30 pesticides, three of which were national-level consultations, EPA will continue discussing with NMFS some of those biological opinions with the intention of implementing the opinions under EPA's FIFRA authorities and processes. Thus, the three agencies are still improving the process for formal nationwide pesticide consultation and have not yet developed standalone interagency guidance for the entire process (*i.e.*, aside from recent biological opinions serving as examples of a process).

Another challenge associated with the existing consultation process is that most nationwide consultations involve both Services, with each Service completing its own biological opinion after EPA consults with each agency. Because FWS has approximately 16 times as many domestic listed species as NMFS, it is not surprising that FWS will likely take longer to complete a consultation than will NMFS (although the ranges of NMFS anadromous fish can be considerably larger than those of many FWS terrestrial species that are habitat specialists). This approach creates several inefficiencies.

First, EPA and the registrants must participate in two separate consultations conducted over different time periods using different approaches and assumptions, and must implement two different sets of labels and *Bulletins Live Two!* changes. Second, this approach generally increases EPA's workload as the Agency often has to provide updated information for the consultation with each of the Services, particularly when the consultation spans several years (*e.g.*, update section 7 "action" to reflect agreed upon mitigations).

Incorporating ESA requirements into the current FIFRA process presents unique challenges

Similar to how the pesticide consultation process is not adapted to the complexity and volume of FIFRA decisions, the current FIFRA process poses challenges to pesticide consultation needs.

First, EPA's current chemical-by-chemical approach for addressing ESA creates unequal mitigation requirements among pesticides and may not result in optimal species protection. Further, this approach does not scale well to addressing the over 1,000 pesticide ingredients and over 18,000 registrations that EPA must evaluate every 15 years as part of registration review. Another reason the current approach is problematic is that growers can often choose among multiple pesticides to address their pest issues. Thus, listed species may not benefit from mitigation for a particular pesticide if a grower switches to another comparable pesticide for which EPA has not yet required ESA mitigation.

Second, as part of final registration review decisions, EPA needs to consider the outcomes of any biological opinion and implement any mitigation the Agency determines is needed. This process will likely include working with the registrants to incorporate the measures onto product labels. If the registrants are not amenable to making these changes, EPA may need to initiate cancellation of uses or products, which is protracted and resource intensive, involving public comment and interagency review. Even when a registrant voluntarily agrees to incorporate ESA mitigation on the label, the current FIFRA process includes spending additional resources to review labels, particularly if the ESA consultation is not completed until several years after the registration review interim decision and if the labels require additional revisions because of the consultation and any public comments. All these processes apply regardless of the number of measures needed to meet ESA obligations.

Finally, the registration review schedule is based on the date of the initial registration of a pesticide or, if a pesticide has completed registration review, the date of the most recent final registration review decision. EPA's schedule for conducting ESA analyses, however, has been largely driven by litigation and court-ordered deadlines. These two schedules are often different, creating misalignments between when EPA evaluates a pesticide in registration review and when the Agency performs the ESA analyses on the pesticide. This misalignment is inefficient for EPA, because the Agency is not conducting all of its analyses for a pesticide at the same time.

Challenges related to data and risk assessment tools

In recent years, EPA and the Services (all of whom have focused their efforts mostly on conventional pesticides) have seen a welcome shift to using more refined data, models, and other risk assessment tools for ESA determinations. This includes better information on species ranges, pesticide use and usage (*e.g.*, typical application rates and number of applications, geographic area treated), and toxicological effects of pesticides on species. The shift in data and tools to increase efficiency, however, has also resulted in biological evaluations that are considerably more detailed, complex, and longer. This trend toward more and better information has generally improved the foundation of both FIFRA and ESA findings but can result in a very lengthy ESA-FIFRA process. Below, EPA discusses several aspects of this tradeoff and other challenges related to data for pesticide consultations.

First, better species data would benefit several aspects of pesticide consultations. For example, spatially refined, subcounty range maps are not available from the Services for all species. Without this refinement, EPA must assume a species occurs in an entire county or multiple counties, even when it likely does not. As a result, mitigation measures will apply even in areas where the species may not occur, creating unnecessary restrictions on pesticide users. In addition, more refined data could also increase the number of EPA's "no effect" or "not likely to adversely affect" determinations, increase stakeholder confidence in EPA's effect determinations, and avoid formal consultation on species or habitat that are unlikely to experience pesticide exposure.

Beyond range species data, pesticide consultations would also benefit from better information on individual species biological responses to pesticides and effective mitigation techniques, especially for species facing the greatest risks from pesticides (those species are still being identified). For instance, information on the effectiveness of offset measures would inform how much EPA must rely on avoidance and minimization.

Despite the value of better data, incorporating the data into biological evaluations can be very resource intensive for EPA and thus extend consultations by several months or longer. For example, incorporating county-specific information for a wide ranging species (*e.g.*, found in many states, such as the Indiana bat) can be much more difficult than for a species with a small range (*e.g.*, may only be found in several counties, such as the Barton Springs salamander). Another example comes from EPA's ESA methods, which have led to increasingly refined analyses to guide its "may affect" and "likely to adversely affect" findings for currently registered pesticides in registration review where usage data are available.[1] Although this trend has generally increased the scientific rigor of the findings, EPA's experience applying the Revised Method is that the process is very resource-intensive when addressing the over 1,600 U.S. listed species and over 800 critical habitat designations. This level of work—which requires adequate staff, subject-matter expertise, and computer resources and which typically spans two years—far exceeds what EPA can handle across the hundreds of pesticides for which it must issue ESA determinations in the coming years. Moving forward, EPA must better distinguish between refined data and methods that generate a good return on investment for the Agency, and those that do not. Stakeholders can help with this tradeoff by focusing their interactions with EPA on the types of data and analyses that are likely to improve ESA effects determination or mitigation. To support this approach, EPA will need to clarify the types of data useful for refinements and the timing to submit the data, as sometimes data submitted in response to a draft biological evaluation are not used in a meaningful way.

EPA is mindful of the limits to which more or better toxicological effects data will increase the number of "no effect" findings or add value to the consultation process. By their nature, pesticides are designed to affect organisms. At the same time, the "may affect" threshold is inherently sensitive, currently defined as covering situations "when a proposed action may pose any effects on listed species or designated critical habitat."[2] Particularly for wide ranging species or species that frequently occur in or near lands or items treated with pesticides, "no effect" findings may be very difficult, if not impossible, to reach without significant mitigation. Thus, better data need to be augmented with more efficient regulatory approaches to handling "may affect" and "likely to adversely affect" situations, especially those accompanied by mitigation that reduces the effects. EPA will thus need to develop approaches that are consistent with the principles of the Revised Method for conventional registration review pesticides but far more efficient to apply.

5 EPA. Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides (March 2020).
6 *See* the definition for "may affect" in U.S. Fish and Wildlife Service and National Marine Fisheries Service Endangered Species Consultation Handbook at page xvi.

Second, another drawback of EPA's historical approach for conducting ESA analyses (focusing on effects determinations) is that it does not direct identify or implement ESA mitigation. As such, EPA has not yet developed a process for registrants to offer mitigation for listed species or critical habitats as part of the FIFRA process. As explained earlier, the Revised Method focuses on assessing exposure and effects at the level of individual organisms, rather than on developing mitigation at the level of the entire species. The former is necessary under the regulations for section 7 consultations, but the latter is more relevant to the ESA's goal of species recovery and the prohibitions on jeopardy and adverse modification. Because pesticide consultations are unique and would benefit from early mitigation, EPA seeks to expand the scope of its ESA assessment to assess and focus on species-level impacts and associated mitigation needs while minimizing resources needed to make effects determinations at the level of the individual.

Third, EPA's current processes and infrastructure limit the Agency's ability to expeditiously or consistently incorporate all updated species or pesticide data it receives from the Services or stakeholders into its biological evaluations and ESA determinations. For example, the current process of developing a biological evaluation for a registration review pesticide takes over two years. Refined data that become available 18 months into the process cannot be incorporated into a draft or final evaluation, without delaying release of the document and without further increasing the resources needed to produce a biological evaluation. In almost all situations, EPA has no ability to delay because it is under a legal deadline to produce a draft or final evaluation. Thus, the Agency has cutoff dates by which it can no longer incorporate additional data into its ESA analyses. Similarly, biological opinions can take several years to produce, and the current timeline in which the Services can complete consultations exacerbates this challenge to updating data. Incorporating additional data during consultation would similarly require EPA resources that have transitioned to working on the next court-ordered biological evaluation, to return to the prior assessment and update information that would not have been needed had the consultation been completed more quickly. EPA's current information management systems for species maps and other key data, combined with the current consultation process, impede the Agency's ability to incorporate all updated data into its ESA determinations.

Fourth, data on pesticide usage for currently registered pesticides are important for accurate risk assessments and meaningful mitigation but must be used in the proper context. Given the strong public interest in usage data, EPA first needs to explain why it uses usage data in ESA assessments. EPA registers pesticide products that include labels with use patterns that are intentionally flexible to allow users to apply pesticides at different intervals and rates depending on a particular pest issue. Although an individual may apply a pesticide at the maximum labeled use, it is highly unlikely that a pesticide would be applied at this maximum rate in all areas by all users simultaneously (or even within a single year).[1] Thus, EPA uses pesticide usage data to better understand where and how the pesticide has been used historically, and to inform where and how it is likely to be used in the future. This prediction allows EPA to refine its assessments to focus resources and mitigation in areas where uses are most likely to occur and thus affect ESA species.

7 Some pesticides require exact application rates, but most do not.

When usage data are unavailable or inadequate—which is especially a challenge for new pesticides with no usage data, and for biopesticides and antimicrobial pesticides for which these data are rarely if ever available—EPA typically makes conservative assumptions (*e.g.*, that 100% of treatable use sites will actually be treated at the maximum label rate). These assumptions overestimate exposure and the potential for incidental take and could result in EPA imposing unnecessary mitigation. Unnecessary mitigation can also complicate pesticide labels, thus stretching limited EPA resources. Certain mitigations can also reduce access to pest management tools or exacerbate pest resistance problems. Thus, high-quality usage data are key to prioritizing limited EPA resources and supporting better risk assessment and management decisions for currently registered pesticides. For new pesticides, other information is necessary to characterize how the pesticide will likely be used.

Despite the importance of usage data for assessing currently registered pesticides, EPA acknowledges several important limits to the use of these data when they are highly spatially refined (*e.g.*, county level). Although high resolution data provide more precise information about how a pesticide was used in a particular location in the past, those data may incorrectly predict future pesticide usage in that area because the actions of a single user can strongly bias historical usage estimates. By contrast, geographically coarser usage data in areas experiencing similar pest pressure (*e.g.*, state level) can offer better insights into the potential for future usage by averaging usage across multiple users, thus accounting for variability in use (*e.g.*, crop rotations) and usage. For conventional pesticides, EPA uses state-level usage averages in its ESA assessments because this approach is unlikely to underestimate future exposure to ESA species.

Further, current usage data for registered pesticides vary considerably in quality. For example, California's Department of Pesticide Regulation usage data are unmatched in their spatial and temporal resolution. Usage in California, however, cannot readily extrapolate to other states. Currently, the only annually collected nationwide data on agricultural pesticide usage come from a pesticide usage survey conducted by Kynetec USA, Inc., that covers approximately 70 of the largest agricultural use sites. The data are provided only through a license and cannot be redistributed to or explored by unlicensed groups in their raw format. As a result, EPA's ability to provide full transparency of usage data is contractually limited. EPA does, however, provide in its biological evaluations the summarized usage data averaged by crop over five years. Besides the Kynetec dataset, EPA also uses other nationwide datasets including USDA National Agricultural Statistics Service (NASS) Chemical Use Program. Although the NASS dataset is publicly available, it does not survey most agricultural use sites annually. EPA uses this dataset to inform and validate usage data from Kynetec, but the publicly available NASS data cannot currently replace the usage data from Kynetec for most crops. EPA generally has high confidence in the usage data from these various sources. Certain use sites, however, are rarely or never surveyed (*e.g.*, small acreage crops and non-agricultural use sites), and usage data sources for biopesticide and antimicrobial active ingredients are generally unavailable.

State-level usage estimates strike a balance between national-level usage, which can mask regional or local differences in usage, and substate usage, which can vary in quality because of the potential low number of individuals used to derive the estimate. State-level estimates can be readily applied in a manner that adequately protects ESA species (*e.g.*, allocate all projected acres treated in the state onto the species range).

In certain cases, EPA could benefit from more spatially refined usage data than those generally available today. One solution may be for pesticide applicators, working with USDA and other organizations, to provide those substate data. If available, the data could also allow EPA to incorporate species mitigation at the substate level, which could avoid unnecessary restrictions in areas where a species and its critical habitat does not occur.

There are additional challenges for conducting ESA assessments for antimicrobial pesticides. For antimicrobial use patterns that could result in outdoor exposures, the highest environmental exposures are expected to occur in aquatic habitats. Out of the many potential use sites that could result in aquatic exposures, EPA currently only has screening level exposure models for a very limited set of uses that are believed to result in the highest potential exposures (*i.e.*, anti-fouling paints, cooling towers, paper mills and other industrial settings, down-the-drain uses, wood treatments for docks, and material preservation for outdoor paints). All the available exposure models are conservative, FIFRA screening-level models intended to inform whether there is the expected potential for risks from a registered antimicrobial use. None of the available screening-level models allows EPA to quantify potential effects to listed species.

Additionally, because of the focus on aquatic exposures, there are generally no existing methods that allow EPA to conduct an exposure assessment for any terrestrial species. Further, ecotoxicity data for terrestrial species are often more limited for antimicrobial pesticides than for conventional pesticides because of differences in data requirements, and EPA receives frequent FIFRA requests to waive these data. This situation may limit EPA's ability to fully address direct and indirect effects without calling in additional data for antimicrobial pesticides. Additionally, data that identify the locations of potential use sites are not currently available for any antimicrobial use patterns. Usage data are generally lacking for antimicrobial uses and are limited to production volumes per year at the national level, if available at all. The lack of available spatial data for antimicrobial use patterns limits the ability to conduct an overlap analysis to identify the species and critical habitats that may need to be assessed. For these reasons, the risk assessment methods and processes developed for conventional pesticides do not apply to assessing antimicrobial uses. Further, the ability to complete ESA determinations for antimicrobial pesticides would require significant model development, data collection, and coordination across stakeholders and the Services.

Need to continue improving the working relationship among agencies

A major aspect of an effective consultation process is trust and mutual respect between EPA and the Services. As many close observers of the ESA-FIFRA process know, there is room for improvement in this area. Particularly as EPA embarks on major improvements to the ESA-FIFRA process, the Agency will need strong working relationships with headquarters and regional or field staff in the Services. For example, identifying and overseeing species mitigation will sometimes require EPA to work with regional staff that are the lead in conserving a species and that have relationships with landowners. Only through mutual trust can the interagency relationships lead to more efficient consultations and conservation. One reason that EPA has written this workplan is to show its federal agency partners and stakeholders how the Agency intends to work in good faith toward the goals of ESA consultation.

STRATEGIES AND ACTIONS TO ADVANCE VISION

STRATEGIES AND ACTIONS TO ADVANCE VISION

To achieve EPA's vision, the workplan establishes four overlapping strategies and multiple actions to implement each strategy. The first strategy is for EPA to meet its ESA obligations for all FIFRA actions that require ESA determinations and consultations. These actions include those with pending court-enforceable deadlines to complete ESA assessments, and the considerably larger number of actions without court-enforceable deadlines. The second strategy is for EPA to improve its approaches to identifying and requiring ESA mitigation earlier in the FIFRA process. These improvements will include prioritizing mitigation for species most vulnerable to pesticides, offering pesticide users greater flexibility in adopting mitigation, and developing internal policy and program changes to support EPA's mitigation goals. The third strategy is to improve the efficiency and timeliness of the consultation process. Unlike the first two strategies, this strategy relies heavily on collaboration with the Services and USDA.

Similarly, the fourth strategy of improving EPA's stakeholder engagement is external facing. The Agency is especially interested in working with stakeholders on data and analyses to support more timely and efficient ESA determinations and consultations.

For each action, EPA has also identified the timeframe for implementation relative to the date of this workplan. In general, actions that are expected to be developed farther in the future are described with less specificity than those in the near term. Many of those details will depend on how EPA implements the latter and on other factors such as its future litigation, workload, backlogs, and resources.

Throughout this section, EPA has been deliberate in conveying whether it is committing to pursue an action. For actions that the Agency will definitively pursue, the workplan uses "will" or other affirmative language. For actions that the Agency cannot yet commit to or is still evaluating, the workplan uses "may," "could," "will consider," or other equivocating words. The workplan thus contains a mix of definitive and aspirational actions.

Divisions of EPA's Pesticide Office

EPA has identified the divisions within its Office of Pesticide Program that will lead each of the actions described in this section. The main responsibilities of each division are as follows.

Antimicrobials Division (AD). AD is responsible for all registration and registration review activities for antimicrobial pesticides including the review of scientific data, development of human health and ecological risk assessments, and regulatory decision making for new registrations, registration review, and reregistration.

Biological and Economic Analysis Division (BEAD). BEAD evaluates use information for identifying the action area, usage information for refining the extent of exposure, and the potential impacts of mitigation on pesticide users in support of biological evaluations and biological opinions through analyses provided to OPP and the Services, respectively.

Biopesticides and Pollution Prevention Division (BPPD). BPPD is responsible for all registration and registration review activities for biopesticides (microbials, biochemicals, and emerging technologies) including the review of scientific data, development of human health and ecological risk assessments, and regulatory decision making for new registrations and registration review.

Environmental Fate and Effects Division (EFED). EFED is responsible for conducting ecological, drinking water, and endangered species assessments to evaluate potential risks posed by conventional pesticides for registration and registration review and effects to listed species. EFED also houses *Bulletins Live! Two*.

Health Effects Division (HED). HED is responsible for conducting human health risk assessments to evaluate potential risks posed by conventional pesticides for registration and registration review.

Pesticide Re-Evaluation Division (PRD). PRD is responsible for the re-evaluation of currently registered conventional pesticides and for the development of risk mitigation measures to ensure that they continue to meet the FIFRA registration standard.

Registration Division (RD). RD is responsible for developing regulatory decisions for conventional pesticides. This involves risk management and regulatory determinations for all conventional new chemicals, new uses, new products, and product amendments. RD is the office lead for emergency exemption requests submitted under section 18 of FIFRA. RD completes product specific science review for acute toxicity, chemistry, and efficacy for public health products. RD also develops risk assessments and regulatory decisions for inert ingredients contained in pesticides.

Overview of improvements to address challenges to ESA-FIFRA process

Challenges \ Improvements	Meet ESA obligations for FIFRA actions					Improve ESA mitigation approaches						Improve consultation process	Improve stakeholder engagement		
	Court-ordered deadlines	New pesticide reg. (conventionals)	Reg. review (conventionals)	All other FIFRA actions (conventionals)	Non-conventional reg.	Mitigate for vulnerable species	Mitigate for high risk species	Flexible mitigation	Coordinate mitigation	Use offsets	Other policy improvements		Obtain better data	Engage growers	Engage others
Large and growing workload											✓✓	✓✓	✓		✓
Process for mitigation															
Broad geographic scope						✓✓	✓			✓	✓	✓	✓✓		
Mitigation too late						✓✓	✓✓			✓	✓				
Not species level						✓	✓✓			✓✓			✓		
Reg. review timing					✓			✓	✓		✓				
Lack of offsets										✓✓			✓	✓	
Mitigation not comparable									✓✓		✓			✓	
FIFRA challenges for ESA															
FIFRA actions complex							✓	✓			✓	✓	✓		
Inefficient consultation process												✓✓			
Incorporating ESA into FIFRA															
FIFRA actions rarely addressed ESA	✓✓	✓✓	✓✓	✓✓	✓✓	✓	✓	✓	✓	✓	✓				
Inefficient chemical-by-chemical approach						✓	✓	✓		✓	✓✓	✓			
Limited ability to require mitigation through reg. review	✓		✓		✓			✓		✓	✓✓		✓	✓	✓
Reg. review and ESA analyses on different schedules			✓		✓	✓	✓	✓		✓	✓				
Data and risk assessment tools															
Tradeoff between better data and faster consultation											✓	✓	✓		
Past ESA methods silent on species-level mitigation						✓	✓✓	✓		✓✓	✓	✓		✓	✓
Difficult to update ESA analyses with new data											✓	✓	✓		
Usage data challenges											✓	✓	✓	✓	✓
Antimicrobials challenges					✓						✓				✓
Improve interagency relationships					✓	✓	✓	✓				✓✓			

Figure 2: Table summarizing how each category of ESA-FIFRA improvement discussed in this workplan addresses each challenge identified in the document. Descriptions are abridged; see table of contents for full descriptions. One checkmark represents a low to moderate connection between the improvement and challenge, and two checkmarks represent a high connection between the two.

✓✓	Indicates strong connection
✓	Indicates low to moderate connection

STRATEGY 1: MEET ESA OBLIGATIONS FOR FIFRA ACTIONS

The overarching purpose of this workplan is for EPA to meet its ESA obligations for all FIFRA actions that require ESA review. Given the hundreds of FIFRA actions annually that trigger these obligations, the Agency cannot simultaneously and immediately meet these obligations for all these actions. Rather, EPA will increase the number of its ESA determinations and consultations as efficiencies and resources allow. As part of this phased approach and as outlined in this workplan, the Agency has identified at this time which types of actions are the highest priorities for addressing ESA obligations and which are lower priorities.

The top priority is for EPA to meet its existing and future court-enforceable deadlines, most of which cover existing pesticides in registration review, newly registered active ingredients, and new uses of existing pesticides. The next priority covers registrations of new conventional active ingredients, which EPA has committed to assessing through its January 2022 announcement on these actions. This means that EPA will not register a new conventional pesticide without ensuring that EPA meets its ESA obligations before granting the registration. EPA has prioritized these actions for several reasons, including to help ensure the legal defensibility of new chemistries, which are often safer than existing chemistries, and because EPA can negotiate mitigation more expeditiously for new registrations than during registration review.

The next tier of priority is for the remaining conventional pesticides in registration review. Given the hundreds of registration review cases that still require an ESA determination, EPA currently needs many years to complete these determinations and, if needed, consult with the Services on each pesticide. The time and resources to complete this work on the part of all three agencies is the main reason EPA has not assigned a higher priority to these actions. With that said, certain actions for pesticides in registration review that are not already subject to litigation-related deadlines are especially urgent and are among EPA's highest priorities for its ESA-FIFRA program within its portfolio of registration review chemicals. In particular, implementing existing NMFS biological opinions with jeopardy findings is crucial to minimizing extinction risks. In addition, EPA is developing early mitigation for a subset of species predicted to be at risk of jeopardy/adverse modification for several registration review pilot chemicals, as outlined in this workplan, and then plans to expand these measures to certain other high priority registration review chemicals. EPA's vulnerable species initiative and the federal interagency mitigation pilot project, both discussed in the mitigation strategy section below, will also inform the Agency's early ESA mitigation efforts.

The final tier of priorities consists of all other FIFRA actions for conventional pesticides (*e.g.*, new uses) and FIFRA actions for non-conventional pesticides. In general, EPA's work to address its ESA obligations for this final tier of actions is the least developed. For example, EPA does not have ESA methods specific to antimicrobials, and ESA methods for biopesticides are not as developed as those for conventional pesticides. Nonetheless, EPA will develop efficient approaches for these actions and will continue to determine, on a case-by-case basis, how best to address its ESA obligations for the actions. For example, certain mitigation actions in this workplan may allow EPA to make ESA determinations and, where necessary, consult on some new uses. In those cases, EPA may be able to prioritize the determinations/consultations by conducting them concurrent with consultations for new active ingredient registrations or for chemicals in registration review. Similarly, through this workplan, EPA expects to adopt systemwide process efficiencies that will allow the Agency to complete more ESA assessments and consultations over time. In that scenario, EPA expects to meet its ESA obligations for this final tier of FIFRA actions sooner.

To help readers better understand the number of FIFRA actions associated with each of the three tiers, **Table 2** shows the approximate number of actions that EPA completes annually that may require an ESA analysis and, where the information is available, the approximate number of ESA "no effect" findings for each category of action. As readers can see, the number of actions for new uses, expansion of existing uses, and geographically limited registrations far exceed the number of actions for new active ingredient registrations and registration review. As discussed above, this is one reason that EPA has prioritized the latter for ESA review.

Table 2. Estimated number of FIFRA actions completed annually that may require ESA review. As explained throughout this workplan, EPA does not currently complete an ESA review for most of these actions.

FIFRA Action	No. of Actions	Comments
New Active Ingredients (AIs) Registration		
Conventional Pesticides	10	EPA may have 15 in-house submissions at any time.
Antimicrobials	5	EPA may have 5 antimicrobial in-house submissions at any time in different stages of registration. EPA estimates that 1/5th of these will have "no effect" on ESA species.
Biopesticides	30	EPA may have 40-50 new AIs in-house at any given time in different stages of registration. While many biopesticides result in "no effect" (approx. 2/3), some will require additional ESA work.
Registration Review		
Conventional Pesticides	40	There is a wide range of the number of registration review risk assessments depending on where EPA stands in its registration review cycle. EPA averaged approximately 40 conventional pesticide DRAs per year over the past 10 years and typically ranges from approximately 20 to 60 annually.
Antimicrobials	15	There is a wide range in the number of registration review risk assessments depending on where EPA stands in its registration review cycle. AD averaged approximately 15 antimicrobial pesticide DRAs per year over the past several years. AD expects that approximately 30 percent of DRAs will be "no effect."
Biopesticides	30 cases	There is a wide range of the number of registration review risk assessments depending on where EPA stands in its registration review cycle. BPPD works on about 30 biopesticide "cases" (some cases have multiple AIs) per year over the past 10 years, on average. While many biopesticides result in "no effect" (approx. 2/3), these calls will need to be reconfirmed, and other cases will require additional work.
New Uses for Existing Pesticides		
Conventional Pesticides	80	Approximately 60 to 100 new use applications are received each year that could require ESA analysis. Many additional new use applications are submitted that may not require new ecological risk assessments to make a FIFRA determination. The amount of risk assessment effort for new use registrations has historically been lower compared to the effort required for new chemical registrations. For example, ecological risk assessments may simply refer to existing assessments if sufficient to inform the FIFRA determination.

Table 2 (cont.). Estimated number of FIFRA actions completed annually that may require ESA review. As explained throughout this workplan, EPA does not currently complete an ESA review for most of these actions.

New Uses for Existing Pesticides		
Biopesticides	20	Approximately 20 new use applications are received each year for BPPD with about 1/3rd of them having the potential to require ESA analysis. Some measure of efficiency would be expected in future years as more BPPD chemicals undergo ESA analyses.
Other Expansions of Existing Use Patterns		
Conventional Pesticides	140	Other actions that may increase ecological exposure and, therefore, require science support may include requests to change existing product application methods for a registered use site (*e.g.,* increase application rate, number of applications, etc.) or applications for products in a new physical form. The number of applications received each year varies and may range from approximately 120 to 160.
Biopesticides	50	Other actions that may increase ecological exposure and, therefore, require science support may include requests to change existing product application methods for a registered use site (*e.g.,* increase application rate, number of applications, etc.) or applications for products in a new physical form. The number of applications received each year varies but only about 1/3rd would be expected to require ESA work.
Geographically Limited Registrations		
Section 18 emergency exemptions (conventional pesticides)	100	Science support is historically more limited for these types of actions and focuses on a review of information submitted by the state applicant. The number of applications received each year varies and may range from approximately 80 to 120. ESA analysis for antimicrobial and biopesticides is expected to be minimal.
Experimental Use Permits (EUPs)	5	EUPs for emerging technologies are basically treated as new AI assessments for BPPD. In recent years, many of these EUPs already receive some type of an ESA analysis. Some of these may result in "no effect," but others will require additional work. ESA analysis for antimicrobial and conventional pesticides is expected to be minimal.
Commitments Prioritized Due to Litigation		
Conventional pesticides	5	This represents resource commitments from various litigations. Litigation discussions are ongoing for dozens of pesticides related to ESA.

Having described the relative priorities of these different types of FIFRA actions, the section below summarizes the steps that EPA will or plans to pursue for each type of action.

Meet court-enforceable ESA deadlines

EPA's highest priority for the pesticide program is to meet its court-enforceable ESA deadlines and other commitments to courts. The deadlines cover dates for issuing draft biological evaluations, final biological evaluations, and implementing biological opinions for a variety of pesticide active ingredients and pesticide decisions (see Appendix A). Although EPA's current ESA workload is largely driven by these settlement deadlines, with this workplan the Agency expects to reduce the number of deadlines established through litigation and be able to set its own priorities using far more efficient approaches to meeting its ESA obligations. Fewer litigation-driven deadlines allow EPA more opportunities to complete the other actions in this workplan and to accommodate ESA assessments for all FIFRA actions that trigger ESA requirements. This is why in the long term, EPA seeks to set deadlines for its ESA obligations based on priorities the Agency establishes on its own.

> Lead division(s): EFED, PRD, RD
> Timing: In progress. As Appendix A shows, EPA has 18 chemicals with court-enforceable deadlines or other court commitments through 2028, with additional chemicals in current litigation where litigants are likely to request EPA add more chemicals to this schedule.

Meet ESA obligations for new registrations for conventional pesticide ingredients

As announced in January 2022, EPA will meet its ESA obligations for all new registrations for conventional pesticide active ingredients.[1] To further this objective, EPA will not issue new registrations for these ingredients without first making ESA assessments (effects determinations and predicting the likelihood of jeopardy and adverse modification), implementing needed mitigation, and initiating consultation with the Service(s) if necessary (consultation is unnecessary if EPA makes "no effect" findings for all covered species and critical habitats). In phasing in the policy, consistent with its ESA obligations, EPA may need to issue a final registration for a pesticide even if the Agency has initiated but not completed consultation for the pesticide. The policy allows the Agency to meet its ESA obligations and to provide regulatory certainty to pesticide registrants and users, and to strive to meet the applicable PRIA deadlines for new pesticide ingredient registrations.

Where EPA initiates consultation and then registers a new pesticide before completing formal consultation, the Agency will include a determination that issuing the registration will not violate the ESA's section 7(d) prohibition on making "any irreversible or irretrievable commitment of resources" that prevent the Agency from formulating or implementing any reasonable and prudent alternatives identified through formal consultation. If EPA deems that a new pesticide submission is unable to adequately mitigate for effects that are likely to trigger a jeopardy or adverse modification finding during formal consultation, the Agency will notify the applicant that its registration cannot be granted until consultation can be completed. At that point the applicant could wait for consultation to be completed, withdraw their application, or request a denial of the registration.

8 EPA. EPA Announces Endangered Species Act Protection Policy for New Pesticides (Jan. 2022).

The ability to complete consultation before a final registration decision will depend on various factors, some of which are outside of EPA's control. These include EPA's and the Services' capacity to complete pesticide consultations, devising a more efficient consultation process, registrant willingness to change labels prior to EPA approval, and existing court-enforceable deadlines for completing biological evaluations. Where EPA has initiated consultation and issues a final registration before completing that consultation, it will have, at a minimum, completed its ESA analysis and made its effects determinations, required early mitigation for ESA species as part of the registration, and required terms of the registration that allow EPA to amend the registration to reflect the outcome of consultation. In particular, for geographically specific mitigation requirements, EPA may implement them through pesticide labels that refer users to EPA's *Bulletins Live! Two* or through updating existing bulletins. Where applicable, EPA will update bulletins shortly after registration to ensure prompt protections for species and to ensure that pesticide users regard bulletins as a reliable source of information.

In the future, EPA expects that any necessary consultation would be completed before registering a new conventional pesticide. Exactly when this will begin depends on the factors identified above.

To implement the January 2022 policy, EPA will:

- **Consult on new conventional registration submissions.** As of January 2022, EPA began implementing this requirement and will continue doing so for new pesticide active ingredient submissions. EPA is currently phasing in this action, starting with new conventional registration submissions that it had already received as of January 2022.

  Lead division(s): RD, EFED, and BEAD

  Timing: Started January 2022

- **Adopt mitigation for species.** EPA plans to predict whether the new AI registration could jeopardize listed species or adversely modify its critical habitat. If jeopardy or adverse modification is predicted to occur, EPA will adopt mitigation intended to avoid both. EPA may also adopt additional mitigation to reduce exposure to listed species even when effects are not predicted to result in jeopardy/adverse modification.
- **Adopt flexible mitigation.** EPA will identify and offer pesticide users more flexible approaches to mitigating for effects to listed species (see mitigation strategy below for more information).
- **Coordinate mitigation between new registrations and registration review.** EPA will begin coordinating mitigation between new registrations of pesticide ingredients and related registration review conventional pesticides, to help ensure consistent mitigation among pesticides that cover similar uses (see mitigation strategy below for more information).

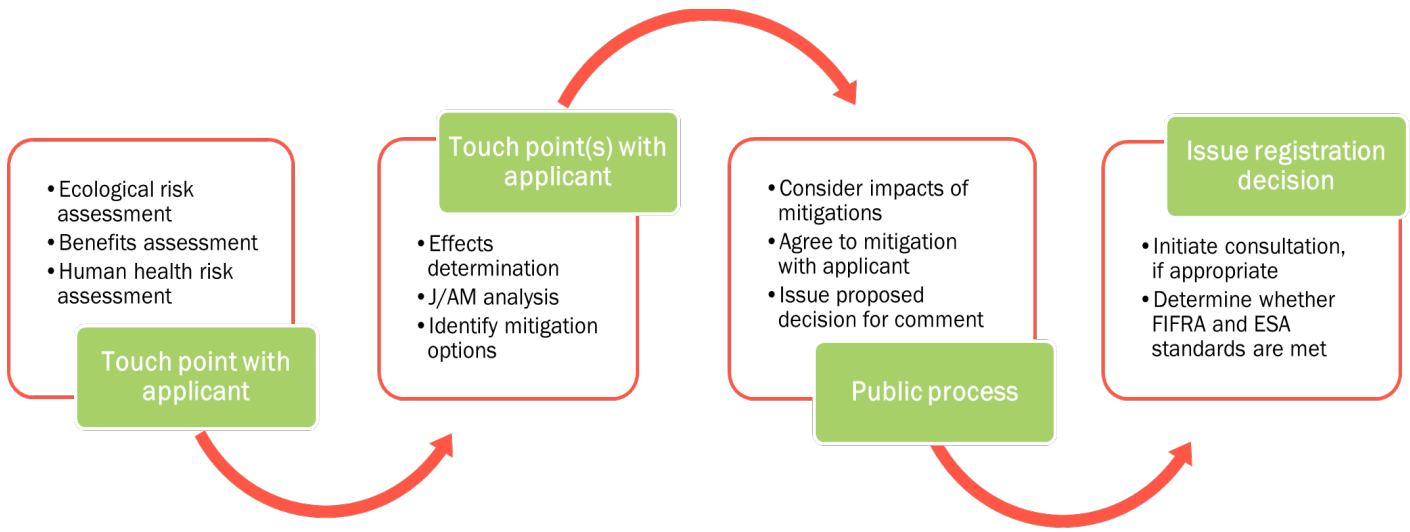

Figure 3."J/AM" analysis refers to EPA's prediction of whether a pesticide is likely to cause jeopardy or adverse modification.

Meet ESA obligations for new registrations for conventional pesticide ingredients already registered or undergoing registration review

Meeting ESA obligations for registration review will continue to represent the bulk of the Agency's ESA workload, as there are far more pesticide cases in registration review than new pesticide ingredient submissions. EPA's current and future ESA workload for registration review consists of (1) pesticides for which the Agency has committed to court-enforceable deadlines, as described earlier, and (2) pesticides not covered by any court-enforceable deadlines, which are the focus of this section.

Under court settlements, EPA has already been consulting on several conventional pesticide registration review pesticides, creating a foundation for the Agency to increase the number and speed of consultations it can complete as part of future registration review decisions for pesticides not covered by a court-enforceable deadline. Although EPA and the Services are improving the consultation process, far more efficiencies are still needed as the current situation creates an unsustainable workload for EPA and the Services and does not result in timely mitigation. The lack of greater efficiencies has resulted in EPA completing biological evaluations for only a small fraction of the pesticides in registration review. Moving forward, EPA, working with the Services, will strive to fulfill its ESA obligations far more efficiently, with priority on early mitigation for vulnerable species (*i.e.*, species at greatest risk of pesticide exposure, as defined later in the mitigation strategy).

The Agency will do so through a multistep process that includes working with the Services to develop general guidance on using offsets for pesticide consultations including ecosystem-scale and advance mitigation opportunities, working with registrants to identify and adopt offsets for specific pesticides and species, ensuring that adopted offsets are legally binding as a condition of a FIFRA registration, and working with the Services to oversee implementation of offsets.

To implement EPA's obligations for registered pesticides, the Agency will:

- **Implement the terms of existing pesticide biological opinions.** Besides the biological opinions for which EPA has court-enforceable deadlines to implement, EPA has other NMFS biological opinions that it is implementing with NMFS. See Appendix A.

  Lead division(s): PRD, EFED

  Timing: In process

- **For select conventional pesticides, mitigate for certain species.** Given EPA's large ESA workload for registration review, the Agency needs to identify a set of pesticides and species as a starting point to focus its early ESA mitigation measures, before the start of formal consultation. To further this objective, EPA has identified the following pesticides with court-enforceable deadlines (some of which have been fulfilled) as pilots to incorporate early mitigation under registration review: methomyl, carbaryl, certain neonicotinoids, and rodenticides. Each of these pesticides or pesticide classes are at different stages in the FIFRA process (*e.g.*, risk assessments conducted, proposed interim decision, interim decision) and in the ESA process (*e.g.*, biological evaluation not yet conducted, biological evaluation in process, formal consultation initiated). This variety will allow EPA to determine how best to incorporate early mitigation at each of those stages. Each of the pilot chemicals will focus on a subset of species that EPA determines has a high likelihood of jeopardy or adverse modification for that chemical. EPA plans to incorporate early mitigation to address likely effects to those selected species as part of the FIFRA process or through EPA's biological evaluations (more details in the mitigation strategy section).

  For these registration review pilots, EPA plans to provide information on the species and associated mitigations in the preliminary interim decision (PID) or an amended PID. In addition to providing a formal opportunity for our stakeholders to provide feedback, EPA hopes this information will help registrants and growers to better understand how EPA identified species for these actions and how EPA selected the proposed mitigations. Although this effort starts with the pesticides/pesticide classes listed above, it will expand to other pesticides in registration review based on staff capacity. As this effort expands, it will benefit from EPA's vulnerable species initiative and the federal interagency mitigation pilot project, both discussed in the mitigation strategy section below.

  Lead division(s): EFED, PRD, BEAD

  Timing: In process

Meet ESA obligations for new registrations for conventional pesticide ingredients already registered or undergoing registration review

- **Meet ESA obligations for all other registration review cases.** EPA is also required to complete ESA determinations for the large number of registration review cases not covered by existing court deadlines or currently in litigation. The first cycle of registration review covers over 450 conventional pesticide cases, but EPA is unable to complete most of the remaining ESA determinations before the end of this cycle. Under this workplan, however, EPA will begin developing a plan on when and how to make those determinations.

  As explained in the earlier *Background and Challenges* section, the optimal order for making those determinations will depend on the interplay between multiple factors. Those factors may include:

  - How a pesticide affects listed species and critical habitat.
  - The amount of use for a pesticide that overlaps with listed species and critical habitat, especially EPA-identified vulnerable species.
  - Early mitigations EPA incorporates that benefits species affected by a pesticide, even before EPA has completed consultation, following public comment and notification procedures under FIFRA.
  - Coordination of mitigation on newly registered pesticides and the existing pesticides they are intended to replace, including through any discussions with USDA and pesticide users.
  - Process efficiencies that allow EPA to group multiple pesticides or classes of pesticides for concurrent ESA determinations and formal consultation.
  - EPA capacity and infrastructure to make ESA effects determinations.

  Developing an efficient ESA schedule that balances these and other factors presents a major challenge for EPA. For this reason, the Agency cannot currently set a timeline for when it can conduct ESA assessments for all the pesticides currently in registration review. The Agency, however, does appreciate the importance of providing a timeline and clear commitments about when these assessments will occur. During the next year, the Agency will continue working toward a timeline. As part of this process, the Agency may determine the order in which it will complete ESA assessments for each conventional chemical, even if it cannot yet identify the dates for the assessments.

  Lead division(s): EFED, PRD, BEAD

  Timing: In process

- **Adopt mitigation for vulnerable species.** Through EPA's vulnerable species effort (see mitigation strategy below for more information) EPA will identify and incorporate early ESA mitigation for those species as part of registration review. This effort is also designed to benefit other ESA species not covered by the vulnerable species effort.

- **Adopt flexible mitigation.** EPA will identify and offer pesticide users more flexible approaches to mitigating for effects to listed species (see mitigation strategy below for more information).
- **Coordinate mitigation between new registrations and registration review.** EPA will coordinate mitigation measures on new conventional pesticide active ingredient registrations and related registration review conventional pesticides, to help ensure consistent mitigation among pesticides that cover similar uses (see mitigation strategy below for more information).

Meet ESA obligations for new use registrations, section 18 emergency use registrations, and other actions on existing conventional pesticides

EPA will develop a strategy to meet its ESA obligations, as needed, for the large number of actions that its registration program receives under PRIA and FIFRA. These include new uses for an existing pesticide, requests for label amendments to an existing pesticide, new product combinations or physical form, temporary permission for an unregistered use in response to a pest emergency under FIFRA section 18, and other FIFRA actions, all of which may invoke ESA obligations. Collectively, these actions far exceed the number of registration review decisions. New food use requests for existing chemicals are especially important to agriculture and have averaged approximately 140 decisions per year. New products and amendments also have a high volume (about 700) of decisions annually.

With the current approaches to ESA determinations and existing agency capacity, EPA is currently unable to meet its ESA obligations for all the large number of new uses, section 18s, and other registration actions. A major reason is that over the next six or more years, EPA has prioritized its workload on ESA assessments for registration and registration review cases needed to meet settlement agreements. New uses, section 18s, and other FIFRA actions will generally be lower priority during this period. Thus, EPA will need to develop considerably more efficient ESA approaches for those FIFRA actions, as its approach for new active ingredients is not designed to apply to the actions. EPA will develop the approaches after it makes progress on the three types of FIFRA actions described earlier. As EPA develops more experience incorporating ESA mitigation through registration of new active ingredients and registration review, it will use this experience to inform mitigation for the FIFRA actions described in this section. Over the long-term, EPA envisions that it can complete enough consultations for commonly used pesticides, so that the Agency can update those consultations to include the other FIFRA actions.

In the meantime, EPA will continue to determine, on a case-by-case basis, how best to address its ESA obligations for these other FIFRA actions. The one exception is new uses for herbicides used on crops genetically engineered for tolerance to those herbicides. For those uses, EPA will continue to meet its ESA obligations by making ESA determinations, initiating consultation as appropriate, and requiring any necessary mitigation before a registration is granted.

Lead division(s): RD, EFED, BEAD

Timing: Case-by-case decision for all FIFRA actions, with development of comprehensive strategy no sooner than 3 years.

Meet ESA obligations for antimicrobial and biopesticide registration and registration review decisions

The ESA-FIFRA assessment methods that EPA has developed were designed for conventional pesticides, rather than antimicrobials or biopesticides. Nonetheless, EPA has completed ESA determinations for some antimicrobials and has often concluded "no effect" because many antimicrobials are used indoors and thus have no direct or indirect exposure to listed species or critical habitats. Similarly, EPA has been able to find "no effect" for some biopesticides based on lack of exposure or lack of toxicity to listed species or critical habitats.

To further meet its ESA obligations in these areas, the Agency will develop ESA assessment methods for antimicrobials and biopesticides that allow it to go beyond the may effect/no effect analysis. EPA does not expect that all future antimicrobial and biopesticide assessments will result in "no effect," so the Agency will need to consider how to assess any potential "likely to adversely affect" determinations for those pesticides and to require early and flexible mitigation. As part of this process, EPA will work with stakeholders to determine when higher tier toxicological data may be needed to support any needed biopesticide or antimicrobial biological evaluations.

EPA will learn important information through the process for addressing ESA obligations in the new conventional pesticide actions. This will inform EPA's development of the process for non-conventional pesticide actions.

To implement these obligations, EPA will:

- **Develop ESA approaches for biopesticides.** Many biopesticides are used similarly to conventional pesticides, so EPA expects to adapt some of the approaches for conventionals to biopesticides, although EPA may also need to develop ESA approaches specific to biopesticides. EPA will describe in any new approaches how the Agency will determine whether a biopesticide "may affect" and is "likely to adversely affect" ESA species and critical habitats.

  Lead division(s): BPPD, EFED

  Timing: Within 18 months

- **Meet ESA obligations for biopesticides.** EPA will adopt policy and program improvements, similar to those for conventional pesticides, to help meet its ESA obligations for biopesticides. These include early and flexible mitigation, and coordination between registration and registration review of biopesticides. EPA plans to use pilot chemical(s) to demonstrate these approaches. EPA will also start reaching out to biopesticide stakeholders who are likely unfamiliar with the ESA process and EPA's obligations.

  Lead division(s): BPPD

  Timing: Pilots ongoing; significant progress on overall action within 18 months

- **Develop ESA approaches for antimicrobials.** EPA will develop ESA approaches specific to antimicrobials. This will describe how the Agency will determine whether an antimicrobial "may affect" and is "likely to adversely affect" listed species and critical habitats. The EPA will try to use data from available sources to help identify the location of potential use sites (*e.g.*, NPDES permits for industrial uses; marina locations for anti-fouling paint uses) and work towards refining available exposure models that will allow EPA to quantify risk to species. EPA will also develop a list of antimicrobial use sites that are not expected to result in any outdoor exposures (*e.g.*, indoor uses that do not go down the drain) for which the EPA can make "no effect" determinations.

  Lead division(s): AD, EFED

  Timing: 3 years

- **Meet ESA obligations for antimicrobials.** EPA will adopt policy and program improvements, similar to those for conventional pesticides, to help meet its ESA obligations for antimicrobials. These include early and flexible mitigation, and coordination between registration and registration review of antimicrobials. EPA plans to use pilot chemical(s) to demonstrate these approaches. EPA will also start reaching out to antimicrobial pesticide stakeholders who are likely unfamiliar with the ESA process and EPA's obligations.

  Lead division(s): AD

  Timing: Within 5 years

STRATEGY 2: IMPROVE APPROACHES TO ESA MITIGATION

This section describes actions that support the mitigation measures that EPA will incorporate into its registration and registration review decisions, including those resulting from litigation-related deadlines. The implementation and rollout of these actions will vary, depending on the nature of each action. Some actions will be announced through an EPA press release or OPP Update, while other actions do not warrant a standalone announcement and will simply be incorporated into future EPA decisions.

Identify and incorporate early mitigation for vulnerable ESA species

EPA will identify and implement early mitigation for vulnerable ESA species, so that the Agency can incorporate the mitigation into its registration and registration review decisions that require ESA mitigation. The goal of this effort is to ensure that EPA is beginning to adopt meaningful protections for species most affected by pesticide use, without the Agency waiting until consultation with the Services is completed. Early mitigation for vulnerable species will also expedite any future pesticide consultation that covers those species, because much of the mitigation needed for those consultations may have already been identified through the vulnerable species effort discussed in step 1 below. Early mitigation for vulnerable species entails three related but distinct steps: (1) identify vulnerable species, (2) identify mitigation for those species, and (3) incorporate mitigation into FIFRA decisions.

The three steps are described below.

- **Step 1: Identify vulnerable species.** Throughout this workplan, "vulnerable species" refers to the subset of ESA species that EPA is currently identifying based on characteristics of the species or its habitat that predisposes it to experiencing pesticide effects. Those characteristics include extent of range in proximity to pesticide use sites, sensitivity of species to pesticidal effects (*e.g.*, insecticide's effects on insects), ability of species to recover from effects, and identification of pesticides as a contributor to a species' declines in ESA recovery documents. EPA expects to publish its working list of vulnerable species in the near future.

  When EPA predicts the likelihood of a future jeopardy or adverse modification finding, that analysis is specific to the pesticide at issue. This is a major difference between those predictions and the identification of vulnerable species, which are not pesticide specific. EPA may predict a high likelihood of jeopardy/adverse modification even for ESA species not on the vulnerable species list. The reason is that the specific interaction between a particular pesticide use and a species may reveal a high likelihood of jeopardy, which was not evident without the pesticide-specific analysis. Conversely, EPA may not predict a species on the vulnerable species list as having a high likelihood of jeopardy/adverse modification for a particular pesticide because, for example, the species range may not overlap with the pesticide's registered uses.

- **Step 2: Identify mitigation for vulnerable species.** EPA intends to identify early mitigation for vulnerable species through two approaches. First is through EPA's internal efforts to determine suitable mitigation for each vulnerable species, based on ESA documents for the species, ecological principles, coordination with Services biologists, and other ESA-FIFRA efforts. These mitigation measures are not specific to a particular FIFRA action but instead designed to address effects from most pesticides to which the species may be exposed.

  Second is through a federal mitigation pilot project with the Services and USDA. Through this pilot, the agencies will develop approaches for identifying and implementing mitigation earlier in the ESA-FIFRA process for select species particularly vulnerable to pesticides. The Services have selected approximately 20 species for the pilot, and EPA has selected an herbicide, an insecticide, and a fungicide with uses that overlap with these species. For each species, the agencies will develop an initial list of suitable mitigation measures to reduce the likelihood of a future jeopardy or adverse modification finding and to minimize the effects of incidental take. The initial list may be based on existing mitigation measures the Service(s) have developed and conservation actions in recovery plans and other ESA documents (*e.g.*, recovery outline, 5-year status review, species status assessment), and will reflect input from species experts. Based on additional input from USDA, registrants, pesticide users, conservation organizations, and others, the agencies will identify the most feasible and effective mitigation measures from the initial list to create a refined list of mitigation measures to incorporate into FIFRA and ESA decisions. The agencies will also assess the success of the refined mitigation measures and expand the approach to include other pesticides and species. The agencies will provide more details on the pilot project later in 2022.

Relationship Among the Three Categories of Species for Targeted Mitigation

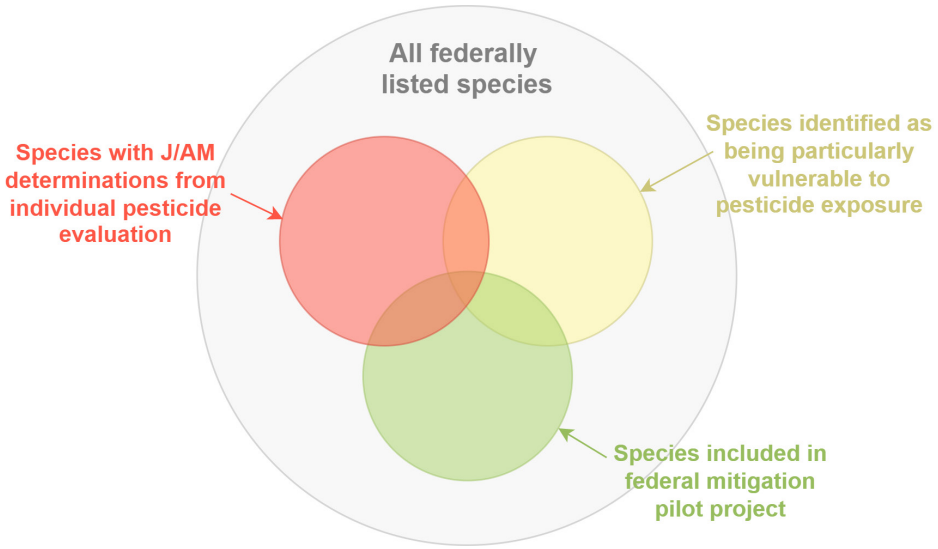

Figure 4. Currently, EPA is compiling a list of vulnerable species based on characteristics of the species or their habitat that predisposes them to pesticide effects. Some of those species are also likely to be at risk of a future jeopardy finding for certain pesticides. But not all species facing a future jeopardy risk have been identified as vulnerable species. All species selected for the federal mitigation pilot project are vulnerable species and some may be at risk of a future jeopardy finding, absent adequate early mitigation. Because the number of species represented by each of the circles has not yet been determined, the size of the circles are not proportionally accurate. Further, the extent of overlap among the inner circles will depend on various factors that EPA is still assessing.

- **Step 3: Incorporate any necessary ESA mitigation into FIFRA actions.** EPA expects to incorporate the identified necessary mitigation measures for vulnerable species into any relevant FIFRA action that invokes ESA obligations. This may include registration of new pesticide active ingredients, registration review, and other registration actions. Further, the measures can be incorporated in any of the following stages of the FIFRA process, before the completion of consultation:
    - Mitigation required to meet the FIFRA standard, before EPA completes a biological evaluation or before the Services complete their biological opinions.
    - Mitigation as part of a FIFRA action where EPA has made a "may affect" finding.
    - Mitigation as part of a FIFRA action where the Agency has made an ESA likely to adversely affect finding. This includes when EPA finds likely to adversely affect but is unable to complete formal consultation with the Service(s) prior to registering a new active ingredient.

  As EPA continues identifying vulnerable species and any necessary mitigation for them, it will explore how to apply those measures. In general, EPA intends to apply the mitigation measures for vulnerable species as broadly as feasible. For example, effective, practical mitigation measures that protect a listed insect species from an insecticide may apply across all insecticides. Depending on the type of mitigation, EPA may first need to complete public notice and comment (*e.g.*, voluntary use deletions).

  Lead division(s): EFED, RD, PRD, BEAD

  Timing: In process for some FIFRA actions

Focus pesticide consultation process on adopting mitigation for species likely to receive a jeopardy or adverse modification determination

To streamline the pesticide consultation process and to address species most affected by pesticides, EPA will prioritize mitigation for species most likely to receive a jeopardy or adverse modification finding during formal consultation. Because both findings focus on effects to species survival and recovery (rather than effects only to individuals of a species, as is the case with "may affect" and "likely to adversely affect" findings), EPA must perform some analysis of those species-level effects before initiating formal consultation with the Services.

This approach will entail two shifts in how the Agency conducts its ESA-FIFRA analyses. First, as part of EPA's effects determinations for certain pesticides, the Agency will assess population-level effects to inform (1) the likelihood of a jeopardy or adverse modification finding during formal consultation and (2) mitigation to address those effects. This approach will help ensure that EPA's assessments are relevant to the ESA's goal of recovering species. It should also reduce the overall length and complexity of consultations.

Thus, although EPA needs to make trade-offs in the type of analyses it performs, the Agency expects those tradeoffs to improve its ability to meet its ESA obligations more expeditiously and to adopt more meaningful mitigation. Nothing about this new approach is intended to lessen the Services' role under the ESA or to abrogate EPA's duty to issue effects findings or consult with the Services.

The second shift is that EPA seeks to work with the Services to expedite formal consultation for species that benefit from early mitigation such that the likelihood of jeopardy or adverse modification becomes negligible or nonexistent, but that still trigger a "likely to adversely affect" finding. In practice, "likely to adversely affect" is triggered if even one individual of a species is likely to experience incidental take. This is the case regardless of the species' recovery status or the overall effects of the proposed action on a species. As a result, for certain species that are wide ranging or that occur near agricultural lands, a likely to adversely affect may be unavoidable even with early mitigation and even if the probability of jeopardy or adverse modification is very low or none. In those situations, EPA seeks to work with the Services to expedite formal consultation for those species, thus creating a tangible incentive for registrants to offer early mitigation to minimize the probability of future jeopardy and adverse modification findings. This approach will require the agreement of both Services.

Lead division(s): EFED, RD, PRD, BEAD

Timing: In process

Identify flexible mitigation for all ESA species

When EPA gives registrants and pesticide users more flexibility in identifying ESA mitigation, those measures are more likely to be implemented. EPA can offer more flexibility in at least two ways. One is by engaging users and registrants earlier in the FIFRA process to identify and adopt suitable ESA mitigation, based on input from those stakeholders about effective mitigation techniques that work best for them. Another is by creating a menu of mitigation that users or registrants can select from, similar to the approach taken by NMFS in recent pesticide biological opinions. A more comprehensive approach for developing mitigation options is to gather information from species experts about effective mitigation techniques and from pesticide registrants and users about techniques that are practical to implement.

For both options, EPA anticipates working with the Services on how best to determine the amount of mitigation necessary to meet ESA obligations, and with USDA and other groups (*e.g.*, American Mosquito Control Association, National Agricultural Aviation Association, and university and extension researchers) on how best to engage with pesticide users to identify and implement mitigation, including existing conservations practices. To promote flexible mitigation, EPA will pursue the following two actions.

- **Start with federal mitigation pilot project.** As described above, EPA is developing menus of mitigation options with the Services and USDA through a pilot project for select species and pesticides. EPA plans to incorporate lessons learned from this pilot to registration review chemicals that overlap with other species that face the likelihood of a future jeopardy or adverse modification finding. EPA hopes the federal pilot will provide additional insight on opportunities to engage pesticide users and registrants on mitigation earlier in the FIFRA registration review process, thereby improving EPA's ability to meet its ESA obligations.

- **Start with federal mitigation pilot project (cont.).** Additionally, as EPA incorporates early mitigation for new conventional pesticide registrations and for the pilot pesticides in registration review (discussed earlier) and completes consultations, it anticipates the resulting mitigations will likely apply to other pesticides and will form the basis of mitigation menus for those pesticides. For example, EPA recently developed a menu of mitigation to address run-off from the herbicide Enlist that may also serve as a starting point to address the effects of run-off to listed species and their critical habitat from other mobile herbicides.

  Lead division(s): EFED, RD, PRD, BEAD

  Timing: In process

- **Expand to other pesticides and species.** EPA will work with the Services and USDA to expand the actions in the efforts described above to other conventional pesticides and other species.

  Lead division(s): RD, PRD, EFED, BEAD, BPPD

  Timing: Within 2-3 years

Coordinate mitigation between registration and registration review decisions

EPA supports the registration of newer chemistries that likely have lower environmental and human health risks. This is one reason that EPA is prioritizing resources to meet its ESA obligations for registration of new active ingredients, especially those designed to replace older chemistries that have greater effects on ESA species. This approach, however, can impose ESA mitigation for those pesticides before mitigation is imposed on a corresponding older pesticide used for the same purposes (*e.g.*, where ESA consultation on the older pesticide has not yet occurred), and in some cases, the older pesticide may have a more harmful health or environmental profile. This disparity in mitigation may be seen as incentivizing use of the older pesticides, because the older pesticide may not have as many use restrictions. The disparity may also be seen as discouraging the development of new pesticides if they are restricted more than older pesticides, thus possibly reducing their market share. To address these problems, EPA will begin coordinating ESA mitigation between new pesticides and corresponding older pesticides.

To identify these pairings, EPA will need to match new and older pesticides based on crop use, target pests, timing of FIFRA and ESA reviews, registrants, and other factors. EPA does not yet have a framework for this type of assessment, so will begin piloting an approach in 2022 through a new pesticide registration decision that the Agency will link to a corresponding conventional pesticide in registration review. This could include new biopesticide registrations that lead to reduced use of existing conventional pesticides with more significant effects on ESA species. EPA will then evaluate how to coordinate its ESA mitigation more broadly between its registration and registration review decisions.

Lead division(s): RD, PRD, EFED, BEAD, BPPD

Timing: Begin within 12 months

Use compensatory mitigation (offsets) to supplement avoidance and minimization

To meet ESA obligations, federal agencies often use compensatory mitigation (also known as offsets) to address the effects of their actions that cannot be avoided or minimized. Offsets can include actions such as habitat preservation or restoration, invasive species control, and species reintroductions. These actions directly further species recovery (sometimes more than on-site avoidance and minimization) and should provide registrants with greater flexibility by creating more options for EPA to meet its ESA obligations. EPA will thus identify opportunities for offsets to complement traditional FIFRA avoidance and minimization measures for ESA species. The Agency will do so through a multistep process that includes working with the Services to develop general guidance on using offsets for pesticide consultations, working with registrants to identify and adopt offsets for specific pesticides and species, ensuring that adopted offsets are legally binding as a condition of a FIFRA registration, and working with the Services to oversee implementation of offsets. In 2022, EPA will be working to pilot the use of offsets for certain chemicals and species, in cooperation with registrants who are seeking to include offsets in their registration. Based on these pilots, EPA seeks to work with the Services to clarify the process for incorporating offsets into pesticide consultations and scaling up that process to handle large numbers of species and pesticide actions.

Lead division(s): EFED, PRD, RD, BEAD

Timing: Pilot projects in 2022

Pursue other policy and program improvements that support mitigation

- **Require *Bulletins Live! Two* language on certain pesticide labels.** *Bulletins Live! Two* is EPA's web-based system for incorporating geographically specific restrictions for ESA species and critical habitats. To help meet ESA obligations, especially for conventional pesticides that EPA registers before completing formal consultation, EPA expects to require that certain labels for new conventional registration actions, certain non-conventional registration actions, and many registration review actions include language directing users to check *Bulletins Live! Two* for restrictions that the user must follow before applying a pesticide. For example, when EPA expects that a pesticide in registration review may require mitigation implemented through *Bulletins*, the Agency will seek *Bulletins* language as part of the label it approves through an Interim Decision. Because EPA will not be able to immediately populate *Bulletins* with mitigation for all listed species affected by approved pesticide uses, the Agency will prioritize developing mitigation for EPA vulnerable species and species covered by the interagency mitigation pilot project, both discussed earlier. To facilitate EPA's efforts to adopt mitigation for these species, the Agency is considering the option to retract or revise the antiquated 2005 Federal Register Notice on its Endangered Species Protection Program (OPP-2002-0311). The reason is that much has changed since 2005 about how EPA addresses its ESA obligations, and the Agency seeks to update and modernize its guidance.

- **Require *Bulletins Live! Two* language on certain pesticide labels (cont.).** The Agency is also considering rulemaking in the future to require the *Bulletins* language on all or a subset of all labels, where that language is necessary, thus standardizing the use of the language across labels that require spatially explicit mitigation. Incorporating the language where necessary also helps with the legal defensibility of EPA's registration and registration review decisions and reduces agency resources to update labels after formal consultation has concluded and a biological opinion is finalized. This approach will also facilitate adopting timely mitigation because the pesticide labels in commerce will already contain the requirement to follow *Bulletins* when EPA issues the *Bulletin* language, thus bypassing the lengthy process from EPA approval of a label to field implementation of that label, which typically takes 18 months or longer.

  Lead division(s): RD, PRD, BPPD

  Timing: In process

- **Update *Bulletins Live! Two*.** Given that *Bulletins Live! Two* will be the main interface for conveying most future geographically specific ESA label restrictions, EPA will upgrade the interface to be more user friendly. In February 2022, EPA completed initial updates to *Bulletins*. The Agency will continue identifying additional updates to implement over the coming years.

  Lead division(s): EFED

  Timing: Ongoing

- **Adopt electronic labeling system.** In the longer term, EPA will focus on shifting to an electronic labeling process that supports quicker label revisions during registration and registration review, in implementing non-geographic mitigations in biological opinions, and that may replace *Bulletins Live! Two* with a more comprehensive system for conveying ESA label restrictions. EPA has been working for several years to set up an electronic labeling program, but implementing the program may require rulemaking, transitioning labels to the electronic system, and other major administrative actions that will span 3-5 years. In the meantime, EPA is considering whether pilot projects with willing registrants can demonstrate how electronic labeling can streamline label amendments that incorporate ESA mitigation.

  Lead division(s): PRD, RD, EFED, BPPD, other OCSPP divisions

  Timing: No earlier than 2 years

- **Develop policies or processes to integrate meeting ESA obligations into FIFRA decisions.** To streamline the ESA-FIFRA program, EPA will consider policies that integrate meeting its ESA obligations into the FIFRA process. EPA will be considering issues such as the situation where the Agency determines that a registration may present a high likelihood of jeopardy or adverse modification, EPA may find that the application does not meet the FIFRA approval standard without adequate mitigation because of ESA concerns.

  Lead division(s): OCSPP, OPP

  Timing: Within 2 years

- **Use existing conservation practices to inform ESA mitigation.** Many landowners are likely implementing stewardship and best management practices to reduce pesticide drift and runoff, but those practices are not often identified and incorporated into EPA's risk assessments nor consistently used to inform ESA mitigation. By addressing this gap, EPA can develop mitigation that landowners are more likely to be familiar with and effectively implement. EPA will work with the Services, USDA, and stakeholders to develop a plan to identify pesticide stewardship practices that EPA and the Services are not currently considering in pesticide consultations, and then determine how best to incorporate that information into the consultation process.

  Lead division(s): BEAD, EFED

  Timing: Within 3 years

- **Evaluate ESA section 7(a)(1) conservation program for pesticides.** Section 7(a)(1) of the ESA requires all federal agencies to use their authorities to help conserve ESA species and complements the section 7(a)(2) requirement for agencies to consult with the Services to avoid jeopardy and adverse modification. How agencies fulfill their section 7(a)(1) duty, however, is flexible and open-ended (*e.g.*, the Services have no regulations on section 7(a)(1)). EPA will consider developing a section 7(a)(1) approach for its pesticide program that can help with meeting its section 7(a)(2) obligations. For example, EPA could work with registrants, pesticide users, and the Services to adopt proactive conservation that, if implemented and shown to be effective, can be incorporated into future pesticide consultations. In this case, USDA could help identify these conservation practices and then EPA could work with the Services and USDA to determine how future pesticide consultations should account for the practices. This approach should also help expand the use of offsets in pesticide consultations. A section 7(a)(1) program could also help address species research needs to inform future pesticide consultations (*e.g.*, effectiveness of specific mitigation techniques). EPA proposes to work with the Services to identify the various opportunities for a section 7(a)(1) program to benefit EPA's ESA-FIFRA work and determine whether and how to pursue those opportunities.

  Lead division(s): EFED, PRD, RD, OCSPP IO

  Timing: Within 3 years

- **Coordinate on research.** OPP will continue coordinating with EPA's Office of Research and Development to help ensure that its research can inform the ESA-FIFRA process. Current coordination already covers important questions on species risk assessments. The two offices may consider expanding this work to cover ESA mitigation and other emerging topics important to ESA pesticide consultations. EPA also envisions coordinating on research with other federal agencies and with academic institutions. In particular, EPA will explore work with the NMFS Northwest Fisheries Science Center on pesticides research, given the Center's long history of pesticide research and their science support for NMFS biological opinions. All these efforts will increase the resources for improving the scientific foundation of pesticide consultations.

  Lead division(s): EFED

  Timing: In progress

STRATEGY 3: IMPROVE INTERAGENCY CONSULTATION PROCESS

Although progress has been made over the last decade, over the next decade far more improvements to the pesticide consultation process are needed to keep pace with EPA's ability to meet its ESA obligations, including for the large backlog of conventional pesticides in registration review. The current consultation process does not optimize use of EPA resources or optimally engage stakeholders, irrespective of resource levels. Improving the consultation process, however, requires considerable interagency coordination; EPA cannot accomplish any of the actions on its own. This section describes how EPA seeks to work with the Services to improve the efficiency of the consultation process.

EPA has determined that the current approach to consulting on individual pesticide ingredients cannot efficiently scale to the hundreds of pesticides that EPA must assess under the ESA within the next decade. This inefficiency applies not only to the individual ESA determinations that EPA must make, but to the process of developing and implementing mitigation. Based on its experience with current and upcoming pesticide consultations, EPA will coordinate with the Services to develop more efficient approaches to consulting on pesticides. For example, programmatic consultations for groups of pesticides (*e.g.*, herbicides) or for all pesticides that share similar use patterns in a region would enable mitigations to be identified together and would be far more efficient than the current pesticide-by-pesticide approach. This approach also avoids the problem of imposing disparate mitigation requirements across pesticides with similar use patterns.

Another example is for EPA to consider consulting with certain regional or field offices of the Services for a pesticide used only in a region, in coordination with the agency's headquarters staff. Although there are barriers to this approach, which would first require Services agreement, there are also benefits such as working directly with the Services biologists who may have connections to the landowners who implement mitigations. In the past, EPA has successfully consulted with FWS headquarters and a regional office on two rodenticides (Rozol and Kaput).

Developing alternatives to the current approach to pesticide consultations will require EPA and the Services to address various logistical and legal issues, all of which take time. EPA, however, sees no choice but to identify more efficient approaches that enable each consultation to cover far more pesticides or that the agencies can complete in far less time than under the current approach.

Lead division(s): EFED, RD, PRD, BEAD

Timing: In process

STRATEGY 4: IMPROVE STAKEHOLDER ENGAGEMENT

Stakeholder engagement is crucial not only to providing transparency about EPA's work, but also for stakeholders to help with ESA-FIFRA improvements. Registrants and pesticide users will especially benefit from many of these improvements that increase the predictability and speed of pesticide consultations.

Obtain data for ESA assessments

In some cases, EPA may lack sufficient data to begin an ESA assessment or complete one efficiently. In these situations, EPA will work with registrants and others to obtain the necessary data before the start of the assessments. This will likely include use and usage data, where applicable, and recommendations on when and how to incorporate those data into ESA determinations. For example, state agricultural extension agencies and USDA may be able to inform EPA about anticipated uses of a new active ingredient for which no usage data exist. EPA may also issue new Data Call-In notices, especially for antimicrobial and biopesticides, to seek data needed for its ESA determinations. In those situations, EPA will also update its Information Collection Request that describes the type of information EPA seeks, the reasons for seeking the information, and the time and cost for the public to provide the information. EPA is also considering issuing a Pesticide Registration Notice to help registrants draft labels that consider ESA mitigation and to discuss other approaches to facilitate the adoption of mitigation. Further, through EPA's quarterly registration review schedule, the Agency may notify stakeholders of upcoming data needs for pesticides in registration review.

Lead division(s): PRD, RD, EFED, BEAD, BPPD, AD

Timing: No earlier than 12 months

Expand engagement with growers through USDA

Growers have an important stake in the outcome of many FIFRA actions and an important role in growing our nation's food and protecting its natural resources. EPA already works with growers on a variety of pesticide matters and envisions a larger role for growers to offer information to support FIFRA actions and ESA determinations and mitigation decisions. EPA views USDA as an important conduit for growers to provide this information and will work with the agency to identify process improvements for grower engagement, including through the federal pilot project described earlier.

Lead division(s): PRD, RD, EFED, BEAD, BPPD

Timing: In process

Expand engagement with non-agricultural organizations

EPA already works with non-agricultural organizations that have an interest in ESA-FIFRA issues. This includes environmental, tribal, and public interest organizations, as well as organizations that represent pesticide users (*e.g.*, American Mosquito Control Association, National Pest Management Association). EPA will expand its engagement with non-agricultural organizations on specific ESA-FIFRA issues and improvements to the ESA-FIFRA process.

Lead division(s): PRD, RD, EFED, BEAD, BPPD

Timing: Beginning within the next 12 months

CLOSING AND FUTURE STEPS

CLOSING AND FUTURE STEPS

Through this workplan, EPA's Pesticide Program hopes that readers appreciate its strong commitment to addressing its historic lapses in fulfilling its ESA obligations. The Program's vision statement will guide the workplan as the Agency works through the monumental backlog of FIFRA actions that require ESA review, compounded by ongoing and future FIFRA actions. The Program understands the limitations of its current capacity and expertise and has taken steps to start addressing this challenge. These steps include major process improvements, many of which depend on collaboration with the Services, USDA, and stakeholders. This workplan is EPA's most comprehensive effort to date that describes the improvements it will pursue and the external partnerships it is seeking.

EPA welcomes feedback from stakeholders about the workplan and particularly about opportunities to partner with EPA on implementing the highest priority actions in the document. Through those partnerships, EPA expects that it can increase the number of ESA assessments it completes on its own without the need for litigation to compel this work, deliver more meaningful conservation for listed species, and offer pesticide registrants and users more practical and flexible mitigation to protect those species.

APPENDIX A

CURRENT SCHEDULE FOR ESA DETERMINATIONS AND IMPLEMENTATION OF NMFS SALMONID BIOLOGICAL OPINIONS

APPENDIX A

CURRENT SCHEDULE FOR ESA DETERMINATIONS AND IMPLEMENTATION OF NMFS SALMONID BIOLOGICAL OPINIONS

EPA has the following court-enforceable deadlines and other agreements (not yet court-enforceable) for ESA determinations and biological evaluations (BE). Pending litigation may add other deadlines to this schedule. The table includes EPA's expected/known timing to complete its biological evaluations as well as work to implement some recent biological opinions from U.S. Fish and Wildlife Service (FWS) or National Marine Fisheries Service (NMFS). "TBD" indicates that timing has not yet been determined for the specified step in the process.

Each date (or TBD) in the table is either green, yellow, or red, where: green = completed; red = expected/planned future work; and yellow = expected/planned future work for pesticides without ESA litigation.

Chemical	EPA Draft BE	EPA Final BE
Court Enforceable or Court Committed Dates		
Methomyl	2020	2021
Carbaryl	2020	2021
Atrazine	2020	2021
Simazine	2020	2021
Glyphosate	2020	2021
Propazine[1]	2020	NA
Enlist One	NA	2022
Enlist Duo	NA	2022
Imidacloprid	2021	June 2022
Clothianidin	2021	June 2022
Thiamethoxam	2021	June 2022
Sulfoxaflor	NA	Spring 2022
Inpyrfluxam	NA	2023
Cyantraniliprole	2023	2023
Dinotefuran	2023	2024
Acetamiprid	2023	2024
Brodifacoum	2023	2024
Warfarin	2023	2024
Bromadiolone	2023	2024
Zinc phosphide	2023	2024
Chlorophacinone	2023	2024
Diphacinone	2023	2024
Difenacoum	2023	2024
Bromethalin	2023	2024
Difethialone	2023	2024
Cholecalciferol	2023	2024
Flupyradifurone	2024	2025
Bicyclopyrone	2024	2025
Streptomycin	2025	2026[2]
Benzovindiflupyr	2026	2027
Halauxifen-methyl	2026	2027

APPENDIX A

CURRENT SCHEDULE FOR ESA DETERMINATIONS AND IMPLEMENTATION OF NMFS SALMONID BIOLOGICAL OPINIONS

Chemical	EPA Draft BE	EPA Final BE
Expected BE Completion Dates		
Approximately 10 new active ingredients	2022	2022/2023
Acephate	2026	2026
Dimethoate	2026	2026
Naled	2026	2026
Tribufos	2026	2026
Bensulide	2027	2027
Ethoprop	2027	2027
Phorate	2027	2027
Phosmet	2027	2027
Active Ingredients in Pending Litigation Without Current Commitments		
1,3-D (Telone)	TBD	TBD
2,4-D	TBD	TBD
Captan	TBD	TBD
Chlorothalonil	TBD	TBD
Dicamba	TBD	TBD
Diuron	TBD	TBD
MCPA	TBD	TBD
Mancozeb	TBD	TBD
Metolachlor	TBD	TBD
Metribuzin	TBD	TBD
Oxyfluorfen	TBD	TBD
Paraquat	TBD	TBD
Pendimethalin	TBD	TBD
Propanil	TBD	TBD
Propargite	TBD	TBD
Phosphorotrithioate	TBD	TBD
Thiobencarb	TBD	TBD
Trifludimoxazin[3]	TBD	TBD
Trifluralin	TBD	TBD

APPENDIX A - continued

Recent Biological Opinions from the Services that EPA is Working to Implement		
Chemical	**FWS/NMFS**	**Final BiOp**
1080	FWS	2021[4]
M-44	FWS	2021[4]
Metolachlor[5]	NMFS	2021
Telone[5]	NMFS	2021
Prometryn[5]	NMFS	2021
Bromoxynil[5]	NMFS	2021
Malathion	FWS	2022
Diazinon[6]	NMFS	2022
Chlorpyrifos[6]	NMFS	2022
Malathion[6]	NMFS	2022

[1] Propazine registrations were voluntarily cancelled; therefore, consultation was no longer necessary.

[2] No sooner than Fall 2026

[3] Trifludimoxazin registrations are going through a voluntary cancellation process.

[4] EPA re-initiated consultation on these two predacides in 2011; a biological opinion was not necessary because the action was changed during the consultation process to avoid jeopardy. Consultation was completed in December 2021.

[5] Consultation was limited to salmonid species in the Pacific Northwest; EPA is working to implement additional salmonid BiOps through the registration review process.

[6] NMFS's 2022 BiOps are the result of a re-initiation process.

Many of the dates in this table are part of various settlement agreements and subject to change depending on the terms of those agreements.
Some dates are not associated with settlement agreements and are subject to change pending resources and prioritization.

APPENDIX A - continued

Implementation of NMFS Salmonid Biological Opinions

EPA is currently working to implement the NMFS salmonid biological opinions #2, 4, and 7 in 2022 as part of registration review proposed interim decisions (PID) or interim decisions (ID) for these pesticides. EPA anticipates focusing on the next set of NMFS salmonid biological opinions once these three biological opinions are implemented.

NMFS Biological Opinion No. and Year Issued	**Chemicals** (strikeout = cancelled product)	**Action/Status**
2 (2009)	Carbaryl, Methomyl ~~Carbofuran~~,	In process, with initial steps in 2022
3 (2010)	Bensulide, Dimethoate, Ethoprop, Naled, Phorate, Phosmet ~~Azinphos-methyl~~, ~~Disulfoton~~, ~~Fenamiphos~~, ~~Methamidophos~~, ~~Methidathion~~, ~~Methyl parathion~~,	Implement through ID
4 (2011)	2,4-D, Captan, Chlorothalonil, Diuron, Linuron, Triclopyr BEE	In process, with initial steps in 2022
5 (2012)	Oryzalin, Pendimethalin, Trifluralin	Implement through amended IDs
6 (2012)	Thiobencarb	Implemented through *Bulletins Two! Live* (2014)
7 (2014)	Diflubenzuron, Fenbutatin-oxide, Propargite	In process, with initial steps in 2022
9 (2021)	Bromoxynil, Prometryn	Label amendments scheduled for December 2022
10 (2021)	1, 3-dichloropropene (1,3-D), Metolachlor	Label amendments scheduled for December 2022

APPENDIX B

PENDING ESA LITIGATION ALLEGING FAILURE TO MAKE EFFECTS DETERMINATIONS ON FIFRA ACTIONS

APPENDIX B

PENDING ESA LITIGATION ALLEGING FAILURE TO MAKE EFFECTS DETERMINATIONS ON FIFRA ACTIONS

Litigation involving new actions to older chemicals for failure to consult:

- Center for Biological Diversity (CBD) v. EPA, No. 11-cv-00293-JCS (N.D. Cal.): "megasuit" challenging 2200 products re 35 active ingredients
- National Research Defense Council (NRDC) v. EPA, No. 20-70787, (9th Cir,), registration review of glyphosate. EPA is awaiting decision from the court.

Litigation involving new uses of existing pesticides

- Migrant Clinicians Network (MCN) v. EPA, No. 21-70719 (9th Cir.). Challenge to select streptomycin registrations. Litigation is currently at briefing stage.
- Center for Food Safety (CFS) v. EPA, No. 19-72109 (9th Cir.). Challenge to registrations of new uses of sulfoxaflor. Parties are awaiting decision from the court.

Litigation involving new AI registrations

- Center for Biological Diversity (CBD) v. EPA, No. 15-1054, (DC Cir.). Challenge to registrations of new AIs flupyradifurone, bicyclopyrone, and benzovindiflupyr, and halauxifen-methyl. Parties are awaiting decision from the court.
- Center for Biological Diversity (CBD) v. EPA, No. 20-73146 (9th Cir.). Challenge to inpyrfluxam registrations. Litigation is currently at briefing stage.
- Center for Food Safety (CFS) v. EPA, No. 21-71180, (9th Cir.). Challenge to trifludymoxazin registrations, for which the registrant has requested voluntary cancellation.


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